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Behavioral Counseling Interventions to Promote a Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors: Updated Systematic Review for the U.S. Preventive Services Task Force

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The information in this report is intended to help healthcare decision makers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information (i.e., in the context of available resources and circumstances presented by individual patients).

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Structured Abstract

Objective: To review the benefits and harms of behavioral counseling interventions to improve diet and increase physical activity in adults with cardiovascular risk factors.

Data Sources: We performed a search of MEDLINE, PubMed (publisher-supplied records only), PsycINFO, and the Cochrane Central Register of Controlled Trials for relevant English-language studies published between January 2013 and September 2019. Additionally, we re-evaluated all studies included in the 2014 USPSTF review and related USPSTF systematic reviews. We conducted ongoing surveillance for relevant literature through July 24, 2020.

Study Selection: Two investigators independently reviewed 14,409 unique citations and 466 full-text articles against a priori inclusion criteria. We included English-language randomized clinical trials of behavioral counseling interventions to help people with elevated blood pressure or lipids improve their diet and increase physical activity. Critical appraisal was completed independently by two investigators. Data were extracted from studies by one reviewer and checked by a second.

Data Analysis: Random effects meta-analysis was used to examine outcomes with sufficient evidence to warrant pooled analyses, including all-cause mortality, cardiovascular events, blood pressure, lipids, adiposity-related outcomes, glucose-related outcomes, dietary measures, and physical activity. Subgroup analyses and meta-regression were used to explore effect modification for systolic blood pressure, total cholesterol, and weight.

Results: Ninety-four randomized trials were included (N=52,174). Behavioral counseling interventions were associated with a lower risk of cardiovascular events (pooled relative risk [RR]=0.80 [95% confidence interval (CI), 0.73 to 0.87]; 9 randomized controlled trials [RCTs] [n=12,551]; I^2=0%), myocardial infarction (MI) (pooled RR=0.85 [95% CI, 0.70 to 1.02]; 6 RCTs [n=10,375]; I^2=0%) and stroke (RR=0.52 [95% CI, 0.25 to 1.10]; 4 RCTs [n=9,800]; I^2=0%), although the pooled effect was not statistically significant for stroke or MI. Event rates were variable; in the largest trial (Prevención con Dieta Mediterránea [PREDIMED]) 3.6 percent in the intervention groups experienced a cardiovascular event, compared with 4.4 percent in the control group. In addition, behavioral counseling interventions were associated with small, statistically significant reductions in continuous measures of blood pressure, total cholesterol, fasting glucose, and adiposity-related outcomes at 12 to 24 months' followup. Blood pressure in intervention groups was reduced by a greater amount than in control groups—by a mean 1.8/1.2 mm Hg—after 12 to 24 months (pooled systolic blood pressure [SBP]=-1.8 [95% CI, -2.5 to -1.1]; 44 RCTs [n=14,580]; I^2=37%; pooled diastolic blood pressure [DBP]=-1.2 [95% CI, -1.6 to -0.8]; 40 RCTs [n=13,098]; I^2=32%). Total cholesterol was reduced by 3.5 mg/dL (95% CI, -5.6 to -1.4; 38 RCTs [n=11,414]; I^2=66%) and low-density lipoprotein cholesterol was reduced by 2.1 mg/dL (95% CI, -4.1 to -0.2; 32 RCTs [n=8,894]; I^2=56%). Intervention groups also showed slightly greater reductions in three adiposity-related measures: pooled body mass index=-0.5 kg/m^2 (95% CI, -0.7 to -0.3); 30 RCTs (n=9,909); I^2=83%; pooled weight=-1.6 kg (95% CI, -2.1 to -1.1); 37 RCTs (n=16,345); I^2=88%; and pooled waist circumference=-1.8 cm (95% CI, -2.4 to -1.1); 23 RCTs (n=11,708); I^2=87%. Reporting of diet and physical activity was very heterogeneous, and evidence suggested small mean improvements in dietary intake consistent

with the intervention targets but small to no impact on physical activity. Results for blood pressure, lipid, and adiposity-related measures were generally consistent with the previous review despite some modifications to the review scope.

Limitations: Health outcomes were reported in a small proportion of the included trials, and many had very few events. Measurement of behavioral outcomes was extremely heterogeneous, and the clinical importance of measures of a single aspect of participants' diet is limited.

Conclusions: Medium- and high-contact multi-session behavioral counseling interventions to improve diet and increase physical activity provided to people with hypertension, dyslipidemia, or elevated blood pressure and lipid levels are effective in reducing CVD events, blood pressure, total cholesterol, and adiposity-related outcomes, with little to no risk of serious harm.

Table of Contents

Figures

Tables

Appendixes

Chapter 1. Introduction

Purpose

This report will be used by the United States Preventive Services Task Force (USPSTF) to update its 2014 recommendation on behavioral counseling to promote a healthy diet and physical activity for cardiovascular disease (CVD) prevention in adults with cardiovascular risk factors.[1]

Condition Background

Condition Definition

CVD Risk Factors

For the purposes of this review, adults with CVD risk factors are defined as individuals with hypertension, dyslipidemia, impaired fasting glucose/impaired glucose tolerance, metabolic syndrome, or calculated 10-year CVD risk of 7.5 percent or greater. Because of the broad and multicomponent nature of cardiovascular risk, not all features of elevated risk are captured by this definition.

Diet

Healthy eating includes a balance and variety of foods and beverages that assist people in achieving and maintaining a healthy weight, supporting health, and preventing disease. For the purposes of this review, we consider any dietary counseling that focuses on increasing consumption of fruits, vegetables, whole grains, fat-free or low-fat dairy, lean proteins, and oils, and decreasing consumption of foods with high sodium levels, saturated- or *trans* fats, and added sugars, as recommended by the United States Department of Agriculture (USDA).[2] This guidance is generally consistent with dietary recommendations of a number of professional medical organizations as well as the USDA (**Table 1**).[3-8]

Physical Activity

Physical activity is broadly defined as any bodily activity that enhances or maintains overall health and physical fitness. Prominent organizations have most recently recommended that adults 18 years and older engage in at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity aerobic physical activity per week in addition to engaging in strengthening activities at least twice per week.[3, 9] These guidelines emphasize that some physical activity is better than none.

Burden of Preventable Illness

CVD is the leading cause of death in the United States for both men and women, and most ethnicities, including Hispanics, African Americans, and whites.[10, 11] In 2016, CVD was the underlying cause of 840,678—or 1 in 3—deaths.[12] CVD prevalence is higher in males (9.6%) than females (8.47%), and is higher for African Americans (10.7% for males, 10.5% for females) than whites (9.76% for males, 8.1% for females among non-Hispanic whites; prevalence is comparable or lower for Hispanics and Asians).[12] CVD prevalence increases with age; among males, CVD prevalence is 7.5 percent among those age 40 to 59 years, 25.1 percent among those age 60 to 79 years, and 43.3 percent among those age 80 and older.[12] Between 2008 and 2010, CVD death rates in the United States were highest in the South and lowest in the West.[10] The American Heart Association (AHA) estimates that by 2035, over 130 million adults in the US will have some form of CVD.[13]

Risk Factors

Risk factors for CVD are well-established, multicomponent, and common in adults. Modifiable risk factors include dyslipidemia or hyperlipidemia (referred to as dyslipidemia in this report), hypertension, diabetes, overweight and obesity, smoking, lack of physical activity, and unhealthy diet.[14-16] Nonmodifiable risk factors include age, sex, and family history.[14, 16] The CDC estimates that nearly half of all U.S. adults age 20 years or older have at least one of the following CVD risk factors: uncontrolled hypertension; uncontrolled, elevated low-density lipoprotein (LDL) cholesterol level; or use of tobacco. Prevalence of risk factors defined by the AHA's "Life's Simple 7" similarly show the pervasiveness of modifiable risk factors (**Table 2**).[12]

Cardiovascular risk can be characterized as the elevation of a single risk factor or can be quantitatively estimated from multivariate risk tools that are readily available in primary care. The most recent of these are the Pooled Cohort Equations, which estimate the 10-year risk of a cardiovascular event through application of the variables of age, sex, race, total and high-density lipoprotein cholesterol, blood pressure (including treatment status), current smoking, and diabetes.[17] Thresholds for pharmacologic treatment with statins are recommended as 10 percent by the USPSTF and 7.5 percent by the American College of Cardiology/American Heart Association (ACC/AHA) (and considered when risk is 5 to 7.5% in the presence of risk-enhancing factors).[3, 18] Recent guidance for adults from the AHA/ACC recommends lifestyle modification when BP is 130–139/80–89 mm Hg and estimated risk is less than 10 percent, and blood pressure-lowering medication when blood pressure is greater than 130/80 mm Hg and 10-year risk is greater than 10 percent.[19] Treatment thresholds recommended by guidelines and definitions around elevated values have generally decreased over time.

Dietary and Physical Activity Behaviors: Association With Health Outcomes and Prevalence in the United States

Large observational studies show that healthy diet and physical activity are associated with lower cardiovascular and all-cause mortality.[20-24] The U.S. Burden of Disease Collaborators found that poor diet was the leading risk factor contributing to death in the United States in 2016—even

greater than tobacco smoking; physical inactivity and low physical activity were also among the leading risk factors for death.[25] A risk assessment study utilizing National Health and Nutrition Examination Survey (NHANES) data estimated that dietary factors were associated with 45.4 percent of deaths due to heart disease, stroke, or diabetes; high sodium, high intake of processed meats, and low fruit and vegetable intake were the dietary components conferring the highest risk.[26]

Despite observational evidence for associations between these behaviors and outcomes, current diet and physical activity behaviors in the United States are suboptimal. Data from the 2015 Behavioral Risk Factor Surveillance System (BRFSS) found only 12.2 percent of adults meet the daily recommendation of 1.5 to 2.0 cups of fruit each day and 9.3 percent of adults met the vegetable consumption target of 2.0 to 3.0 cups per day.[27]. Based on 2013 BRFSS data, an estimated 36.8 percent of U.S. adults met the criteria for the 2014 USPSTF recommendation for intensive behavioral counseling for CVD prevention in adults with risk factors, based on self-reported BMI of 25 or greater and the presence of hypertension, dyslipidemia, or impaired fasting glucose.[28] Adults ≥65 years (56.4%), non-Hispanic blacks (43.3%), and men (40%) were most likely to meet criteria for behavioral counseling according to the existing USPSTF recommendation.[28] Of the AHA's seven components of ideal cardiovascular health—smoking, BMI, physical activity, healthy diet, total cholesterol, blood pressure, and fasting plasma glucose—the proportion of Americans meeting targets for a healthy diet is consistently the lowest among all age groups (**Table 2**).[11] There are some indications of progress, however, as NHANES data show that overall dietary pattern score improved between 1999 and 2016, with slight increases in carbohydrates from high quality sources, including whole grains (+2.95 g/day, p<.001), whole fruits (1.21 g/day, p<.001), non-starchy vegetables (0.44 g/day, p<.001); protein from nuts (+0.44 g/day, p<.001) and legumes (+0.13 g/day, p<.001); and decreased consumption of added sugar (-7.0 g/day, p<.001).[29,27] Progress was uneven, however[27]. The largest improvements in Healthy Eating Index scores were among younger adults and those with high income and education; no differences in eating trends were found by sex or race/ethnicity[27].

More U.S. adults are meeting physical activity guidelines than dietary recommendations; however, the proportion is still low. As of 2018, 54.2 percent of U.S. adults ≥18 years are meeting leisure-time aerobic physical activity goals.[30] However, only 24.0 percent are meeting both the aerobic and muscle-strengthening guidelines.[30] Older people, women of any age, and Hispanics are less likely to meet either of these guidelines.[30] Fortunately, recent trends suggest physical activity among adults in the United States is improving.[31, 32]

Behavioral Counseling Approaches

Most behavioral counseling interventions to reduce cardiovascular risk among those with elevated blood pressure or lipids address both diet and physical activity, although some focus on only one of these. The interventions can include goal setting, self-monitoring, feedback and reinforcement, self-efficacy enhancement, incentives, modeling, problem-solving, and motivational interviewing.[4] These interventions are typically delivered by specially trained health professionals (e.g., health educator, dietitian)[1] and can take different formats, including brief counseling by a primary care provider, with or without accompanying materials or followup counseling; mailed, print-based interventions with tailored feedback; individual or group

counseling; telephone counseling with no face-to-face contact; and computer-based interventions, including web-based sessions, email, or mobile technology.[4] Additionally, support that addresses barriers to change, social support, and general education and advice regarding the benefits of healthy eating or physical activity can be provided.[4] Some interventions included addition of cardiovascular-related components such as smoking cessation support and stress management. Most interventions also encourage weight loss among patients with excess weight.

Current Clinical Practice in the United States and Recent Recommendations

Numerous organizations, including the AHA, Academy of Nutrition and Dietetics, and Department of Veterans Affairs, recommend that all adults adhere to a healthy lifestyle, which includes a balanced diet low in sodium and saturated fats, and regular exercise. Lifestyle counseling for weight loss is additionally recommended for people with overweight or obesity. Details of these and other recommendations appear in **Table 3**.

The 2018 U.S. physical activity guidelines recommend that all adults engage in at least 150–300 minutes of moderate-intensity or 75-150 minutes a week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity aerobic activity in addition to engaging in strengthening activities at least twice per week. For adults with chronic conditions, including hypertension, who are not able to meet the key guidelines for general adult populations, the guideline recommends they engage in regular physical activity according to their abilities and should avoid inactivity.[9]

Despite these recommendations, counseling referral rates in primary care remain low and there are a number of barriers to referral from the clinician's perspective. A 2015 survey of U.S. primary care providers found that 58.6 percent discussed physical activity with most of their patients with CVD risk factors.[33] Nearly all providers that reported discussing physical activity with their patients reported encouraging increased physical activity (98.5%), but only 8.1 percent actually referred at-risk patients to intensive behavioral counseling. A major barrier to low rates of referral included attitudes and beliefs of providers that "patients won't do it" (53.4% of providers) and that "counseling is ineffective" (10%).[33] With respect to system-level barriers, "not enough time during visit" (60.9%), "insurance doesn't cover it" (12.1%) and "referral services aren't available" (11.4%) were among the barriers cited.

These findings are supported by other studies assessing treatment of at-risk patients in primary care. A 2014 review of physicians' use of the 5 A's model for weight loss counseling (Assess, Advise, Agree, Assist and Arrange) found that physicians frequently asked about or assessed patients' behavioral habits and readiness for change and provided behavior change advice, but rarely assisted patients in achieving goals or arranging support or referral to more intensive treatment.[34] Another review found that general practitioners tended to provide very little combined diet and physical activity advice to patients who were overweight or had obesity.[35] A survey of practitioners found that while 70 percent encountered conditions related to nutrition on a daily or weekly basis, only 25 percent felt "very confident" in providing nutrition advice.[36] It was also found that physicians infrequently referred patients to specialists such as dietitians for tailored interventions and advice.[35]

Previous USPSTF Recommendation

In 2014, the Task Force recommended offering or referring adults who were overweight or had obesity and had additional CVD risk factors to intensive behavioral counseling interventions to promote a healthy diet and physical activity for CVD prevention (**Grade: B recommendation**).[1] Specific guidance was not provided on what constituted an "intensive" intervention, but the recommendation statement noted that effective interventions involved multiple contacts over an extended period of time, typically 5 to 16 contacts over 9 to 12 months. This recommendation applied to adults age 18 years or older in primary care settings who were overweight or had obesity and known CVD risk factors, defined as hypertension, dyslipidemia, impaired fasting glucose, or the metabolic syndrome. The USPSTF maintains reviews and recommendations for a number of other conditions associated with increased cardiovascular risk, including obesity, smoking, diabetes, lipids, peripheral artery disease, carotid artery stenosis, and nontraditional risk factors.[37-43] Because these risk factors and conditions frequently coexist with those encompassed in this review, there exists some overlap of included populations and interventions. The recommendations related to behavioral counseling in adults without risk factors, those with abnormal blood glucose levels or diabetes, and those with obesity are particularly inter-related and are shown in **Table 4**. The recommendation on screening and treatment of adults for abnormal blood glucose is being updated concurrently with this recommendation.

Chapter 2. Methods

Scope and Purpose

This review is an update of the systematic review[44] that supported the 2014 USPSTF recommendation on this topic.[1] In contrast to the previous review, the current review excluded studies limited to or predominantly in populations with diabetes or prediabetes. This change was made because the USPSTF has commissioned a companion, concurrent systematic review to support the update of the recommendation on screening for abnormal blood glucose in adults that will include the evidence on behavioral counseling in populations with diabetes or prediabetes.[45] Thus, that population will be addressed in the separate diabetes screening review. In addition, weight loss trials that specifically targeted people with relevant cardiovascular risk factors were included in this review but were not included in the previous review.

Analytic Framework and Key Questions

With input from the USPSTF, we developed an Analytic Framework (**Figure 1**) and four Key Questions (KQs) to guide the literature search and selection of studies, data abstraction, and data synthesis.

Key Questions

1. Do primary care-relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior improve cardiovascular disease (CVD) and related health outcomes (e.g., morbidity, mortality) in adults with known CVD risk factors (hypertension or elevated blood pressure, dyslipidemia, or mixed or multiple risk factors [e.g., 10-year CVD risk >7.5%, metabolic syndrome])?
2. Do primary care-relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior improve intermediate outcomes associated with CVD (e.g., blood pressure, lipid levels, blood glucose, body mass index) in adults with known CVD risk factors (hypertension or elevated blood pressure, dyslipidemia, or mixed or multiple risk factors [e.g., 10-year CVD risk >7.5%, metabolic syndrome])?
3. Do primary care-relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior improve behavioral outcomes (e.g., diet, physical activity, sedentary behavior) in adults with known CVD risk factors (hypertension or elevated blood pressure, dyslipidemia, or mixed or multiple risk factors [e.g., 10-year CVD risk >7.5%, metabolic syndrome])?
4. What are the harms of primary care-relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior in adults with known CVD risk factors (e.g., hypertension or elevated blood pressure, dyslipidemia, or mixed or multiple risk factors [e.g., 10-year CVD risk >7.5%, metabolic syndrome])?

Data Sources and Searches

In addition to evaluating all studies that were included in the previous review of lifestyle counseling in populations with CVD risk factors,[44] we conducted a search to find studies published since the previous review, covering literature published from January 2013 through September 5, 2019. Additionally, to identify studies published during the search window of the previous review that might meet our updated inclusion criteria, we also evaluated selected studies *excluded* from the previous review and studies that were included in related reviews.[46, 47] The search strategy was developed by a research librarian and was peer-reviewed by a second research librarian (**Appendix A**). It included searches of MEDLINE, PubMed (publisher-supplied records only), PsycINFO, and the Cochrane Central Register of Controlled Trials. All searches were limited to articles published in the English language.

In addition to these database searches, we examined the reference lists of other previously published reviews, meta-analyses, and primary studies to identify additional potential studies for inclusion. We supplemented our searches with suggestions from experts and articles identified through news and table-of-content alerts such as those produced by the USPSTF Scientific Resource Center LitWatch activity. We also searched ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry Platform (www.who.int/ictrp) for ongoing trials through August 2019. Active surveillance was conducted through July 24, 2020 via article alerts and targeted journal searches to identify major studies that might affect the conclusions or understanding of the evidence. None were identified. We managed the literature search results using version X9 of EndNote® (Thomson Reuters, New York, NY), a bibliographic management software database.

Study Selection

Two reviewers independently reviewed 14,409 unique citations and 466 full-text articles against a priori inclusion and exclusion criteria (**Appendix A Table 1, Appendix B**). We included studies that targeted populations at increased risk of cardiovascular disease due to hypertension or elevated blood pressure, dyslipidemia, or through examination of multiple risk factors. Examination of multiple risk factors may include estimated 10-year CVD risk of >7.5 percent or higher (e.g., using the Pooled Cohort Equations[17] or Framingham risk calculators[15]), presence of the metabolic syndrome, or having any of multiple risk CVD factors (as long as hypertension/elevated blood pressure and dyslipidemia are among the eligible risk factors). For all key questions, we included randomized controlled trials (RCTs), including cluster-randomized trials, as well as nonrandomized controlled trials of behavioral counseling interventions to improve diet and increase physical activity in people with CVD risk factors. In addition, we allowed inclusion of systematic reviews, comparative cohort studies, and population-based case-control studies for assessments of harms of lifestyle counseling (KQ4).

We excluded studies that targeted populations with known CVD, diabetes, or chronic kidney disease; and studies that targeted populations with prediabetes. We also excluded studies of behavioral counseling interventions that targeted prevention or management of other medical conditions, such as cognitive impairment, serious mental health conditions, arthritis, falls,

chronic pain, and cancer. We included trials whose primary aim was weight loss if the study targeted people with CVD risk factors and involved a behavioral counseling intervention. We limited inclusion to studies in adult populations in countries rated as "Very High" on the human development index according to the UN, based on 2015 indicators.[48]

We included studies of behavioral counseling interventions on diet and nutrition, physical activity (including sedentary behavior), or a combination thereof. Interventions could be delivered alone or as part of a larger multicomponent intervention that also addressed other health behaviors (e.g., smoking cessation, medication adherence). There were no restrictions on the contact time or duration of the interventions for inclusion, however, 6 months after randomization or the baseline assessment was the required minimum followup time for outcome assessment. Interventions had to have been conducted in a healthcare setting or be feasible for a healthcare setting to implement, meaning that the intervention could be "referable" from primary care were it to be implemented in a healthcare system. Thus, we excluded interventions with components that were not feasible for implementation in healthcare settings (e.g., interventions conducted within existing social networks, media campaigns, environmental interventions, public policy interventions). We also excluded studies conducted in settings that were not generalizable to primary care, such as inpatient facilities, emergency departments, nursing homes or other institutional settings, classrooms, and occupational settings. Comparative effectiveness studies were excluded, and allowable control groups included no intervention (e.g., usual care, wait list), a minimal intervention (e.g., pamphlets, links to preexisting internet resources, brief counseling of no more than an estimated 60 minutes annually), and attention controls with similar format and intensity but a different content area.

For the main search results, pairs of independent reviewers assessed a sample of 1,500 abstracts for inclusion, and discrepancies were resolved by discussion and consultation with the larger review team as needed. An artificial intelligence (AI) program embedded in the DistillerSR platform (Evidence Partners, Ottawa, Canada) then "trained" on these 1,500 abstracts and the abstracts of other known included studies from the previous review and related reviews. For the remaining abstracts, we conducted dual human review (if the AI score was equivocal for inclusion; 2,241 abstracts) or used the AI program in place of one of two human reviewers (if the AI score indicated a low probability of inclusion; 4,217 abstracts). Every abstract was assessed by at least one human reviewer. All abstracts identified in subsequent updating bridge searches (6,451 abstracts) were reviewed only by human reviewers. Discrepancies between any two reviewers (either two human reviewers or the AI and a human reviewer) were resolved by a different human reviewer or consultation with the larger team. Two independent (human) reviewers assessed full-text articles against our inclusion criteria and discrepancies were resolved by discussion or consultation with the larger review team as necessary.

Quality Assessment and Data Abstraction

Two reviewers independently rated the studies' methodological quality using USPSTF design-specific criteria (**Appendix A Table 2**).[49] Studies were rated as "good," "fair," or "poor," and discrepancies between raters were resolved by discussion or consultation with the larger review team. Good-quality studies were those that met nearly all of the specified quality criteria (e.g.,

comparable groups were assembled initially and maintained throughout the study and followup was approximately 90% or higher), whereas fair-quality studies did not meet these criteria but did not have serious threats to their internal validity related to their design, execution, or reporting. Poor-quality studies typically had several important limitations, including at least one of the following risks of bias: very high attrition (generally >40%), differential attrition between intervention arms (generally >20%); substantial lack of baseline comparability between groups without adjustment; or issues in trial conduct, analysis, or reporting of results (e.g., possible selective reporting, inappropriate exclusion of participants from analyses, questionable validity of randomization and allocation concealment procedures). Studies rated as "poor" quality were excluded from the review. For studies that had been included in the previous review on this topic or the recent USPSTF review of weight management interventions, we did not repeat critical appraisal of the original studies since we were updating our own work.

For all of the included studies, one reviewer extracted key elements into standardized abstraction forms in DistillerSR (Evidence Partners, Ottawa, Canada). A second reviewer checked the data for accuracy. For each study, we abstracted general characteristics (e.g., author, year, study design), clinical and demographic characteristics of the sample and setting (e.g., age, race/ethnicity, baseline clinical characteristics, setting, country), intervention details, and results. Outcomes of interest included health outcomes (cardiovascular events and related morbidity, including myocardial infarction [MI], stroke, coronary event, transient ischemic attack, arrhythmia, incident peripheral artery disease, angina, claudication, congestive heart failure, any CVD event); mortality; quality-of-life and related measures), intermediate outcomes (blood pressure, lipids, glucose, adiposity-related measures, 10-year CVD risk, cardiorespiratory fitness), and behavioral outcomes (dietary intake, physical activity, sedentary behavior). We abstracted objectively measured weight loss outcomes (weight, BMI, waist circumference) instead of self-reported weight or energy intake. We required that all outcomes were measured 6 months or more after baseline assessment.

For population risk factors, we categorized studies based on the risk factors required by the studies' inclusion criteria. We labeled trials limited to people with hypertension or elevated blood pressure as "Hypertension," even if the trial was limited to people with elevated blood pressure and excluded those meeting criteria for hypertension. Similarly, the label "Dyslipidemia" was used for trials that required all participants to have lipid levels outside of the optimal range, including both borderline and high LDL (or low for HDL) levels. Trials that included participants with any of multiple risk factors are labeled as "Multiple." Trials are described as "weight loss" trials if the study required all participants to have a specified level of excess weight at study entry and had an explicit goal of weight loss for all participants. Trials were categorized as targeting low socioeconomic status (SES) populations if the community in which recruitment took place was described as low-income by the authors, or if any of the following were true: there was 20 percent or higher unemployment among participants, or 30 percent or more of participants were either unemployed or disabled, among working-age populations; fewer than 70 percent or participants were high school graduates (U.S. studies only); more than 20 percent of participants were at or below the 100 percent of federal poverty limit; more than 30 percent of participants were on Medicaid; or all participants were recruited from Federally Qualified Health Centers (designed to serve low-income individuals).

For intervention characteristics, we abstracted a detailed description of the interventions and information on the setting, format, mode of delivery (i.e., in-person, telephone, electronic, or print), dietary approach (Dietary Approaches to Stop Hypertension [DASH], fat-modified [low in saturated fat, low in all fats, or moderate levels of fats], low sodium, Mediterranean), duration, number and length of sessions, providers and provider training, and adherence. We estimated the total hours of interventionist contact based on the planned number and length of contacts. If a study did not report the length of sessions, we estimated session length as follows: a session described as "brief" was assumed to last 15 minutes if there was face-to-face, individual contact and 5 minutes if it was a phone session and for sessions that were not described as "brief," individual face-to-face or interactive web-based sessions were assumed to last 30 minutes and group sessions was assumed to last for 60 minutes. Consistent with the previous review, we grouped the studies into three levels of contact dose (referred to as "intensity" in the previous review): low (estimated ≤30 minutes of phone or in-person contact), medium (31–360 minutes), and high (>360 minutes). Interventions that consisted of only print materials were categorized as low contact. Mailings and print materials were not included in the estimated of number of sessions or session length.

During data abstraction, we catalogued the availability and characteristics of subgroup analyses by age, sex, race/ethnicity, and other characteristics of interest (e.g., BMI or weight status). We noted whether subgroup analyses were prespecified or post-hoc and whether interaction testing was reported.

Data Synthesis and Analysis

We created summary tables for all KQs showing study, population, intervention characteristics, and outcomes for qualitative evidence synthesis. For both continuous and dichotomous outcomes, adjusted effect estimates reported by primary studies were used over unadjusted values. Crude effect estimates were calculated if between-group results were not reported. For pooling, we used the Restricted Maximum Likelihood model with the Knapp-Hartung correction for small numbers of studies.[50, 51] We chose this method because there was either a small number of trials to be pooled or high statistical heterogeneity (commonly I^2>50%, often >80%) for most analyses.[52] We generated analyses that included all available intervention groups for each study and that were limited to the single most intensive or comprehensive intervention group per study (termed primary intervention group). Effect sizes were generally slightly larger when limited to the primary intervention group, with slightly larger confidence intervals, but statistical significance was almost always consistent between the two approaches. Meta-analyses limited to the primary intervention group are presented for all intermediate (KQ2) and behavioral (KQ3) outcomes except diabetes incidence and metabolic syndrome, where we included results for both groups from the Prevención con Dieta Mediterránea (PREDIMED) study, since a substantial proportion of the evidence would have been lost if one PREDIMED arm was excluded. However, for mortality and cardiovascular event outcomes, for which the absolute number of events was generally small, results for multiple intervention groups were combined. For pooled analyses of intermediate (KQ2) and behavioral (KQ3) outcomes, the followup time point closest to 12 months was selected if there were multiple followup assessments. For systolic blood

pressure, total cholesterol, and weight outcomes, we generated funnel plots and ran Egger's test to explore small-study effects, which can be related to publication bias.[53]

Additionally, we conducted meta-regression and subgroup analyses to explore whether there were study, population, or intervention characteristics that were associated with effect size for systolic blood pressure, total cholesterol, and weight. These outcomes were selected for prespecified subgroup and meta-regression analyses because they were the most commonly reported outcome in each of the three main intermediate outcome domains. Characteristics explored were: intervention contact (number of sessions, estimated contact hours, high- vs. medium- vs. low-contact category, duration [in weeks]); diet recommendation (fat-modified, low-sodium); delivery (group, in-person contact); weight loss approach (recommended for all participants, recommended for the subset of participants with overweight or obesity); use of motivational interviewing; incorporation of the Transtheoretical (Stages of Change) Model; active medication management; provision of pedometers; provision of blood pressure monitors; primary care staff involvement; population targets (older adults, CVD risk factor selection, low SES), U.S. setting; and indicators of study quality (quality rating, time to followup, sample size, year of publication). Initially we also planned to explore whether trials with majority nonwhite samples differed from those that did not; however, almost all trials with high race/ethnic minority representation were in economically disadvantaged populations, so we were unable to disentangle these effects and instead focused on socioeconomic status.

The availability of subgroup analyses within individual studies was audited to determine the proportion of studies reporting outcomes according to various subgroups. Subgroup analyses were sparsely and inconsistently conducted in included studies and thus were not quantitatively pooled. Analyses were qualitative and aimed to determine whether interventions were broadly effective among various subpopulations.

We used Stata 15.1 (StataCorp LLC, College Station, TX) and R 3.5.2 (R Foundation for Statistical Computing, Vienna, Austria). All significance testing was 2-sided, and results were considered statistically significant if the p-value was 0.05 or less.

Grading the Strength of the Body of Evidence

We graded the strength of the overall body of evidence for each key question. We adapted the Evidence-based Practice Center approach,[54] which is based on a system developed by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group.[55] Our method explicitly addresses four of the five Evidence-based Practice Center-required domains: consistency (similarity of effect direction and size), precision (degree of certainty around an estimate), reporting bias (potential for bias related to publication, selective outcome reporting, or selective analysis reporting), and study quality (i.e., study limitations). We did not address the fifth required domain—directness—as it is implied in the structure of the key questions (i.e., pertains to whether the evidence links the interventions directly to a health outcome).

The domain of consistency was rated as reasonably consistent, inconsistent, or not applicable

(e.g., single study). The domain of precision was rated as reasonably precise, imprecise, or not applicable (e.g., no evidence). Study quality reflects the quality ratings of the individual trials and indicates the degree to which the included studies for a given outcome have a high likelihood of adequate protection against bias. The body-of-evidence limitations field highlights important restrictions in answering the overall key question (e.g., evidence of reporting bias, lack of replication of interventions, nonreporting of outcomes important to patients).

At least two independent reviewers rated the overall strength of evidence for each intervention type. We resolved discrepancies through consensus discussion with the full review team, consulting with outside reviewers as needed. We graded the overall strength of evidence as high, moderate, low, or insufficient. "High" indicates high confidence that the evidence reflects the true effect and that further research is very unlikely to change our confidence in the estimate of effects. "Moderate" indicates moderate confidence that the evidence reflects the true effect and that further research may change our confidence in the estimate of effect and may change the estimate. "Low" indicates low confidence that the evidence reflects the true effect and that further research is likely to change our confidence in the estimate of effect and to change the estimate. A grade of "insufficient" indicates that evidence is either unavailable or does not permit an estimate of an effect.

Expert Review and Public Comment

The draft Research Plan was posted from June 14 to July 17, 2018. Comments addressed the types of eligible interventions, selection of outcomes, eligible settings, clarity about included populations, and integration of findings with the diabetes review. Clarifying text was added to the intervention inclusion and exclusion criteria. Waist circumference was added as an outcome, and cardiorespiratory fitness was explicitly listed as an included intermediate outcome. The setting description was broadened to include the term primary care-referable in addition to primary care-generalizable. With respect to included populations, language in the KQs was clarified, and the condition definition in the inclusion and exclusion criteria table was modified to explicitly define the included populations; newly included in this update are populations with elevated blood pressure in addition to populations with hypertension. The draft version of this report was reviewed by three invited experts and 9 individuals at 5 USPSTF Federal Partner agencies. Experts were selected based on their expertise with fundamental methodologic and content aspects of the review (i.e., nutrition, physical activity, hypertension, and dyslipidemia, CVD epidemiology, and population health) and were selected to obtain diverse informed perspectives. All expert comments were considered, and selected comments from experts were used to clarify and extend the synthesis of evidence to ensure accuracy and address scientifically relevant concerns. All comments were shared with members of the USPSTF and the Agency for Healthcare Research and Quality (AHRQ). Finally, a draft report was posted for public comment on the AHRQ website from May 12 to June 9, 2020. Additional minor modifications were made in response to comments received, including some added detail, minor clarifications, and mention of additional evidence limitations.

USPSTF Involvement

This systematic review was funded by AHRQ under contract to support the USPSTF. We consulted with USPSTF liaisons at key points in the review regarding the development of the research plan (i.e., KQs, analytic framework, and inclusion and exclusion criteria) and the finalization of the systematic review. An AHRQ Medical Officer provided project oversight, reviewed the draft and final versions of the review, and assisted with public comment on the research plan and draft review. The USPSTF and AHRQ had no role in the study selection, quality assessment, or writing of the systematic review.

Chapter 3. Results

Description of Included Studies

Ninety-four randomized and cluster-randomized trials[56-149] (N=52,174) of diet and physical activity counseling, reported in 227 publications[56-282] (**Appendix B**), met our inclusion criteria. Twenty-nine trials reported a health (KQ1) outcome (n=23,854), 91 reported an intermediate (KQ2) outcome (n=47,951), 70 reported a behavioral (KQ3) outcome (n=43,243), and 20 reported on harms or potential harms (n=18,263). Forty-two trials were newly identified in this update.[108-137, 139-144, 261]

Of all included studies, 32 (34.0%) were limited to people with hypertension or elevated blood pressure, 16 (17.0%) were limited to those with dyslipidemia, and the remaining 46 (49.0%) included people with any of multiple risk factors, typically including excess weight, impaired glucose tolerance, metabolic syndrome, type 2 diabetes, smoking, and/or elevated 10-year cardiovascular risk in addition to hypertension and dyslipidemia (**Table 5**). Most trials recruited participants from healthcare settings: 38 (40.4%) in primary care settings and 20 (21.3%) in similar settings, such as community health clinics or health plan membership databases. Forty-three (45.7%) of the trials were conducted in the United States. The median (interquartile range [IQR]) sample size was 314 (154 to 601). One of the newly published trials was the PREDIMED trial, a large (n=7,447) multisite trial with long-term (5-year) followup conducted by Estruch and colleagues.[131]

Included Populations

Across all trials, 49.5 percent of the participants were female and the mean (SD) age was 56.0 (8.3) years. Eleven trials had a minimum age of 50 or higher (**Table 6**), including PREDIMED, which had a mean age of 67 years. Among the trials reporting baseline CVD risk factor status, 62.0 percent of the participants had hypertension, 70.3 percent had dyslipidemia, 20.2 percent had diabetes, 2.8 percent had known cardiovascular disease, and 22.7 percent were current smokers. Twenty-one trials were limited to individuals with excess weight,[58, 60, 69, 84, 98, 109, 116, 119-121, 123-130, 134, 141, 144] and although this was not an inclusion requirement for the remaining trials, most participants in the included trials were overweight or had obesity; the mean (SD) baseline BMI was 29.8 (2.6) kg/m^2. Of the 43 trials conducted in the United States, 16 trials (37.2%) appeared to include majority Hispanic or nonwhite samples. Overall, 19 (20.2%) focused on low-SES populations. Detailed population characteristics are available in **Appendix F Table 1**.

Among the 32 trials that were limited to people with hypertension or elevated blood pressure , the mean (SD) baseline systolic and diastolic blood pressure values were 136 (10) and 86 (6) mm Hg, respectively, with 61.1 percent of participants meeting diagnostic criteria for hypertension according to study criteria. Nine of these studies (28.1%) were limited to patients taking antihypertensive medications, and nine other trials (28.1%) excluded patients taking antihypertensive medications. Four trials (n=4,659) excluded people with hypertension and limited participation to those with elevated blood pressure , with the goal of preventing progression to hypertension.[120, 122, 133, 138] Among the 16 trials limited to patients with

dyslipidemia, baseline mean (SD) total cholesterol was 254 (20.2) mg/dL and LDL cholesterol was 160 (22) mg/dL. Ten (62.5%) of the trials in populations with dyslipidemia excluded patients who were taking lipid-lowering medications, and the remaining trials had no restrictions related to medication use. Among the 46 trials that recruited patients with any of multiple CVD risk factors, 42 (91.3%) had no restrictions related to medication use.

Included Interventions

The 94 included trials had 120 active intervention arms (**Table 7**). Eighty-one (67.5%) of the interventions provided counseling that encompassed both diet and physical activity, 33 (27.5%) addressed only diet, and six (5.0%) addressed only physical activity. None of the physical activity trials focused exclusively on reducing sedentary behavior. The median (IQR) number of contacts was 12 (5–27), with an estimated 6 (2.2–15.8) hours of contact over 12 (6–18) months. Fifty-four (45.0%) of the interventions offered high-contact interventions, that is, over 6 hours of contact time with an interventionist (in person or over the phone), 59 (49.2%) offered medium-contact interventions, or an estimated 31 minutes to 6 hours of contact, and only 7 (5.8%) were low-contact interventions with 30 minutes or less of direct contact. The trials that only addressed physical activity had relatively low contact time, ranging up to an estimated 4.5 hours of contact at most.[61, 87, 90, 94, 132, 140] See **Figure 2** for a graph showing the distribution of contact time by intervention target. Almost all of the interventions involved some one-on-one time with an interventionist; however, nine (7.5%) were limited to group sessions and four (3.3%) were entirely computer- and/or print-based,[97, 103, 123, 142] including one that tested an online training module for primary care physicians without any specific patient-facing components.[97] The use of motivational interviewing was described in 43 (35.8%) interventions. Other common elements included typical behavior change techniques such as goal setting, problem solving, and self-monitoring. Primary care clinicians were involved in delivering 27 (22.5%) of the interventions, and primary clinicians or their staff delivered all or most of the interventions in eight (6.7%) trials.[77, 80, 83, 97, 102, 119, 128, 129] Other interventionists included nutritionists, registered dieticians, exercise specialists, nurses, master's- and doctoral-level counselors trained in behavioral methods, and lifestyle coaches.

Among the trials targeting people with hypertension or elevated blood pressure, the most commonly used dietary approaches were a low-sodium diet (29 of 50 groups [58.0%]) and the DASH diet (11 of 50 groups [22.0%]), which also recommends moderate or restricted sodium intake. Eighteen of these trials (36.0%) included management of antihypertensive medications, and five (10.0%) provided blood pressure monitors. Of the interventions limited to people with dyslipidemia or suboptimal lipid levels, 12 (60%) recommended a fat modified diet. Of all studies, the approach for weight loss was variable: 29 (24.2%) interventions were limited to people with excess weight and explicitly recommended weight loss for all participants, 31 (25.8%) interventions recommended weight loss for those in the sample with excess weight, and 11 interventions (9.2%) focused on improving diet and physical activity without explicitly promoting weight loss. The remaining 49 (40.8%) interventions did not report whether or for whom weight loss was promoted. Usual care was the most common type of control group (73 [77.7%] of the trials), but 7 trials instructed control group participants to maintain their usual habits.[57, 58, 72, 87, 95, 121, 148] For detailed information about intervention characteristics for each

trial, see **Appendix F Tables 2 and 3**. **Table 8** lists recommended eating plans for two diets used in the included trials, the DASH diet and the Mediterranean diet.

The PREDIMED trial was a large trial conducted in Spain among adults age 55 to 80 years who had any of a number of CVD risk factors and did not score as "unlikely to change" according to the Stages of Change model. The trial is an important addition to this literature base, given its large sample size and length of followup. Participants in both active intervention groups first met with a dietitian to discuss individual recommendations to help them adopt the Mediterranean diet based on a dietary assessment. Next, they participated in a group educational session covering dietary goals, meal plans, shopping lists, and questions they had about the recommended diet. Participants then had quarterly visits with the dietitian, who assessed their progress, discussed dietary goals, and offered support for an estimated 20 sessions of individual diet counseling. Throughout the program, interventionists emphasized the holistic approach to lifestyle change in order to tailor the intervention to nutritional assessment and individual needs, instill a sense of empowerment, and support a sense of accomplishment for each upward step in the 14-point Mediterranean diet score. Interventionists used cognitive behavioral techniques such as goal setting, self-monitoring, feedback and reinforcement, self-efficacy enhancement, incentives, problem solving, relapse prevention, and motivational interviewing in individual and group sessions. In addition, participants received either 20 1.5-liter allotments of extra virgin olive oil (intervention group 1 [IG1]) or 20 allotments of 2,700–3,700 grams of mixed nuts (intervention group 2 [IG2]). The dietary recommendations are listed in **Table 8**. Also, dietitians insisted that two main meals per day should be eaten seated at a table and last more than 20 minutes. Control group participants received a brief counseling session promoting a low-fat diet and annual leaflets, and in the fourth year of the study and beyond, received quarterly invitations to individual and group-based sessions focused on low-fat diets.

Study Quality

Among all trials, 19 (20.2%) were rated as "good" quality, and the remaining were rated as "fair." The median (IQR) study retention was 86 percent (79%–92%) at 12 months' followup or the closest to 12 months reported by the trial. Among those that did not receive the "good" rating, attrition was typically 15 percent or greater; important methodologic information was often missing, such as blinding of allocation and outcomes assessment, and, particularly for smaller trials, groups were not clearly comparable at baseline. The PREDIMED trial received a "fair" rating primarily due to noted protocol violations regarding enrollment of household members without randomization and inconsistent use of randomization tables. The study investigators issued a retraction of the original publication after violations were discovered with updated analyses,[193] including extensive sensitivity analyses to explore the impact of the violations (e.g., dropping sites in which the violations had occurred) and found that effect sizes were only minimally affected. Results reported here are from the updated version of the results. Eleven trials were excluded due to quality concerns; most had either very high attrition (>40%) or very differential attrition between groups (>20%), or we had serious concerns about the baseline comparability of the groups and usually other concerns as well (e.g., failure to report randomization methods and blind, lack of information about outcomes assessment).

Adherence to the interventions was variable and reporting of adherence was very heterogeneous. In general, most trials providing data indicated that a very high proportion (typically >90%) engaged in the intervention at least minimally, and that roughly 60 to 80 percent of participants participated in more than half of the offered sessions. A few trials reported attendance rates that exceeded ~80 percent of all sessions, for all participants, for interventions involving two,[143] three,[81] five,[63, 65, 80] six,[67] and nine sessions.[104]

KQ1. Do Behavioral Counseling Interventions to Improve Diet and Increase Physical Activity Improve CVD and Related Health Outcomes in Adults With Known CVD Risk Factors?

Summary of Results

Only 29 of the 94 included studies reported health outcomes. Twelve trials[59, 65, 75, 105, 116, 120, 121, 125, 131, 138, 141, 148] reported CVD events with followup ranging from six months to sixteen years, and medium- or high-contact behavioral counseling was associated with lower risk of any CVD event (RR=0.80 [95% CI, 0.73 to 0.87]; 9 RCTs [n=12,551]; I^2=0%), myocardial infarction (MI, RR=0.85 [95% CI, 0.70 to 1.02]; 6 RCTs [n=10,375]; I^2=0%), and stroke (RR=0.52 [95% CI, 0.25 to 1.10]; 4 RCTs [n=9,800]; I^2=0%), although the pooled effect was only statistically significant for the composite CVD events outcome (**Figure 3, Table 9**). Only three of these trials were included in the previous review.[59, 75, 105] The PREDIMED study reported a number of cardiovascular outcomes at 5-year followup, with statistically significant reductions in stroke, incident peripheral artery disease (PAD), and all CVD events combined, but not MI (**Table 10**). Overall, 3.6 percent (179/4997) of PREDIMED intervention participants, compared with 4.4 percent (109/2450) of control participants, experienced a CVD event, for a 30 percent reduction in risk (HR=0.70 [95% CI, 0.55 to 0.89]).[131] Few studies were powered for mortality, and neither individual large studies nor the pooled estimate showed a beneficial effect on mortality (pooled RR=0.89 [95% CI, 0.71 to 1.11]; 18 RCTs [n=17,939], I^2=0%, **Figure 4**) at followup ranging from 6 months to 16 years. Among three large trials,[75, 131, 138] all findings for both all-cause and cardiovascular-related mortality were in the direction of a greater benefit for intervention participants relative to control participants; however, results were statistically significant in only one trial.[75] This trial was limited to men with treated hypertension and offered seven diet and physical activity counseling sessions for all participants as well as smoking cessation counseling to the 29 percent of participants who were smokers (estimated 11.5 hours of interventionist contact for non-smokers and 17.5 hours for smokers). Both all-cause mortality (RR=0.62 [95% CI, 0.42, 0.92]) and cardiovascular mortality (RR=0.56 [95% CI, 0.34, 0.92]) were reduced at 6.6-year followup.[75] A variety of patient-reported subjective well-being measures were reported in eleven trials, but group differences were generally very small and statistically nonsignificant.

Detailed Results by Outcome

CVD Events

CVD events were reported in 12 trials (**Figure 3, Appendix G Figures 1 and 2**, **Appendix H Table 1**).[59, 75, 105, 116, 120, 121, 125, 131, 138, 141, 148] Only three of these trials were included in the previous review.[59, 75, 105] Among the eight trials reporting a composite outcome of any CVD event, the pooled effect showed lower risk among those participating in a behavioral counseling intervention (pooled RR=0.80 [95% CI, 0.73 to 0.87]; 9 RCTs [n=12,551]; I^2=0%, **Figure 3, Table 9**). A sensitivity analysis dropping outcomes assessed prior to 2 years of followup showed almost identical results (pooled RR=0.80 [95% CI, 0.72 to 0.88]; 7 RCTs [n=12,105]; I^2=0%). Populations in these trials were recruited based on hypertension or the presence of multiple risk factors, and control group event rates suggest that these trials included populations with a broad range of underlying CVD risk. For example, in PREDIMED, 4.4 percent of the control group experienced an event over 5-year followup. Considering that 49 percent of participants had diabetes and 47 percent were obese, event rates may be lower than expected; however, 49 percent were on antihypertensive medication and 40 percent were on statin-lowering medication at baseline.[131] On the other hand, in the trial by Fagerberg, 32.9 percent of the control group experienced a CVD event over 6.6 years of followup. Thirteen percent of participants in this study had a history of a prior CVD event, 29 percent were smokers, and mean BP was 155/91 mm Hg despite participants having taken multiple antihypertensive medications for a decade or more.[75] The behavioral counseling interventions employed in these trials reporting CVD events were heterogeneous in terms of dietary messages and did not consistently include a PA component. For example, the PREDIMED trial[131] was based on the Mediterranean diet, and the Fagerberg trial[75] promoted a fat-modified diet consistent with older NCEP guidelines at the time; additionally, it offered a robust 6-session smoking cessation component. In contrast, two of three intervention groups in the TONE trial involved sodium reduction.[105] Among trials reporting CVD events, three[105, 116, 141] were weight loss trials, three[120, 121, 131] made no mention of weight loss (although one of these had no observed CVD events[121]), and two recommended weight loss for participants with excess weight.[75, 138]

Pooled analysis of MI (RR=0.85 [95% CI, 0.70 to 1.02]; 6 RCTs [n=10,375]; I^2=0%) and stroke (RR=0.52 [95% CI, 0.25 to 1.10]; 4 RCTs [n=9,800]; I^2=0%) showed a statistically non-significant lower risk of events in the intervention groups. The PREDIMED trial accounted for approximately two-thirds of the individuals included in these analyses, and reported hazard ratios for a number of cardiovascular outcomes at 5-year followup (**Table 10**). PREDIMED reported statistically significant reductions in stroke (1.6% in intervention group vs. 2.4% in control group, HR=0.58 [95% CI, 0.42 to 0.82]), incident PAD (0.7 to 1.1% in the intervention groups vs. 1.8% in the control group, HR=0.36 to 0.52, [95% CI, range 0.20 to 0.86 for both intervention groups), and all CVD events combined (3.6% in the intervention groups vs. 4.4% in the control group, HR=0.70 [95% CI, 0.55 to 0.89]), but not MI (1.4% in the intervention groups vs. 1.6% in the control group, HR=0.80 [95% CI, 0.53 to 1.21]).[131] The overall beneficial effect on any CVD event was maintained in a sensitivity analysis dropping the PREDIMED trial from the meta-analysis (pooled RR=0.79 [95% CI, 0.70 to 0.90], 8 RCTs [n=5,104], **Table 9**). Of all trials reporting CVD outcomes, other outcomes reported included transient ischemic attacks, arrhythmias, angina, claudication, congestive heart failure, and "other CVD event." Most of

these outcomes were hampered by small numbers of events, however, and results were wide-ranging, typically very imprecise (i.e., very wide confidence intervals), and usually not statistically significant.

PREDIMED also reported on the consistency of effects on any CVD event (their primary endpoint) among a number of patient subgroups.[131] They found that the effect was larger for people with a baseline BMI of 30 or more (HR=0.51 [95% CI, 0.37 to 0.71]) than those with a BMI of 25 to 30 (HR=1.04 [95% CI, 0.71 to 1.54]) or less than 25 (HR=0.69 [95% CI, 0.29 to 1.67], interaction p=0.05). In addition, intervention effects were larger for those with hypertension (HR=0.65 [95% CI, 0.50 to 0.84]) and dyslipidemia (HR=0.60 [95% CI, 0.44 to 0.80]) at baseline compared with their counterparts (no baseline hypertension HR=1.25 [95% CI, 0.64 to 2.45], no baseline dyslipidemia HR=0.95 [95% CI, 0.64 to 1.42], interaction p=0.06 for both). They found no differences in the impact of the intervention on effect size by sex, age (<70 vs. ≥70), presence of diabetes at baseline, smoking status (never vs. ever smokers), family history of premature CHD, waist circumference (<median vs. ≥median), or baseline Mediterranean diet adherence score (<10 vs. ≥10).

Mortality

Eighteen trials of medium and high-contact interventions reported all-cause mortality (**Figure 4, Appendix H Table 2**), and the pooled effect did not demonstrate a benefit (pooled RR=0.89 [95% CI, 0.71 to 1.11], 18 RCTs [n=17,939], I^2=0%) at followup ranging from 6 months to 16 years. Among these 18 studies are three that reported that there were no deaths,[110, 126, 127] and other studies had a limited number of deaths, likely due to trial duration and sample sizes. Only three had sufficient sample size and time to followup to have more than 10 deaths per study group.[75, 131, 138] A sensitivity analysis dropping mortality outcomes assessed prior to 2 years of followup showed similar results (pooled RR=0.85 [95% CI, 0.67 to 1.07]; 10 RCTs [n=14,017]; I^2=3%).

The most recent of the large trials was PREDIMED.[131] PREDIMED found no difference between groups in all-cause mortality after 5 years, but did show slightly reduced cardiovascular-related mortality, with 1.1 percent of intervention participants dying (57/4,997), compared with 1.2 percent of control participants (30/2,450). However, this difference was not statistically significant (HR=0.83 [95% CI, 0.54 to 1.29]).[131] The trial with the largest effect, offering a high-contact intervention limited to 508 men with treated hypertension, found statistically significant reductions in mortality after 6.6 years for both all causes (16.2% [41/253] of intervention participants vs. 25.1% [64/255] of control participants, RR=0.62 [95% CI, 0.42 to 0.92]) and cardiovascular-related mortality (9.5% [24/253] vs. 16.5% [42/255], RR=0.56 [95% CI, 0.34 to 0.92]), but smaller statistically nonsignificant findings at 3.3 years' followup.[75] This trial also offered smoking cessation counseling to the 29 percent of participants who were smokers. The third large trial to examine mortality was the Trial of Hypertension Prevention-II (TOHP-II) trial among adults younger than age 50 with elevated blood pressure who were 110 to 165 percent of their ideal weight, offering sodium reduction and/or weight loss interventions in a 2x2 factorial design.[138] TOHP-II found no group differences for all-cause mortality at 16-year followup (RR=0.90 [95% CI, 0.52 to 1.52], 2.1% [25/1,191] deaths in the intervention group vs. 2.4% [28/1,191] in the control group) comparing sodium reduction vs. no sodium reduction.

Patient-Reported Outcomes of Subjective Well-Being

Eleven[59, 62, 68, 75, 103, 109, 114, 126, 148, 149, 224] trials reported some type of patient-reported health outcome, including SF-36 or SF-12 scores;[59, 68, 126, 148, 224] Minor Symptoms Evaluation Profile measures of vitality, contentment, and sleep;[75] the General Health Questionnaire;[62] the EQ-5D quality of life measure;[109, 114, 224] the European Quality of Life instrument,[149] and quality-adjusted life years (**Appendix H Table 3**).[103] Although most results favored the intervention groups in absolute differences, very few differences were statistically significant and most group differences in change were less than one point. The single measure that showed a benefit among multiple intervention groups or timepoints was the SF-36 vitality score in a single study of a 33-session intervention promoting either the DASH diet or a low-sodium diet for patients with untreated elevated blood pressure or hypertension.[59] This trial reported 1.8- to 3.6-point greater improvement in the intervention groups on a 100-point scale at 6- and 18-month followup.

KQ2. Do Behavioral Counseling Interventions to Improve Diet and Increase Physical Activity Improve Intermediate Outcomes in Adults With Known CVD Risk Factors?

Summary of Results

Behavioral counseling interventions were associated with small, statistically significant reductions in continuous measures of blood pressure, total cholesterol, fasting glucose, and adiposity-related outcomes at 12 to 24 months' followup. There was a mean 1.8/1.2 mm Hg greater reduction in blood pressure in intervention than control groups after 12 to 24 months (pooled systolic blood pressure [SBP]=-1.8 [95% CI, -2.5 to -1.1]; 42 RCTs [44 effects, n=14,580]; I^2=37%; pooled diastolic blood pressure [DBP]=-1.2 [95% CI, -1.6 to -0.8]; 38 RCTs [40 effects, n=13,098]; I^2=33%; **Figure 5, Table 11**). In addition, in trials reporting incidence of hypertension, intervention groups had a 26 percent lower risk of onset (pooled RR=0.74 [95% CI, 0.58 to 0.94]; 5 RCTs [n=2,707]; I^2=12%) (**Table 12**). For lipids, the pooled average mg/dL difference in change between groups was -3.5 for total cholesterol, -2.1 for LDL, and 0.6 for HDL (total cholesterol MD=-3.5 [95% CI, -5.6 to -1.4]; 36 RCTs [38 effect, n=11,414]; I^2=66%; LDL=-2.1 [95% CI, -4.1 to -0.2]; 30 RCTs [32 effects, n=8,894]; I^2=56%; HDL= 0.6 [95% CI, 0.2 to 1.0]; 32 RCTs [34 effects, n=8,974]; I^2=34%; **Figures 9 and 10, Table 11**). The impact on diabetes was mixed in four trials and the pooled effect was not statistically significant (RR=0.82 [95% CI, 0.66 to 1.03]; 5 effects [4 RCTs, n=7,848]; I^2=19%; **Figure 13, Table 12**). Among 20 trials reporting on fasting glucose, there was an average 2.3 mg/dL greater reduction in fasting blood glucose in the intervention than the control groups at 12 to 24 months' followup (MD=-2.3 [95% CI, -3.6 to -1.0]; 20 RCTs [22 effects, n=5,950]; I^2=82%, **Figure 12, Table 11**). At 12 to 24 months, the intervention groups showed slightly greater reductions in all three adiposity-related measures examined: pooled BMI MD=-0.5 kg/m^2 (95% CI, -0.7 to -0.3); 30 RCTs (n=9,909); I^2=83%; pooled weight=-1.6 kg (95% CI, -2.1 to -1.1); 37 RCTs (n=16,345); I^2=88%; pooled waist circumference=-1.7 cm (95% CI, -2.4 to -1.1); 23 RCTs (n=11,708); I^2=87%; **Figure 15, Table 11**). Very few trials offered low-contact interventions, and there was no clear difference in effect size between medium- and high-contact interventions.

Detailed Results by Outcome

Blood Pressure

Some type of blood pressure outcome was reported by 67 trials (n=36,079), most commonly mean change in systolic and diastolic blood pressure (**Appendix H Tables 5 and 6**). Among all trials reporting these outcomes at 12 to 24 months, the pooled average difference between groups in blood pressure reductions was 1.8/1.2 mm Hg (pooled SBP mean difference between groups [MD]=-1.8] [95% CI, -2.5 to -1.1]; 42 RCTs [44 effects, n=14,580]; I^2=37%; pooled DBP=-1.2 [95% CI, -1.6 to -0.8]; 38 RCTs [40 effects, n=13,098]; I^2=33%; **Figure 5, Table 11, Appendix G Figures 3 and 4**). Among all intervention arms and timepoints in the 12- to 24-month range, the median reductions in blood pressure at 12 to 24 months were 5.1/3.4 mm Hg in the intervention groups and 2.9/1.6 mm Hg in control groups, with a baseline mean blood pressure of 139/84 mm Hg. Effects were similar when limited to studies that only recruited participants with hypertension or elevated blood pressure, which also had similar mean baseline blood pressure (136/86 mm Hg).

Meta-regressions and subgroup analyses on SBP (the most commonly reported blood pressure outcome) demonstrated generally consistent effects among studies with various characteristics, including study quality, setting, baseline weight selection and weight loss approach, some key intervention characteristics, and socioeconomic status (**Figure 6**). There was no indication that smaller studies were associated with larger effect sizes (Egger's test of bias=0.01, p=0.99).

Some trials reported the number of participants who met the blood pressure goal established for the study (typically SBP<140 mm Hg, DBP<90 mm Hg, or both) or the percent meeting criteria for hypertension at followup (**Table 12**). For incidence of hypertension, the pooled RR reflected a 26 percent lower likelihood of hypertension onset at 6 to 36 months' followup (RR=0.74 [95% CI, 0.58 to 0.94]; 5 RCTs [n=2,707]; I^2=12%). Three[120, 122, 138] of the five[59, 62, 120, 122, 138] trials reporting hypertension incidence were limited to people with elevated blood pressure (without hypertension) with the goal of preventing progression, and the other trials included both patients who did and did not meet criteria for hypertension.[59, 62] Of all available timepoints and intervention groups, the median (interquartile range [IQR]) percent with incident hypertension was 21.7 percent (8.0% to 31.9%) in the intervention groups and 21.1 percent (11.2% to 39.2%) in the control groups. The median (IQR) absolute risk difference was -5.3 (-6.4 to -3.1).

Similarly, there was a 14 percent higher likelihood of meeting the study BP goal at followup among intervention participants (pooled RR=1.13 [95% CI, 1.04 to 1.23]; 13 RCTs [n=6,485]; I^2=70%). The median (IQR) percent meeting the study goal at followup was 64.9 percent (48.6% to 79.4%) in the intervention groups and 60.9 percent (43.0% to 75.0%) in the control groups with a median (IQR) absolute risk difference of 5.0 (1.0 to 8.1). Most of the trials reporting this outcome were limited to patients with existing hypertension and included medication management as an intervention component. Thus, the blood pressure goal was achieved through a combination of lifestyle modification and optimized medication use for most of these trials. The pooled effect for five trials reporting the *prevalence* of hypertension at 12 to 60 months' followup (as opposed to the *incidence* of hypertension) did not show group differences (pooled RR=0.98 [95% CI, 0.89 to 1.08]; 5 RCTs [n=5,633]; I^2=56%).

Lipids

Total cholesterol, LDL, or HDL were reported by 59 trials (n=30,245; **Appendix H Tables 7 and 8**). Among all trials reporting these outcomes at 12 to 24 months, the pooled average mg/dL difference in change between groups was -3.5 for total cholesterol, -2.1 for LDL, and 0.6 for HDL (total cholesterol MD=-3.5 [95% CI, -5.6 to -1.4]; 36 RCTs [38 effects, n=11,414]; I^2=66%; LDL=-2.1 [95% CI, -4.1 to -0.2]; 30 RCTs [32 effects, n=8,894]; I^2=56%; HDL= 0.6 [95% CI, 0.2 to 1.0]; 32 RCTs 34 effect, [n=8,974]; I^2=34%; **Figures 9 and 10, Table 11**). Among all intervention arms and timepoints in the 12- to 24-month range, the median (IQR) reduction in total cholesterol at 12 to 24 months was 7.1 (12.4 to 2.3) mg/dL in the intervention groups and 4.4 (6.6 to 0) in control groups, from an average baseline of 217 mg/dL. Effects were similar when limited to studies that only recruited participants with dyslipidemia. Pooled effects for LDL change were slightly smaller than for total cholesterol and not statistically significant in the near-term (<12 months followup) nor when limited to studies that only recruited participants with dyslipidemia. Most pooled effects did not show group differences in HDL change from baseline to followup and were generally of a magnitude that is unlikely to be of clinical importance.

Meta-regressions and subgroup analyses of total cholesterol (the most commonly reported lipid outcome [46 RCTs]) identified some statistically significant or nearly statistically significant bivariate relationships, with larger effects found in trials that were conducted in older adults (p<0.01), were conducted outside of the United States (p=0.04), and included medication management as an intervention component (p=0.06); smaller effects were found in weight loss trials (p=0.01) and those that targeted low-income populations (p=0.01) (**Figure 11**). However, only medication management (p=0.003) and older adult population (p=0.03) were statistically significant in models controlling for the other population or intervention characteristics showing bivariate relationships. Larger effects were seen when medication management was included and trials were limited to older adults. There was no indication that small studies were associated with larger effect sizes (Egger's test of bias=-0.7, p=0.29).

Glucose and Metabolic Outcomes

The proportion of participants with diabetes in the included trials ranged from 0 (in 27 trials) to 49 percent. Per our inclusion and exclusion criteria, we excluded trials if 50 percent or more of participants had impaired glucose tolerance or diabetes. Fasting glucose, diabetes incidence, or metabolic syndrome was reported by 31 of the included trials (n=21,521; **Appendix H Tables 9 and 10**). There was an average 2.3 mg/dL greater reduction in fasting blood glucose in the intervention than the control groups at 12 to 24 months' followup (MD=-2.3 [95% CI, -3.6 to -1.0]; 20 RCTs [22 effects, n=5,950]; I^2=82%, **Figure 12, Table 11**). Four trials reported diabetes incidence,[62, 65, 100, 131] and the pooled effect using calculated RRs did not show an association between behavioral counseling and reduced diabetes onset (pooled RR=0.82 [95% CI, 0.66 to 1.02]; 5 effects [4 RCTs, n=7,848]; I^2=0%, **Figure 13, Table 12**). However, interventions in two trials reduced diabetes incidence, either as calculated based on unadjusted results as shown in the forest plot[65, 131] or in study-reported adjusted analyses.[131] PREDIMED reported a 40 percent reduction in the risk of incident diabetes in the intervention group that was given olive oil (HR=0.60 [95% CI, 0.43 to 0.85]; 6.9% in the intervention group, 8.8% in the control group), but

the effect was slightly smaller and not statistically significant for the group that was given nuts (HR=0.82 [95% CI, 0.61 to 1.10]; 7.4% in the intervention group, 8.8% in the control group) after 48 months of observation.[131] Another small trial found a large effect after only 12 months (OR=0.23 [95% CI, 0.06 to 0.85]; 1.8% in the intervention group, 7.2% in the control group), but included a total of only 15 cases of incident diabetes.[65] Calculated RRs in the other trials showed no impact: 0.98 (95% CI, 0.47 to 0.07)[62] and 1.03 (95% CI, 0.67 to 1.59).[100] Metabolic syndrome incidence or prevalence was reported in five trials; the effects were wide-ranging, PREDIMED showed no benefit, and the pooled effect did not demonstrate an association (pooled RR=0.78 [95% CI, 0.53 to 1.16]; 5 effects [5 RCTs, n=1,847]; I^2=85%) (**Figure 14, Table 12**).

Weight/Adiposity

Weight, BMI, or waist circumference was reported by 72 trials (n=35,228; **Appendix H Tables 11 and 12**). At 12 to 24 months, the intervention groups were associated with slightly greater reductions in all three measures: pooled BMI MD=-0.5 kg/m^2 (95% CI, -0.7 to -0.3); 30 RCTs (n=9,909); I^2=83%; pooled weight=-1.6 kg (95% CI, -2.1 to -1.1); 35 RCTs (37 effects, n=16,345); I^2=88%; pooled waist circumference=-1.8 cm (95% CI, -2.4 to -1.1); 22 RCTs (23 effects, n=11,708); I^2=87%; **Figure 15, Table 11**). Among all intervention arms and timepoints in the 12- to 24-month range, the median (IQR) change in BMI at 12 to 24 months was -0.5 kg/m^2 (-0.9 to -0.2) in the intervention groups and -0.1 (-0.4 to 0) in control groups. For weight, median (IQR) intervention group effect wase -1.5 kg (-2.8 to -0.8), compared with -0.3 (-1.0, 0.0) in the control groups. The median (IQR) change in waist circumference was -2.2 cm (-3.7 to -0.8) in the intervention groups and -0.9 (-1.8 to -0.2) in the control groups (**Table 11**). Effects were larger in weight loss trials (that is, trials in which participants were only included if they had excess weight and weight loss was an explicit goal of the trial), where the pooled mean between-group difference in weight change was -2.6 kg (95% CI, -3.4 to -1.7; 12 RCTs [n=3,193]; I^2=67%), BMI was -0.9 kg/m^2 (95% CI, -1.4 to -0.4; 7 RCTs [n=1,520]; I^2=78%), and waist circumference was -2.5 cm (95% CI, -4.0 to -1.0; 8 RCTs [n=1,654]); I^2=85%) (**Table 11**). Effects were intermediate among those that had a mix of people with and without excess weight and only recommended weight loss for those with excess weight (e.g., weight change: -1.4 kg (95% CI, -2.0 to -0.7); 15 RCTs [n=6,486]; I^2=73%). Five[57, 98, 122, 131, 148] trials appeared to focus only on behavior change without directly assigning a weight loss goal for participants, and did not result in greater weight loss than control groups (pooled MD=-1.1 [95% CI, -2.5to 0.4]; 6 RCTs [n=6124]; I^2=90%).

In addition, 11 trials reported the proportion of participants who lost at least 5 percent of their weight or had a 5 percent reduction in BMI.[82, 107, 110, 116, 123, 125, 126, 129, 132, 134, 141] Behavioral counseling interventions were associated with a 86 percent increase in the likelihood of losing 5 percent of baseline weight or BMI (pooled RR=1.86 [95% CI, 1.33 to 2.60]; 11 RCTs [n=3,970]; I^2=68%, **Figure 16**). Other than one small trial that focused only on increasing physical activity,[132] all trials reporting this outcome were either weight loss trials[116, 123, 125, 129, 134, 141] or explicitly stated that weight loss was recommended for all participants with overweight or obesity.[82, 107, 110, 126] Three trials also reported the proportion who lost 10 percent or more of their baseline weight and all found an increased probability of this level of weight loss at one or more followup timepoints (percent with 10% weight loss ranged from 7.5% to 25.0% in the intervention groups and 2.3% to 8.6% in the control groups).[125, 126, 129]

Meta-regressions and subgroup analyses on weight (the most commonly reported adiposity-related outcome) identified some statistically significant bivariate relationships, with larger effects being found in trials conducted in the United States (p=0.01), those that were limited to individuals with obesity or who were overweight (p=0.04), and in weight loss trials (p<0.03) (i.e., trials that recruited people with excess weight and had an explicit weight loss goal for all participants), but no effect modification based on intervention contact, age group, socioeconomic status, and whether a fat-modified diet was recommended (**Figure 17**). Most weight loss trials were conducted in the USA and all were limited to individuals with obesity or who were overweight, so we were unable to disentangle the relative impacts of these factors. The test of small study effects was statistically significant (Egger's test of bias=-2.8, p<0.001), indicating that smaller trials tended to have larger effects. Weight loss trials tended to be smaller studies: the average sample size in weight loss trials was 461, compared with 585 in non-weight loss trials. Thus, small studies effects may be related to intervention content and target population rather than publication bias.

Cardiovascular Risk

Twelve trials used published models or calculators to calculate 5- or 10-year risk of CVD or CHD events[68, 70, 77, 106, 109, 142, 144, 224] or mortality[84, 85, 98, 99] (**Appendix H Table 13**). Two trials found statistically significant reductions in 10-year CVD risk after 1 year, reporting reductions of 1.8 (95% CI, -3.0 to -0.6)[106] and 2.1 (95% CI, -4.1 to -0.1)[142] percentage points, although the pooled effect was not statistically significant when combining all trials reporting 8- or 10-year CVD risk outcomes (pooled MD=-0.5 percentage points [95% CI, -1.3 to 0.3]; 7 RCTs [n=2,533]; I^2=53%, **Figure 18**). None of the trials reporting the 10-year CVD *mortality* risk found group differences, nor was the pooled effect statistically significant (pooled MD=-0.1 percentage points (95% CI, -0.3 to 0.2); 5 effects [4 RCTs, n=1,764]; I^2=0%).

Impact of Population, Study, and Intervention Characteristics on Effect Size

Based on direct within-study comparisons using study-reported subgroup analyses, we found no indication that any demographic subgroups consistently benefited more or less than others. Sixteen trials examined variability in effects by sex,[59, 69, 85, 91, 98, 114, 116, 120, 123, 127, 129-131, 138, 142, 144] and while some showed larger effects for some outcomes in men than women (overall[69, 98, 127, 142] or among African-American participants only[59]), one showed larger effects in women for some outcomes[130] and the remaining reported no differential effect by sex. Some trials found that effect sizes increased with age for weight loss[59, 123, 138] and blood pressure,[59, 93] but other trials found no association between intermediate outcomes and age.[91, 114, 130, 131] Most trials examining interactions by race or ethnicity reported no differential effectiveness;[120, 123, 129, 144] however, TOHP II reported a larger effect for weight loss in white participants than African-American participants.[138] Risk factor status was associated with effect size in several trials: people with hypertension experienced a greater reduction in blood pressure than those without hypertension,[59] those with the highest 10-year CVD risk had the greatest reductions in future CVD risk,[68, 71] and people with dyslipidemia had the greatest reductions in lipids.[76] However, other trials did not show an association between baseline risk and improvement in intermediate outcomes.[75, 130, 131] Effects on lipids were not moderated by medication status in three trials.[78, 80, 83]

As described under the outcome-specific results, we found very few intervention or population characteristics that were clearly associated with effect size. In meta-regressions examining the association between study and intervention characteristics and effect size, we did not see a clear indication that high-contact (>360 min) trials showed larger effects than medium-contact trials, nor was there an association between continuous measures of contact (number of sessions, total estimated minutes of contact) and effect size. However, very few trials offered low-contact (<30 min) interventions (**Figure 2**). See the Methods section for the full list of characteristics explored.

While there were no differences in effect size between interventions that counseled people only to change their diet compared with those that addressed both diet and physical activity, evidence was limited on interventions that only addressed physical activity. Only five studies[61, 87, 94, 132, 140] with interventions that addressed physical activity alone reported intermediate outcomes. Among these 5 trials, sample sizes were generally very small and outcome reporting was inconsistent.

We attempted to identify common intervention elements of effective trials by examining trials that showed the largest beneficial effects on intermediate outcomes. For this exercise, we limited to trials that randomized at least 150 participants to limit the risk of spurious findings. We focused on four intermediate outcome domains of blood pressure, lipids, fasting glucose, and weight. Then we identified studies with the 10 largest absolute effect sizes for outcomes in each domain. Sixteen trials had relatively large effects in at least two of the four intermediate outcome domains.[65, 69, 75, 76, 79, 92, 95, 98, 99, 106, 107, 113, 120, 126, 139, 141] Five of these trials had relatively large effects in the three[92, 106, 107, 141] or four[65] domains and are listed in **Table 13**. Each of these five trials selected participants based on having any of multiple CVD risk factors or metabolic syndrome and included counseling for both diet and physical activity. Interventions in these 5 trials are described below.

One of these successful trials was a good-quality, U.S.-based weight-loss trial that was part of the NHLBI-funded Practice-Based Opportunity for Promotion of Weight Reduction Trials (POWER) project.[141] This intervention included 18 10–15 minute coaching sessions by phone, a median of three brief counseling visits with the primary care provider, and 52 brief interactive voice recognition calls.[141] Intervention participation in this study was generally good: participants completed a median of 89 percent of the coaching calls and a median of 93 percent of their weekly self-monitoring forms. Another successful trial was a good-quality Canadian trial that recruited participants with a 10-year CVD risk of 10 percent or more based on the Framingham model.[106] The intervention involved two 30-minute phone sessions 6 months apart, a CVD risk "report card" sent to each participant and their provider, and two additional mailings after each call summarizing the counseling sessions and including education materials addressing smoking, diet, physical activity, weight management, and stress management as appropriate to the participant's profile. Smokers were eligible for four additional smoking-cessation phone counseling sessions.

The other three trials—which were given fair-quality ratings—were conducted in Europe among Italians with metabolic syndrome,[65] Spaniards with moderate or high Framingham CHD risk (specific thresholds not reported) and elevated fibrinogen levels,[92] and Europeans from six countries with a 10-year CVD mortality risk score of 5 percent or higher.[107] While none of these

was a weight loss trial, specifically, all promoted weight loss for participants who were overweight or with obesity. The Italian trial involved one individual and four group sessions lasting 1 hour each, covering diet and physical activity, with participants attending an average of 4.1 to 4.5 of the five sessions.[65] The Spanish trial included 12 individual sessions with the primary care provider and 12 follow-up phone sessions with a psychologist covering diet, physical activity, medication management, and smoking cessation (if applicable).[92] The multi-country European trial included family members in the intervention and involved an individual nurse assessment with a personal "report card," a family support pack, and eight group workshops on diet, physical activity, and risk factor management.[107] Intervention adherence was not reported in either of these trials.[92, 107]

The range of average between-group difference in change for blood pressure in these five trials was -0.9 (-4.9 to 3.1)[141] to -6.8 (-10.7 to -2.8)[92] SBP and -1.0 (-3.5 to 1.5)[141] to -4.4 (-6.8 to -2.0)[92] DBP (**Table 13)**. Differences in total cholesterol change ranged from +3.1 mg/dL (-4.7 to 10.9)[141] to -19.2 mg/dL (-25.6 to -12.7),[92] and BMI change differences ranged from -0.1 kg/m^2 (-0.6 to 0.3)[106] to -1.7 kg/m^2 (-2.2 to -1.1).[92]

Role of Weight Management

We were unable to provide a robust analysis of the importance of weight loss on the impact of intermediate outcomes, since this question is better approached with individual patient data. Weight loss interventions did have a larger pooled effect on weight change than interventions that did not promote weight loss (**Figure 17**). There was no bivariate or multivariate association between weight loss promotion and SBP, and an inverse association with total cholesterol such that smaller reductions in total cholesterol were seen in weight loss trials, however this effect disappeared when controlling for medication management and older adult populations.

We examined trials with multiple intervention arms with direct comparison of weight-loss versus other messages to evaluate the role of weight loss on intermediate outcomes. Four trials had this design.[120, 122, 138, 144] All of these trials targeted people with hypertension and the diet-only intervention arms (with no explicit mention of weight loss) encouraged either sodium reduction or sodium reduction and an increase in potassium intake. Effect sizes were generally slightly larger in intervention arms that promoted weight loss, however the intervention conditions encouraging sodium reduction without apparent encouragement to lose weight also had statistically larger reductions in blood pressure than control groups for three of these trials.[120, 122, 138] One small (n=95) trial of people with untreated elevated blood pressure who were either overweight or had obesity explicitly instructed participants to focus on adopting the DASH diet without changing their weight or physical activity level.[121] The intervention involved four in-person individual instructional sessions and 14 30- to 45-minute group sessions, and was effective in reducing systolic but not diastolic blood pressure. At 12-month followup, there was a 5.6 (95% CI, -9.8 to -1.4) mm Hg greater reduction in systolic blood pressure in the intervention group: a 9.5 (SD 9.1) mm Hg reduction in the intervention group compared with a 3.9 (SD 11.8) mm Hg reduction in the control group.[121]

KQ3. Do Behavioral Counseling Interventions to Improve Diet and Increase Physical Activity Improve Behavioral Outcomes in Adults With Known CVD Risk Factors?

Summary of Results

Altogether, 70 of the included trials reported some type of behavioral outcome (n=43,243); however, most specific outcomes were reported by fewer than 15 trials, and there was substantial variability in measurement for most of these outcomes. Behavioral counseling interventions were associated with dietary improvements, including reductions in saturated fat consumption and increases in the consumption of fruits, vegetables, and fiber (**Table 14**). The average difference in reduction in the percent of calories from saturated fat was 1.5 percentage points after 12 to 24 months (pooled MD=-1.5 [95% CI, -1.9 to -1.1]; 15 RCTs [17 effects, n=6,229]; I^2=72%). The median (IQR) reduction in the intervention groups was -1.9 (-3.0 to -1.4), compared with -0.6 (-1.0 to -0.1) in the control groups. For fruits and vegetables, the intervention groups increased consumption by an average of 0.7 servings per day more than the control groups (pooled MD=0.7 [95% CI, 0.1 to 1.3]; 11 RCTs [n=4,310]; I^2=90%). The average increase in fiber consumption was 1.3 grams per day (95% CI, 0.1 to 2.6, 5 RCTs [n=1,350], I^2=42%) more than control groups. In addition, trials among people with hypertension or elevated blood pressure who were counseled to reduce sodium consumption did show reduced urinary sodium (pooled MD=-18.0 [95% CI, -34.8 to -1.2]; 9 RCTs [n=3,583]; I^2=89%). Dietary pattern scores, arguably the better measures of dietary improvement than those that capture only a single aspect of diet, generally showed greater improvement in intervention groups, but measurement was heterogeneous and interpretation of effect sizes was unclear. Physical activity outcomes were highly variable in terms of both measurement and results, with minimal evidence to suggest that interventions were associated with increased physical activity. Trials that had relatively large benefits for intermediate outcomes also tended to report mean differences in change in behavioral outcomes that were at or above the means for the full body of evidence.

Detailed Results by Outcome

Dietary Fat Intake

Behavioral counseling interventions were associated with small reductions in saturated fat: the average difference in reduction in the percent of calories from saturated fat was 1.5 percentage points after 12 to 24 months (pooled MD=-1.5 [95% CI, -1.9 to -1.1]; 17 effects [15 RCTs] [n=6,229]; I^2=72%; **Table 14, Appendix G Figure 12**). The median (IQR) reduction in the intervention groups was -1.9 (-3.0 to -1.4), compared with -0.6 (-1.0 to -0.1) in the control groups. Effects were similar in trials that specifically encouraged people to adopt a fat-modified diet (pooled MD=-1.5 [95% CI, -2.3 to -0.8]; 10 effects [8 RCTs] [n=3,951]; I^2=72%). Polyunsaturated fat intake did not change (**Table 14, Appendix G Figure 13**), and monounsaturated fat (MUFA) intake was reduced on average (pooled MD=-1.7 [95% CI, -2.5 to -0.9]; 8 effects [7 RCTs] [n=1,827]; I^2=83%; **Table 14, Appendix G Figure 14**). However, in PREDIMED, which encouraged a Mediterranean diet and supplied participants with either olive

oil or nuts, MUFA increased by 1.9 (95% CI, 1.4 to 2.3) percentage points more in the group receiving nuts and 3.0 (95% CI, 2.6 to 3.5) percentage points in the olive oil group, compared with the control group.[131] All other trials reporting MUFA and most reporting polyunsaturated fat intake found reductions in intake. Trials reporting other fat-related outcomes (grams per day, score on a dietary fat scale) generally found group differences in the direction of greater reductions in the intervention groups, with most reporting only saturated fat (**Appendix H Tables 15 and 16**).

Fruits and Vegetables

Behavioral counseling interventions were also associated with an average 0.7 greater increase in servings per day of fruits and vegetables compared with control groups after 12 to 24 months (pooled MD=0.7 [95% CI, 0.1 to 1.3]; 11 RCTs [n=4,310]; I^2=90%, **Table 14, Appendix G Figure 15**). The median (IQR) increase in fruit and vegetable servings per day was 0.5 (0 to 1.2) in the intervention groups, compared with 0.1 (0 to 0.3) in the control groups. Fruit consumption was typically reported as servings or pieces per day, and there was in average 0.2 greater increase in servings per day for intervention than the control groups (pooled MD=0.2 [95% CI, 0.0 to 0.3]; 9 RCTs [n=3,698]; I^2=72%, **Table 14, Appendix G Figure 16**). The two most common vegetable-specific outcomes were servings per day and grams per day, which were combined into a single meta-analysis of standardized mean differences (SMD). The results indicated a very small effect in the direction of benefit (SMD=0.12 [95% CI, 0.02 to 0.21]; 9 RCTs [n=3,555]; I^2=50%, **Table 14, Appendix G Figure 17**). Intervention groups increased consumption by a median (IQR) of 0.5 (0 to 0.8) servings or 11 (9 to 16) grams per day, while the control groups increased consumption by 0.3 (0.2 to 0.3) servings or 2 (-3 to 12) grams per day. Interestingly, the effect measured in grams/day appears to be smaller; one serving (0.5 cup of cooked vegetables) is approximately 75g, so 11 grams is equivalent to approximately 1 tablespoon, while 0.5 of a serving is 4 tablespoons. Data were insufficient to determine whether this was due to random chance or related to the measurement approach. At 12 to 24 months' followup, the median (IQR) consumption of fruits and vegetables was 5.1 (4.3 to 6.4) servings per day in the intervention groups and 4.6 (3.4 to 6.2) servings per day in the control groups.

Fiber

Seven trials reported change in grams per day of fiber (**Appendix H Table 15**).[57, 65, 69, 72, 82, 104, 131] Most trials reported group differences in change that ranged up to 5 grams per day, and most differences were not statistically significant. At 12-24 months' followup, the pooled mean difference in change was 1.3 grams per day (95% CI, 0.1 to 2.6, 5 trials [n=1,350], I^2=42.4%, **Table 14, Appendix G Figure 18**). The USDA recommends eating 28 grams per day for a heart-healthy diet, for a 2,000-calorie-per-day diet.[2]

Sodium

Twelve trials in populations with hypertension or elevated blood pressure reported urinary sodium to determine whether participants had reduced sodium intake as encouraged by their interventions.[59, 61, 63, 69, 79, 82, 97, 111, 120, 122, 138, 144] Most trials reported greater reductions in 24-hour urinary sodium excretion in intervention groups that were coached to reduce their sodium intake

than control groups (pooled MD=-18.0 [95% CI, -34.8 to -1.2]; 9 RCTs [n=3,583]; I^2=89%; **Appendix G Figure 19**); at 12 to 24 months' followup, the median (IQR) change in the interventions groups was -18.4 mmol/L (-45.4 to -5.3) and was -6 mmol/L (-10 to -3.4) in the control groups. The largest reduction seen in any control group was 16.8 mmol/L, while reductions in the intervention group ranged up to 72 mmol/L (**Appendix H Table 15**). In addition, trials that had separate intervention arms that did and did not promote a low-sodium diet saw reductions in the low-sodium diet intervention arms but not the other intervention arms.[122, 138] The typical American diet includes approximately 150 mmol per day of sodium, while the recommended intake is below 100 mmol per day.[283]

Dietary Pattern

Ten trials reported some type of dietary pattern or quality measure (**Appendix H Table 15**).[58, 70, 86, 97, 106, 109, 114, 131, 137, 143] For most of these outcomes, dietary patterns improved in intervention participants and showed very little change in control group participants, and quite a few group differences were statistically significant, although the clinical importance of the effects are difficult to interpret. For example, two trials[131, 137] (one of them PREDIMED) reported MEDAS-14 scores, which measures adherence to the Mediterranean diet. Considering all available followup assessments and intervention groups in both studies, intervention groups generally improved their adherence scores by 1.4 to 2.0 points on a 14-point scale. Intervention groups showed greater improvements than the control group that were statistically significant at all timepoints in PREDIMED. No other instrument was used in more than one trial.

Physical Activity

Altogether, 50 trials reported some type of physical activity outcome (n=34,028), and no consistent evidence of benefit emerged using a variety of self-report measures (**Appendix H Tables 17 and 18**). Outcome reporting was highly variable both in the measure reported (e.g., any, moderate, moderate-to-vigorous, leisure physical activity, meeting goal) and unit of measurement (e.g., minute/week, MET-hours/week, sessions/week, kJ/kg/day, steps/day). When standardized mean differences of the continuous outcomes were examined, effect sizes were very heterogeneous and inconsistent, with a number of effects favoring control groups, although those were typically not statistically significant. The pooled effect was not statistically significant, represented an effect size well below what would typically be considered a "small" effect, and had high statistical heterogeneity (pooled SMD=0.06 [95% CI, -0.03 to 0.14]; 32 effects [30 RCTs, n=19,834]; I^2=64%) (**Appendix G Figure 20**). When similar outcomes were isolated, there was an average 9.1 additional minutes' increase in physical activity per week in the intervention groups compared with the control groups (pooled MD=9.1 minutes/week [95% CI, -4.6 to 22.8]; 11 effects [10 RCTs, n=9,746]; I^2=48%), and 83 MET-minutes per week (pooled MD=83 [95% CI, -83 to 249]; 7 effects [6 RCTs, n=4,958]; I^2=62%), however neither of these findings were statistically significant. For comparison, an hour of walking briskly expends approximately 200 MET-minutes, so the pooled effect is roughly equivalent to an additional 25 minutes of walking per week. Again, the discrepancy in effect sizes using different measures is puzzling.

Of the six[61, 87, 90, 94, 132, 140] trials with intervention arms that addressed only physical activity (and not diet), four[61, 90, 132, 140] found greater improvements in physical activity in the intervention groups and one reported only intermediate outcomes.[87] Of those reporting physical activity outcomes, no two studies used the same measure and the clinical significance of the effects was difficult to understand. Results included:

- 17 kJ/kg/d greater total energy expenditure (95% CI, 5.6 to 28.4)[61]
- 6-fold increase in the risk of increasing physical activity over baseline levels (RR=6.13 [95% CI, 3.07 to 12.23], 52.7% in the intervention group vs. 8.6% in the control group)[140]
- 29 percent increase in the odds of increasing by one of five levels on a measure of total physical activity (95% CI, 1.04 to 1.60)[90]
- 1,400 additional kcal/week (95% CI, -1299 to 4100) of moderate to vigorous physical activity (p=0.03 in an adjusted analysis)[132]
- No difference in the likelihood of meeting physical activity guideline recommendations (OR=0.99 [95% CI, 0.62 to 1.57])[94]

Intervention groups had a higher likelihood of meeting the study-defined physical activity goal, which typically was 90–180 minutes per week of moderate to vigorous physical activity (pooled RR=1.22 [95% CI, 1.00 to 1.50]; 11 RCTs [n=5,887]; I^2=91%, **Appendix G Figure 21**). The median (IQR) percent meeting the study goal was 36 percent (28.1% to 52.8%) in the intervention groups and 23.8 percent (22.9% to 50.8%) in the control groups, with median (IQR) absolute risk differences of 3.7 percent (0.4% to 10.1%).

Two trials reported change in resting heartbeat, with greater reductions representing improved cardiorespiratory fitness (**Appendix H Table 17**).[59, 69] Both found greater reductions in the intervention groups. For example, one of these reported 8 and 9 beat-per-minute reductions in intervention groups at stage 2 of a submaximal exercise test, compared with 5.3 beats per minute reduction in the control group at 6 months' followup.[59] This study reported a slightly smaller difference after 18 months, when the control group average had dropped 2 more beats per minute, but the intervention groups maintained the previous changes.[59] In the other trial, the intervention group saw a 1-beat-per-minute increase in 24-hour heart rate after 16 months, while the control group had increased by 7 beats per minute, but there was no difference between groups after 40 months (2 years after the intervention had ended).[69] Three trials explored sedentary time using a variety of measures but found no group differences on any measure.[85, 109, 135]

Consistency With Intermediate and Health Outcomes

We addressed the issue of consistency between the intermediate and behavioral outcomes in two ways. First, we examined subgroup analyses reported by the included trials and noted whether participant subgroups with large behavioral effects also had large effects on intermediate outcome within the same study. Some trials reported that subgroups with the largest changes in behavioral outcomes also showed the largest improvements in intermediate outcomes.[59, 64, 69, 73]

Next, we examined behavior change in the trials with relatively large intermediate and health outcome effects, and found that behavior change in these trials tended to be higher than the

pooled average effects. Of the five trials that had relatively large effects in three or four domains of intermediate outcomes; two also reported behavioral outcomes.[65, 107] After 12 months, the Italian trial reported greater reductions in saturated fat percent of energy in the intervention group (MD in change=-1.8 percentage points [95% CI, -2.6 to -1.0]) and increases in polyunsaturated fatty acids (PUFA) (MD in change=1.0 percentage point [95% CI, 0.6 to 1.4]), fiber intake (MD in change=1.5 g/day [95% CI, 0.8 to 2.3]), and physical activity (MD in change=5.0 MET-hours/week [95% CI, 3.0 to 6.9], roughly equivalent to 1.5 additional hours of brisk walking per week) (**Appendix H Tables 15 and 17**).[65] The multi-country European study reported that after 12 months, intervention participants were more likely to have consumed 400 or more grams of fruits and vegetables per day (78.4% in the intervention group vs. 38.8% in the control group, difference in probability= 39.7 [95% CI, 18.1 to 61.3]) and to have reported 30 or more minutes of physical activity on 4 or more days per week (50.3% in the intervention group vs. 22.1% in the control group, difference in probability=29.4 [95% CI, 10.7 to 48.0]).[107]

In addition, the PREDIMED trial had relatively large beneficial effects on health outcomes. It also showed improvements in both intervention groups at all follow-up assessments on the MEDAS-14, a measure of adherence to the Mediterranean diet, on the order of 1.3 to 1.6-point greater increases on a 14-point scale.[131] Regarding specific dietary components, PREDIMED intervention participants reported greater increases in MUFA, PUFA, saturated fat (for the olive oil supplementation group only), and fiber (for the nuts supplementation group only), but did not differ from the control group on fruit and vegetable consumption.[131]

Several additional trials with relatively large effects in two domains of intermediate outcomes also reported behavioral outcomes, with findings that were generally in the direction of benefit for the intervention group, often at or above the pooled mean difference, but with mixed findings in terms of statistical significance.[69, 76, 79, 95, 98, 106, 131] For example, relative to change in control groups, fruit and vegetable consumption increased in intervention groups by 0.8 servings per day (95% CI, 0.3 to 1.3)[69] after 16 months, 0.70 servings per day (95% CI, -0.18 to 1.58)[76] after 18 months, 23.5 g/day (95% CI, -15.0 to 62.0) after 12 months,[98] and 0.07 (95% CI, -0.11 to 0.25, study-reported $p<0.05$) and 0.18 servings per day (95% CI, 0.00 to 0.36 study-reported $p<0.05$) after 5 years (**Appendix H Table 15**).[131] Of the four trials[69, 76, 79, 98] reporting the percent meeting physical activity goals, most did not find that the groups differed, with absolute risk differences generally on the order of 0.2 to 10 percent (**Appendix H Table 18**). These same four trials also reported a continuous measure of change in physical activity, with mixed findings. Differences in change in these trials included: 53 minutes per week vigorous activity (95% CI, 15 to 91, study-reported $p=0.007$) at 40 months' followup, but a smaller, statistically nonsignificant difference at 16 months;[69] 3.1 MET-hours per week walking (95% CI, -2.2 to 8.3, study-reported $p<0.01$) at 18 months, but no statistically significant findings for either moderate- or vigorous-intensity physical activity;[76] 723 steps per day (95% CI, -519 to 1966, p not reported) at 18 months;[79] and 38.0 minutes per day walking (95% CI, 0.2 to 75.8, $p=0.05$) at 12 months, but no differences in minutes per week of moderate to vigorous or total physical activity, or in any physical activity outcomes at 36-month followup (**Appendix H Table 17**).[98] The PREDIMED intervention did not discuss physical activity and found no group differences in leisure physical activity.[131]

KQ4. What Are the Harms of Behavioral Counseling Interventions to Improve Diet and Increase Physical Activity in Adults With Known CVD Risk Factors?

Summary of Results

We narrowly focused this question on harms of counseling interventions, rather than broadly on harms of dietary or physical activity changes themselves. We examined the 94 trials included for KQs 1 through 3 for harms, as defined by the study authors, or any paradoxical change in outcomes (e.g., worsening of blood pressure, lipids, glucose, measures of weight, dietary intake, physical activity). We searched for additional studies examining harms of healthy lifestyle counseling interventions but did not find any such studies.

The reporting of adverse events was sparse and variable. A subset of 20 of the 94 included trials reported one or more adverse events. Adverse events related to diet and physical activity counseling appear to be exceedingly rare, with generally no statistically significant differences in any study for: serious adverse events, any adverse events, hospitalizations, musculoskeletal injuries, or withdrawals due to adverse events. There was no consistent evidence of paradoxical effects for intermediate or behavioral outcomes. There were occasional instances of control groups showing more improvement than intervention groups, but this was usually not statistically significant and was often accompanied by greater improvement for the intervention group for other outcomes.

Detailed Results for Harms

Twenty trials reported harms (N=18,263),[59, 65, 69, 73, 93, 105, 107, 112, 114, 116, 125-127, 131, 134, 139, 141, 148, 149, 224] (**Appendix H Table 19**). Seven of these 20 trials reported that there were no adverse events or no serious adverse events,[65, 73, 107, 131, 134, 139, 224] and other trials reported one or more of the following: serious adverse events, any adverse events, hospitalizations, musculoskeletal injuries, withdrawals due to adverse events, gallbladder disease, and headaches.

Serious Adverse Events

Three trials reported serious adverse events, all of which included medium- to high-intensity diet and physical activity counseling interventions.[112, 114, 125] While serious adverse events were not rare—occurring in 6.8 to 15.3 percent of intervention group participants and 7.6 to 12.3 percent of control group participants—serious adverse events attributed to interventions were exceedingly rare. In a U.K. primary-care based telephone and web-based intervention study of adults with multiple risk factors, one serious adverse event was potentially associated with the intervention: hospitalization due to low blood pressure. This could have been related to antihypertensive drug dose not being reduced after weight loss, according to the trial authors.[114] In the Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-UP) trial of weight loss in participants with CVD risk factors, three serious adverse events—two cholecystectomies and one case of syncope—were determined to be related to the

intervention.[125] In the Counseling African Americans to Control Hypertension (CAATCH) trial, which recruited African Americans with hypertension, one serious adverse event in the intervention group was considered possibly related to the intervention and two serious adverse events, one in the intervention group and one in the control group, were considered definitely related; however, the nature of these events was not reported.[112] Differences in serious adverse events were not statistically significant between groups in any study.

Any Adverse Events

Seven trials reported that no adverse events occurred,[65, 73, 107, 131, 134, 139, 224] and three trials reported a general measure of "any adverse events."[93, 112, 114] In these three trials, the rates of any adverse events among intervention group participants ranged from 0 to 11.7 percent and from 0 to 12.0 among control group participants. Differences in any adverse events were not statistically significant in any study, and details were not described in any reporting study.

Withdrawal Due to Adverse Events

Only two trials explicitly mentioned withdrawals due to adverse events. The study by Rodriguez[93] noted that nine participants were withdrawn by study staff due to an adverse event that would affect study participation, but events by group are not reported. The CAATCH trial reported that no individuals terminated study participation due to adverse events.[112]

Hospitalizations

Five trials reported hospitalizations.[112, 116, 126, 127, 141] In four of these trials, there were no statistically significant differences between groups, and the nature of the hospitalizations was not further specified.[112, 116, 126, 127] A study of the Track intervention—a medium-intensity diet and physical activity intervention with weight loss focus that was conducted in obese adults with at least one risk factor—reported 11 hospitalizations in the intervention group and one in the control group (6.3% vs. 0.6%).[141] Hospitalizations were for causes other than CVD, cancer, or musculoskeletal injury, and authors reported that no events were deemed to be related to the trial. The study by Rosas et al additionally reported emergency department visits, which occurred in 35.4 percent and 27.4 percent of the two intervention arms and 41.5 percent in the control arm.[127]

Musculoskeletal Injuries

Six trials reported musculoskeletal injuries or serious musculoskeletal injuries, all of which were trials of medium- to high-intensity diet and physical activity counseling interventions.[59, 116, 126, 141, 148, 149] Rates of injuries ranged from 0.0 to 6.3 percent in intervention groups and 0.0 to 7.3 percent in control groups, with no statistically significant differences in any study. Two trials reported one case each of musculoskeletal injury related to the intervention, one as the result of an assault while exercising,[126] and the other a twisted ankle sustained while running.[148]

Other Outcomes

Other adverse events were variably reported among trials, with no between-group differences

noted (**Appendix H Table 19**).[105, 116, 131]

Paradoxical Changes

There was little evidence to suggest any paradoxical changes in intermediate outcomes. For each continuous intermediate outcome, there were a few studies in which the control group performed better than the intervention group, but in only one case was this statistically significant and it was offset by benefit for other outcomes. This occurred for the outcome of total cholesterol in the POWER study at 12-24 months (between-group difference of 7.80 mg/dL favoring the control group [95% CI, 0.39 to 15.21]), but LDL was not statistically significantly worsened (5.70 mg/dL favoring the control group [95% CI, -1.00 to 12.40]).[126] However, weight loss was the primary outcome of this study, which had an impressive between-group difference favoring the intervention group of -4.30 kg (95% CI, -6.30 to -2.30)—one of the largest weight-loss effects in this body of literature. The study by Liira showed nonstatistically significant poorer outcomes in the intervention group (IG) for several intermediate outcome categories (blood pressure, lipids, adiposity), yet had a statistically significant improvement in fasting blood glucose favoring the IG at 12-24 months (-5.41 mg/dl [95% CI, -9.76 to -1.06]). This was a small Finnish study of adults with multiple risk factors who received a one-time 90-minute risk assessment and counseling intervention from a public health nurse.[117]

With respect to behavioral outcomes, a small number of studies showed greater control group improvements for some dietary intake outcomes compared with intervention groups, but none was statistically significant in adjusted analyses. Authors of the Activity, Diet, and Blood Pressure Trial (ADAPT) study noted that there was a reported decrease in the consumption of high-fat dairy that wasn't necessarily replaced with low-fat dairy and considered a potential reduction in calcium intake a possible harm.[69] For physical activity, effects favored control groups in a few studies, although those were typically not statistically significant in analyses reported by authors.

Chapter 4. Discussion

Summary of Evidence

Consistent with our prior review to support the previous recommendation, this review found that medium- and high-contact behavioral counseling interventions to improve diet and physical activity in people with cardiovascular risk factors was associated with improvements spanning a range of intermediate and behavioral outcomes, including blood pressure; lipids; adiposity; blood glucose; and intake of saturated fat, fruits and vegetables, fiber, and sodium. We found very similar effect sizes for most of these outcomes compared with the previous review (**Table 15**), despite the change in the composition of the evidence. Unlike the previous review, the current review included weight loss trials (as long as the trial was limited to people with CVD risk factors) and trials in people with elevated blood pressure and lipids (rather than requiring participants to meet criteria for hypertension or dyslipidemia), and excluded diabetes prevention trials that required all or most participants to have impaired fasting glucose. Thus, the current review was more heavily weighted toward populations with hypertension, dyslipidemia, and obesity, and de-emphasized diabetes prevention, which is addressed in a separate, concurrent USPSTF review.

Unlike the previous review, the current review found that behavioral counseling interventions were associated with a lower likelihood of CVD events, based on 12 trials reporting CVD event outcomes. Nine of these trials were new in this update. The overall pooled effect showed a 20 percent lower risk of CVD events with behavioral counseling interventions (pooled RR=0.80 [95% CI, 0.73 to 0.87], 9 RCTs [n=12,551]). This translates to a number needed to treat (NNT) of 100 (95% CI, 74 to 154) to prevent one CVD event, assuming a baseline rate of 5 percent. Population risks of 7.5 percent and 10 percent translate to NNTs of 67 (95% CI, 49 to 103) and 50 (95% CI, 37 to 77), respectively. This evidence is based largely on the strength of PREDIMED, a recently completed large trial conducted in Spain that was not included in the previous review.[131] The PREDIMED study reduced stroke, PAD, and total CVD events. Total CVD events were reduced from 4.4 percent in the control group to 3.6 percent in the intervention group after 5 years. The PREDIMED findings were supported by a number of additional trials targeting patients with hypertension or selected based on having any of multiple CVD risk factors, and the effect was still statistically significant in a sensitivity analysis excluding PREDIMED (pooled RR=0.79 [95% CI, 0.70 to 0.90], 8 RCTs [n=5,104]) (**Table 9**).

Applicability of Findings

We considered this evidence to generally have good applicability to most U.S. primary care settings. Many of the trials were conducted in or recruited from primary care settings or other related healthcare settings (e.g., enrollment records from health clinics or systems), and almost half were conducted in the United States. Although data were very limited for persons age 75 years and older, PREDIMED had an average age of 67, supporting the benefits of dietary counseling adults age 65 and older. Most interventions were delivered by professionals of the type embedded in large health systems (e.g., registered dieticians, nurses, health educators) and

25 (22%) of the included trials involved the primary care provider or their staff directly. However, we acknowledge that access to these professionals may not be widely available in all primary care settings, and there may be more opportunities in large healthcare delivery systems. Additionally, recruitment from most studies (63%) was not self-selected or volunteer-based, improving the generalizability to primary care.

While PREDIMED was conducted in primary care settings, two factors limit the generalizability of its results: first, it excluded patients who were not ready to change according to the Stages of Change model, and second, it provided nuts or olive oil to all participants on a weekly basis. Indeed, some commenters have suggested that the results of PREDIMED might largely reflect the impact of supplemental food rather than overall dietary pattern.[284] Given evidence to support the benefits of food subsidies for low-income families,[285, 286] food provision may be a powerful intervention that could reduce socioeconomic health disparities. However, it does likely limit generalizability since most primary care settings are unlikely to distribute food directly. An additional limitation to the generalizability of PREDIMED is that it was conducted in Spain, where the typical diet already has Mediterranean elements. One group has noted that the typical U.S. diet would probably score 1 to 2 on the MEDAS, based largely on NHANES data,[287] in contrast to the baseline score in PREDIMED of approximately 8.5. The typical diet in the United States includes a substantial quantity of prepared and processed foods, and cooking from scratch is relatively rare. Thus, a 2-point increase on the MEDAS from 8.5, as was seen in the PREDIMED study, may not have the same health impact as a 2-point increase from a score of 1.5. It is plausible that the effect could be larger from such a different starting point.

Importantly, we found that behavioral counseling interventions appear to be effective in low-SES populations as well as those with more ample resources, which may provide an opportunity to help reduce income-related health disparities. There is a body of literature demonstrating an association between low socioeconomic status and unhealthy diet, which relates to the relatively higher burden of obesity and other cardiovascular risk factors among low-income individuals.[288,289] These groups therefore have the potential for substantial benefit from these interventions. A number of mechanisms have been suggested as reasons economically disadvantaged individuals have poorer quality diets: such diets cost less per calorie and people with very limited funds may need to prioritize price over healthfulness; knowledge is lacking about what constitutes a healthy diet and how to prepare foods to maximize their healthful qualities; and environmental factors may play a role, including limited access to fresh fruits and vegetables and greater access to fast-food outlets.[288] A systematic review of 35 RCTs examined factors associated with greater effectiveness of healthy lifestyle behavioral interventions in low-income individuals.[290] It found that self-monitoring, targeting multiple behaviors, and delivery through personal contact were all associated with greater improvement in healthy eating for people with low incomes. Features that were associated with more limited benefits included providing feedback on their eating, providing information about the emotional consequences of an unhealthy diet, and encouraging participants to use prompts and cues to be meeting dietary goals. They also found that physical activity interventions that included behavioral practice or instruction on how to perform the activity tended to report larger improvements in physical activity in low-income individuals.[290]

Comparisons with Other Reviews and Implementation Studies

Our findings were consistent with another recent review of 36 trials of multifactorial (primarily diet and physical activity) lifestyle interventions.[291] At 12-month followup among trials it categorized as being in "moderate" risk populations (generally meaning participants had one or more CVD risk factors but not CVD), it reported findings that were very similar to ours for blood pressure, (-2.48 mm Hg [95% CI, -4.34 to -0.62]/ -1.66 mm Hg [95% CI, -2.17 to -1.14], SBP/DBP change), and slightly larger for lipids (total cholesterol=-8.8 mg/dL [95% CI, -17.0 to -0.1], LDL=-4.2 mg/dL [95% CI, -8.5 to -0.0]) and adiposity (BMI=-0.8 kg/m^2 [95% CI, -1.8 to 0.2], waist circumference=-2.4 cm [95% CI, -5.4 to 0.6]). However, unlike our review, this review included trials with supervised physical activity. Similarly, USPSTF reviews[47, 292] on adult obesity also found larger mean differences between groups in adiposity-related outcomes (e.g., BMI: -1.0 [95% CI, -1.2 to -0.7], **Table 15**), and LDL (-4.9 [95% CI, -7.3 to -2.6]), but had similar SBP results (SBP=-2.0 [95% CI, -2.9 to -1.2]), with 13 trials appearing in both reviews.[109, 116, 119, 120, 123-130, 138] The USPSTF review on diet and physical activity counseling in people who do not have CVD risk factors reported slightly smaller pooled effects for most intermediate outcomes and minimal evidence on the impact in CVD events but larger increases in physical activity than our review.[293] It found approximately 35 more minutes per week of physical activity with lifestyle counseling interventions, and that USPSTF review included 43 trials of interventions that only addressed physical activity, many of which recruited adults with low levels of physical activity.[293] Indeed, studies whose primary inclusion criterion was suboptimal physical activity (without reference to CVD risk factors) were included in that review and not the present review.

Large implementation trials may provide insight into how well review results will generalize to real-life settings. A retrospective cohort study of the Veterans Administration MOVE! weight loss program included 1,463,003 veterans with obesity or overweight with weight-related health conditions and no baseline CVD, of whom 169,248 participated in the MOVE! program.[294] The MOVE! program involves group-based educational sessions on nutrition, physical activity, and goal-setting. After a mean of 4.9 years of followup, participants in the MOVE! program had lower incidence of total CVD (hazard ratio [HR]=0.83 [95% CI, 0.80 to 0.86]), coronary artery disease (HR=0.81 [95% CI=0.77, 0.86]), cerebrovascular disease (HR=0.87 [95% CI, 0.82 0.92]), peripheral vascular disease (HR=0.89 [95% CI, 0.83 to 0.94]), and heart failure (HR=0.78 [95% CI, 0.74 to 0.83]), all controlling for age, race, sex, BMI, statin use, and baseline comorbidities. These results held up when examined for the categories of race/ethnicity, BMI, diabetes, hypertension, smoking status, and statin use. These effect sizes are consistent with our observed 19 percent reduction in CVD events. In this study, 49 percent had hypertension, 19 percent had diabetes, and 41 percent had dyslipidemia at baseline.

Another implementation study included 12,513 patients with multiple cardiovascular risk factors or history of atherosclerotic disease who were followed for 5 years in primary care clinics in Italy that implemented a program of annual screening and counseling by primary care providers for cardiovascular risk factors, including hypertension, hypercholesterolemia, diabetes, obesity, smoking, unhealthy diet, and physical inactivity.[295] If control of any major modifiable cardiovascular risk factors was suboptimal, general practitioners use a brief checklist to develop

action plans to improve the patients' global risk profile. From the first to the last year of the program, control of all major modifiable risk factors except physical inactivity improved ($p<0.0001$). The improvement in the global cardiovascular risk profile during the first year was associated with a lower rate of major cardiovascular events in the following years (HR=0.94 [95% CI, 0.88 to 0.99]).

Intervention Approach

We identified no single optimal or representative intervention, but rather found that a wide range of approaches improve health profiles (**Table 16**). A number of effective trials used group-based counseling, and almost all of these also provided at least one individual support or assessment session as well. Quite a few interventions only provided individual contact, either in person or over the phone. Interestingly, an evaluation of participation in a health coaching program in a large integrated delivery system found that 80 percent of patients who participated in their program opted to receive one-on-one counseling over the phone rather than in-person individual or group sessions.[296]

In the included trials, the intervention contact time required to show a benefit was as low as 1 hour over two sessions, although not all interventions with this level of contact were beneficial. In addition, weight loss interventions tended to offer more contact time than general diet and physical activity interventions. Most effective group-based programs offered five to 12 sessions over 4 to 12 months, or if weight loss was a primary focus, 20 to 30 sessions over 24 months. One-on-one interventions were generally briefer, typically four to 17 sessions over 6 to 16 months, and up to 32 or more sessions over 24 months for interventions focusing on weight loss. Medium contact interventions were typically delivered individually while high contact trials usually involved groups, often in addition to individual contact. Two trials included interventions both with and without human contact, using technology[123] or print-based[103] approaches for one of the intervention groups. Compared with a high-contact intervention, an online-only intervention resulted in less weight loss but no clear differences in diet composition or physical activity,[123] and the four-session medium contact intervention showed comparable levels of behavior change as four tailored letters.[103]

In general, the interventions involved both physical activity and dietary counseling, which typically advised participants to reduce saturated fat; reduce sodium intake to below 1,500 or 2,300 mg/day for hypertension prevention and management; increase consumption of fruits, vegetable, whole grains, healthy fats, and fish; and reduce consumption of sweets and added sugar. The DASH diet and the Mediterranean diet were both employed by multiple interventions. A recently published diet described as optimal for both human and planetary health similarly emphasizes fish, vegetables, fruit, legumes, whole grains, and nuts.[297]

Among interventions showing a benefit, common behavior-change techniques included goal setting, active use of self-monitoring, and addressing barriers related to diet, physical activity, or weight change. Some of the interventions offered smoking cessation support to smokers. Motivational interviewing was commonly employed. The most common type of provider to deliver the bulk of the interventions was a registered dietician, but a wide range of providers

were employed, such as health educators, nurses, lifestyle coaches, psychologists or psychology graduate students, and exercise physiologists. Few of the included interventions were primarily or wholly delivered through the computer or other electronic means, and a systematic review of lifestyle counseling to improve components of metabolic syndrome found that while technology could be a useful tool, interventions with personal contact were most effective.[298] This approach was employed by an included U.S.-based trial that supplemented 18 phone-based coaching sessions with interactive voice recognition calls. It found relatively large benefits on lipids, fasting blood glucose, and weight.[141] The same review found that team-based, interactive approaches with high-frequency contact with patients who were motivated found the largest effects.[298]

Most of the interventions had weight loss goals for all or some of the participants. Consistent with our review, another review found that explicitly targeting weight loss in behavioral counseling interventions was associated with greater weight loss.[299] This review also found that providing dietary goals or meal plans and feedback on behavior change were associated with greater weight loss.[299] A comparative effectiveness study compared the effects of a weight loss intervention against a weight-neutral approach for health promotion in 80 women with BMI ≥30 and age 30–45.[300] At postintervention, the weight-neutral program had larger reductions in LDL cholesterol and greater improvements in intuitive eating, while the weight loss program had larger reductions in BMI, weight, and (in the short-term only) larger decreases in a dietary risk score. Both groups improved on waist-to-hip ratio, total cholesterol, physical activity, fruit and vegetable intake, self-esteem, and quality of life at the 24-month followup. These findings highlight that important health benefits can accrue for people with excess weight even in the absence of weight loss or encouragement to lose weight. This trial was not limited to people with CVD risk factors, however, so generalizability to this group is unclear.

Further arguing for the benefits of improved diet and physical activity even without weight loss are the results from a large epidemiologic study combining participants from the Nurses' Health Study and the Health Professionals Follow-up Study.[301] After 32 years, it found that all-cause mortality was lower in people with BMIs between 30 and 39.9 kg/m^2 who had engaged in at least three of the following healthy behaviors: healthy diet, physical activity, moderate alcohol consumption, and not smoking (incidence rate [IR]=51.7/10,000 person-years for BMI 30.0 to 34.9; IR=81.1/10,000 person-years for BMI 35.0 to 39.9) than people of healthy weight who reported engaging in only one of these four healthy behaviors (IR=96.5/10,000 person-years for BMI 22.5 to 24.9). Thus, for people with excess weight, particularly for those with a history of unsuccessful weight loss, unhealthy weight loss approaches, or disordered eating, promoting diet and physical activity goals without targeting weight loss is likely to improve their health status.

We did not find that physical activity consistently increased with lifestyle counseling for patients with CVD risk factors, despite evidence that suggests physical activity can improve cardiometabolic profiles among people with CVD risk factors.[9, 302, 303] In contrast, the USPSTF-commissioned systematic review of behavioral counseling for diet and physical activity in adults without CVD risk factors found a statistically significant 35-minute increase in physical activity per week and 32 percent higher odds of meeting physical activity recommendations.[293] Like the current review, it also excluded trials with supervised physical activity. In both reviews, only a small subset of trials reported physical activity outcomes, although reporting was even more

sparse in our review. It is possible that supervised activity is an important factor in helping adults with CVD risk factors increase and maintain physical activity regimens. Indeed, semi-structured interviews of participants who had declined participation in an intervention to increase walking identified existing medical conditions as one of the more common reasons for declining,[304] so people with CVD risk factors may similarly prefer to undertake physical activity under the supervision of a health or exercise professional. However, it remains unclear why improvements in physical activity were consistent and statistically significant in one review and not another. While we theorize that differences may be due to differing needs of patients with cardiovascular risk factors, we were unable to provide a clear explanation and other hypotheses cannot be ruled out, including reporting issues in primary trials.

Observational Evidence on the Association Between Differences in Intermediate and Behavioral Outcomes and Health Outcomes (Contextual Question)

Observational data from very large individual participant data (IPD) meta-analyses of prospective cohort studies show that small differences in blood pressure, non-HDL cholesterol, fasting glucose, and adiposity translate into small reductions in the risk of cardiovascular-related mortality (**Table 17**).[305-307] In our review we found that behavioral counseling interventions in persons with CVD risk factors had a pooled effect size of 1.9 mm Hg greater reduction in SBP. Using observational data, an effect of 2 mm Hg was associated with reductions of 6 percent or more in the risk of cardiovascular-related mortality, and the effect appears to hold down to blood pressure levels of 115/75 mm Hg.[305] A recent analysis extended these findings to show that important associations between blood pressure and CVD events exist regardless of threshold (e.g., 140/90 mm Hg vs 130/90 mm Hg) and when using real-world clinical databases that do not use research-quality blood pressure measurements.[308] An average decrease in non-HDL cholesterol of 3 mg/dL (slightly smaller than the 3.7 mg/dL greater reduction in total cholesterol found in our review) was associated with a 4 percent reduction in IHD mortality in adults ages 40 to 49 years old (HR=0.96 [95% CI, 0.95 to 0.96].[305] An incremental 2 mg/dL decrease in fasting blood glucose above 100 mg/dL was associated with an estimated 1 percent decreased risk of fatal plus nonfatal coronary heart disease (HR=0.99 [95% CI, 0.98 to 0.99]),[309] vascular deaths (HR=0.99 [95% CI, 0.98 to 0.99]),[310] and all-cause mortality (HR=0.99 [95% CI, 0.99 to 0.99]).[310] The relationship between BMI and cardiovascular-related mortality is found only above a BMI of 25 kg/m^2. A BMI decrease of 0.4 kg/m^2 (the effect size found in our pooled analysis) was associated with an estimated 3 percent decreased risk of death caused by ischemic heart disease (HR=0.97 [95% CI, 0.96 to 0.97]) and fatal strokes (HR=0.97 [95% CI, 0.97 to 0.98]) among adults with a BMI above 25 kg/m^2 and ranging from ages 35 to 59 years.[307] Based on data pooled from multiple prospective cohort studies, we estimated that a 1.7 cm decline in waist circumference could be associated with a 5 percent lower risk of ischemic heart disease events (HR=0.95 [95% CI, 0.95 to 0.98])[311] and a 1 to 3 percent lower risk of all-cause mortality (men: HR=0.97 [95% CI, 0.96 to 0.98] for a 2 cm decline; women: HR=0.99 [95% CI, 0.98 to 0.99] for a 1 cm decline).[312]

For dietary outcomes, the impact of individual diet components is difficult to evaluate, as the totality of the diet is most important.[288] One meta-analysis of 16 cohort studies found a 5 percent

lower risk of all-cause mortality for an increment of one serving of fruit and vegetables per day (pooled HR=0.95 [95% CI, 0.92 to 0.98]),[20] although our analysis found a mean difference in change of less than one serving. The effect of a 17.9 mmol/L greater reduction in sodium is unclear. Meta-analyses of cohort studies indicate that a 40 mmol/L reduction was associated with reduced incidence of stroke and fatal coronary heart disease events, but some other cardiovascular-related outcomes did not show a clear association.[313] The DASH feeding study found that a reduction in urinary sodium of approximately 50 mmol per day (a level of change consistent with someone who eats a typical American diet reducing their intake to meet current recommendations) was associated with approximately 2 mm Hg reduction in SBP,[313] which is the effect we found in this review.

The findings on intake of different types of dietary fats are less clear, although evidence suggests that a fat-modified diet may not assist with weight loss or decrease CVD and cancer mortalities.[314-317] Evidence suggests that replacing 5 percent of energy from saturated fats with other types of fats or whole-grain carbohydrates is associated with health benefits,[21] but not all researchers agree with this conclusion.[318-320] Further, a 5 percent change is larger than the 1.5 percent difference in change that we found in this review.

There is a strong body of evidence showing substantial health benefits associated with physical activity, and current evidence suggests that there is no threshold that must be exceeded before benefits can occur.[9] Thus, despite the small, statistically nonsignificant findings for minutes and MET-minutes per week of exercise, any increase in physical activity is likely beneficial.

See **Appendix E** for a more detailed description of observational evidence supporting the link between changes in behavior and intermediate outcomes of the magnitude found in this review and long-term cardiovascular health outcomes. However, it is always worth emphasizing that observational evidence may overestimate the benefits of behavior change due to the inherent difficulty in controlling for confounding factors in non-randomized studies. Biases in observational results may be even more pronounced when long-term adherence to drug or behavioral change is assumed in order to maintain benefits. Some have noted that this concern is particularly important for applying effects of observational evidence to preventive interventions in primary care settings.[321] Moreover, observational evidence does not reflect changes in intermediate or behavioral outcomes based on counseling interventions.

Limitations of Our Approach

This review addressed a subset of a larger body of literature on behavioral counseling interventions to promote a healthy diet and increase physical activity to encourage health and wellness more broadly. We focused narrowly on CVD prevention, limited further to patients with problematic blood pressure or lipids, to complement related USPSTF-sponsored reviews surrounding CVD prevention.[45, 46, 322] Interventions targeting other health conditions are not represented, such as those focused on reducing or managing chronic pain, stress, limiting disability/frailty in older adults, improving mental health, or myriad other conditions that may be affected by diet and physical activity. We also did not include studies limited to some important underrepresented populations, such as those with physical or intellectual disabilities, and some of

the included trials specifically excluded these individuals from their studies, although these interventions are relevant to these populations.[323]

In addition, we limited our definition of high risk to hypertension, dyslipidemia, and any of multiple risk factors (including estimated 10-year risk). However, increasing age is a primary risk factor for CVD and studies restricted to older adults but without 10-year CVD risk inclusion requirements were excluded. In addition, we did not include studies focused on persons with mild chronic kidney disease, many of whom also have hypertension and dyslipidemia and who may also benefit from behavioral counseling for diet and physical activity.

Our search did not comprehensively address weight loss for trials published prior to 2016. Since the previous review did not include weight loss trials, the previous search did not include weight loss terms. We used the USPSTF review on weight management interventions to identify weight loss trials in people with CVD risk factors that were published prior to 2016.[322] In addition, we searched the excluded studies lists from the previous on lifestyle counseling for people with CVD risk factors to identify studies that had been excluded because they were considered to be weight loss studies.[324]

Additionally, we excluded populations with prediabetes or identified with a diabetes risk score. A concurrent companion systematic review is addressing behavioral counseling interventions to prevent diabetes in those at increased risk of diabetes. While we are confident that this targeted approach will not miss any literature, we acknowledge that prediabetes commonly coexists in adults with obesity, hypertension, and dyslipidemia.

Limitations of the Studies and Future Research Needs

Although the evidence base for the impact of diet and physical activity counseling on health outcomes has improved since the previous review, one limitation of the literature is that only a small proportion of trials had sufficient sample size and length of followup to explore the impact of their interventions on important health outcomes such as stroke, MI, and mortality. Continued long-term followup presents a valuable opportunity to assess the impact on these important outcomes. Data were also very limited on lifestyle counseling's impact on subjective well-being, which reflect health outcomes of great importance to patients.

Another important limitation of this literature is the highly variable reporting of behavioral outcomes, particularly physical activity outcomes. The variability in specific measures used, as well as the general lack of reporting of behavioral outcomes in studies reporting intermediate outcomes, made it very difficult to understand the range of effects and to interpret the pooled effects. In addition, for dietary outcomes, it is difficult to understand the clinical importance of changes in a single aspect of diet, particularly in the area of fat consumption, because recommendations have changed over the past decades and controversy remains over the role of saturated fats in the development of heart disease.[318, 325] Given the importance of substitutions when modifying diet,[21] validated measures of overall diet pattern would be a more valuable outcome; however, the field has not converged on a consistent measure of overall optimal diet pattern. The Healthy Eating Index (HEI), for example, is a validated measure of overall diet

quality assessing alignment with the Dietary Guidelines for Americans, and is associated with all-cause, CVD, and cancer mortality.[326] Yet, only two included studies reported this measure.[97, 123] This field would benefit from establishing a set of core outcome measures of optimal diet and physical activity.

Additionally, changes over time in eating patterns, treatment guidelines, and our understanding of the science of nutrition increase the clinical heterogeneity of participants as well as the interventions used in these trials. Treatment guidelines for hypertension and dyslipidemia have changed over time, generally becoming more aggressive. At the same time, rates of smoking have declined. Dietary messages as well as technology platforms available to deliver interventions have similarly undergone rapid change. While we restricted our included literature to trials published from 1990 to present, this review encompasses nearly 30 years of literature, during which the clinical context of behavioral counseling for individuals with CVD risk factors has changed. The sparse reporting of baseline estimated 10-year CVD risk—coupled with the rarity of trials powered for CVD events—makes it difficult to characterize the risk levels of participants in terms consistent with treatment guidelines that are informed by 10-year risk levels.

The wide-ranging clinical characteristics of the study populations also made it difficult to generalize from study-reported subgroup analyses, which were rarely available from more than one or two studies for any given outcome for a given patient subpopulation. Thus, we were not able to provide a robust analysis of differential effectiveness across patient characteristics. While we conducted meta-regression and subgroup analysis in our meta-analyses to address effect modification to the extent possible, these analyses were very limited due to the risk of ecological bias, and the best analysis of effect modification across patient subpopulations is with individual-level data. Another analysis issue that is best addressed in individual-level analyses is controlling for the confounding effects of medication use. Medication use may have systematically differed between groups if control participants had a greater need for medication use due to poorer lifestyle behaviors. Individual studies rarely controlled for this potentially important confounding variable.

In addition, there was little literature on the use of technology, online resources, or other low-contact approaches, which may be valuable in settings with very limited resources. Relatedly, there was very limited use of modern wearable activity trackers in the included interventions, but these may be useful tools to increase engagement in physical activity as well as to provide objective physical activity outcomes. Research suggests that these devices can even be acceptable to adults over the age of 50 with chronic illnesses.[327] The included studies also provided very limited information on whether lifestyle change can reduce the risk of CVD in older adults, such as those age 75 and older. Many studies had upper age limited in the 60s or 70s and few included a substantial number of participants older than 70.

Despite the large number of included trials in this review, there were few replication studies, unlike DPP in the diabetes prevention literature. Large replication studies of interventions showing reduction in CVD events are urgently needed. Given the recency and magnitude of benefit from PREDIMED, it would be of great value to determine if these findings could be replicated in the United States. Our review includes only one U.S.-based trial explicitly stating

that a Mediterranean diet message was evaluated.[136] This 12-month trial of 184 participants showed statistically significant improvement in blood pressure, adiposity, and saturated fat outcomes; however, it was too small to assess impact on CVD events.

The PREDIMED-Plus (ISRCTN89898870) trial currently underway in Spain intends to build upon the findings of PREDIMED. PREDIMED-Plus, for which 6,874 individuals were recruited, will compare a Mediterranean diet (with supplemental olive oil and nuts given at no cost) to a Mediterranean diet (with the same supplemental foods) together with promotion of physical activity, behavioral support, and weight loss goals. The primary outcome of this trial is a CVD event composite, and the anticipated trial completion date is 2020. Many behavioral counseling trials are currently in progress, with many being conducted in the United States (**Appendix I**). The trials are evaluating different intervention formats in both general and targeted populations with CVD risk factors. With the exception of PREDIMED-Plus, none of the trials appear to be powered for CVD events.

Finally, we agree with the Hypertension Canadian Priority Setting Partnership Group that more research is needed to determine the combinations of healthy lifestyle modifications that are necessary and sufficient to reduce the need for medications to manage CVD risk factors, and the optimal use of educational tools and technologies to improve patient motivation and health behavior change.[328] While great strides have been made in developing and testing numerous interventions, it is still unclear exactly which intervention components and messages are most effective, how much contact time is required, and who should deliver these interventions to help most individuals substantially improve their diet or increase physical activity, and to maintain the changes for the long term. Comparative effectiveness studies are the best vehicle for addressing these types of questions; however, they fall outside the scope of the current review.

Thus, with the caveats surrounding the need to standardized measures, future research needs include:

- Replication of effective studies (e.g., PREDIMED, others showing reductions in CVD events or relatively large effects on intermediate outcomes) in the current US environment with respect to clinical care, dietary recommendations, and food intake patterns
- Long-term followup on previously completed studies examining CVD and mortality outcomes
- Large-scale implementation studies of effective interventions in health systems
- Studies examining the impact of lifestyle counseling interventions in older adults, including endpoints that are relevant to older individuals, such as subjective well-being.

Conclusions

Medium- and high-contact multisession behavioral counseling interventions to improve diet and increase physical activity provided to people with hypertension or dyslipidemia, or who have elevated blood pressure and lipid levels, are effective in reducing CVD events, blood pressure, total cholesterol, and adiposity-related outcomes, with little to no risk of serious harm.

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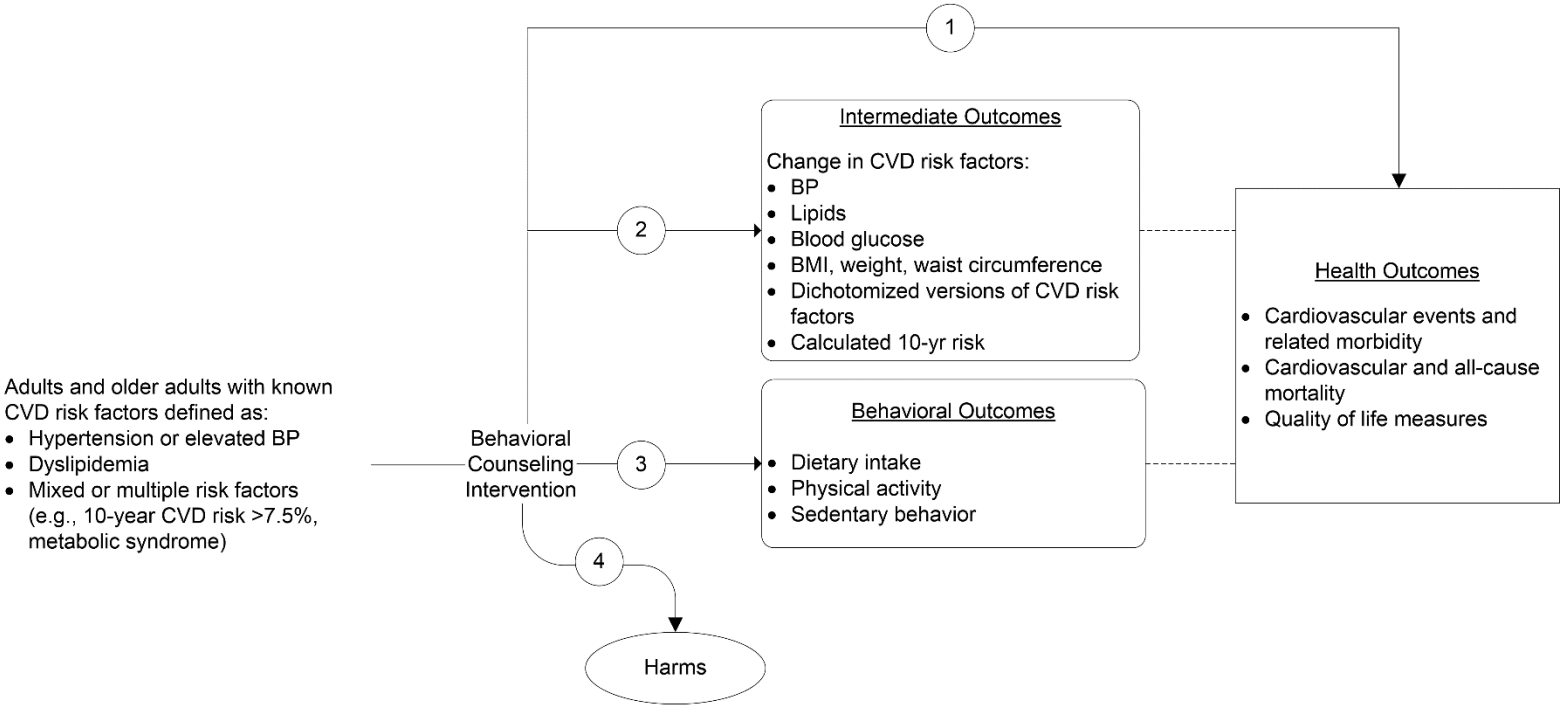
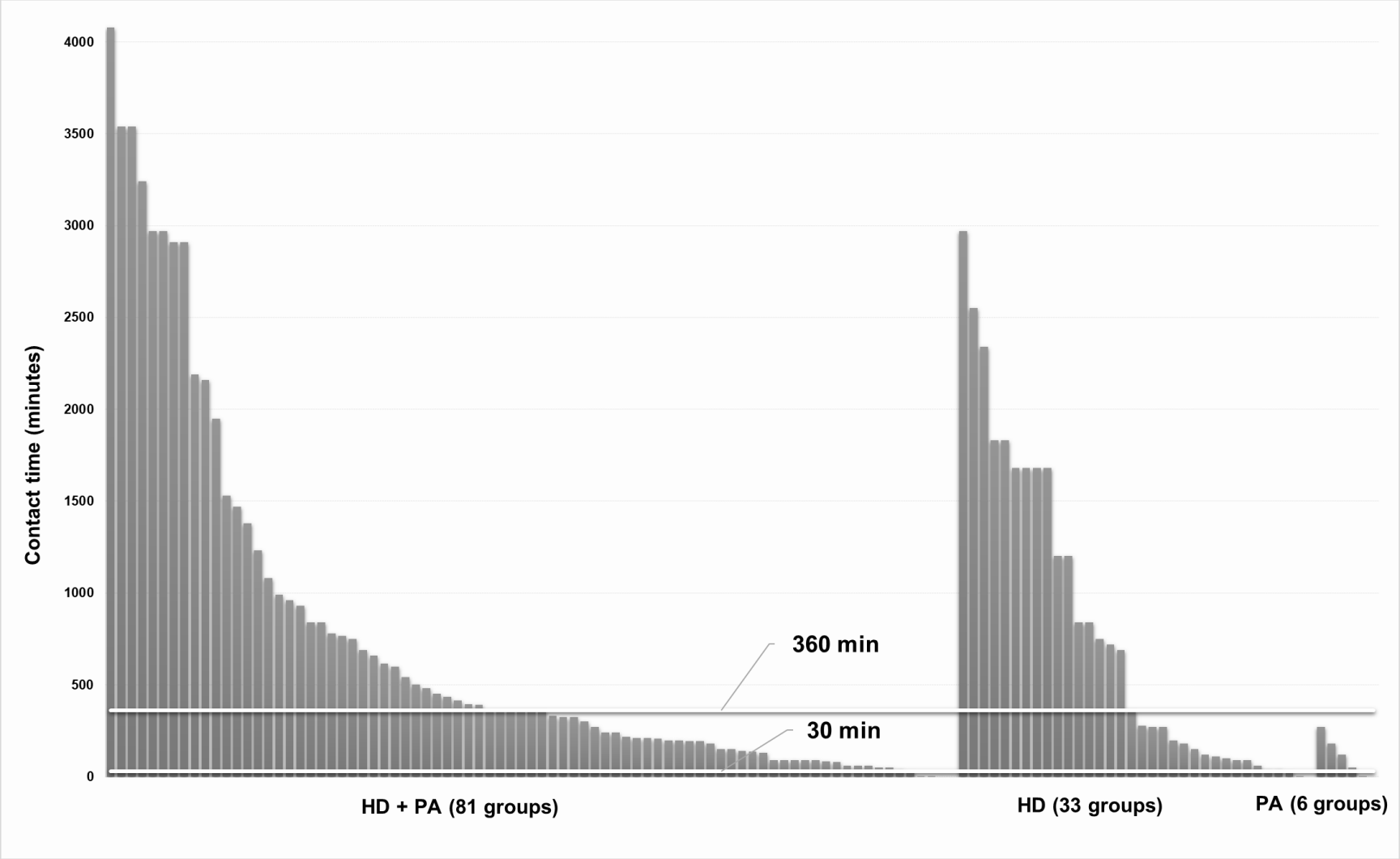
Figure 1. Analytic Framework



Abbreviations: BP = blood pressure, BMI = body mass index, CVD = cardiovascular disease

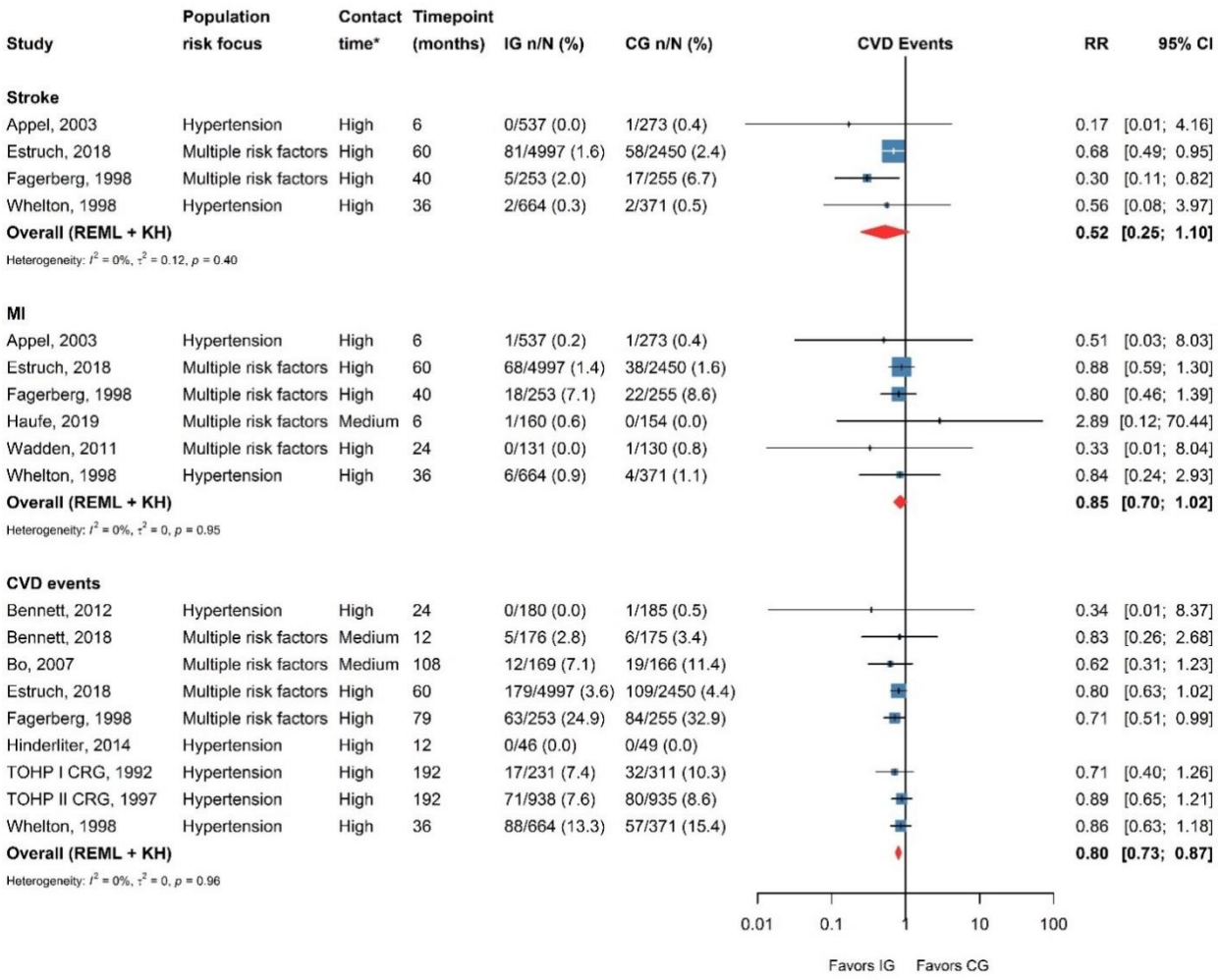
Figure 2. Distribution of Intervention Arms by Contact Time* and Focus



Abbreviations: HD = healthy diet only; HD + PA = healthy diet and physical activity; min = minutes; PA = physical activity only

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

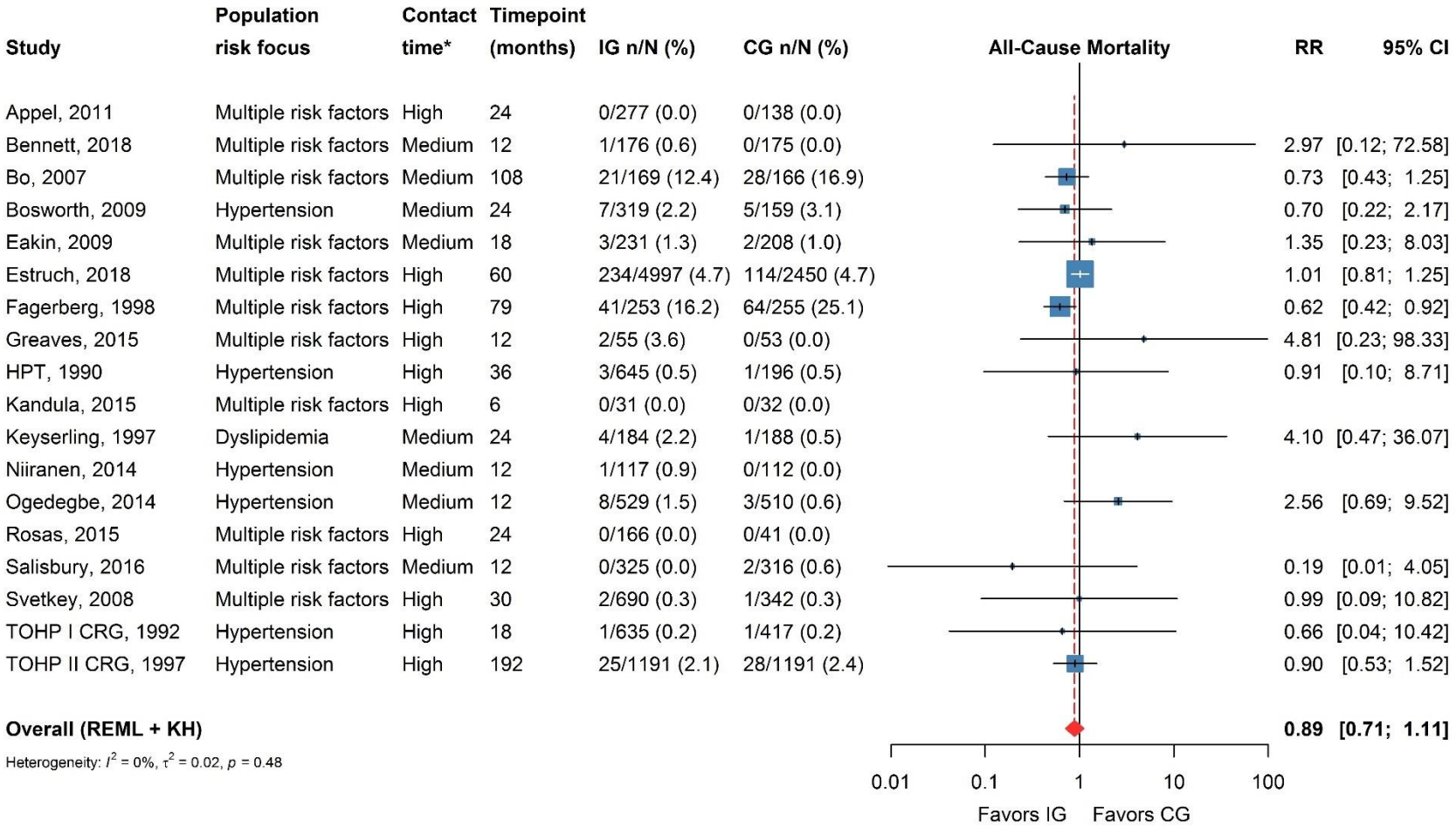
Figure 3. CVD Events (KQ1)



Abbreviations: CG = control group; CI = confidence interval; CVD = cardiovascular disease; IG = intervention group; KH = Knapp-Hartung adjustment; MI = myocardial infarction; REML = restricted maximum likelihood; RR = risk ratio; TOHP I CRG = The Trials of Hypertension Prevention – Phase I Collaborative Research Group; TOHP II CRG = The Trials of Hypertension Prevention – Phase II Collaborative Research Group

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

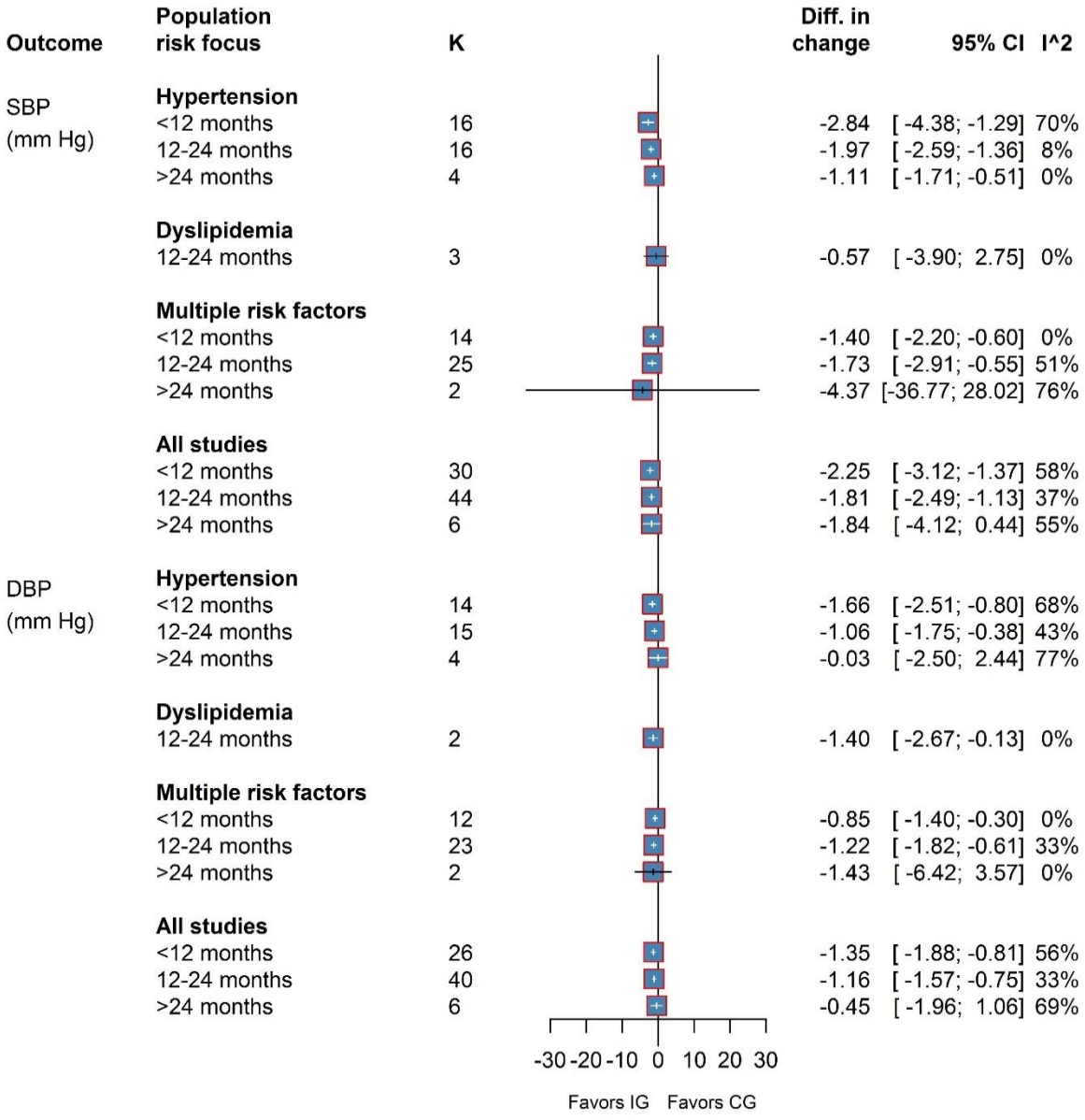
Figure 4. All-Cause Mortality (KQ1)



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; RR = risk ratio; TOHP I CRG = The Trials of Hypertension Prevention – Phase I Collaborative Research Group; TOHP II CRG = The Trials of Hypertension Prevention – Phase II Collaborative Research Group

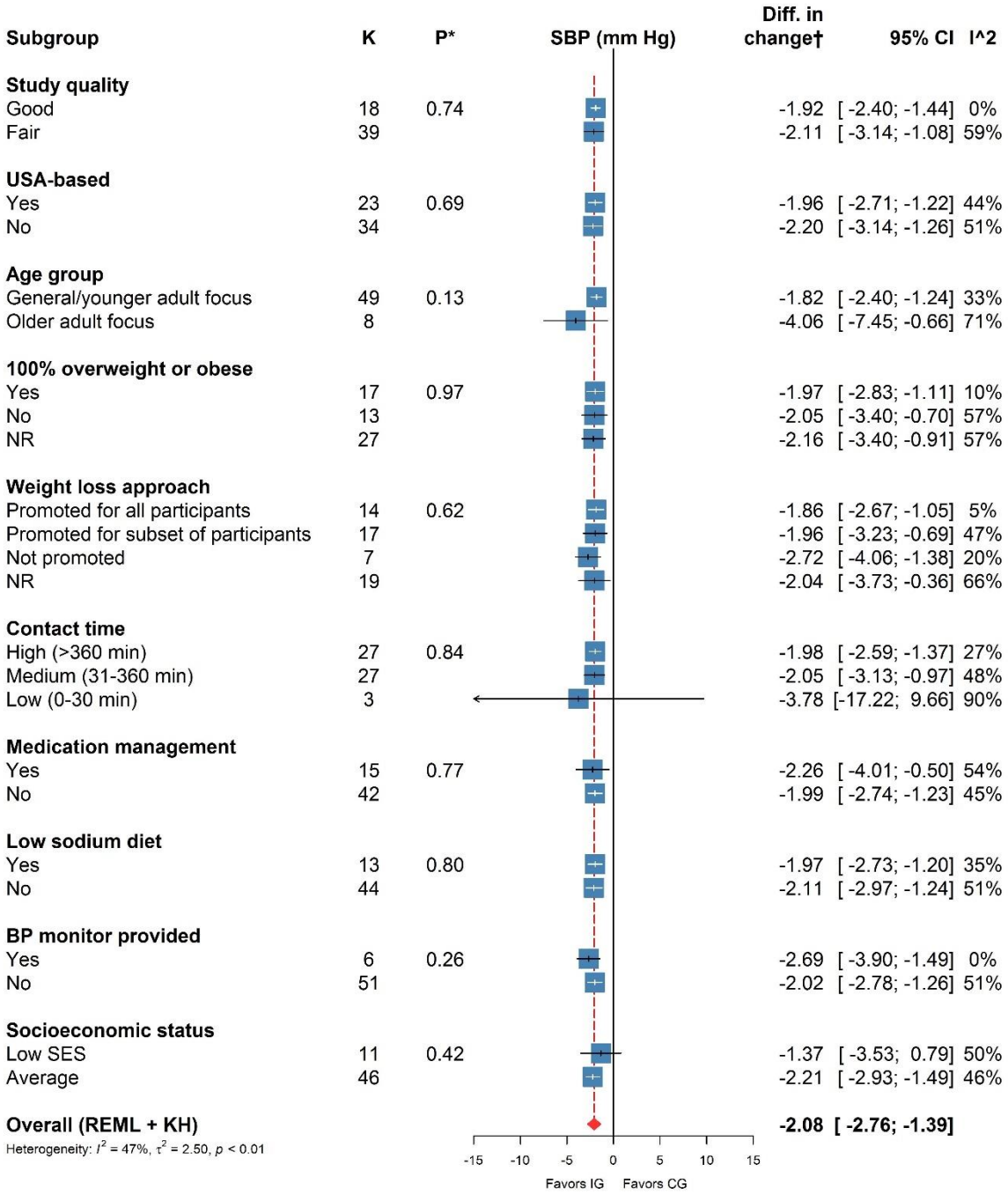
*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Figure 5. Systolic and Diastolic Blood Pressure Summary (KQ2)



Abbreviations: CI = confidence interval; DBP = diastolic blood pressure; Diff. = difference; studies (including studies reported by subgroups); mm Hg = millimeter of mercury; SBP = systolic blood pressure

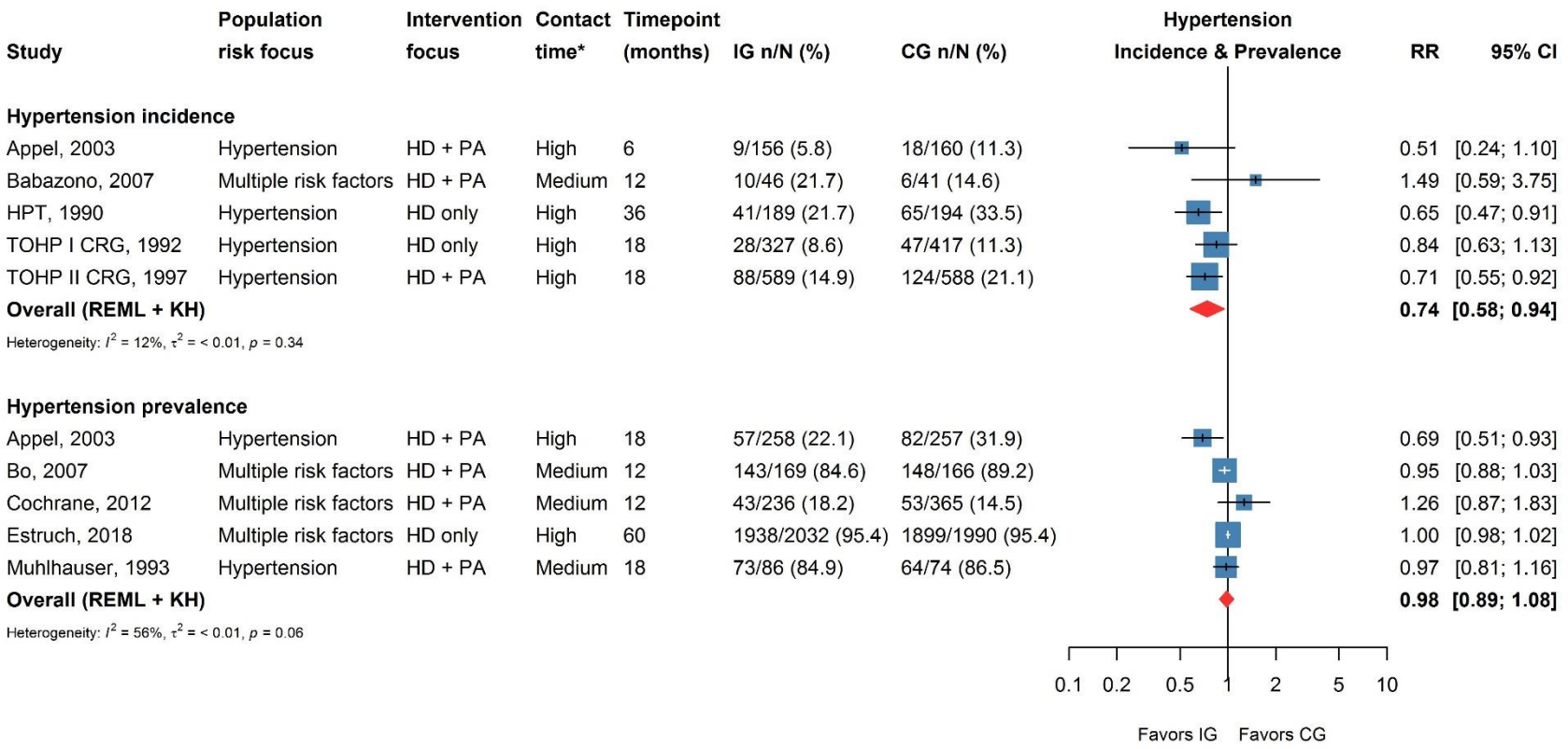
Figure 6. Systolic Blood Pressure Subgroup Analyses (KQ2)



Abbreviations: BP = blood pressure; CI = confidence interval; Diff. = difference; K = number of studies (including studies reported by subgroups); KH = Knapp-Hartung adjustment; mm Hg = millimeters of mercury; NOS = not otherwise specified; NR = not reported; REML = restricted maximum likelihood; SES = socioeconomic status

*Bivariate P-values derived from Q test of between-subgroups heterogeneity (based on random effects model)
†For this analysis, the most comprehensive or highest dose intervention group was selected if a study had multiple intervention groups, and the followup timepoint closest to 12 months was selected of there were multiple followup assessments

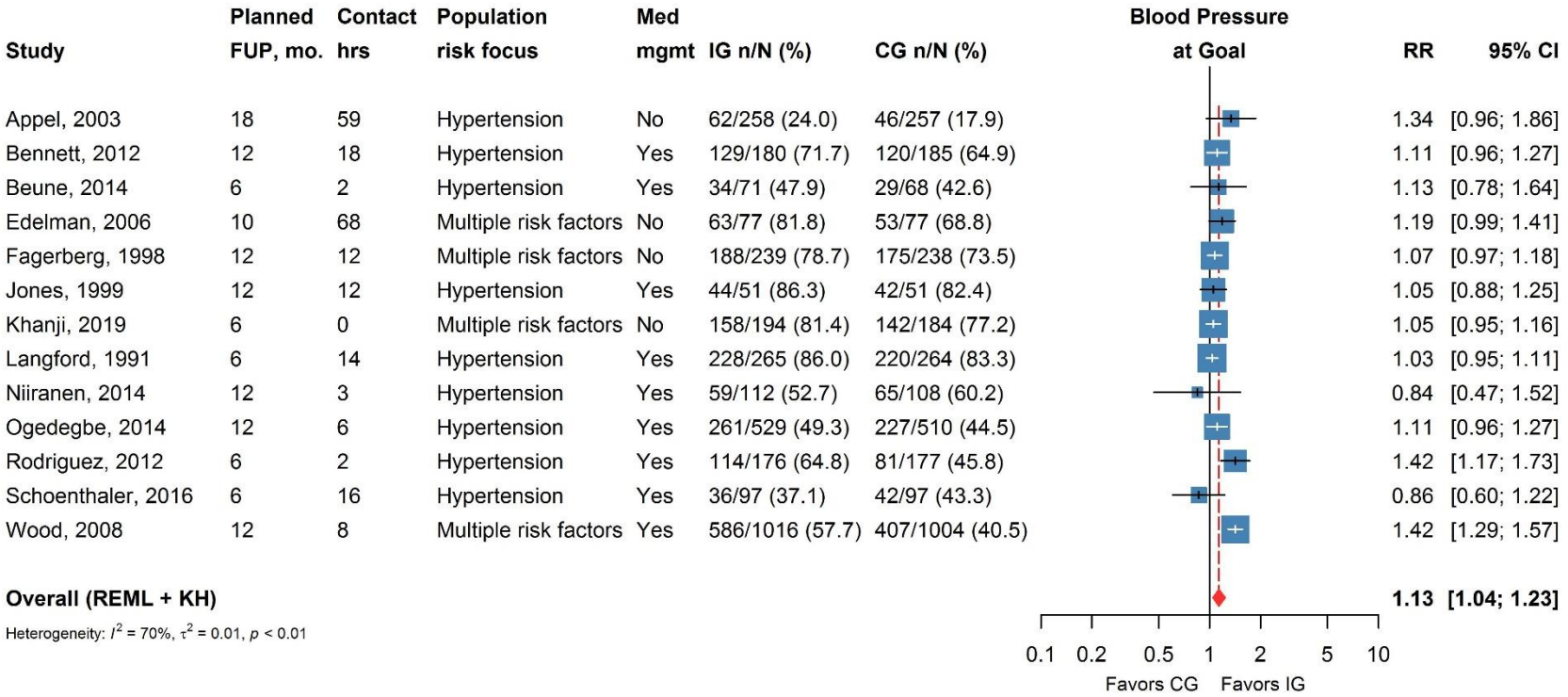
Figure 7. Hypertension Incidence and Prevalence (KQ2)



Abbreviations: CI = confidence interval; HD = healthy diet; HD + PA = healthy diet and physical activity; K = number of studies (including studies reported by subgroups); KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; RR = risk ratio; TOHP I CRG = The Trials of Hypertension Prevention – Phase I Collaborative Research Group; TOHP II CRG = The Trials of Hypertension Prevention – Phase II Collaborative Research Group

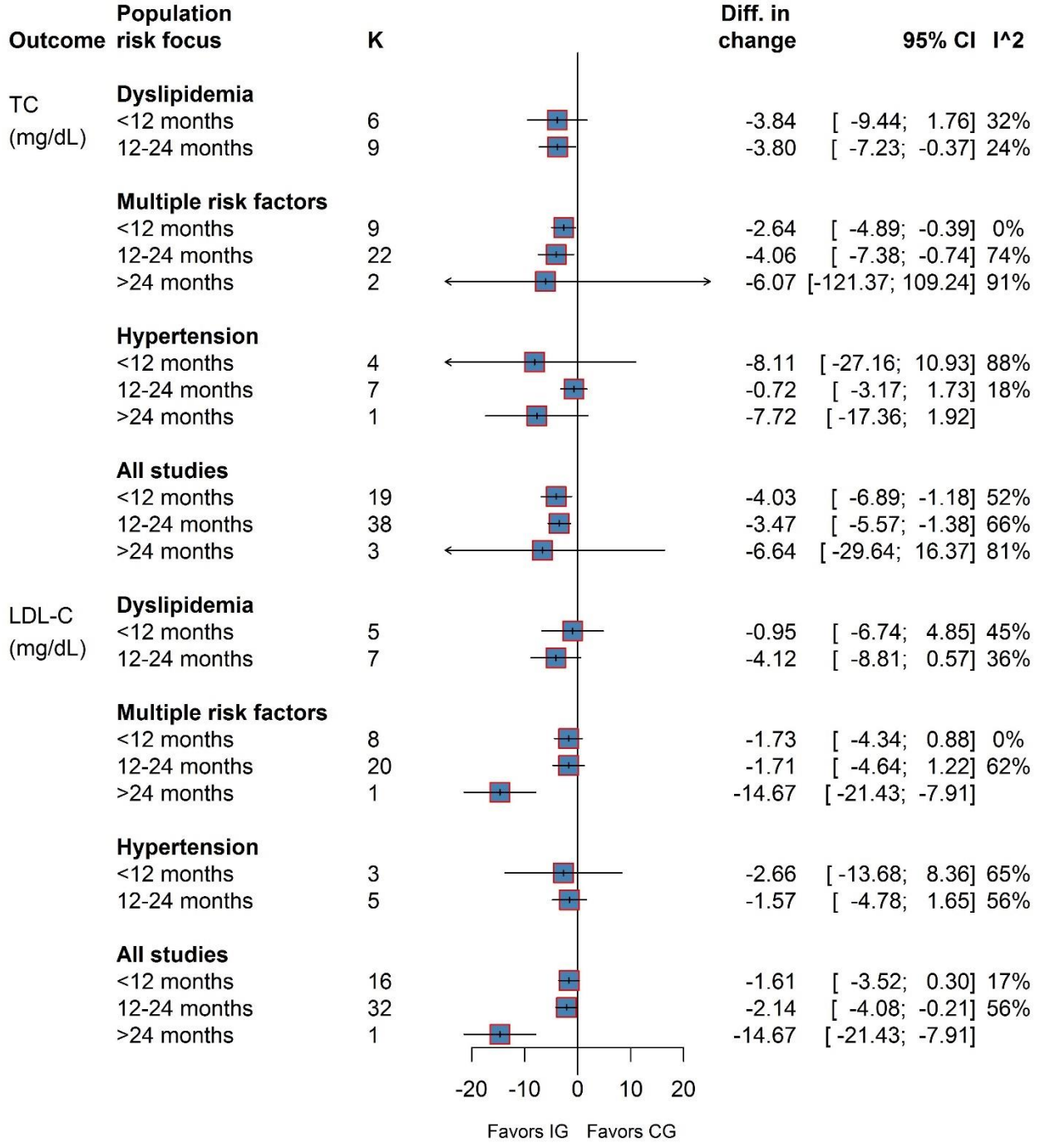
*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Figure 8. Blood Pressure at Goal (KQ2)



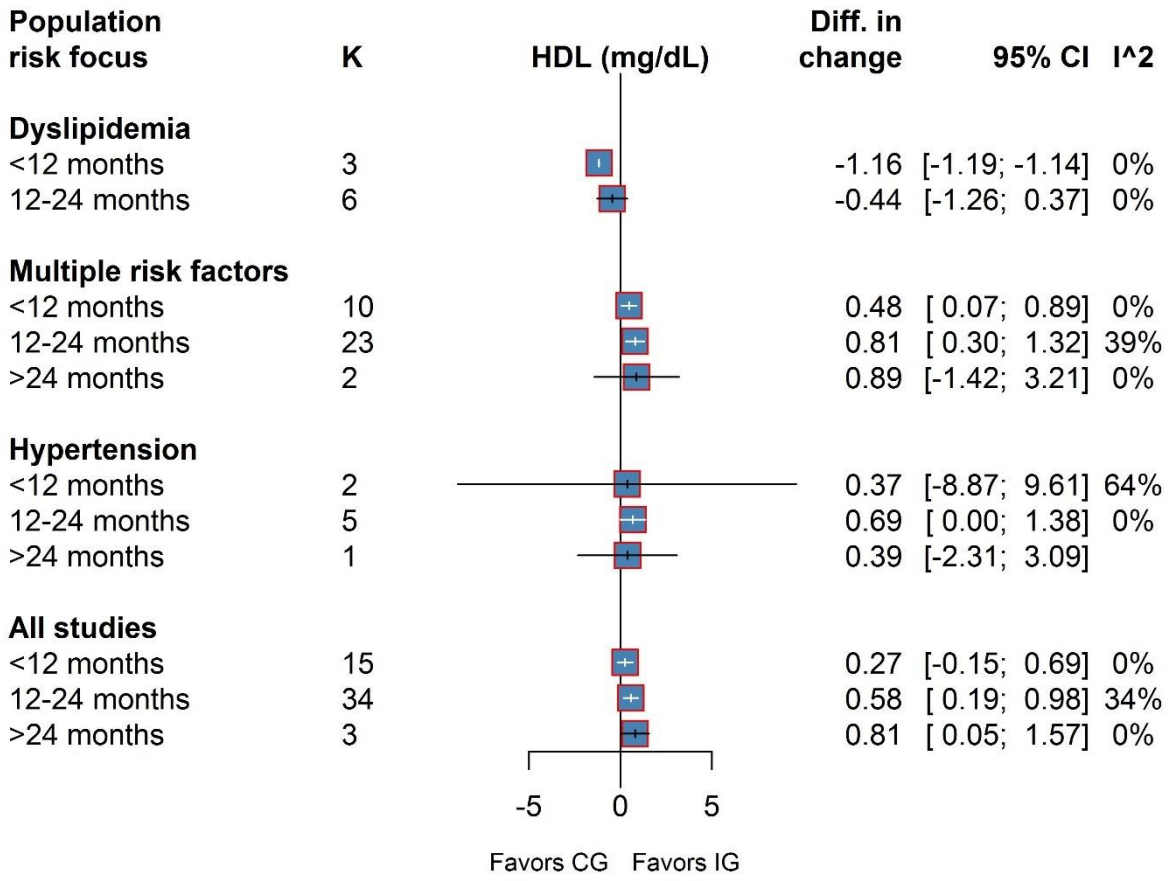
Abbreviations: CG = control group; CI = confidence interval; FUP = followup; hrs = hours; IG = intervention group; K = number of studies; KH = Knapp-Hartung adjustment; Med mgmt. = medication management; mo. = months; REML = restricted maximum likelihood; RR = risk ratio

Figure 9. Total Cholesterol and Low-Density Lipoprotein Cholesterol Summary (KQ2)



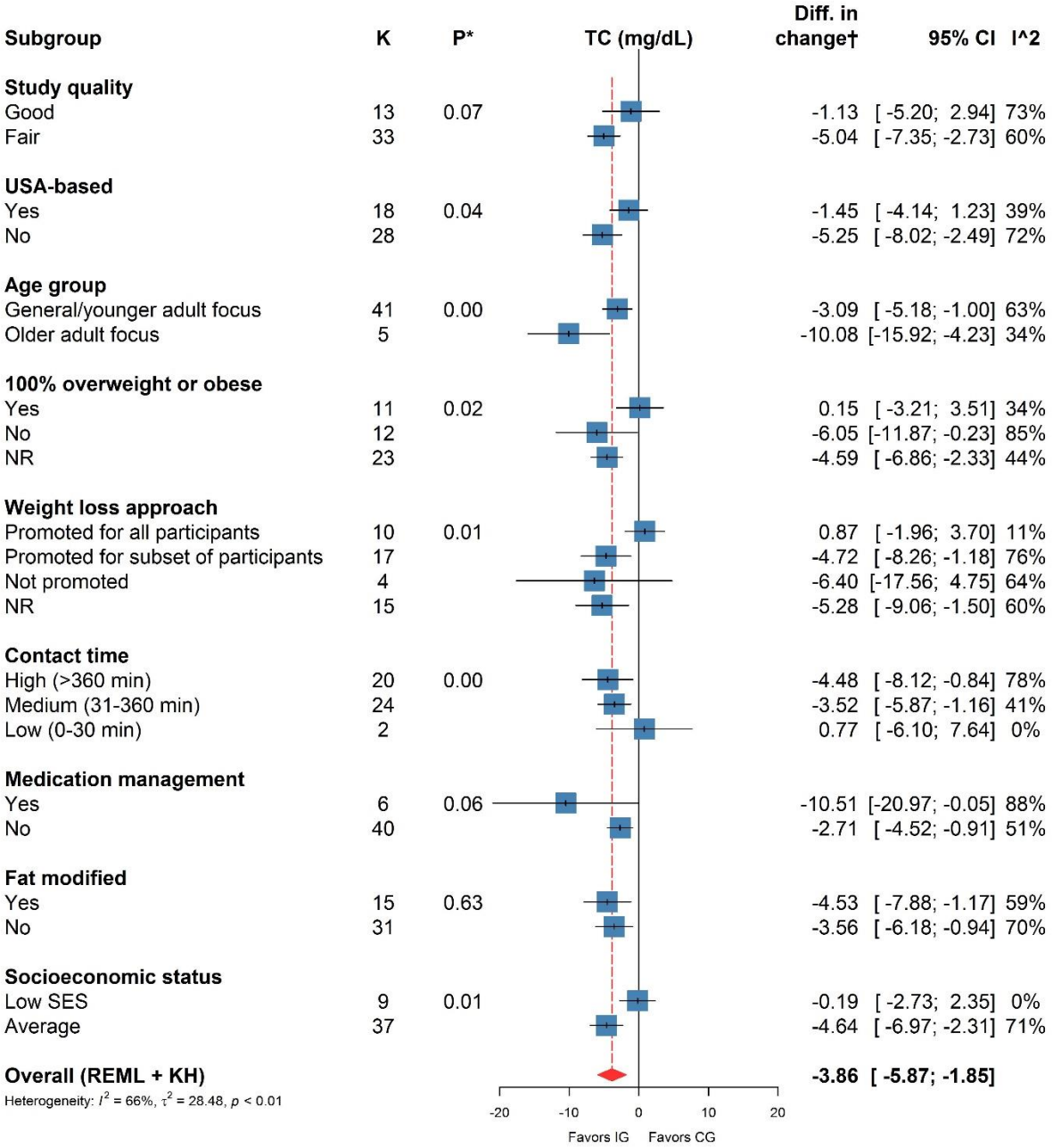
Abbreviations: CI = confidence interval; Diff. = difference; K = number of studies (including studies reported by subgroups); LDL-C = low-density lipoprotein cholesterol; mg/dL = milligrams per deciliter; TC = total cholesterol

Figure 10. High-Density Lipoprotein Cholesterol (KQ2)



Abbreviations: CI = confidence interval; Diff. = difference; HDL = high-density lipoprotein cholesterol; K = number of studies (including studies reported by subgroups); mg/dL = milligrams per deciliter

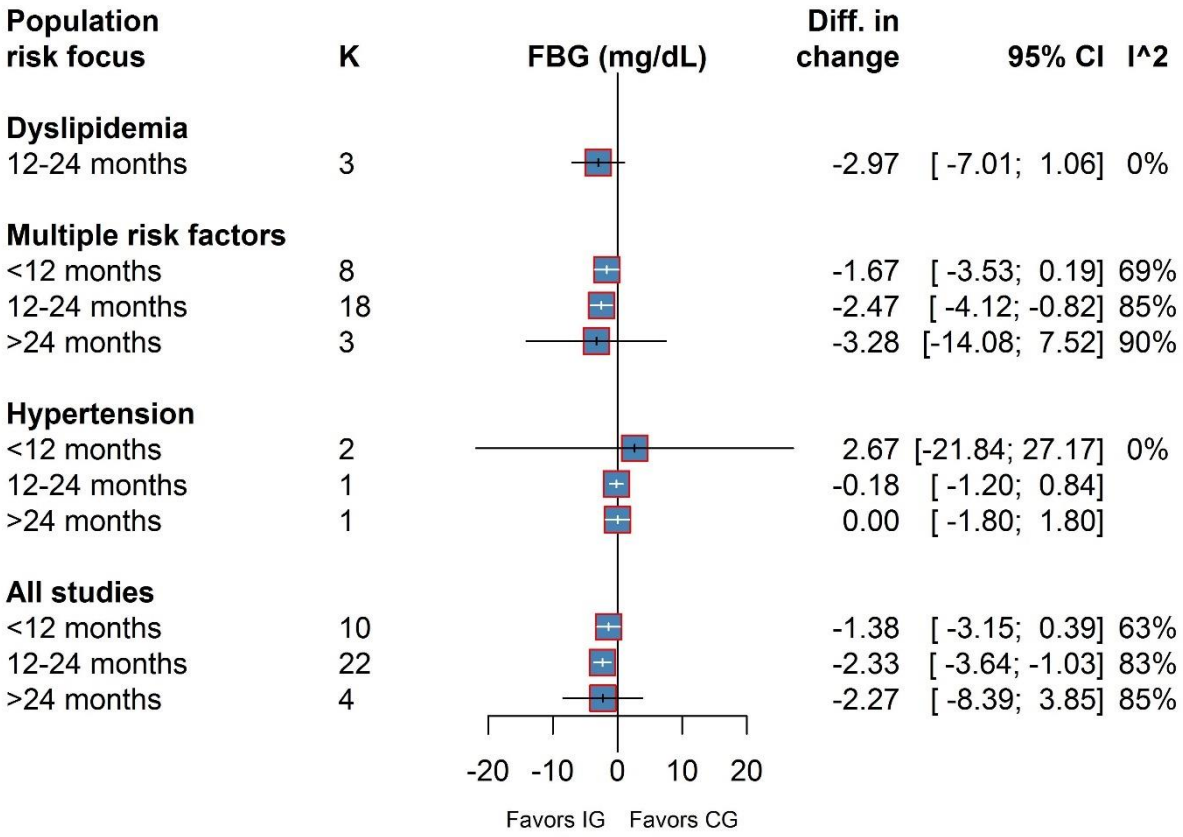
Figure 11. Total Cholesterol Subgroup Analyses (KQ2)



Abbreviations: CI = confidence interval; CG = control group; Diff. = difference; IG = intervention group; K = number of studies (including studies reported by subgroups); KH = Knapp-Hartung adjustment; mg/dL = milligrams per deciliter; NR = not reported; REML = restricted maximum likelihood; SES = socioeconomic status; TC = total cholesterol

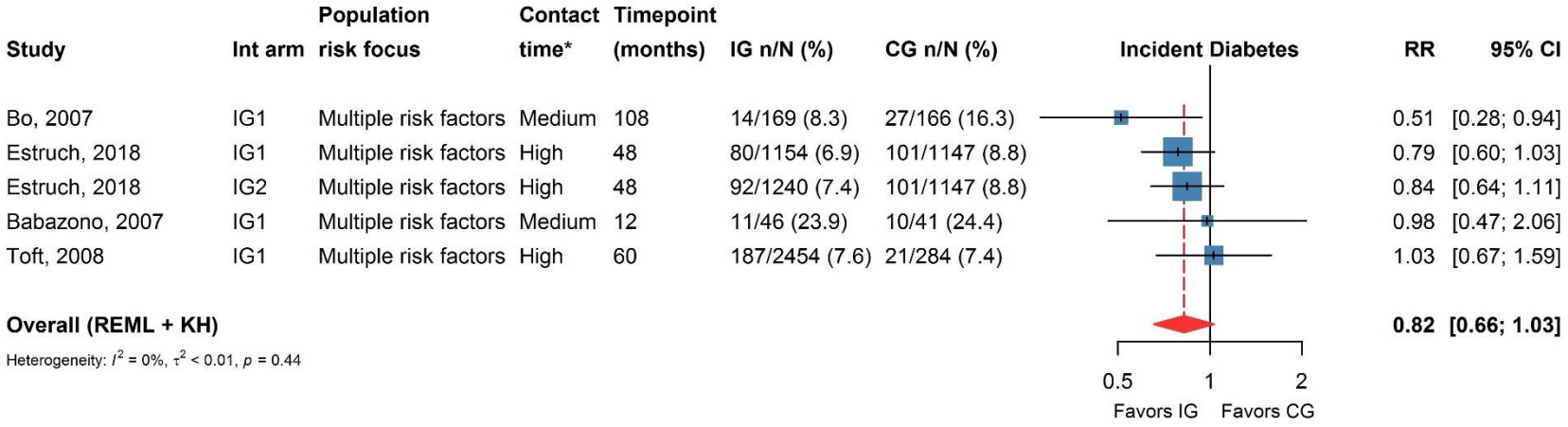
*Bivariate P-values derived from Q test of between-subgroups heterogeneity (based on random effects model)
†For this analysis, the most comprehensive or highest dose intervention group was selected if a study had multiple intervention groups, and the followup timepoint closest to 12 months was selected of there were multiple followup assessments

Figure 12. Fasting Blood Glucose (KQ2)



Abbreviations: CI = confidence interval; Diff. = difference; FBG = fasting blood glucose; K = number of studies (including studies reported by subgroups); mg/dL = milligrams per deciliter

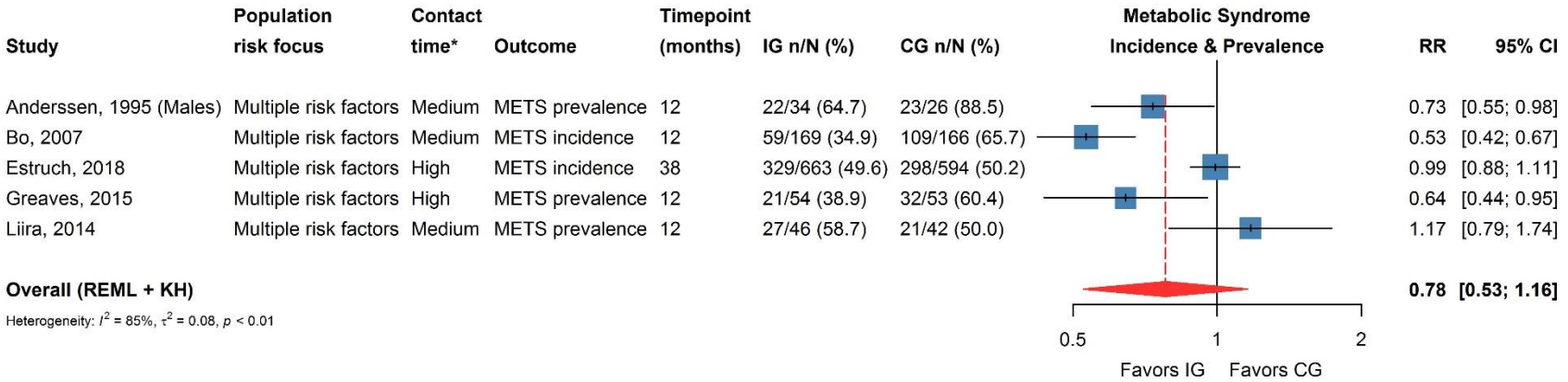
Figure 13. Incident Diabetes (KQ2)



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; Int arm = intervention arm; KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; RR = risk ratio

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

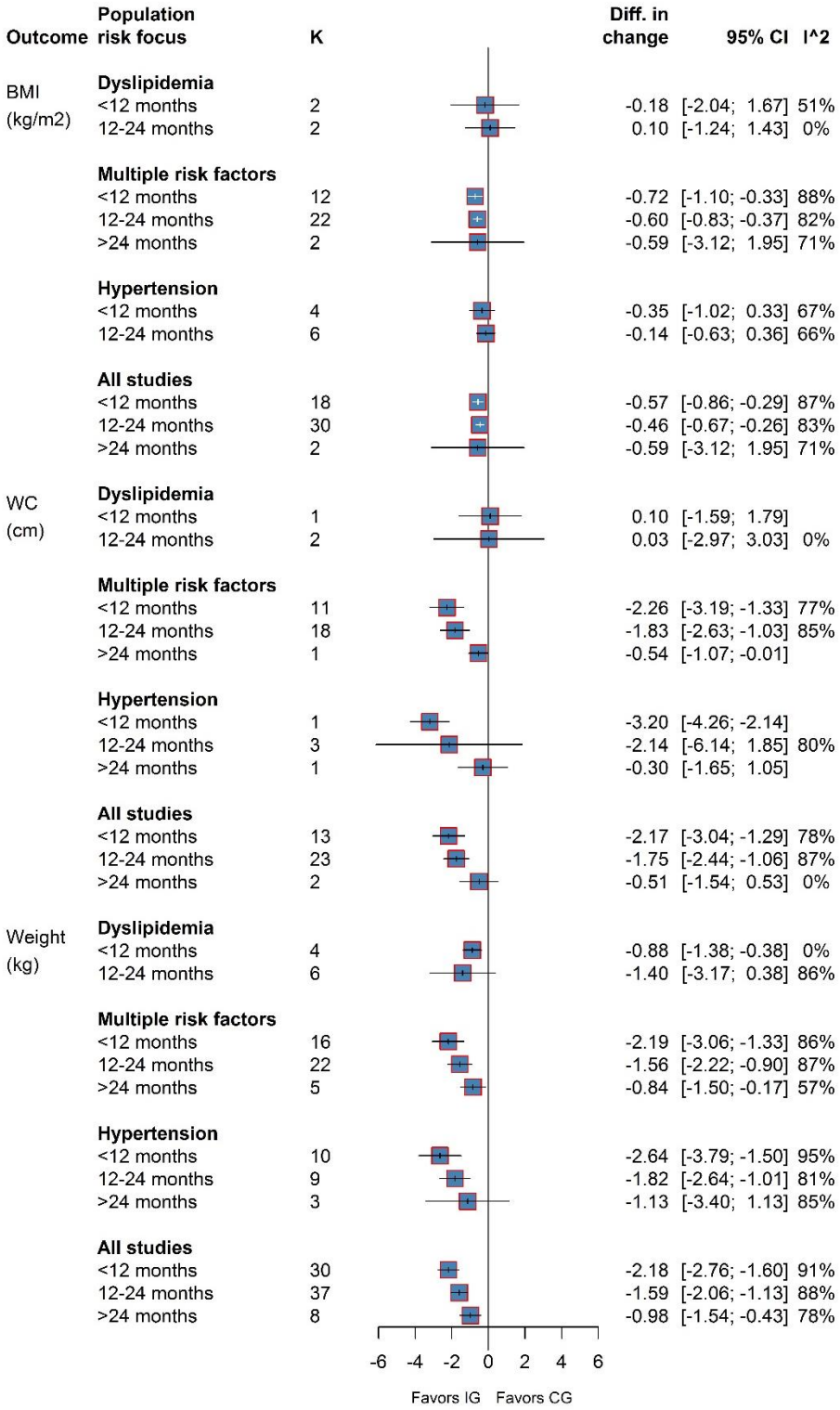
Figure 14. Metabolic Syndrome Incidence and Prevalence (KQ2)



Abbreviations: CG = control group; CI = confidence interval; Int arm = intervention arm; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; METS = metabolic syndrome; REML = restricted maximum likelihood; RR = risk ratio

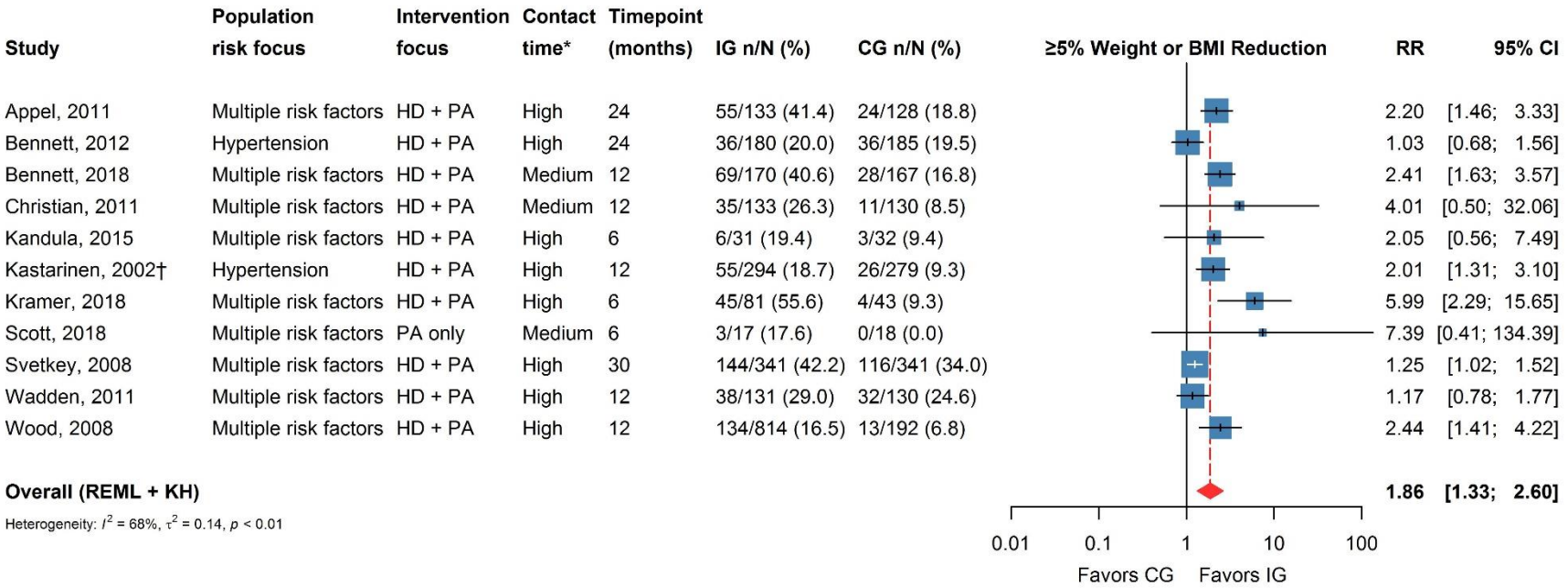
*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Figure 15. Weight, BMI, WC Summary Plot (KQ2)



Abbreviations: BMI = body mass index; CI = confidence interval; cm = centimeters; Diff. = difference; IG = intervention group; K = number of studies (including studies reported by subgroups); kg = kilograms; kg/m^2 = kilograms per meter squared; WC = waist circumference

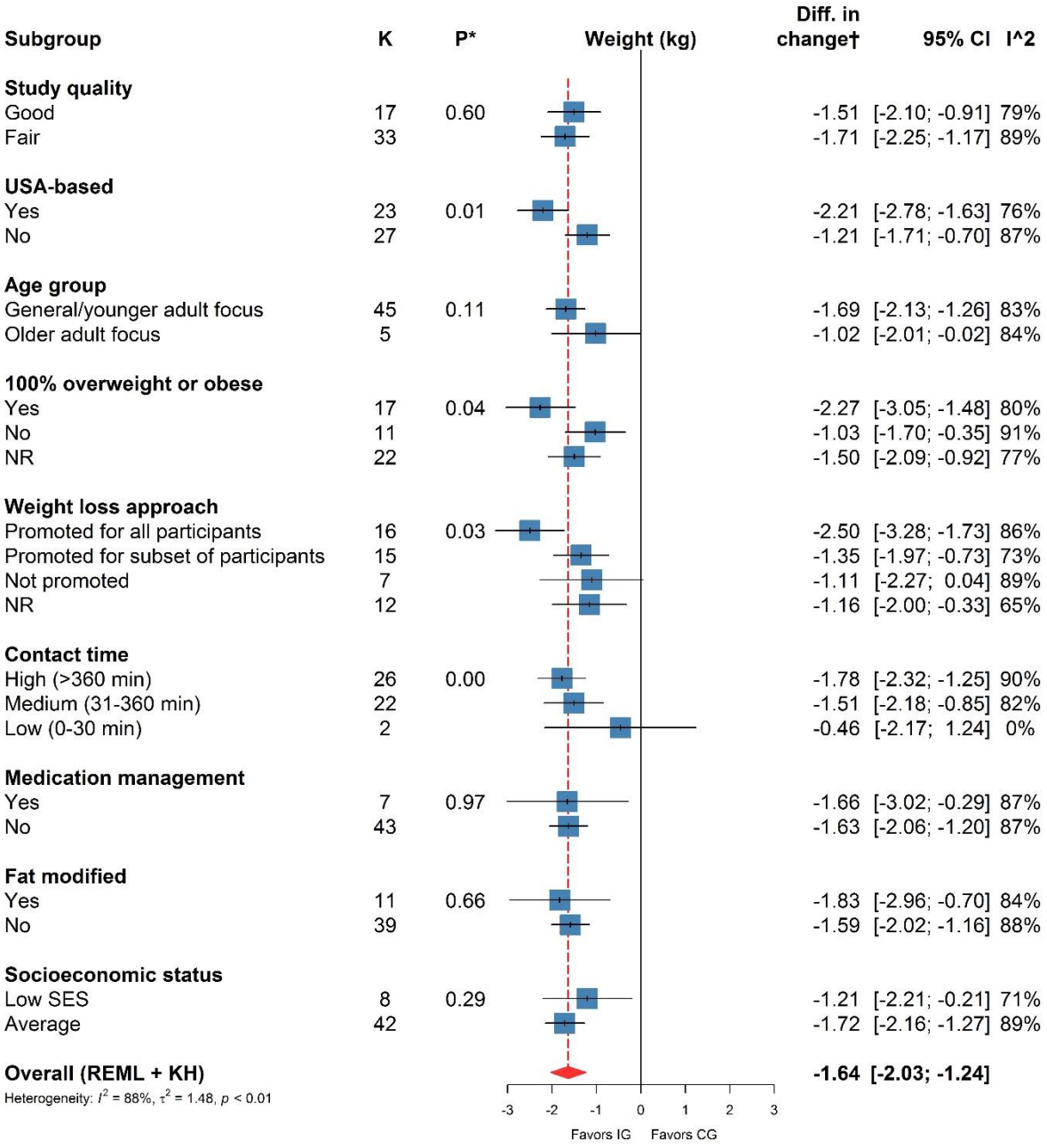
Figure 16. ≥5% Reduction in Weight or BMI (KQ2)



Abbreviations: BMI = body mass index; CG = control group; CI = confidence interval; Int arm = intervention arm; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; RR = risk ratio

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min
†Reflects ≥5% BMI reduction; all other studies reflect ≥5% weight reduction

Figure 17. Weight Subgroup Analyses (KQ2)

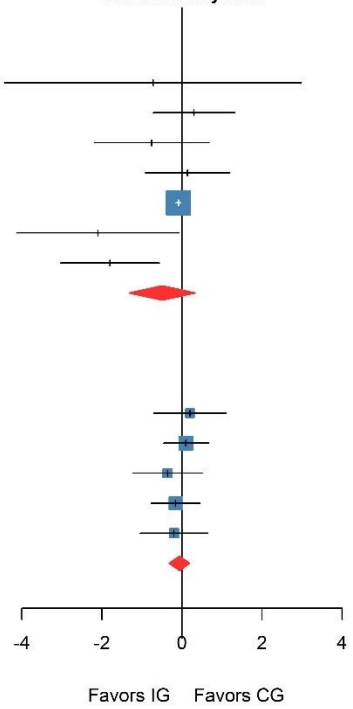


Abbreviations: CI = confidence interval; Diff. = difference; K = number of studies (including studies reported by subgroups); kg = kilograms; KH = Knapp-Hartung adjustment; NR = not reported; REML = restricted maximum likelihood; SES = socioeconomic status

*P-values derived from Q test of between-subgroups heterogeneity (based on random effects model)
†For this analysis, the most comprehensive or highest dose intervention group was selected if a study had multiple intervention groups, and the followup timepoint closest to 12 months was selected of there were multiple followup assessments

Figure 17. Weight Subgroup Analyses (KQ2)

Study	Population risk focus	Intervention focus	Contact time*	Timepoint (months)	IG N analyzed	IG mean change (SD)	CG N analyzed	CG mean change (SD)	Diff. in change	95% CI
10-year CVD risk										
Bruckert, 2008	Dyslipidemia	HD + PA	Medium	6	274	-0.7 (8.4)	199	0.1 (8.0)	-0.72	[-4.42; 2.98]
Cochrane, 2012	Multiple risk factors	HD + PA	Medium	12	236	-2.8 (6.2)	365	-3.1 (6.5)	0.30	[-0.72; 1.32]
Greaves, 2015	Multiple risk factors	HD + PA	High	12	55	NR (NR)	51	NR (NR)	-0.76	[-2.19; 0.67]
Khanji, 2019	Multiple risk factors	HD + PA	Low	6	194	-1.2 (8.9)	183	-1.4 (9.8)	0.14	[-0.92; 1.20]
Langford, 1991†	Hypertension	HD + PA	High	6	235	0.9 (0.3)	229	1 (0.3)	-0.09	[-0.15; -0.03]
Nolan, 2018	Hypertension	HD + PA	High	12	100	-1.9 (7.1)	97	0.2 (7.3)	-2.10	[-4.12; -0.08]
Wister, 2007	Multiple risk factors	HD + PA	Medium	12	157	-3.1 (5.6)	158	-1.3 (5.6)	-1.80	[-3.03; -0.57]
Overall (REML + KH)									**-0.49**	**[-1.32; 0.33]**
Heterogeneity: I^2 = 53%, τ^2 = 0.41, p = 0.05										
10-year CVD mortality risk										
Koelewijn-van Loon, 2009	Multiple risk factors	HD + PA	Medium	12	286	-0.5 (4.6)	261	-0.7 (5.9)	0.20	[-0.70; 1.10]
Lakerveld, 2013	Multiple risk factors	HD + PA	Medium	12	314	0 (3.0)	308	-0.1 (4.0)	0.10	[-0.47; 0.67]
Ter Bogt, 2009 (Females)	Multiple risk factors	HD + PA	High	12	103	0.1 (1.7)	114	0.5 (4.3)	-0.36	[-1.22; 0.50]
Ter Bogt, 2009 (Males)	Multiple risk factors	HD + PA	High	12	98	-0.2 (2.8)	101	-0.1 (1.3)	-0.16	[-0.77; 0.45]
Tiessen, 2012	Multiple risk factors	HD + PA	Medium	12	89	-1.8 (2.9)	90	-1.6 (2.9)	-0.20	[-1.04; 0.64]
Overall (REML + KH)									**-0.07**	**[-0.32; 0.19]**
Heterogeneity: I^2 = 0%, τ^2 = 0, p = 0.86										



Abbreviations: CG = control group; CI = confidence interval; CVD = cardiovascular disease; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; RR = risk ratio; SD = standard deviation

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min
†8-year CVD risk

Table 1. U.S. Dietary Intake and Physical Activity Recommendations

Recommendations category	Category	Amount
Dietary[2]	Fiber	28 g/day
	Vegetables	2.5 c-eq
	Fruits	2 c-eq
	Saturated fat	<20 g/day
	Sodium	<2,300 mg/day
	Potassium	4,700 mg/day
Physical activity[9]	Sedentary behavior	All adults should avoid inactivity. Some physical activity is better than none, and adults who participate in any amount of physical activity gain some health benefits.
	Moderate-to-vigorous physical activity	≥150 minutes per week of moderate-intensity, or ≥75 minutes per week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity aerobic activity.
		≥2 days per week muscle-strengthening activities that involve all major muscle groups.

Abbreviations: c-eq = cup equivalents; g/day = grams per day; mg/day = milligrams per day

Table 2. Prevalence of Risk Factors Defined by the AHA's Life's Simple 7*[12]

Risk factor	Definition of Intermediate or Poor	Age 20-39 (%)	Age 40-59 (%)	Age ≥60 (%)
Smoking	Smoker or quit <12 months ago	25.0	23.0	13.5
Body mass index	BMI ≥25 kg/m^2	63.7	74.6	74.4
Physical activity	<150 mins/week moderate or <75 mins/week vigorous or equivalent combination of moderate and vigorous	55.0	65.8	73.3
Healthy diet score	<4–5 Diet goals met†	100	99.8	99.6
Total cholesterol	≥200 mg/dL or not reaching treatment goal	27.1	61.0	74.8
Blood pressure	SBP ≥120 mm Hg or DBP ≥80 mm Hg or not reaching treatment goal	38.3	65.9	74.8
Fasting plasma glucose	≥100 mg/dL or not reaching treatment goal	21.5	42.3	64.6

Abbreviations: BMI = body mass index; DBP = diastolic blood pressure; kg/m^2 = kilograms per meter squared; mg/dL = milligrams per deciliter; mins = minutes; mm Hg = millimeters of mercury; SBP = systolic blood pressure

*Percentages represent those with intermediate or poor cardiovascular health

†In the context of a healthy dietary pattern that is consistent with a Dietary Approaches to Stop Hypertension (DASH)–type eating pattern, with goals to: (1) consume ≥4.5 cups/day of fruits and vegetables, (2) ≥2 servings/wk of fish, and (3) ≥3 servings/day of whole grains, (4) and no more than 36 ounces/week of sugar-sweetened beverages and (5) 1500 mg/day of sodium.

Table 3. Other Relevant Guidelines on Diet and Physical Activity for CVD Risk Reduction

Organization ***Title (year)***	**Recommendation(s)**
American Academy of Family Physicians *Management of Blood Cholesterol* (2019)[329]	The AAFP refer to and affirm the ACC/AHA 2018 guideline on management of blood cholesterol[8] which recommends that a heart-healthy lifestyle should be emphasized for all individuals. Lifestyle therapy should be the primary intervention for metabolic syndrome.
American College of Cardiology/American Heart Association *Guideline on the Primary Prevention of Cardiovascular Disease*, 2019[3]	All adults should consume a diet emphasizing intake of vegetables, fruits, legumes, nuts, whole grains and fish; replacement of saturated fat with dietary monounsaturated and polyunsaturated fats; reduced amounts of cholesterol and sodium; minimized intake of processed meats, refined carbohydrates, and sweetened beverages; and intake of trans fats avoided. For adults with overweight and obesity, counseling and comprehensive lifestyle interventions, including caloric restriction are recommended for achieving and maintaining weight loss. Adults should be routinely counseled in healthcare visits to optimize a physically active lifestyle and should engage in at least 150 minutes per week of accumulated moderate-intensity or 75 minutes per week of vigorous-intensity aerobic physical activity (or an equivalent combination of moderate and vigorous activity). For adults unable to meet the minimum physical activity recommendations, engaging in some moderate- or vigorous-intensity physical activity, even if less than this recommended amount, can be beneficial. Decreasing sedentary behavior in adults may be reasonable to reduce ASCVD risk. In adults with elevated blood pressure (BP) or hypertension, including those requiring antihypertensive medications, nonpharmacological interventions are recommended to reduce BP. These include: • weight loss • a heart-healthy dietary pattern • sodium reduction • dietary potassium supplementation • increased physical activity with a structured exercise program; and • limited alcohol
US Department of Health and Human Services *Physical Activity Guidelines for Americans, 2nd edition, 2018*[9]	For the general adult population: • Adults should move more and sit less throughout the day. Some physical activity is better than none. Adults who sit less and do any amount of moderate-to-vigorous physical activity gain some health benefits. • For substantial health benefits, adults should do at least 150 minutes (2 hours and 30 minutes) to 300 minutes (5 hours) a week of moderate-intensity, or 75 minutes (1 hour and 15 minutes) to 150 minutes (2 hours and 30 minutes) a week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity aerobic activity. Preferably, aerobic activity should be spread throughout the week. • Additional health benefits are gained by engaging in physical activity beyond the equivalent of 300 minutes (5 hours) of moderate-intensity physical activity a week. • Adults should also do muscle-strengthening activities of moderate or greater intensity and that involve all major muscle groups on 2 or more days a week, as these activities provide additional health benefits PA in adults with chronic health conditions: • When adults with chronic conditions or disabilities are not able to meet the above key guidelines, they should engage in regular physical activity according to their abilities and should avoid inactivity.

Table 3. Other Relevant Guidelines on Diet and Physical Activity for CVD Risk Reduction

Organization ***Title (year)***	**Recommendation(s)**
American Association of Clinical Endocrinologists and American College of Endocrinology *Guidelines for Management of Dyslipidemia and Prevention of Cardiovascular Disease, 2017*[5]	A comprehensive strategy to control lipid levels and address associated metabolic abnormalities and modifiable risk factors is recommended primarily using lifestyle changes and patient education with pharmacotherapy as needed to achieve evidence-based targets. A reasonable and feasible approach to fitness therapy (i.e., exercise programs that include at least 30 minutes of moderate-intensity physical activity [consuming 4-7 kcal/min] 4 to 6 times weekly, with an expenditure of at least 200 kcal/day) is recommended; suggested activities include brisk walking, riding a stationary bike, water aerobics, cleaning/scrubbing, mowing the lawn, and sporting activities. Daily physical activity goals can be met in a single session or in multiple sessions throughout the course of a day (10 minutes minimum per session); for some individuals, breaking activity up throughout the day may help improve adherence with physical activity programs. In addition to aerobic activity, muscle-strengthening activity is recommended at least 2 days a week. For adults, a reduced-calorie diet consisting of fruits and vegetables (combined ≥5 servings/day), grains (primarily whole grains), fish, and lean meats is recommended. For adults, the intake of saturated fats, transfats, and cholesterol should be limited, while LDLC-lowering macronutrient intake should include plant stanols/sterols (~2 g/day) and soluble fiber (10-25 g/day).
American Association of Clinical Endocrinologists and American College of Endocrinology *Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity, 2017*[6]	Patients with overweight or obesity and dyslipidemia (elevated triglycerides and reduced HDL-c) should be treated with lifestyle therapy to achieve 5 to 10% weight loss or more as needed to achieve therapeutic targets. The lifestyle intervention should include a physical activity program and a reduced-calorie healthy meal plan that minimizes sugars and refined carbohydrates, avoids trans fats, limits alcohol use, and emphasizes fiber. Patients with overweight or obesity and elevated blood pressure or hypertension should be treated with lifestyle therapy to achieve 5 to 15% weight loss or more as necessary to achieve blood pressure reduction goals in a program that includes caloric restriction and regular physical activity.
Academy of Nutrition and Dietetics *Hypertension evidence-based nutrition practice guideline, 2015*[330]	Medical Nutrition Therapy (MNT) provided by a registered dietitian nutritionist (RDN) is recommended to reduce blood pressure (BP) in adults with hypertension (HTN). To reduce BP in adults with HTN, the RDN should provide MTN encounters at least monthly for the first year. After the first year, the RDN should schedule follow-up sessions at least two to three times per year to maintain reductions in BP. The RDN should counsel on a DASH dietary pattern plus reduced sodium intake for BP reduction in adults with HTN. The RDN should encourage adults with HTN to engage in regular aerobic activity to lower BP. Physical activity should be of moderate intensity to vigorous intensity three to four times per week for an average of 40 minutes per session.
Department of Veterans Affairs / Department of Defense *VA/DoD Clinical Practice Guideline for the diagnosis and management of hypertension in the primary care setting, 2014*[331] Update in Progress	Offer lifestyle modification interventions for patients with prehypertension or hypertension based on patient indications and preferences as well as assessment of available local resources. Discuss healthy weight range and advising overweight or obese hypertensive patients to reduce their body mass index to below 25; if a normal body mass index (<25) cannot be achieved, advise patients that a weight reduction of at least 10 pounds can achieve a decrease in blood pressure. Target aerobic exercise at 30 to 45 minutes per session, at least four times per week and the use of a self-monitoring device (e.g., pedometer, mobile apps, etc.) to increase adherence to physical activity. Recommend a dietitian-led Dietary Approaches to Stop Hypertension (DASH) Diet for the treatment and/or prevention of hypertension for patients with hypertension and/or interested patients with prehypertension and other cardiovascular risk factors. In patients with additional cardiovascular risk factors, such as dyslipidemia, we suggest considering a dietitian-led Mediterranean Diet as an alternative to the DASH Diet. Recommend against the use of soy protein supplements for the treatment of hypertension. In patients with hypertension or prehypertension, sodium intake should be limited to no more than 2300 mg/day (100 mmol/day), with referral to a dietitian or other support as appropriate.

Table 3. Other Relevant Guidelines on Diet and Physical Activity for CVD Risk Reduction

Organization ***Title (year)***	**Recommendation(s)**
	Advise hypertensive and prehypertensive patients to limit alcohol intake to no more than 1 oz per day for men or 0.5 oz of alcohol per day for women.
Department of Veterans Affairs / Department of Defense *VA/DoD Clinical Practice Guideline for the management of dyslipidemia for cardiovascular risk reduction, 2014*[332] Update in Progress	Recommend all adults adopt healthy lifestyles to reduce CVD risk, including Therapeutic Lifestyle Changes (TLC) diet to optimize nutrition and optimal physical activity per the 2008 physical activity guidelines. Suggest offering high-risk patients a dietitian-monitored Mediterranean diet supplemented with either extra-virgin olive oil or mixed nuts for the reduction of CVD events. Suggest that each patient's diet be individualized based on a nutrition assessment other CVD risk factors, other disease conditions, and lifestyle.
American Academy of Family Physicians *Lifestyle Management to Reduce Cardiovascular Risk* (2014)[7]	The AAFP refer to and endorse the AHA/ACC 2014 guideline on lifestyle management to reduce cardiovascular risk[333] which recommends the following: Adults who would benefit from lowering of LDL-C and/or lowering of blood pressure should consume a dietary pattern that emphasizes intake of vegetables, fruits, and whole grains; includes low-fat dairy products, poultry, fish, legumes, non-tropical vegetable oils and nuts; and limits intake of sweets, sugar-sweetened beverages and red meats. Adults who would benefit from lowering of LDL-C should reduce the percent of calories in their diet that come from saturated- and trans-fat, and should aim for a dietary pattern that achieves 5-6% of calories from saturated fat. Adults who would benefit from lowering of their blood pressure should lower their sodium intake, consuming no more than 2,400 mg of sodium per day. Further reduction of sodium to 1,500 mg/day is associated with an even greater reduction in blood pressure. Reducing intake of sodium by at least 1,000 mg/day will decrease blood pressure, even if the desired daily sodium intake is not achieved. Adults should engage in aerobic physical activity to reduce LDL-C and non-HDL-C and to lower blood pressure. This should include 3-4 sessions per week lasting an average of 40 minutes per session and involving moderate-to-vigorous intensity physical activity.

Table 4. Related USPSTF Behavioral Counseling Recommendations

Risk Factors	Normal Weight (BMI 18.5 to <25)*	Overweight (BMI 25 to <30)*‡	Obese (BMI ≥30)*‡
No hypertension, dyslipidemia, or abnormal blood glucose levels	Individualize the decision to provide or refer to behavioral counseling[334]	Individualize the decision to provide or refer to behavioral counseling[334]	Provide or refer to intensive behavioral counseling[335]
Hypertension, dyslipidemia, or both	Individualize the decision to provide or refer to behavioral counseling[334†]	Provide or refer to intensive behavioral counseling[1]	Provide or refer to intensive behavioral counseling[1, 335]
Abnormal blood glucose levels or diabetes	Provide or refer to intensive behavioral counseling[43]	Provide or refer to intensive behavioral counseling[1, 43]	Provide or refer to intensive behavioral counseling[1, 43, 335]

Abbreviations: BMI = body mass index; USPSTF = US Preventive Services Task Force

*BMI calculated as weight in kilograms divided by the square of height in meters.
†From the "Other Considerations" section of the referenced recommendation statement
‡The 2015 USPSTF recommendation also recommends screening for abnormal blood glucose levels as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or have obesity. Patients with certain risk factors (family history of diabetes, personal history of gestational diabetes or polycystic ovarian syndrome, or being a member of certain racial/ethnic groups [African Americans, American Indians or Alaskan Natives, Asian Americans, Hispanics or Latinos, or Native Hawaiians or Pacific Islanders]) may also be at increased risk of diabetes at a younger age or at a lower BMI and should be considered for earlier screening.[43]

Table 5. Summary of Study Characteristics of All Included Studies (94 Studies, n=52,174), Overall and by Risk Focus

Characteristics	All studies		Hypertension		Dyslipidemia		Mixed Risk Factors	
	No. studies	%	No. studies	%	No. studies	%	No. studies	%
All studies	94	100	32	100	16	100	46	100
Study design								
RCT	78	83.0	27	84.4	11	68.8	40	87.0
Cluster RCT	16	17.0	5	15.6	5	31.2	6	13.0
Good quality rating*	19	20.2	9	28.1	1	6.2	10	21.7
Conducted in the US	43	45.7	19	59.4	9	56.2	15	32.6
Recruitment setting								
Primary care	38	40.4	12	37.5	5	31.2	21	45.6
Other health care	20	21.3	3	9.4	5	31.2	12	26.1
Other (e.g., media, community settings, research center, epidemiologic surveys, etc.)	36	38.3	17	53.1	6	37.5	13	28.3
Risk group								
Hypertension	32	34.0						
Dyslipidemia	16	17.0						
Multiple risk factors	46	48.9						
Medication use restrictions								
Limited to those taking medications to manage risk factors	11	11.7	9	28.1	0	0	2	4.4
Excluded those taking medications to manage risk factors	21	22.3	9	28.1	10	62.5	2	4.4
No restrictions	62	66.0	14	43.8	6	37.5	42	91.3
Control Group								
No intervention/usual care	73	77.7	22	68.8	14	87.5	37	80.4
Minimal intervention	19	20.2	9	28.1	1	6.2	9	19.6
Attention control	2	2.1	1	3.1	1	6.2	0	0
Control group instructed to maintain typical habits	7	7.4	2	6.3	3	18.8	2	4.4
Median sample size (IQR), Range	314 (154 – 601)	24 – 7447	272 (197 – 762)	24– 2382	222 (133 – 420)	80 – 1197	342 (154 – 601)	37 – 7447
Median % followup at 12 months or closest (IQR), Range	86 (79 – 92)	63 – 100	88 (80– 92)	69– 100	88 (78– 96)	73 – 99	84 (78 – 91)	63 – 100

Abbreviations: IQR = Interquartile range; No. = Number; RCT = Randomized controlled trial; US = United States

*12 additional studies were rated as poor quality and excluded from the review

Table 6. Summary of Population Characteristics of All Included Studies (94 Studies), Overall and by Risk Factor Focus

	All studies (k=94)		Hypertension (k=32)		Dyslipidemia (k=16)		Mixed Risk Factors (k=46)	
Baseline Characteristic (No. studies reporting)	**Weighted Mean or Percent***	**SD or k/K**	**Weighted Mean or Percent***	**SD or k/K**	**Weighted Mean or Percent***	**SD or k/K**	**Weighted Mean or Percent***	**SD or k/K**
Age; Mean (k=92)	56.0	8.3	52.9 (31)	7.9	57.6 (16)	8.5	57.3 (45)	8.0
% of trials restricted to older adults (minimum age ≥50)	11.7	11/94	15.6	5/32	6.2	1/16	10.9	5/46
Female; % (k=90)	49.5	20.5	45.1 (31)	18.0	57.2 (15)	23.6	50.6 (44)	20.7
Hypertension; % (k=61)	62.0	35.5	62.7 (30)	44.2	30.9 (8)	21.3	67.0 (23)	24.2
Systolic blood pressure; Mean (k=63)	138.6	10.3	135.5 (28)	10.3	115.0 (2)	2.8	140.8 (33)	9.5
Diastolic blood pressure; Mean (k=62)	83.8	5.3	85.6 (30)	5.5	76.0 (2)	1.4	82.3 (30)	4.4
Dyslipidemia; % (k=39)	70.3	23.7	32.2 (5)	10.8	100 (16)	0	65.9 (18)	17.3
Total cholesterol; Mean mg/dL (k=50)	217.4	21.4	218.7 (9)	16.7	254.5 (12)	20.2	210.7 (29)	14.5
Low-density lipoprotein; Mean mg/dL (k=39)	135.9	18.6	132.0 (4)	8.0	160.4 (10)	22.4	131.3 (25)	14.1
Diabetes; % (k=60)	20.2	18.5	13.1 (17)	16.1	7.5 (11)	6.7	25.3 (32)	18.8
Fasting blood glucose; Mean mg/dL (k=33)	110.0	12.0	105.3 (5)	9.4	115.7 (2)	8.2	110.0 (26)	12.3
Cardiovascular disease; % (k=51)	2.8	6.1	3.2 (18)	5.1	13.3 (10)	8.8	0.6 (23)	3.0
Current smokers; % (k=62)	22.7	17.6	17.5 (25)	17.0	17.7 (10)	7.1	26.6 (27)	18.0
BMI; Mean kg/m^2 (k=77)	29.8	2.6	29.8 (26)	2.9	27.9 (11)	1.9	30.0 (40)	2.5
% of trials restricted to persons with excess weight	22.3	21/94	25.0%	8/32	0	0/16	28.3%	13/46
% of trials majority Hispanic or non-white†‡	37.2	16/43	36.8	7/19	22.2	2/9	46.7	7/15
% of trials targeted low socioeconomic status population§	20.2	19/94	25.0	8/32	25.0	4/16	17.4	8/46

Abbreviations: IQR = Interquartile range; k = number of trials with the stated characteristics; K = total number of trials in the analysis; SD = Standard deviation; US = United States

*Mean or percent across all trials, weighted by number randomized in each trial; numbers in parentheses are the numbers of trials reporting on the pertinent characteristics

†Limited to trials conducted in the US (43 trials)

‡Assuming majority white, non-Hispanic if race and ethnicity were not reported

§Described as targeting a low-resource community or any of the following (or equivalent): >20% unemployment, >30% combination of unemployed or disabled (among the working-age population), <70% high school graduates, >20% ≤100% of federal poverty level, >30% in Medicaid, recruited from a Federally Qualified Healthcare Clinic

Table 7. Summary of Intervention Characteristics of All Included Studies (94 Studies, 120 Intervention Groups), Overall and by Risk Factor Focus

Characteristics	All studies (120 groups)		Hypertension (50 groups)		Dyslipidemia (20 groups)		Mixed Risk Factors (50 groups)	
	No.	%	No.	%	No.	%	No.	%
Behavioral target								
Diet and Physical Activity	81	67.5	33	66.0	6	30.0	42	84.0
Diet only	33	27.5	14	28.0	14	70.0	5	10.0
Physical Activity only	6	5.0	3	6.0	0	0	3	6.0
Contact time								
Low (0-30 minutes)	7	5.8	6	12.0	0	0	1	2.0
Medium (31-360 minutes)	59	49.2	18	36.0	17	85.0	24	48.0
High (>360 minutes)	54	45.0	26	52.0	3	15.0	25	50.0
Intervention directed at								
Patient (only)	115	95.8	47	94.0	19	95.0	49	98.0
Provider (only)	1	0.8	1	2.0	0	0	0	0
Both	4	3.3	2	4.0	1	5.0	1	2.0
Primary care clinician involvement								
Delivered all/most	8	6.7	2	4.0	3	15.0	3	6.0
Delivered part	19	15.8	7	14.0	2	10.0	10	20.0
No involvement	84	70.0	34	68.0	15	75.0	35	70.0
Not described	9	7.5	7	14.0	0	0	2	4.0
Type of sessions								
Individual session (only)	63	52.5	19	38.0	13	65.0	31	62.0
Group sessions (only)	9	7.5	5	10.0	1	5.0	3	6.0
Both individual and group	44	36.7	23	46.0	6	30.0	15	30.0
Tech or print-based (only)	4	3.3	3	6.0	0	0	1	2.0
Included family members	11	9.2	4	8.0	2	10.0	5	10.0
Motivational Interviewing	43	35.8	14	28.0	2	10.0	27	54.0
Dietary recommendation*								
General heart healthy, or not described	59	49.2	19	38.0	8	40.0	32	64.0
Low sodium	31	25.8	29	58.0	0	0	2	4.0
Fat modified	23	19.2	5	10.0	12	60.0	6	12.0
DASH	14	11.7	11	22.0	0	0	3	6.0
Mediterranean	5	4.2	0	0	0	0	5	10.0
DPP-based approach	5	4.2	0	0	0	0	5	10.0
Weight loss approach								
Promoted for all	29	24.2	13	26.0	0	0	16	32.0
Promoted if excess weight	31	25.8	13	26.0	4	20.0	14	28.0
Not promoted	11	9.2	5	10.0	2	10.0	4	8.0
Not described	49	40.8	19	38.0	14	70.0	16	32.0
Equipment/Services								
Pedometer	22	18.3	7	14.0	0	0	15	30.0

Table 7. Summary of Intervention Characteristics of All Included Studies (94 Studies, 120 Intervention Groups), Overall and by Risk Factor Focus

Characteristics	All studies (120 groups)		Hypertension (50 groups)		Dyslipidemia (20 groups)		Mixed Risk Factors (50 groups)	
	No.	%	No.	%	No.	%	No.	%
Blood pressure monitor	7	5.8	5	10.0	0	0	2	4.0
Medication management	23	19.2	18	36.0	1	5.0	4	8.0
Intervention Contact	**Median (IQR)**	**Range**	**Median (IQR)**	**Range**	**Median (IQR)**	**Range**	**Median (IQR)**	**Range**
Intervention duration, months	12 (6–18)	1 day – 60 mo.	14 (6-24)	1 day-36 mo.	8.5 (6-12)	2-12	12 (6-24)	1 day – 60 mo.
Est. contact hours	6 (2.2-15.8)	0-68	9.9 (3.2-28)	0-59	2.8 (1.8-4.2)	0.7-20	5.4 (2.1-12.8)	0-68
Number of contacts†	12 (5-27)	0-73	18 (8-32)	0-60	6 (4-13)	2-28	9 (5-20)	0-73

Abbreviations: DASH = Dietary Approaches to Stop Hypertension; DPP = Diabetes Prevention Program; IQR = Interquartile range; SD = Standard deviation; US = United States

*Interventions may advocate multiple diet approaches (e.g., low sodium and low fat)
†Contacts involving a live interventionist; excludes print, text message, technology-only contacts

Table 8. Daily and Weekly DASH and Mediterranean Eating Plan Goals for a 2,000-Calorie-a-Day Diet*

Food Group	DASH[336] Servings	Mediterranean[131] Servings
Grains	6–8 per day	(not specified)
Vegetables	4–5 per day	≥2 (≥1 fresh vegetables)
Fruit	4–5 per day	≥2 to 3
Low-fat or fat-free dairy products	2–3 per day	(not specified)
Fats and oils	2–3 per day	Abundant use of olive oil for cooking and dressing dishes; minimize food products high in saturated fats
Sodium	≤2,300 mg per day (1,500 mg for even greater blood-pressure lowering benefits)	(not specified)
Alcohol	--	≤300 ml/day, primarily wine
Meats, poultry, and fish	6 or less per week	≥3 of fish or seafood per week, use chicken or rabbit rather than other red or processed meats
Nuts, seeds, dry beans, and peas	4–5 per week	≥3 of legumes per day ≥1 of nuts or seeds per day
Sweets	5 or less per week	Minimize consumption of sweets and simple carbohydrates
Other	--	Cook at least twice per week with tomato, garlic, and onion with other aromatic herbs; dress vegetables, pasta, and rice with tomato, garlic, and onion.

Abbreviations: DASH = Dietary Approaches to Stop Hypertension; mg = milligrams; ml = milliliters

*Adapted from https://www.nhlbi.nih.gov/health-topics/dash-eating-plan. This is the reduced-sodium version of the DASH diet plan; the initial DASH diet included 3,000 mg/day of sodium (and demonstrated efficacy in reducing blood pressure in the original DASH feeding study).

Table 9. Summary of Pooled Analyses of CVD Events

CVD Outcome	Pooled RR (95% CI)	N	No. Studies	I^2	Tau^2
Stroke	0.52 (0.25, 1.10)	9,800	4	0	0.1
Myocardial Infarction	0.85 (0.70, 1.02)	10,375	6	0	0.0
CVD Events	0.80 (0.73, 0.87)	12,551	9	0	0.0
CVD Events sensitivity analysis: Dropping PREDIMED	0.79 (0.70, 0.90)	5,104	8	0	0.0

Abbreviations: CI = confidence interval; CVD = cardiovascular disease; No. = number; PREDIMED = Primary Prevention of Cardiovascular Disease with a Mediterranean Diet; RR = risk ratio

Table 10. PREDIMED CVD Events: Hazard Ratios and Number of CVD Events for Each Group Reported by the PREDIMED[131] Study (n=7,447)

Outcome	Group	Intervention n/N (%)	Control n/N (%)	HR (95% CI)
Stroke	Both	81/4997 (1.6)	58/2450 (2.4)	0.58 (0.42 to 0.82)
Myocardial Infarction	Both	68/4997 (1.4)	38/2450 (1.6)	0.80 (0.53 to 1.21)
Incident PAD	Olive oil	18/2539 (0.7)	45/2444 (1.8)	0.36 (0.20 to 0.62)
Incident PAD	Nuts	26/2452 (1.1)	45/2444 (1.8)	0.52 (0.32 to 0.86)
Total CVD Events	Both	179/4997 (3.6)	109/2450 (4.4)	0.70 (0.55 to 0.89)

Abbreviations: CI = confidence interval; CVD = cardiovascular disease; HR = hazard ratio; PAD = peripheral artery disease

Table 11. Pooled Difference in Mean Change for Blood Pressure, Lipids, Glucose, and Adiposity-Related Outcomes at 12 to 24 Months' Followup

Outcome	Study population risk focus	Effect size (95% CI)*	K	N	I^2	Median (IQR) change, IG	Median (IQR) change, CG
SBP (mm Hg)	All available trials	-1.81 (-2.49, -1.13)	44	14580	37.3%	-5.1 (-7.6, -1.7)	-2.9 (-6.0, -0.2)
	Hypertension	-1.97 (-2.59, -1.36)	16	5769	7.8%	-5.8 (-8.6, -3.9)	-3.1 (-7.5, -1.8)
DBP (mm Hg)	All available trials	-1.16 (-1.57, -0.75)	40	13098	32.5%	-3.4 (-4.6, -0.7)	-1.6 (-3.7, -0.2)
	Hypertension	-1.06 (-1.75, -0.38)	15	5461	43.4%	-4.4 (-6.0, -2.2)	-3.2 (-5.0, -0.3)
TC (mg/dL)	All available trials	-3.48 (-5.57, -1.38)	38	11414	65.9%	-7.1 (-12.4, -2.3)	-4.4 (-6.6, 0)
	Dyslipidemia	-3.80 (-7.23, -0.37)	9	2001	24.0%	-8.8 (-15.8, -7.6)	-8.6 (-12.8, -5.0)
LDL-C (mg/dL)	All available trials	-2.14 (-4.08, -0.21)	32	8894	55.9%	-4.8 (-11.2, -1.5)	-3.9 (-7.7, 0.1)
	Dyslipidemia	-4.12 (-8.81, 0.57)	7	1271	36.3%	-11.0 (-19.6, -7.3)	-10.4 (-15.4, -4.6)
HDL-C (mg/dL)	All available trials	0.58 (0.19, 0.98)	34	8974	33.7%	0.8 (0.3, 2.6)	0.5 (0, 1.7)
	Dyslipidemia	-0.44 (-1.26, 0.37)	6	1033	0.0%	0.4 (0, 3.1)	1.0 (0.4, 2.7)
FBG (mg/dL)	All available trials	-2.33 (-3.64, -1.02)	22	5950	82.5%	-2.9 (-5.7, -0.4)	0.2 (-2.0, 3.6)
Weight (kg)	All available trials	-1.59 (-2.06, -1.12)	37	16345	88.1%	-1.5 (-2.8, -0.8)	-0.3 (-1.0, 0)
	Weight loss trials†	-2.55 (-3.40, -1.70)	12	3193	66.9%	-1.9 (-3.6, -1.2)	-0.6 (-1.1, 0)
BMI (kg/m^2)	All available trials	-0.46 (-0.66, -0.26)	30	9909	83.3%	-0.5 (-0.9, -0.2)	-0.1 (-0.4, 0)
	Weight loss trials†	-0.91 (-1.43 to -0.40)	7	1520	78.0%	-1.0 (-1.6, -0.6)	-0.3 (-0.4, -0.2)
Waist circumference (cm)	All available trials	-1.75 (-2.44, -1.06)	23	11708	87.3%	-2.2 (-3.7, -0.8)	-0.9 (-1.8, -0.2)
	Weight loss trials†	-2.50 (-3.97 to -1.03)	8	1654	85.4%	-2.9 (-4.6, -1.4)	-1.2 (-2.3, -0.7)

Abbreviations: BMI = body mass index; CG = control group; CI = confidence interval; cm = centimeters; DBP = diastolic blood pressure; FBG = fasting blood glucose; IG = intervention group; IQR = interquartile range; HDL-C = high-density lipoprotein cholesterol; K = number of effects analyzed; N = number of participants analyzed; kg = kilograms; kg/m^2 = kilograms per meter squared; LDL-C = low-density lipoprotein cholesterol; mg/dL = milligrams per deciliter; mm Hg = millimeters of mercury; TC = total cholesterol

* Between-group mean difference in change unless otherwise specified

† Weight loss trials are those that required all participants to have a specified level of excess weight at baseline and had an explicit goal of weight loss for all participants.

Table 12. Pooled Results for Group Differences in the Proportion With Hypertension, Meeting Blood Pressure Goal, Diabetes, and Metabolic Syndrome, for All Trials Reporting Each Outcome

Outcome	RR (95% CI)	K	N	I^2	Median (IQR) percent, IG	Median (IQR) percent, CG	Median (IQR) Absolute risk difference
Hypertension incidence	0.74 (0.58, 0.94)	5	2707	12%	21.7 (8.0, 31.9)	21.1 (11.2, 39.2)	-5.3 (-6.4, -3.1)
Hypertension prevalence	0.98 (0.89, 1.08)	5	5633	56%	24.1 (18.2, 84.9	31.9 (26.1, 89.2)	-4.5 (-8.9, -0.6)
Meeting blood pressure goal	1.13 (1.04, 1.23)	13	6485	70%	64.9 (48.6, 79.4)	60.9 (43.0, 75.0)	5.0 (1.0, 8.1)
Diabetes incidence	0.82 (0.66, 1.03)	5	7848	0%	7.4 (6.9, 8.3)	8.8 (7.4, 16.3)	-1.6 (-5.5, -0.5)
Metabolic syndrome	0.78 (0.53, 1.16)	5	1847	85%	54.5 (44.3, 64.8)	63.0 (50.2, 68.6)	-2.8 (-22.6, -0.2)

Abbreviations: CG = control group; CI = confidence interval; cm = centimeters; IG = intervention group; IQR = interquartile range; K = number of effects analyzed; N = number of participants analyzed

Table 13. Results in Trials With Relatively Large Effects* Across Multiple Domains of Blood Pressure, Lipids, Fasting Glucose, or Weight

Outcome	Measure	Bennett, 2018[141]	Bo, 2007[65]	Rodriguez-Cristobal, 2012[92]	Wister, 2007[106]	Wood, 2008[107]
		18 phone, 3 PCP weight loss counseling sessions, 52 IVR calls (est 324 min)	1 individual, 4 group 60 min sessions, 3 mailings (est 300 min)	24 individual in-person and phone sessions (est 540 min)	2 phone sessions, 4 additional calls for smokers (est 60 min for non-smokers)	Individual assessment, 8 group sessions (est 480 min)
SBP (mm Hg)	Mean difference in change (95% CI)	-0.9 (-4.9 to 3.1)	-6.8 (-10.6 to -3.0)	-6.8 (-10.7 to -2.8)	-3.9 (-7.4 to -0.4)	-4.8 (-10.2 to 0.6)
	IG mean change (SD)	-8.4 (20.3)	-2.0 (18.8)	-4.2 (17.2)	-7.5 (15.9)	-7.6 (NR)
	CG mean change (SD)	-7.5 (19.5)	4.8 (17.0)	2.2 (17.4)	-3.6 (16.0)	-2.8 (NR)
DBP (mm Hg)	Mean difference in change (95% CI)	-1.0 (-3.5 to 1.5)	-2.3 (-4.4 to -0.2)	-4.4 (-6.8 to -2.0)	NR	-2.7 (-5.9 to 0.6)
	IG mean change (SD)	-5.2 (12.6)	-2.6 (9.3)	-5.2 (10.2)	NR	-4.1 (NR)
	CG mean change (SD)	-4.2 (12.2)	-0.3 (10.0)	-1.3 (9.5)	NR	-1.6 (NR)
TC (mg/dL)	Mean difference in change (95% CI)	3.1 (-4.7 to 10.9)	-2.3 (-9.6 to 4.9)	-19.2 (-25.6 to -12.7)	-10.4 (-20.2 to -0.6)	-13.1 (-20.9 to -5.8)
	IG mean change (SD)	-3.5 (41.7)	0.0 (33.2)	-6.7 (24.2)	-15.8 (44.4)	-14.7 (NR)
	CG mean change (SD)	-6.6 (41.4)	2.3 (34.4)	14.2 (24.8)	-5.4 (44.4)	0.0 (NR)
LDL (mg/dL)	Mean difference in change (95% CI)	-3.2 (-10.5 to 4.1)	NR	1.9 (-6.0 to 9.9)	NR	-13.1 (-20.1 to -6.2)
	IG mean change (SD)	-5.0 (37.6)	NR	-3.5 (23.0)	NR	-15.8 (NR)
	CG mean change (SD)	-1.8 (38.0)	NR	-4.7 (25.2)	NR	-1.2 (NR)
HDL (mg/dL)	Mean difference in change (95% CI)	3.5 (1.1 to 5.9)	3.5 (2.2 to 4.7)	2.1 (-0.9 to 5.1)	0.4 (-1.2 to 2.0)	NR
	IG mean change (SD)	3.2 (12.6)	0.8 (5.4)	7.5 (8.0)	1.5 (7.3)	NR
	CG mean change (SD)	-0.3 (12.4)	-2.7 (6.2)	5.1 (7.7)	1.2 (7.3)	NR
FBG (mg/dL)	Mean difference in change (95% CI)	-8.1 (-17.1 to 0.9)	-5.9 (-8.4 to -3.5)	NR	-6.8 (-18.3 to 4.6)	-2.0 (-13.5 to 9.6)
	IG mean change (SD)	-4.9 (48.2)	-4.7 (11.9)	NR	-6.7 (55.3)	-8.3 (NR)
	CG mean change (SD)	3.2 (48.0)	1.3 (10.6)	NR	0.2 (48.5)	-5.1 (NR)
BMI (kg/m^2)	Mean difference in change (95% CI)	-1.4 (-1.8 to -0.9)	-0.9 (-1.3 to -0.5)	-1.7 (-2.2 to -1.1)	-0.1 (-0.6 to 0.3)	-0.6 (-0.9 to -0.2)
	IG mean change (SD)	-1.4 (2.3)	-0.3 (1.8)	-0.7 (2.0)	-0.5 (2.0)	-0.5 (NR)
	CG mean change (SD)	0.0 (2.0)	0.6 (2.0)	1.3 (1.6)	-0.3 (1.8)	0.1 (NR)
Weight (kg)	Mean difference in change (95% CI)	-3.8 (-5.1 to -2.5)	-2.4 (-3.5 to -1.3)	NR	NR	-1.5 (-2.5 to -0.5)

Table 13. Results in Trials With Relatively Large Effects* Across Multiple Domains of Blood Pressure, Lipids, Fasting Glucose, or Weight

Outcome	Measure	Bennett, 2018[141]	Bo, 2007[65]	Rodriguez-Cristobal, 2012[92]	Wister, 2007[106]	Wood, 2008[107]
		18 phone, 3 PCP weight loss counseling sessions, 52 IVR calls (est 324 min)	1 individual, 4 group 60 min sessions, 3 mailings (est 300 min)	24 individual in-person and phone sessions (est 540 min)	2 phone sessions, 4 additional calls for smokers (est 60 min for non-smokers)	Individual assessment, 8 group sessions (est 480 min)
	IG mean change (SD)	-4.0 (6.3)	-0.7 (4.9)	NR	NR	NR
	CG mean change (SD)	-0.1 (5.9)	1.6 (5.2)	NR	NR	NR
WC (cm)	Mean difference in change (95% CI)	-3.6 (-5.0 to -2.1)	-4.5 (-5.8 to -3.2)	NR	-0.5 (-2.1 to 1.1)	-1.6 (-2.6 to -0.6)
	IG mean change (SD)	-2.9 (7.0)	-2.5 (5.2)	NR	-2.8 (7.0)	-1.7 (NR)
	CG mean change (SD)	0.6 (6.6)	2.0 (6.7)	NR	-2.3 (7.1)	-0.2 (NR)

Abbreviations: BMI = body mass index; CG = control group; CI = confidence interval; cm = centimeters; DBP = diastolic blood pressure; est = estimated; FBG = fasting blood glucose; HDL = high-density lipoprotein cholesterol; IG = intervention group; IVR = interactive voice recognition; kg = kilograms; kg/m^2 = kilograms per meter squared; LDL = low-density lipoprotein cholesterol; mg/dL = milligrams per deciliter; min = minutes; mm Hg = millimeters of mercury; NR = not reported; PCP = primary care provider; SD = standard deviation; SBP = systolic blood pressure; TC = total cholesterol; WC = waist circumference

*One of the 10 largest absolute effect sizes for the specified outcome, at 12 to 24 months' followup

Table 14. Pooled Difference in Mean Change for Dietary Fats, Fruit Vegetable, Urinary Sodium, and Physical Activity Outcomes at 12 to 24 Months' Followup

Outcome	Unit	Effect size (95% CI)*	K	N	I^2	Median (IQR) change, IG	Median (IQR) change, CG
Saturated fat	% of energy	-1.5 (-1.9, -1.1)	15	6229	72%	-1.9 (-3.0, -1.4)	-0.6 (-1.0, -0.1)
Saturated fat (Fat modified diet interventions only)	% of energy	-1.5 (-2.3, -0.8)	8	3951	72%	-2.2 (-3.0, -1.6)	-0.5 (-1.0, -0.01)
Polyunsaturated fat	% of energy	-0.4 (-1.0, 0.3)	7	2032	90%	-0.9 (-1.2, -0.1)	0 (-0.3, 0)
Monounsaturated fat	% of energy	-1.7 (-2.5, -0.9)	7	1827	83%	-2.0 (-2.1, -1.9)	-0.2 (-0.4, 0)
Fruits and vegetables	Servings/day	0.7 (0.1, 1.3)	11	4310	90%	0.5 (-0.01, 1.2)	0.1 (0, 0.3)
Fruits	Servings or pieces/day	0.2 (0.04, 0.3)	9	3698	71%	0.2 (0.1, 0.5)	0 (0, 0.1)
Vegetables	Standardized mean difference	0.1 (0.02, 0.2)	9	3555	50%	s/d: 0.5 (0, 0.8) g/d: 11 (9, 16)	s/d: 0.3 (0.2, 0.3) g/d: 2 (-3, 12)
Fiber	Grams/day	1.3 (0.1, 2.6)	5	1350	42%	1.7 (0, 3.0)	0.1 (-0.7, 0.2)
Urinary Sodium	mmol/L	-18.0 (-34.8 to -1.2)	9	3583	89%	-18.4 (-45.4, -5.3)	-6 (-10.0, -3.4)
Physical activity	Standardized mean difference	0.1 (-0.03 to 0.1)	30	19834	64%	--	--
Physical activity	Minutes/week	9.1 (-4.6 to 22.8)	13	10758	48%	44.4 (-2.5, 97.0)	31.2 (-13.0, 74.7)
Physical activity	MET-min/week	83 (-101 to 267)	7	5580	62%	130 (33, 289)	70 (-16, 112)
Physical activity	% Meeting PA goal	RR=1.22 (1.00, 1.50)	11	5887	91%	36.0 (28.1, 52.8)†	23.8 (22.9, 50.8)†

Abbreviations: CG = control group; CI = confidence interval; g/d = grams/day; IG = intervention group; IQR = interquartile range; K = number of studies; MET = metabolic equivalent; mmol/L = millimoles per liter; N = number of participants analyzed; PA = physical activity; RR = risk ratio; s/d = servings per day

*Between-group mean difference in change unless otherwise specified

†Median (IQR) percent meeting physical activity goal

Table 14. Pooled Difference in Mean Change for Dietary Fats, Fruit Vegetable, Urinary Sodium, and Physical Activity Outcomes at 12 to 24 Months' Followup

Outcome	Current Review	Previous Review[44]	2017 Adult Obesity review*[47], 2011 Adult Obesity review[292], behavioral counseling interventions†
Mortality	17 trials, no clear benefit (Pooled RR NSD, mixed findings in 3 adequately powered trials)	3 trials, no benefit	4 trials, small number of deaths, no benefit
CVD events	12 trials, reduced MI, total events; pooled RRs (95% CI): Total: 0.80 (0.73 to 0.87), k=9 MI: 0.85 (0.70 to 1.02), k=6 Stroke: 0.52 (0.25 to 1.10), k=4	5 trials, no benefit, low event rates	2 trials in persons with prediabetes, no differences in CVD events.
Blood Pressure	Pooled MD (95% CI): SBP: -1.8 (-2.5 to -1.1), k=44 DBP: -1.2 (-1.6 to -0.8), k=40 HTN Incidence: 0.74 (0.58, 0.94), k=5	Pooled MD (95% CI): SBP: -2.0 (-2.9 to -1.2), k=48 DBP: -1.4 (-1.9 to -0.8), k=24 HTN Incidence: Not examined	Pooled MD (95% CI): SBP: -2.0 (-2.9 to -1.2), k=48
Lipids	Pooled MD (95% CI): TC: -3.5 (-5.6 to -1.4), k=38 LDL: -2.1 (-4.1 to -0.2), k=32 HDL: 0.6 (0.2, 1.0), k=34	Pooled MD (95% CI): TC: -4.5 (-6.4 to -2.6), k=34 LDL: -3.4 (-5.4 to -1.5), k=25 HDL: 0.7 (0.1, 1.3), k=19	Pooled MD (95% CI): LDL: -4.9 (-7.3 to -2.6), k=8
Glucose	Pooled MD (95% CI): FBG: -2.3 (-3.6 to -1.0), k=22 DM Incidence: 0.82 (0.66, 1.03), k=5 (4 trials)	Pooled MD (95% CI): FBG: -2.1 (-3.3 to -0.9), k=22 DM Incidence: 0.58 (0.37, 0.89), k=8	2 trials in persons with prediabetes, 30% to 50% reductions in diabetes incidence
Weight	Pooled MD (95% CI): BMI: -0.5 (-0.7 to -0.3), k=30 Weight: -1.6 (-2.1, -1.1), k=37 WC: -1.8 (-2.4, -1.1), k=23	Pooled MD (95% CI): Hedge's g (BMI or weight): -0.26 (-0.35 to -0.16), k=34	Pooled MD (95% CI), 12-18 months: BMI: -1.0 (-1.2 to -0.7), k=40 Weight: -2.4 (-2.9, -1.9), k=67 WC: -2.5 (-3.2, -1.9), k=41

Abbreviations: BMI = body mass index; CI = confidence interval; CVD = cardiovascular disease; DBP = diastolic blood pressure; DM = diabetes mellitus; FBG = fasting blood glucose; HTN = hypertension; HDL = high-density lipoprotein cholesterol; LDL = low-density lipoprotein cholesterol; MD = mean difference; MI = myocardial infarction; NSD = no statistically significant difference; RR = risk ratio; SBP = systolic blood pressure; TC = total cholesterol; WC = waist circumference

*For mortality, CVD events, and weight outcomes
†For blood pressure, lipids, and glucose outcomes

Table 16. Behavioral Intervention Implementation Table: Summary and Examples of Included Interventions

Primary Population	Adults with hypertension, prehypertension, dyslipidemia, or any of multiple cardiovascular disease risk factors; most participants were overweight or with obesity (mean BMI=29.8)			
Primary Outcomes Measured	Cardiovascular events (stroke, myocardial infarction, any CVD event); blood pressure; lipids; weight			
Study Findings	Intervention groups had fewer cardiovascular events at 1 to 16 years' followup (pooled RR=0.81 (0.74 to 0.88), with 10 trials reporting. At 12 to 24 months, the intervention groups showed greater reductions in blood pressure (SBP=-1.8 [-2.5 to -1.2] / DBP=-1.2 [-1.6 to -0.7] mm Hg), total cholesterol (-3.7 mg/dL [-5.9 to -1.5]), low-density lipoproteins (-2.3 mg/dL [-4.3 to -0.2]), BMI (-0.4 kg/m^2 [-0.7 to -0.2]), weight (-1.5 kg [-2.1 to -1.1]), and waist circumference (-1.6 [-2.3 to -0.9]).			
Behavior change goals and techniques	Designed to help participants improve dietary intake (e.g., reduce saturated fat; reduce sodium intake to below 1500-2300 mg/day; increase consumption of fruits, vegetable, whole grains, healthy fats, fish; reduce sweets and added sugar) and increase physical activity. Many interventions also had weight loss goals for all or some of the participants, some also offered smoking cessation support. Behavior change techniques included goal setting, active use of self-monitoring, and addressing barriers related to diet, physical activity, or weight change. Motivational interviewing commonly employed. A small number of trials in each category below included family members as well as the individual with CVD risk factors themselves.			
Duration of interventions	Typically 6 to 18 months			
Settings of Studies	Most took place in primary care settings, 46% took place in the United States.			
To Whom is Intervention Targeted?	Adults with hypertension, prehypertension, dyslipidemia, or any of multiple cardiovascular disease risk factors; most participants were overweight or with obesity (mean BMI=29.8)			
INTERVENTION TYPE	**Group-based counseling with individual support, broadly targeted intervention**	**Individual-based support only, broadly targeted intervention**	**Hypertension prevention or management**	**Dyslipidemia management**
Mode and intensity of delivery	Psychoeducational group sessions lasting 1 to 2 hours for each session, typically with an additional single individual meeting for each person. Number of sessions typically ranged from 20-30 over 24 months (~16-36 contact hours) for weight loss interventions and 5-12 sessions over 4-12 months (~6-13 contact hours) for general behavior change interventions.	Typically face-to-face sessions, with or without additional telephone support. Some also used web-based programs or other technology-enhanced components. Number of sessions typically ranged from 2-32 over 9-24 months (~1-7 contact hours) for weight loss interventions and 4-17 sessions over 6-16 months (~1.5-7 contact hours) for general behavior change interventions.	Prevention interventions were most commonly delivered in group settings, but hypertension management interventions were evenly split between offering group sessions and only seeing participants individually. Number of sessions typically ranged from 28-53 over 18-36 months (~28-42 contact hours) for hypertension prevention interventions and 5-24 sessions over 6-18 months (~3-14 contact hours) for hypertension management interventions. Typically recommended a low-sodium diet, often specifically promoting the DASH diet. Hypertension management interventions frequently included active monitoring and management of blood pressure medications.	Number of sessions typically ranged from 4-12 over 6-12 months (~2-4 contact hours), most commonly delivered during individual face-to-face sessions. Typically recommended limiting overall fat intake or limiting saturated fat intake.

Table 16. Behavioral Intervention Implementation Table: Summary and Examples of Included Interventions

Example interventions*	General: Bo 2007; RIS (Fagerberg 1998); EUROACTION (Wood 2008) Weight loss: POWER Hopkins (Appel 2011)†; Track (Bennett 2018)†	General: Hardcastle 2008; PREDIMED (Estruch 2018); Rodriguez-Cristobol 2012; SPRING (Tiessen 2012); Wister 2008 Weight loss: GOAL (Ter Bogt 2009)	Prevention: TOHP I & II (TOHP I CRG, 1992 & TOHP II CRG, 1997)†; Management: ADAPT (Burke 2006); Hyman 2007†	DEER (Stefanick 1998)†
Materials Provided for Practice (Materials for specific cited programs)	Track: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4885789/ (study protocol)	PREDIMED: https://www.nejm.org/doi/suppl/10.1056/NEJMoa1800389/suppl_file/nejmoa1800389_appendix.pdf (pages 20-24, study protocol)	TOHP II: https://www.ncbi.nlm.nih.gov/pubmed/7795834 (study protocol)	‡
Evidence of effect modification	Larger weight loss effects were evident in weight loss trials. No pattern of effects was based on intensity of the intervention, duration of the intervention, whether there as in-person support, whether individual in-person or telephone sessions were offered, whether medication management was offered, or whether blood pressure monitors or pedometers were provided.			
Comparison group	Typically usual care consisting of brief messages from the primary care provider.			
Interventionist and Training Required	Many trials used Registered Dieticians as interventionists, but other common providers were health educators, nurses, lifestyle coaches, psychologists or psychology graduate students, and exercise physiologists. Brief (60-90 minute) training was typically provided to primary care providers and their staff when they were involved in the delivery of the intervention (22% of trials included the primary care provider or staff), and 2- to 5-day intensive training sessions were typically required for other front-line interventionists, as well as regular check-ins or supervised sessions to ensure fidelity to intervention protocol.			
Reported adherence to Intervention	Relatively high adherence with most studies reporting more than two-thirds of the intervention participants at least half of the intervention sessions. Participation rates declined over time, especially as intervention intensity lessened.			

Abbreviations: ADAPT = Activity, Diet, and Blood Pressure Trial; DEER = Diet and Exercise for Elevated Risk; GOAL = Groningen Overweight and Lifestyle; PREDIMED = Primary Prevention of Cardiovascular Disease with a Mediterranean Diet; RIS = Risk Factor Intervention Study; TOHP I = Trials of Hypertension Phase 1; TOHP II = Trials of Hypertension Phase 2

*Primarily focused on trials that had one of the top 10 largest absolute effect sizes across 2 more of the four intermediate outcome domains of blood pressure, lipids, fasting glucose, and weight.
†Study conducted in US
‡DEER intervention materials not provided, based on out-of-date guidance

Table 17. Association Between Changes in Intermediate Outcomes and Mortality Outcomes, Based on Individual Patient Data Meta-Analysis of Epidemiological Studies

Intermediate Outcome	Original Increment Difference	HR (95% CI) for Health Outcome for Original Increment Change in Intermediate Outcome	Converted Increment Difference	Age, years	Mortality Outcome	HR (95% CI) for Health Outcome for Converted Increment Change in Intermediate Outcome
SBP[305]*	↓20 mm Hg	0.49 (0.45 to 0.53)	↓2 mm Hg	40-49	IHD	0.93 (0.92 to 0.94)
	↓20 mm Hg	0.54 (0.53 to 0.55)	↓2 mm Hg	60-69	IHD	0.94 (0.94 to 0.94)
	↓20 mm Hg	0.36 (0.32 to 0.40)	↓2 mm Hg	40-49	Stroke	0.90 (0.89 to 0.91)
	↓20 mm Hg	0.43 (0.41 to 0.45)	↓2 mm Hg	60-69	Stroke	0.92 (0.91 to 0.92)
	↑14 mm Hg[337] ABPM	1.58 (1.55 to 1.60)	↓2 mm Hg	58.4[#]	CVD	0.94 (0.93 to 0.94)
	↑19 mm Hg[337] clinic-based	1.54 (1.52 to 1.56)	↓2 mm Hg	58.4[#]	CVD	0.96 (0.95 to 0.96)
Non-HDL-C[306]†	↓1 mmol/L	0.57 (0.52 to 0.62)	↓3 mg/dL	40-59	IHD	0.96 (0.95 to 0.96)
	↓1 mmol/L	0.66 (0.61 to 0.71)	↓3 mg/dL	60-69	IHD	0.97 (0.96 to 0.97)
TC[306§]	↓1 mmol/L	0.44 (0.42 to 0.48)	↓3 mg/dL	40-49	IHD	0.94 (0.93 to 0.94)
	↓1 mmol/L	0.72 (0.69 to 0.74)	↓3 mg/dL	60-69	IHD	0.97 (0.97 to 0.98)
TC[306‖]	↓1 mmol/L	0.90 (0.84 to 0.97)	↓3 mg/dL	40-59	Stroke	0.99 (0.99 to 1.00)
	↓1 mmol/L	1.02 (0.97 to 1.08)	↓3 mg/dL	60-69	Stroke	1.00 (1.00 to 1.01)
FBG[309, 310¶]	↑1 mmol/L	1.12 (1.08 to 1.15)	↓2 mg/dL	56[#]	F+NF CHD	0.99 (0.98 to 0.99)
	↑18.02 mg/dL	1.13 (1.11 to 1.15)	↓2 mg/dL	53[#]	Vascular	0.99 (0.98 to 0.99)
	↑18.02 mg/dL	1.10 (1.09 to 1.11)	↓2 mg/dL	53#	All-cause	0.99 (0.99 to 0.99)
BMI[307]**	↑5 kg/m^2	1.50 (1.39 to 1.62)	↓0.4 kg/m^2	35-59	IHD	0.97 (0.96 to 0.97)
	↑5 kg/m^2	1.40 (1.32 to 1.49)	↓0.4 kg/m^2	60-69	IHD	0.97 (0.97 to 0.98)
	↑5 kg/m^2	1.76 (1.52 to 2.04)	↓0.4 kg/m^2	35-59	Stroke	0.94 (0.94 to 0.97)
	↑5 kg/m^2	1.49 (1.34 to 1.67)	↓0.4 kg/m^2	60-69	Stroke	0.97 (0.96 to 0.98)

Abbreviations: BMI = body mass index; CHD = coronary heart disease; CI = confidence interval; dL = deciliter; F+NF = fatal plus nonfatal; FBG = fasting blood glucose; HDL-C = high-density lipoprotein cholesterol; Hg = mercury; HR = hazard ratio; IHD = ischemic heart disease; kg = kilogram(s); m = meter(s); mg = milligram(s); mm = millimeter(s); mmol = millimole(s); NS = not significant; SBP = systolic blood pressure; TC = total cholesterol.

*For SBPs above 115 mm Hg. Adjusted for age (within range being considered), sex, and study. Adjustments for lipids, diabetes, weight, alcohol, and smoking did not change results

†Adjusted for age (within range being considered), sex, and study. Formal test for heterogeneity NS for sex (significant for age)

‡Directionality inverted from negative to positive

§Adjusted for age (within range being considered), sex, and study. Result slightly attenuated by adjustment for SBP and unaltered by adjustment for smoking. Formal test for heterogeneity NS for sex for age <69 years; formal test for heterogeneity significant for age

‖Adjusted for age (within range being considered), sex, and study. Result attenuated with adjustment for SBP and minimal increase in HR with further adjustment for smoking for 40-59-year group only

¶For FBG above 100 mg/dL and assuming log-linear association. Adjusted for age, smoking, BMI, SBP

#Mean age

**For BMI above 25 kg/m^2. Adjusted for sex and smoking

Table 17. Association Between Changes in Intermediate Outcomes and Mortality Outcomes, Based on Individual Patient Data Meta-Analysis of Epidemiological Studies

Key Question	No. of Studies (No. of observations) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
KQ1	CVD events: 12 RCTs (15,107) Mortality: 18 RCTs (18,146) Subjective well-being: 11 RCTs (5684)	CVD events were reported in 10 trials of medium or high-contact interventions and pooled analyses showed lower rates of total CVD events (pooled RR=0.80 [95% CI 0.73 to 0.87], k=9), and fairly large but statistically non-significant associations with myocardial infarction (pooled RR=0.85 [95% CI 0.70 to 1.02], k=6) and stroke (RR=0.52 [95% CI 0.25 to 1.10], k=4). Event rates were variable, but the largest trial reported 3.6% of intervention participants having CVD events, compared with 4.4% of control participants. Few studies were powered for mortality, neither those few studies nor the pooled estimate clearly demonstrated an impact on mortality (pooled RR=0.89 [95% CI 0.71 to 1.11]). Patient-reported measures of subjective well-being were sparely reported and showed no clear pattern of clinically important benefit.	Mortality: Reasonably consistent, Imprecise CVD events: Reasonably consistent, Reasonably precise Subjective well-being: Inconsistent, Imprecise	Sparsely reported, few trials had sufficient power and length of followup for mortality and CVD events; trial with the strongest evidence suffered from protocol violations in allocation, however extensive sensitivity analyses showed limited impact on results.	CVD events: Moderate for benefit Mortality: Low for small to no benefit Subjective well-being: Insufficient	CVD events: Most trials conducted in the US, however, the largest trial providing the strongest evidence was conducted in Spain. Most participants across all trials were middle aged and older adults who were predominantly white and not socioeconomically disadvantaged.
KQ2	Continuous clinical measures: 89 RCTs (46,354) Hypertension incidence: 5 RCTs (2707) Diabetes incidence: 4 RCTs (6701) Metabolic syndrome: 5 RCTs (3103)	Behavioral counseling interventions were associated with small, statistically significant reductions in blood pressure, total and LDL cholesterol, fasting glucose, and adiposity-related outcomes at 12 to 24 months' followup. Hypertension incidence was lower with interventions designed to prevention hypertension in those who did not have it already (pooled RR=0.74 [95% CI 0.58 to 0.94]; 5 RCTs, [n=2707]; I^2=12%). No intervention factors were clearly	Reasonably consistent, Reasonably precise	Hypertension prevalence, diabetes and metabolic syndrome were reported in very few trials, raising concerns about reporting bias	High for benefit	Substantial number of trials conducted in the US and in conducted in or recruited from primary care. Most participants across all trials were middle aged and older adults who were predominantly white and not socioeconomically disadvantaged.

Table 17. Association Between Changes in Intermediate Outcomes and Mortality Outcomes, Based on Individual Patient Data Meta-Analysis of Epidemiological Studies

Key Question	No. of Studies (No. of observations) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
		associated with effect size, but among trials with the largest effects across multiple domains, most offered more than 6 hours of intervention contact and offered group as well as individual contact. Selected Pooled MDs were as follows: • SBP= -1.8 (95% CI -2.5 to -1.1), k=44 • DBP= -1.2 (95% CI -1.6 to -0.8), k=40 • TC= -3.5 (95% CI -5.6 to -1.4), k=38 • LDL= -2.1 (95% CI -4.1 to -0.2), k=32 • FBG=-2.3 (95% CI -3.6 to -1.0), k=22 • BMI=-0.5 (95% CI -0.7 to -0.2), k=30 Evidence primarily in medium and high-contact interventions.				
KQ3	70 RCTs (43,243)	Interventions were associated with small reductions in saturated fat and small increases in fruit, vegetable, and fiber consumption. For example, fruit and vegetables consumption increased by an average of 0.7 servings/day more in the intervention than the control groups (pooled MD=0.7 [95% CI 0.1 to 1.3]; 14 effects [11 RCTs] [n=4310]; I^2=90%). The average increase in fiber consumption was 1.3 grams per day (95% CI 0.1 to 2.6, 5 trials [n=1350], I^2=42%). In addition, trials of persons with hypertension or elevated blood pressure who were counseled to reduce	Diet: Reasonably consistent, imprecise Physical activity: inconsistent, imprecise	Sparse reporting with substantial variability in measures used, particularly for physical activity. Clinical importance of effect sizes could not be clearly determined	Diet: Low for benefit Physical activity: Low for no benefit	Substantial number of trials conducted in the US and in conducted in or recruited from primary care. Most participants across all trials were middle aged and older adults who were predominantly white and not socioeconomically disadvantaged.

Table 17. Association Between Changes in Intermediate Outcomes and Mortality Outcomes, Based on Individual Patient Data Meta-Analysis of Epidemiological Studies

Key Question	No. of Studies (No. of observations) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
		sodium consumption showed greater reductions in urinary sodium (pooled MD=-18.0 [95% CI -34.8 to -1.2]; 9 RCTs [n=3583]; I^2=89%). Findings were mixed for physical activity. Most trials included medium or high-contact interventions.				
KQ4	20 RCTs (18,263)	Adverse events related to diet and physical activity counseling were very rare, with generally no statistically significant differences in any study for: serious adverse events, any adverse events, hospitalizations, musculoskeletal injuries, withdrawals due to adverse events, gallbladder disease, and headaches. There was no consistent evidence of paradoxical effects for intermediate or behavioral outcomes.	Reasonably consistent, imprecise	Sparsely reported, ascertainment typically not described.	Low for no harms	Substantial number of trials conducted in the US and in conducted in or recruited from primary care. Most participants across all trials were middle aged and older adults who were predominantly white and not socioeconomically disadvantaged.

Abbreviations: BMI = body mass index; CI = confidence interval; CVD = cardiovascular disease; DBP = diastolic blood pressure; FBG = fasting blood glucose; k = number of studies analyzed; KQ = key question; LDL = low-density lipoprotein cholesterol; MD = mean difference; No. = number; RCT = randomized controlled trial; RR = risk ratio; SBP = systolic blood pressure; TC = total cholesterol

Appendix A. Literature Search Strategies

Key:
/ = MeSH subject heading
$ = truncation
** = truncation*
? = wildcard
ab = word in abstract
adj# = adjacent within x number of words
bt = book title
fs= floating subheading
hw = subject heading word
id =key phrase identifier
kf= keyword heading [word not phrase indexed]
kw = keyword
md = methodology
near/# = adjacent within x number of words
pt = publication type
ti = word in title

Cochrane Central Register of Controlled Clinical Trials (CENTRAL)

#1 diet:ti
#2 diets:ti
#3 dietary:ti
#4 (fruit or vegetable*):ti*
#5 exercis:ti*
#6 walking:ti
#7 "physical activity":ti,ab,kw
#8 pedometer:ti,ab,kw*
#9 fitbit:ti,ab,kw*
#10 "steps per":ti,ab,kw
#11 distance walked:ti,ab,kw
#12 (measuring next step):ti,ab,kw*
#13 (step next count):ti,ab,kw*
#14 (activity or fitness):ti,ab,kw near/1 track:ti,ab,kw*
#15 sedentary:ti,ab,kw next (lifestyle or (life next style*) or behavior* or behaviour* or time):ti,ab,kw*
#16 (sitting or lying):ti,ab,kw near/2 time:ti,ab,kw
#17 "screen time":ti,ab,kw
#18 (television or tv):ti,ab,kw next viewing:ti,ab,kw
#19 (watch or view*):ti,ab,kw next (television or tv):ti,ab,kw*
#20 (computer or internet):ti,ab,kw next (time or use or usage):ti,ab,kw
#21 (computer or video):ti,ab,kw next game:ti,ab,kw*
#22 (screen or screen-based):ti,ab,kw next (entertainment or behavior or behaviour* or use or usage):ti,ab,kw*
#23 (low next energy next expenditure):ti,ab,kw*
#24 (physical next inactiv*):ti,ab,kw*
#25 {or #15-#24}
#26 (reduce or reduction* or decrease* or change* or target*):ti,ab*
#27 #25 and #26
#28 {or #1-#14, #27}

#29 counsel:ti,ab,kw*
#30 (advice or advise or consultation):ti,ab,kw*
#31 Behavio:ti,ab,kw near/2 (therap* or chang* or modification* or improv*):ti,ab,kw*
#32 referral:ti,ab,kw*
#33 (set near/2 goal*):ti,ab,kw*
#34 (action next plan):ti,ab,kw*
#35 (self next monitor):ti,ab,kw*
#36 "follow up feedback":ti,ab,kw
#37 (assessment near/5 feedback):ti,ab,kw
#38 "support planning":ti,ab,kw
#39 "risk factor management":ti,ab,kw
#40 "life style":ti,ab,kw
#41 lifestyle:ti,ab,kw
#42 motivation:ti,ab,kw*
#43 health:ti,ab,kw next (coach or behavio* or education):ti,ab,kw*
#44 (education next program*):ti,ab,kw*
#45 "patient education":ti,ab,kw
#46 "health promotion":ti,ab,kw
#47 promot:ti,ab,kw near/3 (exercise or physical activit* or weight loss):ti,ab,kw*
#48 (nonpharmacologic or "non pharmacologic"):ti,ab,kw next intervention:ti,ab,kw*
#49 intervention:ti*
#50 {or #29-#49}
#51 (cardiovascular or cardiometabolic):ti
#52 #28 and (#50 or #51)
#53 (lifestyle near/2 intervention):ti,ab,kw or ("life style" near/2 intervention*):ti,ab,kw or ((health* next lifestyle)*
or (health next "life style")):ti,ab,kw*
#54 (cardiovascular or cardiometabolic or coronary or heart):ti,ab,kw
#55 (insulin or glucose or diabet):ti,ab,kw*
#56 (lipoprotein or lipid* or triglyceride* or hyperlipidemia* or cholesterol):ti,ab,kw*
#57 (bmi or body mass index or body weight):ti,ab,kw
#58 (hypertension or "blood pressure"):ti,ab,kw
#59 {or #54-#58}
#60 #53 and #59
#61 #52 or #60 Publication Year from 2016 to 2018

Ovid Medline, Ovid MEDLINE In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily Update

1 Diet, Reducing/
2 Caloric Restriction/
3 Diet, Fat-Restricted/
4 Diet, Mediterranean/
5 Diet, Sodium-Restricted/
6 Diet, Carbohydrate-Restricted/
7 Diet, Carbohydrate Loading/
8 Diet, High-Protein Low-Carbohydrate/
9 Diet, Ketogenic/
10 Diet, Diabetic/
11 Diet, Gluten-Free/
12 Diet, High-Protein/

13 Diet, High-Protein Low-Carbohydrate/
14 Diet, Paleolithic/
15 Diet, Protein-Restricted/
16 Diet, Vegetarian/
17 Diet, Macrobiotic/
18 Diet, Vegan/
19 Fruit/
20 Vegetables/
21 Functional food/
22 Feeding behavior/
23 Healthy diet/
24 Healthy lifestyle/
25 Weight Reduction Programs/
26 Exercise/
27 physical conditioning, human/
28 circuit-based exercise/
29 high-intensity interval training/
30 plyometric exercise/
31 resistance training/
32 running/
33 jogging/
34 swimming/
35 walking/
36 stair climbing/
37 Fitness trackers/
38 Accelerometry/
39 Actigraphy/
40 Exercise Therapy/
41 Physical Fitness/
42 (diet or diets or dietary).ti,bt,kf.
43 (fruit or vegetable*).ti,bt,kf.*
44 (exercise or physical activity).ti,bt,kf.
45 walking.ti,bt,kf.
46 pedometer.ti,ab,kf.*
47 fitbit.ti,ab,kf.*
48 steps per.ti,ab,kf.
49 distance walked.ti,ab,kf.
50 measuring step.ti,ab,kf.*
51 step count.ti,ab,kf.*
52 ((activity or fitness) adj1 track).ti,ab,kf.*
53 Sedentary lifestyle/
54 (sedentary adj (lifestyle or life style* or behavio* or time)).ti,ab,kf.*
55 ((sitting or lying) adj2 time).ti,ab,kf.
56 Screen time.ti,ab,kf.
57 ((television or TV) adj viewing).ti,ab,kf.
58 ((watch or view*) adj (television or TV)).ti,ab,kf.*
59 ((computer or internet) adj (time or "use" or usage)).ti,ab,kf.
60 ((computer or video) adj game).ti,ab,kf.*
61 ((screen or screen based) adj (entertainment or behavio or "use" or usage)).ti,ab,kf.*
62 low energy expenditure.ti,ab,kf.*
63 physical inactiv*.ti,ab,kf.*

64 or/54-63
65 (reduce or reduction* or decrease* or change* or target*).ti,ab.*
66 64 and 65
67 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or
22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or
41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 66
68 Counseling/
69 Directive Counseling/
70 "Behavior-Therapy"/
71 Cognitive Therapy/
72 "Referral and Consultation"/
73 Persuasive Communication/
74 Social Control, Informal/
75 Risk Reduction Behavior/
76 Life Style/
77 Healthy aging/
78 Motivation/
79 Social Support/
80 Feedback, Psychological/
81 Self Efficacy/
82 Health Knowledge, Attitudes, Practice/
83 Health Behavior/
84 Health Education/
85 Health Promotion/
86 Patient Education as Topic/
87 counsel.ti,ab,kf.*
88 (advice or advise or consultation).ti,ab,kf.*
89 (behavio adj2 (therap* or chang* or modification* or improv*)).ti,ab,kf.*
90 referral.ti,ab,kf.*
91 (set adj2 goal*).ti,ab,kf.*
92 action plan.ti,ab,kf.*
93 self monitor.ti,ab,kf.*
94 follow-up feedback.ti,ab,kf.
95 (assessment adj5 feedback).ti,ab,kf.
96 support planning.ti,ab,kf.
97 risk factor management.ti,ab,kf.
98 (life style or lifestyle).ti,ab,kf.
99 motivation.ti,ab,kf.*
100 health coach.ti,ab,kf.*
101 health behavio.ti,ab,kf.*
102 health education.ti,ab,kf.
103 education program*.ti,ab,kf.*
104 patient education.ti,ab,kf.
105 health promotion.ti,ab,kf.
106 (promot adj3 (exercise or physical activit* or weight loss)).ti,ab,kf.*
107 nonpharmacologic intervention.ti,ab,kf.*
108 non pharmacologic intervention.ti,ab,kf.*
109 intervention.ti,bt.*
110 or/68-109

111 (cardiovascular or cardiometabolic).ti,bt.
112 67 and (110 or 111)
113 Healthy lifestyle/ or Healthy diet/
114 ((lifestyle adj2 intervention) or (life style adj2 intervention*) or health* lifestyle or health* life style).ti,ab,kf.*
115 113 or 114
116 (cardiovascular or coronary or cardiometabolic or heart).ti,ab,kf,hw.
117 (insulin or glucose or diabet).ti,ab,kf,hw.*
118 (lipoprotein or lipid* or triglyceride* or hyperlipidemia* or cholesterol).ti,ab,kf,hw.*
119 (bmi or body mass index or body weight).ti,ab,kf,hw.
120 (hypertension or blood pressure).ti,ab,kf,hw.
121 or/116-120
122 115 and 121
123 112 or 122
124 limit 123 to "all child (0 to 18 years)"
125 limit 123 to "all adult (19 plus years)"
126 124 not 125
127 123 not 126
128 Animals/ not (Humans/ and Animals/)
129 127 not 128
130 (clinical trial or controlled clinical trial or randomized controlled trial or adaptive clinical trial or equivalence
clinical trial or pragmatic clinical trial or meta analysis).pt.
131 clinical trials as topic/ or controlled clinical trials as topic/ or randomized controlled trials as topic/ or adaptive
clinical trials as topic/ or equivalence clinical trials as topic/ or pragmatic clinical trials as topic/
132 Meta-Analysis as Topic/
133 Random allocation/
134 clinical trial.ti,ab,kf.*
135 (control adj3 (study or studies or trial*)).ti,ab,kf.*
136 random.ti,ab,kf.*
137 trial.ti.
138 or/130-137
139 129 and 138
140 (harm or harms or harmful or harmed).ti,ab,kf.
141 (risky behavior or risky behaviour*).ti,ab,kf.*
142 (adverse effects or mortality).fs.
143 Mortality/
144 Morbidity/
145 death/
146 Athletic injuries/
147 Malnutrition/
148 nutritional defici.ti,ab,kf.*
149 (death or deaths).ti,ab,kf.
150 fracture.ti,ab,hw.*
151 or/140-150
152 129 and 151
153 observational study/ or clinical study/ or case-control studies/ or cohort studies/ or longitudinal studies/ or
follow-up studies/or prospective studies/
154 case control.ti,ab,kf.*

155 cohort.ti,ab,kf.
156 longitudinal.ti,ab,kf.
157 (follow-up or followup).ti,ab,kf.
158 prospective.ti,ab,kf.*
159 (comparison group or control group*).ti,ab,kf.*
160 observational.ti,ab,kf.
161 retrospective studies/
162 retrospective.ti,ab,kf.*
163 database.ti,ab,kf.*
164 nonrandomi.ti,ab,kf.*
165 population.ti,ab.
166 or/153-165
167 152 and 166
168 139 or 167
169 limit 168 to (english language and yr="2016 -Current")

PsycInfo

1 Diets/
2 Dietary Restraint/
3 Eating Behavior/
4 fruit.ti,ab,id.*
5 vegetable.ti,ab,id.*
6 (diet or diets or dietary).ti,ab,id.
7 Exercise/
8 Physical Activity/
9 Aerobic Exercise/
10 Walking/
11 (exercise or physical activity).ti,ab,id.
12 walking.ti,ab,id.
13 (pedometer or fitbit* or steps per or distance walked or measuring step* or step count*).ti,ab,id.*
14 ((activity or fitness) adj1 track).ti,ab,id.*
15 Activity Level/
16 Sedentary behavior/
17 (sedentary adj (lifestyle or life style* or behavio* or time)).ti,ab,id.*
18 ((sitting or lying) adj2 time).ti,ab,id.
19 Screen time/
20 Television/
21 Television Viewing/
22 Computers/
23 Computer Games/
24 Role Playing Games/
25 Simulation Games/
26 screen time.ti,ab,id.
27 ((television or TV) adj viewing).ti,ab,id.
28 ((watch or view*) adj (television or TV)).ti,ab,id.*
29 ((computer or internet) adj (time or "use" or usage)).ti,ab,id.
30 ((computer or video) adj game).ti,ab,id.*
31 ((screen or screen based) adj (entertainment or behavio or "use" or usage)).ti,ab,id.*
32 low energy expenditure.ti,ab,id.*
33 physical inactiv*.ti,ab,id.*

34 or/1-33
35 behavior therapy/
36 cognitive behavior therapy/
37 cognitive therapy/
38 Cognitive Techniques/
39 Behavior Modification/
40 Behavior Change/
41 Lifestyle Changes/
42 Lifestyle/
43 Persuasive Communication/
44 Motivation/
45 Motivational Interviewing/
46 Self Efficacy/
47 Health Knowledge/
48 Health Behavior/
49 Health Education/
50 Health Promotion/
51 Client Education/
52 counseling/
53 counsel.ti,ab,id,hw.*
54 (advice or advise or consultation).ti,ab,id,hw.*
55 (behavio adj2 (therap* or chang* or modification* or improv*)).ti,ab,id.*
56 referral.ti,ab,id.*
57 (set adj2 goal*).ti,ab,id.*
58 action plan.ti,ab,id.*
59 self monitor.ti,ab,id.*
60 follow-up feedback.ti,ab,id.
61 (assessment adj5 feedback).ti,ab,id.
62 support planning.ti,ab,id.
63 risk factor management.ti,ab,id.
64 (life style or lifestyle).ti,ab,id.
65 motivation.ti,ab,id.*
66 (health adj (coach or behavio* or education)).ti,ab,id.*
67 education program*.ti,ab,id.*
68 patient education.ti,ab,id.
69 health promotion.ti,ab,id.
70 (promot adj3 (exercise or physical activit* or weight loss)).ti,ab,id.*
71 nonpharmacologic intervention.ti,ab,id.*
72 non pharmacologic intervention.ti,ab,id.*
73 intervention.ti.
74 or/35-73
75 (cardiovascular or cardiometabolic).ti.
76 34 and (74 or 75)
77 ((lifestyle adj2 intervention) or (life style adj2 intervention*) or health* lifestyle or health* life style).ti,ab,id.*
78 (cardiovascular or coronary or cardiometabolic or heart).ti,ab,id.
79 (insulin or glucose or diabet).ti,ab,id.*
80 (lipoprotein or lipid* or triglyceride* or hyperlipidemia* or cholesterol).ti,ab,id.*
81 (bmi or body mass index or body weight).ti,ab,id.
82 (hypertension or blood pressure).ti,ab,id.
83 or/78-82

84 77 and 83
85 76 or 84
86 (control adj3 (study or studies or trial*)).ti,ab,id,hw.*
87 clinical trial.ti,ab,id,hw.*
88 random.ti,ab,id,hw.*
89 trial.ti.
90 (treatment outcome or clinical trial).md.
91 or/86-89
92 85 and 91
93 (harm or harms or harmful or harmed).ti,ab,id,hw.
94 (risky behavior or risky behaviour*).ti,ab,id,hw.*
95 adverse effect.ti,ab,id,hw.*
96 mortality.ti,ab,id,hw.
97 morbidity.ti,ab,id,hw.
98 death.ti,ab,id,hw.
99 nutritional defici.ti,ab,id,hw.*
100 fracture.ti,ab,id,hw.*
101 or/93-100
102 85 and 101
103 case control.ti,ab,id,hw.*
104 cohort.ti,ab,id,hw.
105 longitudinal.ti,ab,id,hw.
106 (follow-up or followup).ti,ab,id,hw.
107 prospective.ti,ab,id,hw.*
108 (comparison group or control group*).ti,ab,id,hw.*
109 observational.ti,ab,id,hw.
110 retrospective.ti,ab,id,hw.*
111 database.ti,ab,id,hw.*
112 nonrandomi.ti,ab,id,hw.*
113 population.ti,ab,id,hw.*
114 or/103-113
115 102 and 114
116 92 or 115
117 limit 116 to (100 childhood <birth to age 12 yrs> or 120 neonatal <birth to age 1 mo> or 140 infancy <2 to 23 mo> or 160 preschool age <age 2 to 5 yrs> or 180 school age <age 6 to 12 yrs> or 200 adolescence <age 13 to 17 yrs>)
118 limit 116 to ("300 adulthood <age 18 yrs and older>" or 320 young adulthood <age 18 to 29 yrs> or 340 thirties <age 30 to 39 yrs> or 360 middle age <age 40 to 64 yrs> or "380 aged <age 65 yrs and older>" or "390 very old <age 85 yrs and older>")
119 117 not 118
120 116 not 119
121 limit 120 to animal
122 limit 120 to human
123 121 not 122
124 120 not 123
125 limit 124 to (english language and yr="2016 -Current")

Appendix A Table 2. Study Design-Specific Quality Rating Criteria*

	Include	Exclude
Condition definition	The current review will target populations at increased risk of cardiovascular disease due to hypertension or elevated blood pressure, dyslipidemia, or through examination of multiple risk factors. Examination of multiple risk factors may include 10-year CVD risk of >7.5% (e.g., using the Pooled Cohort Equations or Framingham risk calculators), presence of the metabolic syndrome, or mixed risk factors (i.e. studies that include persons with any of a number of CVD risk factors (e.g., hypertension, dyslipidemia, prediabetes, smoking, obesity, etc.).	Increased risk of cardiovascular disease solely due to prediabetes (trials in this population will be included in a concurrent review of screening for abnormal blood glucose and type 2 diabetes mellitus).
Populations	Adults age >18 with known hypertension or elevated blood pressure, dyslipidemia, the metabolic syndrome, or with 10-year CVD risk of 7.5% or greater based on a CVD risk assessment tool, or trial inclusion criteria specifies that population has one or more CVD risk factors	Trials limited to or predominantly: • Children and adolescents • Parents (if intended behavior change is directed towards children) • Persons with prediabetes • Persons with known CVD or diabetes mellitus such that >50% of participants have known CVD, severe chronic kidney disease, or diabetes (including gestational diabetes) • Persons with medical conditions limiting their generalizability to primary care-based populations of persons with CVD risk factors (e.g., acute illness, cognitive impairment, severe and persistent mental illness, cancer, chronic pain) • Institutionalized persons
Settings	• Conducted in or recruited from primary care or a health care system or could feasibly be implemented in or referred from primary care. • Trials in countries rated as “very high” on the UN Human Development Index (based on 2015 indicators): Andorra, Argentina, Australia, Austria, Bahrain, Belgium, Brunei Darussalam, Canada, Chile, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Qatar, Romania, Russia, Saudi Arabia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland,	• Settings not generalizable to primary care (e.g., inpatient hospital units, emergency departments, nursing home and other institutionalized settings, school classroom-based programs, occupational settings, dental clinics

Appendix A Table 2. Study Design-Specific Quality Rating Criteria*

	Include	Exclude
	United Arab Emirates, United Kingdom, United States	
Interventions	Behavioral counseling intervention alone or as part of a larger multicomponent intervention on diet and nutrition, physical activity, sedentary behavior, or a combination, including but not limited to: assessment with feedback, advice, collaborative goal-setting, assistance, exercise prescriptions (referral to exercise facility or program), or arranging further contacts Interventions may be delivered via face-to-face contact, telephone, print materials, or technology (e.g., computer-based, text messages, remote video feed) and can be delivered by a number of potential interventionists, including but not limited to: physicians, nurses, exercise specialists, dietitians, nutritionists, and behavioral health specialists Dietary counseling may involve any of: • Increased consumption of fruits, vegetables, whole grains, fat-free or low-fat dairy, lean proteins • Limited consumption of sodium, saturated fat, trans fat, sugar-sweetened food and beverages Physical activity (PA) counseling may involve any of: • Aerobic activities that involve repeated use of large muscles, such as walking, cycling, and swimming • Resistance training designed to improve physical strength • Reduction of sedentary behaviors • Optional or access to guided physical activity or exercise classes allowed Limited guided physical activity (i.e., 1-2 sessions) or provision of food samples allowed if intention is to teach or demonstrate healthy lifestyle principles	• Non-counseling interventions (e.g., use of incentives, supervised exercise with the goal of assessing effects of exercise); • Interventions providing controlled diets; • counseling interventions aimed at diabetes prevention, falls prevention, depression, cognitive functioning, or disease prevention other than CVD • Prenatal or post-natal dietary counseling; • Counseling interventions with components that are not feasible for implementation in healthcare settings, e.g., occupational/worksite, church, or school-based interventions that are conducted within existing social networks; social marketing (e.g., media campaigns); or policy (e.g., local or state public/health policy); • Stress management interventions (e.g., meditation; yoga or tai chi-based interventions that have minimal aerobic or strength-building activities) • Dietary counseling solely focused on increasing specific vitamins, micronutrients or anti-oxidants through dietary change or supplementation, or on alcohol moderation • Physical activity counseling solely focused on balance, flexibility, or gait •

Appendix A Table 2. Study Design-Specific Quality Rating Criteria*

	Include	Exclude
Comparisons	• No intervention (e.g., wait-list, usual care) • Minimal intervention (e.g., pamphlets, links to general information web sources, in-person counseling of no more than an estimated 60 minutes annually, presenting information similar to what individuals can receive through usual care in a primary care setting, but without personalized prescription based on standardized assessment) • Attention control (e.g., similar format and intensity intervention on a different content area)	• Comparative-effectiveness trials without a control (as defined in inclusion column) • PA only: studies in which the control group is instructed not to exercise
Outcomes	KQ1: Health outcomes • Cardiovascular events and related morbidity (e.g., stroke, myocardial infarction, heart failure, heart failure) • Cardiovascular and all-cause mortality • Quality of life measures and related outcomes (e.g., functioning, well-being) KQ2: Intermediate outcomes • Blood pressure • TC, LDL and HDL cholesterol • Hba1c, fasting glucose, 1- and 2-hr glucose tolerance • BMI, weight, waist circumference • Dichotomized versions of CVD risk factors (hypertension, dyslipidemia, diabetes, overweight or obesity, incidence of metabolic syndrome) • Calculated 10-year CVD risk • Cardiorespiratory fitness (e.g., VO2max, heart rate, exercise tolerance, 6 minute walk) KQ 3: Behavioral outcomes • Dietary intake or patterns • Physical activity • Sedentary behavior KQ4: Adverse outcomes • Harms requiring medical attention (e.g., nutritional deficiencies, musculoskeletal injuries, cardiovascular events)	• Initiation or withdrawal of medication • Knowledge, attitudes, self-efficacy, • Mental health symptom scores • Balance, flexibility • Less than 6 months • Less than 60% followup
Timing of outcome assessment	≥6 months post-baseline	<6 months post-baseline

Appendix A Table 2. Study Design-Specific Quality Rating Criteria*

	Include	Exclude
Study Designs	• Fair to good quality studies • KQ1, 2, 3: RCT, CCT (Prior to 2001: RCTs only) • KQ4: systematic reviews, RCT, CCT, comparative cohort, population-based case-control studies	• Poor quality studies • KQ1, 2: any observational studies • KQ3: ecological studies, case-series, case reports
Publication Date	• Trials published from 1990 to present	• Trials whose primary results were published prior to 1990

Abbreviations: CCT = controlled clinical trial; CVD = cardiovascular disease; HDL = high-density lipoprotein; HTN = hypertension; KQ = key question; LDL = low-density lipoprotein; RCT = randomized, controlled trial; TC = total cholesterol; USPSTF = United States Preventive Services Task Force

Appendix A Table 2. Study Design-Specific Quality Rating Criteria*

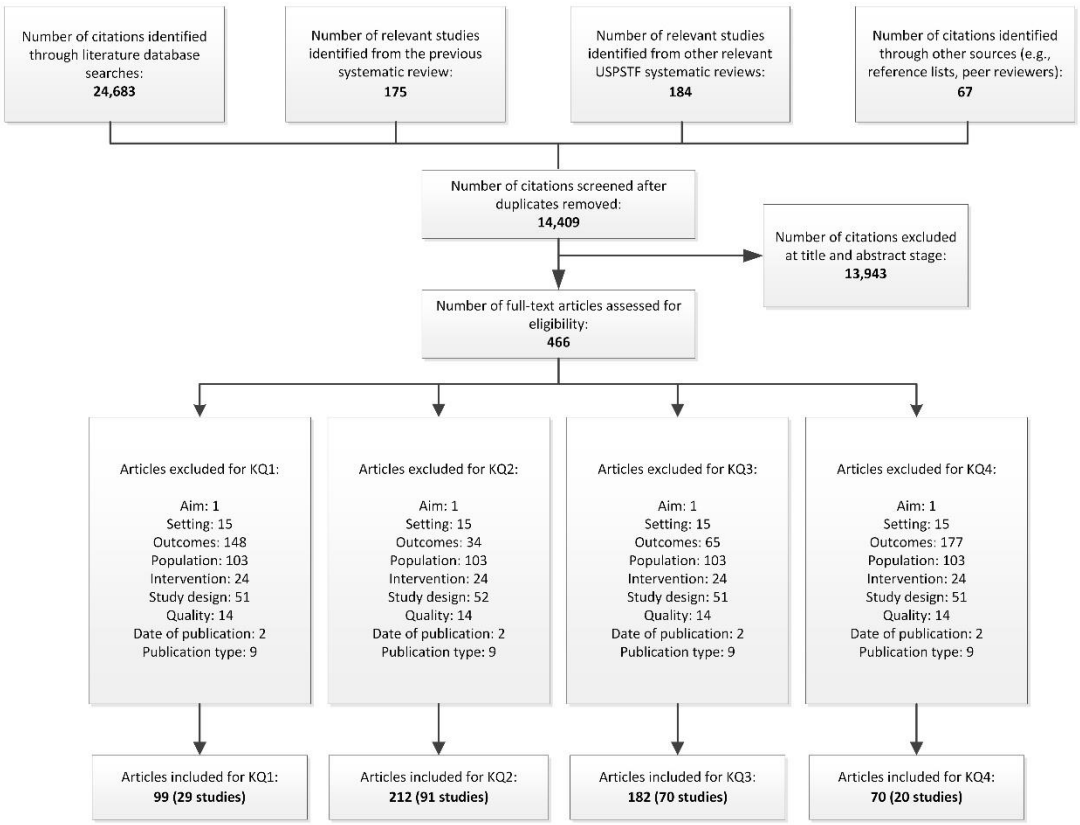
Study Design	Adapted Quality Criteria
Randomized clinical trials, adapted from U.S. Preventive Services Task Force Manual[1]	**Bias arising in the randomization process or due to confounding** • Valid random assignment/random sequence generation method used • Allocation concealed • Balance in baseline characteristics **Bias in selecting participants into the study** • CCT only: No evidence of biased selection of sample **Bias due to departures from intended interventions** • Fidelity to the intervention protocol • Low risk of contamination between groups • Participants were analyzed as originally allocated **Bias from missing data** • No, or minimal, post-randomization exclusions • Outcome data are reasonably complete and comparable between groups • Reasons for missing data are similar across groups • Missing data are unlikely to bias results **Bias in measurement of outcomes** • Blinding of outcome assessors • Outcomes are measured using consistent and appropriate procedures and instruments across treatment groups • No evidence of biased use of inferential statistics **Bias in reporting results selectively** • No evidence that the measures, analyses, or subgroup analyses are selectively reported
Cohort studies, adapted from Newcastle-Ottawa Scale[2]	**Bias arising in randomization process or due to confounding** • Balance in baseline characteristics • No baseline confounding • No time-varying confounding **Bias in selecting participants into the study** • No evidence of biased selection of sample • Start of followup and start of intervention coincide **Bias due to departures form intended interventions** • Participant intervention status is clearly and explicitly defined and measured • Classification of intervention status is unaffected by knowledge of the outcome or risk of the outcome **Bias in classifying interventions** • Fidelity to intervention protocol • Participants were analyzed as originally allocated **Bias from missing data** • Outcome data are reasonably complete and comparable between groups • Confounding variables that are controlled for in analysis are reasonably complete • Reasons for missing data are similar across groups

Appendix A Table 2. Study Design-Specific Quality Rating Criteria*

Study Design	Adapted Quality Criteria
	• Missing data are unlikely to bias results **Bias in measurement of outcomes** • Blinding of outcome assessors • Outcomes are measured using consistent and appropriate procedures and instruments across treatment groups • No evidence of biased use of inferential statistics **Bias in reporting results selectively** No evidence that the measures, analyses, or subgroup analyses are selectively reported

* All randomized clinical trials were classified as good, fair, or poor according to the USPSTF Procedure Manual[1]

Appendix B. Literature Flow Diagram



Appendix C. List of Included Studies

Below is a list of included studies and their ancillary publications (indented below main results publication):

1. Ammerman AS, Keyserling TC, Atwood JR, et al. A randomized controlled trial of a public health nurse directed treatment program for rural patients with high blood cholesterol. *Prev Med*. 2003;36(3):340-51. PMID: 12634025.
    a. Keyserling TC, Ammerman AS, Atwood JR, et al. A cholesterol intervention program for public health nurses in the rural southeast: description of the intervention, study design, and baseline results. *Public Health Nurs*. 1999;16(3):156-67. PMID: 10388332. http://dx.doi.org/10.1046/j.1525-1446.1999.00156.x
2. Anderson JW, Garrity TF, Wood CL, et al. Prospective, randomized, controlled comparison of the effects of low-fat and low-fat plus high-fiber diets on serum lipid concentrations. *Am J Clin Nutr*. 1992;56(5):887-94. PMID: 1329482.
3. Anderssen SA, Haaland A, Hjerman I, et al.. Oslo diet and exercise study: a one year randomized intervention trial. Efect on Haemostatic variables and other coronary risk factors. *Nutr Metab Cardiovasc Dis.* 1995;5:189-200. PMID: 8339552. http://dx.doi.org/10.1016/0197-2456(93)90005-X
    a. Anderssen SA, Carroll S, Urdal P, et al. Combined diet and exercise intervention reverses the metabolic syndrome in middle-aged males: results from the Oslo Diet and Exercise Study. *Scand J Med Sci Sports*. 2007;17(6):687-95. PMID: 17331082. http://dx.doi.org/10.1111/j.1600-0838.2006.00631.x
    b. Anderssen SA, Hjermann I, Urdal P, et al. Improved carbohydrate metabolism after physical training and dietary intervention in individuals with the "atherothrombogenic syndrome'. Oslo Diet and Exercise Study (ODES). A randomized trial. *J Intern Med*. 1996;240(4):203-9. PMID: None. http://dx.doi.org/10.1046/j.1365-2796.1996.22848000.x
    c. Anderssen S, Holme I, Urdal P, et al. Diet and exercise intervention have favourable effects on blood pressure in mild hypertensives: the Oslo Diet and Exercise Study (ODES). *Blood Press*. 1995;4(6):343-9. PMID: None. http://dx.doi.org/10.1111/j.1365-2796.1994.tb00858.x
    d. Jacobs DR, Jr., Sluik D, Rokling-Andersen MH, et al. Association of 1-y changes in diet pattern with cardiovascular disease risk factors and adipokines: results from the 1-y randomized Oslo Diet and Exercise Study. *Am J Clin Nutr*. 2009;89(2):509-17. PMID: 19116328. http://dx.doi.org/10.3945/ajcn.2008.26371
    e. Odes Investigators. The Oslo Diet and Exercise Study (ODES): design and objectives. *Control Clin Trials*. 1993;14(3):229-43. PMID: 8339552. http://dx.doi.org/10.1016/0197-2456(93)90005-X
    f. Reseland JE, Anderssen SA, Solvoll K, et al. Effect of long-term changes in diet and exercise on plasma leptin concentrations. *Am J Clin Nutr*. 2001;73(2):240-5. PMID: 11157319. http://dx.doi.org/10.1093/ajcn/73.2.240\
    g. Torjesen PA, Birkeland KI, Anderssen SA, et al. Lifestyle changes may reverse development of the insulin resistance syndrome. The Oslo Diet and Exercise Study: a randomized trial. *Diabetes Care*. 1997;20(1):26-31. PMID: 9028689.
4. Appel L, Clark J, Yeh H, et al. Comparative effectiveness of weight-loss interventions in clinical practice. *N Engl J Med*. 2011;365(21):1959-68. PMID: 22085317. http://dx.doi.org/10.1056/NEJMoa1108660
    a. Jerome GJ, Dalcin A, Coughlin JW, et al. Longitudinal accuracy of web-based self-reported weights: results from the Hopkins POWER Trial. *J Med Internet Res*. 2014;16(7):e173. PMID: 25042773. http://dx.doi.org/10.2196/jmir.3332
    b. Rubin RR, Peyrot M, Wang NY, et al. Patient-reported outcomes in the practice-based opportunities for weight reduction (POWER) trial. *Qual Life Res*. 2013;22(9):2389-98. PMID: 23515902. http://dx.doi.org/10.1007/s11136-013-0363-3

5. Appel LJ, Champagne CM, Harsha DW, et al. Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial. *JAMA*. 2003;289(16):2083-93. PMID: 12709466. http://dx.doi.org/10.1001/jama.289.16.2083
    a. Crist LA, Champagne CM, Corsino L, et al. Influence of change in aerobic fitness and weight on prevalence of metabolic syndrome. *Prev Chronic Dis*. 2012;9:E68. PMID: 22405475. http://dx.doi.org/10.5888/pcd9.110171
    b. Elmer PJ, Obarzanek E, Vollmer WM, et al. Effects of comprehensive lifestyle modification on diet, weight, physical fitness, and blood pressure control: 18-month results of a randomized trial. *Ann Intern Med*. 2006;144(7):485-95. PMID: 16585662. http://dx.doi.org/10.7326/ACPJC-2006-145-2-042
    c. Funk KL, Elmer PJ, Stevens VJ, et al. PREMIER--a trial of lifestyle interventions for blood pressure control: intervention design and rationale. *Health Promot Pract*. 2008;9(3):271-80. PMID: 16803935. http://dx.doi.org/10.1177/1524839906289035
    d. Lien LF, Brown AJ, Ard JD, et al. Effects of PREMIER lifestyle modifications on participants with and without the metabolic syndrome. *Hypertension*. 2007;50(4):609-16. PMID: 17698724. http://dx.doi.org/10.1161/HYPERTENSIONAHA.107.089458
    e. Lin PH, Appel LJ, Funk K, et al. The PREMIER intervention helps participants follow the Dietary Approaches to Stop Hypertension dietary pattern and the current Dietary Reference Intakes recommendations. *J Am Diet Assoc*. 2007;107(9):1541-51. PMID: 17761231. http://dx.doi.org/10.1016/j.jada.2007.06.019
    f. Maruthur NM, Wang NY, Appel LJ. Lifestyle interventions reduce coronary heart disease risk: results from the PREMIER Trial. *Circulation*. 2009;119(15):2026-31. PMID: 19349322. http://dx.doi.org/10.1161/CIRCULATIONAHA.108.809491
    g. Svetkey LP, Erlinger TP, Vollmer WM, et al. Effect of lifestyle modifications on blood pressure by race, sex, hypertension status, and age. *J Hum Hypertens*. 2005;19(1):21-31. PMID: 15385946. http://dx.doi.org/10.1038/sj.jhh.1001770
    h. Young DR, Coughlin J, Jerome GJ, et al. Effects of the PREMIER interventions on health-related quality of life. *Ann Behav Med*. 2010;40(3):302-12. PMID: 20799005. http://dx.doi.org/10.1007/s12160-010-9220-6
    i. Young DR, Vollmer WM, King AC, et al. Can individuals meet multiple physical activity and dietary behavior goals? *Am J Health Behav*. 2009;33(3):277-86. PMID: 19063649. http://dx.doi.org/10.5993/AJHB.33.3.6
6. Applegate WB, Miller ST, Elam JT, et al. Nonpharmacologic intervention to reduce blood pressure in older patients with mild hypertension. *Arch Intern Med*. 1992;152(6):1162-6. PMID: 1599343. http://dx.doi.org/10.1001/archinte.1992.00400180034005
7. Arroll B, Beaglehole R. Salt restriction and physical activity in treated hypertensives. *N Z Med J*. 1995;108(1003):266-8. PMID: 7637923.
8. Babazono A, Kame C, Ishihara R, et al. Patient-motivated prevention of lifestyle-related disease in Japan: A randomized, controlled clinical trial. *Dis Manage Health Outcomes*. 2007;15(2):119-26. PMID: None. http://dx.doi.org/10.2165/00115677-200715020-00007
9. Beckmann SL, Os I, Kjeldsen SE, et al. Effect of dietary counselling on blood pressure and arterial plasma catecholamines in primary hypertension. *Am J Hypertens*. 1995;8(7):704-11. PMID: 7546496.
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    a. Foley P, Steinberg D, Levine E, et al. Track: a randomized controlled trial of a digital health obesity treatment intervention for medically vulnerable primary care patients. *Contemp Clin Trials*. 2016;48:12-20. PMID: 26995281. http://dx.doi.org/10.1016/j.cct.2016.03.006

    b. Steinberg D, Kay M, Burroughs J, et al. The effect of a digital behavioral weight loss intervention on adherence to the Dietary Approaches to Stop Hypertension (DASH) dietary pattern in medically vulnerable primary care patients: results from a randomized controlled trial. *J Acad Nutr Diet*. 2019;119(4):574-84. PMID: 30905430. http://dx.doi.org/10.1016/j.jand.2018.12.011

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    a. Greaney ML, Quintiliani LM, Warner ET, et al. Weight management among patients at community health centers: the "Be Fit, Be Well" study. *Obes Weight Manag*. 2009;5(5):222-8. PMID: None. http://dx.doi.org/10.1089/obe.2009.0507
12. Beune EJ, Moll van Charante EP, Beem L, et al. Culturally adapted hypertension education (CAHE) to improve blood pressure control and treatment adherence in patients of African origin with uncontrolled hypertension: cluster-randomized trial. *PLoS One*. 2014;9(3):e90103. PMID: 24598584. http://dx.doi.org/10.1371/journal.pone.0090103
    a. Haafkens JA, Beune EJ, Moll van Charante EP, et al. A cluster-randomized controlled trial evaluating the effect of culturally-appropriate hypertension education among Afro-Surinamese and Ghanaian patients in Dutch general practice: study protocol. *BMC Health Serv Res*. 2009;9:193. PMID: 19849857. http://dx.doi.org/10.1186/1472-6963-9-193
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    a. Blackford K, Jancey J, Lee AH, et al. Effects of a home-based intervention on diet and physical activity behaviours for rural adults with or at risk of metabolic syndrome: a randomised controlled trial. *Int J Behav Nutr Phys Act*. 2016;13:13. PMID: 26830197. http://dx.doi.org/10.1186/s12966-016-0337-2
    b. Blackford K, Jancey J, Lee AH, et al. A randomised controlled trial of a physical activity and nutrition program targeting middle-aged adults at risk of metabolic syndrome in a disadvantaged rural community. *BMC Public Health*. 2015;15:284. PMID: 25885657. http://dx.doi.org/10.1186/s12889-015-1613-9
    c. Blackford K, Lee A, James AP, et al. Process evaluation of the Albany Physical Activity and Nutrition (APAN) program, a home-based intervention for metabolic syndrome and associated chronic disease risk in rural Australian adults. *Health Promot J Austr*. 2017;28(1):8-14. PMID: 27426475. http://dx.doi.org/10.1071/HE16027
14. Bloemberg BP, Kromhout D, Goddijn HE, et al. The impact of the Guidelines for a Healthy Diet of The Netherlands Nutrition Council on total and high density lipoprotein cholesterol in hypercholesterolemic free-living men. *Am J Epidemiol*. 1991;134(1):39-48. PMID: 1853859.
15. Bo S, Ciccone G, Baldi C, et al. Effectiveness of a lifestyle intervention on metabolic syndrome. A randomized controlled trial. *J Gen Intern Med*. 2007;22(12):1695-703. PMID: 17922167. http://dx.doi.org/10.1007/s11606-007-0399-6
    a. Ponzo V, Gentile L, Gambino R, et al. Incidence of diabetes mellitus, cardiovascular outcomes and mortality after a 12-month lifestyle intervention: a 9-year follow-up. *Diabetes Metab*. 2018;44(5):449-51. PMID: 29773350. http://dx.doi.org/10.1016/j.diabet.2018.04.008
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    b. Broekhuizen K, van Poppel MN, Koppes LL, et al. No significant improvement of cardiovascular disease risk indicators by a lifestyle intervention in people with familial hypercholesterolemia compared to usual care: results of a randomised controlled trial. *BMC Res Notes.* 2012;5:181. PMID: 22490761. http://dx.doi.org/10.1186/1756-0500-5-181
    c. Broekhuizen K, van Poppel MN, Koppes LL, et al. A tailored lifestyle intervention to reduce the cardiovascular disease risk of individuals with Familial Hypercholesterolemia (FH): design of the PRO-FIT randomised controlled trial. *BMC Public Health*. 2010;10:69. PMID: 20156339. http://dx.doi.org/10.1186/1471-2458-10-69
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Appendix D. List of Excluded Studies

Exclusion Code and Definition*
E1. Study relevance **E1c.** Not CVD focused
E2. Setting **E2a.** Not a "very high" development country **E2b.** Not generalizable to primary care
E3. Population **E3a.** Symptomatic, ≥50% with CHD or DM **E3b.** Participants not selected for CVD high-risk criteria **E3c.** Other (e.g., children, pregnant, etc.) **E3d.** ≥50% with pre-DM
E4. Outcomes: No relevant outcomes
E5. Intervention: Not an included intervention **E5a.** Yoga or tai chi **E5b.** Supervised PA too extensive **E5c.** Food provision too extensive
E6. Study design **E6a.** Not a trial **E6b.** Less than 6 months followup **E6c.** Comparative effectiveness **E6d.** Control group told not to change diet or PA
E7. Study quality **E7a.** High or differential attrition
E8. Main outcomes published prior to 1990
E9 Publication not in English **E9a.** Publication type (e.g., conference abstract)

* Assigned at the full-text screening phase

1. Ackermann RT, Edelstein SL, Narayan KM, et al. Changes in health state utilities with changes in body mass in the Diabetes Prevention Program. *Obesity (Silver Spring).* 2009;17(12):2176-81. PMID: 19390518. **KQ1E3d, KQ2E3d, KQ3E3d, KQ4E3d.**
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Appendix E. Observational Evidence on the Association Between Differences in Intermediate and Behavioral Outcomes and Health Outcomes

Building on the methods used in the recent USPSTF of lifestyle counseling in adults without CVD risk factors,[3] we looked for new observational evidence to support the association between effects of the size seen in the included studies and health outcomes, and updated this evidence where it was available. However, it is always worth noting that observational evidence may overestimate the benefits of behavior change, due to the inherent difficulty in controlling for confounding factors in non-randomized studies. Biases in observational results may be even more pronounced when long-term adherence to drug or behavioral change is assumed in order to maintain benefits. Some have noted that this concern is particularly important for applying effects of observational evidence to preventive interventions in primary care settings.[4] Moreover, observational evidence does not reflect changes in intermediate or behavioral outcomes based on counseling interventions.

Blood Pressure

Overall, we found that behavioral counseling was associated with a greater decrease in SBP/DBP by 1.9/1.2 mm Hg after 12 to 24 months follow-up compared to individuals in control groups, which was typically usual care. In trials that were limited to persons with hypertension or prehypertension, there was an average greater reduction of 2.0/1.1 mm Hg SBP/DBP, compared to control participants. Median reductions in SBP/DBP were 5.1/3.4 mm Hg in the intervention groups and 2.9/1.6 mm Hg in the control groups for all included trials at 12-24 months, from a mean baseline SBP/DBP of 139/84 mm Hg.

Blood pressure declines of this magnitude have been associated with decreased risk of CVD-related mortality in epidemiologic literature.[5, 6] An IPD meta-analysis of 61 prospective observational cohort studies with nearly 1 million adults without CVD revealed a strong relationship between blood pressure and age-specific stroke deaths and ischemic heart disease deaths which persisted after adjusting for lipid levels, diabetes, weight, alcohol intake, and smoking.[6] The positive associations between lowering blood pressures down to 115/75 mm Hg and outcomes were apparent through all age groups categorized by each decade of life. The hazard ratios were originally reported in incremental decreases in 20 mm Hg in SBP and 10 mm Hg in DBP. To allow for comparability to our results, we converted the blood pressures to smaller incremental decreases of 2 mm Hg in SBP and 1 mm Hg in DBP, respectively (**Table 17**). In adults between ages 40-49, a 2 mm Hg decrease in SBP was associated with lower mortality due to stroke by 10 percent (HR, 0.90 [95% CI, 0.89 to 0.91]) and mortality due to ischemic heart disease by 7 percent (HR, 0.93 [95% CI, 0.92 to 0.94]).

Similarly, a prospective cohort study of 63,000 patients with suspected hypertension found an association between increased in-clinic and ambulatory blood pressure measurements (ABPM) and increased cardiovascular mortality. The average age of the subjects was 58.4 years old and the results were adjusted for age, sex, smoking status, BMI, diabetes, dyslipidemia, history of CVD and number of antihypertensive drugs used. The study results reported hazard ratios per 1-SD (14 mm Hg) SBP increase in ABPM and 1-SD (19 mm Hg) SBP increase in the clinic. To comparably assess the effects of decreased SBP, the inverse of the HRs were calculated and converted to incremental 2 mm Hg decreases (**Table 17**). This resulted in a 6 percent (HR, 0.94 [95% CI, 0.93 to 0.94]) and a 4 percent (HR, 0.96 [95% CI, 0.95 to 0.96]) reduction in CVD mortality for ABPM and clinical BP measurements, respectively.[5] Further, a IPD meta-analyses of randomized controlled trials and prospective studies supported the overall benefits of a broad class of antihypertensives in lowering blood pressure decreasing cardiovascular mortality risks.[7, 8] For example, one of these found that among trials with baseline SBP between 130 and 139 mm Hg, a 10 mm Hg reduction was associated with a 13% reduction in major CVD events (RR=0.87 [95% CI 0.82 to 0.92]), 27% reduction in strokes (RR=0.73 [95% CI 0.62 to 0.85]) and a 11% reduction in all-cause mortality (RR=0.89 [95% CI 0.82 to 0.98]).[8]

Similarly, CVD events were reduced in a combined analysis of long-term followup of the two TOHP trials, in which the average change in blood pressure was a 1.2/0.7 mm Hg greater reduction than control groups after 36 months, presumably due to restricted sodium intake found by the TOHP trials.[9] In this follow-up study, risk of a cardiovascular event was 25% lower among those in the intervention group (RR= 0.75 [95% CI 0.57 to 0.99]), adjusted for trial, clinic, age, race, and sex, and was 30% lower after further adjustment for baseline sodium excretion and weight (RR=0.70 [95% CI 0.53 to 0.94]). This was after approximately 10 years for TOHP I and 5 years for TOHP II. However, there was not a statistically significant reduction in all-cause mortality in this combined analysis (RR=0.80 [95% CI 0.51 to 1.26]; 67 deaths total).

Lipids

We found that behavioral counseling interventions were associated with a 3.7 mg/dL greater reduction in total cholesterol than control groups and a 2.3 mg/dL greater reduction in LDL compared to the control groups after 12 to 24 months of follow-up. Individuals with dyslipidemia experienced similar outcome in TC levels, decrease by 3.8 mg/dL and a decrease of 4.1 for LDL. The mean baseline LDL levels were 136 mg/dL across all included studies, and 160 in trials that were limited to persons with dyslipidemia or levels that were outside the optimal range. Median reductions in LDL were 4.8 mg/dL in the intervention groups and 4.2 mg/dL in the control groups for all studies, and absolute reductions were larger in trials limited to participants selected for lipid levels (median 11.0 and 10.4 mg/dL reductions in the intervention and control groups, respectively). There was a minimal impact on HDL.

The variety in lipid components and their interactions with each other creates complications when determining the health impact of cholesterol levels, but epidemiologic evidence suggests that decreases in LDL can lead to decrease in cardiovascular mortality.[10, 11] However, evidence is mixed on the likelihood that changes of the magnitude found in our review are associated with long-term health benefits. In an IPD meta-analysis of 61 prospective observational studies consisting of 900,000 adults without a history of known diseases revealed a positive relationship between non-HDL cholesterol levels and IHD mortality after a median 13 years followup. This trend persisted through each decade of life beginning at age 40 but weakened through subsequent decades. An average decrease in non-HDL cholesterol of 3 mg/dL was associated with a 4 percent reduction in IHD mortality in adults ages 40 to 49 years old (HR, 0.96 [95% CI, 0.95 to 0.96]) (**Table 17**).[11] This study did not find a relationship between non-HDL cholesterol levels and stroke mortality (e.g., HR=0.99 [95% CI 0.99 to 1.00] for adults ages 40 to 49 years). A separate meta-analysis of 34 trials with 135,000 subjects supported the usage of intensive statin therapy to decrease all-cause mortality and CVD mortality over less-intensive.[10] For example, among persons with a baseline LDL between 100 and 129 mg/dL, 48 weeks of LDL lowering therapy was associated with a 12% lower risk of all-cause mortality (RR=0.88 [95% CI 0.79 to 0.98]). However, this analysis found that there was no benefit in trials with average absolute reductions of less than 35 mg/dL (RR=0.98 [95% CI 0.94 to 1.01]).

Fasting Glucose

We excluded trials if 50% or more of participants had diabetes or prediabetes, but nevertheless found that behavioral counseling interventions were associated with a 2.4 mg/dL greater reduction in FBG and control groups after 12 to 24 months of follow-up. The mean baseline FBG levels were 86 mg/dL across all included studies, and the median change was a 2.9 mg/dL reduction in the intervention groups and 0.2 mg/dL increase in the control groups. The percent with diabetes at baseline ranged from 0 to 49 percent, with 12.7 percent of all participants having diabetes across all studies reporting diabetes prevalence.

Appendix E. Observational Evidence on the Association Between Differences in Intermediate and Behavioral Outcomes and Health Outcomes

Epidemiologic evidence suggests that maintaining a normoglycemic level is associated with the best cardiovascular outcomes and incremental increases beyond normoglycemia increases cardiovascular mortality. In an IPD meta-analysis of 54 prospective studies that included 284,686 individuals without known CVD, all-cause mortality and vascular death was not associated with a fasting blood glucose level between 70 and 100 mg/dL adjusted for age, smoking, and BMI.[12] A different IPD meta-analysis generated similar results for coronary heart disease and stroke events, both fatal and nonfatal. An incremental 2 mg/dL increases in fasting blood glucose above 100 mg/dL was associated with a 1 percent decreased risk of fatal plus nonfatal coronary heart disease (HR, 0.99 [95% CI, 0.98 to 0.99]),[12] vascular deaths (HR, 0.99 [95% CI, 0.98 to 0.99]),[12] and all-cause mortality (HR, 0.99 [95% CI, 0.99 to 0.99]).[12] The link between diabetes and cardiovascular events is well-established; the incidence rate is doubled for fatal and nonfatal coronary heart disease and stroke. The previous review on this topic found that counseling individuals with known impaired fasting glucose or glucose intolerance about interventions reduced their risk of progressing to diabetes by 42 percent in 12 to 24 months (pooled RR, 0.58 [95% CI, 0.37 to 0.89]; k=8; I^2=32%).[13] These results demonstrate the importance of preventing the progression to diabetes in risk populations.

Adiposity

We found that behavioral counseling interventions were associated with a 0.4 kg/m^2 greater reduction in BMI than control groups and a 1.6 cm greater reduction in waist circumference compared to the control groups after 12 to 24 months of follow-up. Among the weight loss trials in this review, the average BMI and waist circumference reductions were 0.9 kg/m^2 and 2.5 cm, respectively. The mean baseline BMI was 29.8 across all included studies, 89.3% of all participants were either overweight or had obesity across all studies reporting the prevalence of excess weight. Median reductions in BMI were 0.5 kg/m^2 in the intervention groups and 0.1 kg/m^2 in the control groups, and absolute reductions were larger in weight loss trials (i.e., participants were selected on the basis of excess weight and all were given a weight loss goal: median 1.0 and 0.3 kg/m^2 reductions in the intervention and control groups, respectively).

We found data to support that even modest changes in BMI may be associated with small reductions in cardiovascular related mortality. An IPD meta-analysis of 57 prospective studies that included 900,000 individuals found that all-cause mortality was lowest in BMI ranges between 22.5 to 25 kg/m^2 in adults without CVD.[14] Applying conversions to determine the impact of a BMI change comparable to that found in our review, a BMI decrease of 0.4 kg/m^2 was associated with a 3 percent lower risk of death caused ischemic heart disease (HR, 0.97 [95% CI, 0.96 to 0.97]) and fatal strokes (HR, 0.97 [95% CI, 0.97 to 0.98]), among adults with a BMI above 25 kg/m^2 and ranging from ages 35 to 59 years. These results were not adjusted for mechanisms which affect vascular mortality such as blood pressure levels, lipid levels, or diabetes.[14] A Danish study published in 2016 investigated the relationship between BMI and mortality over time from three different cohorts and found smaller associations between BMI and mortality over time.[15] In the most recent cohort, a BMI greater than 30 kg/m^2 was not associated with an increased risk of all-cause mortality relative to a BMI of 18.5 to 24.9 (HR, 0.99 [95% CI, 0.92 to 1.07]), in contrast to earlier cohorts (1991–1994: HR, 1.13 [95% CI, 1.04 to 1.22]; 1976–1978: HR, 1.31 [95% CI, 1.23 to 1.39]).[15] An analysis of the most recent cohort (2003-2013) revealed a BMI of 27.0 kg/m^2 to have the lowest all-cause mortality, which is 3.3 kg/m^2 higher than at was in the earliest cohort. They hypothesized that improved treatment for cardiovascular risk factors and CVD complications may have had a greater impact at higher BMI levels than at lower BMI levels. Body mass index is known to be associated with other cardiovascular risk factors such as blood pressure, lipid levels and diabetes and therefore the clinical significance of weight loss should also be considered when examining these outcomes.[15]

Evidence was not as extensive for waist circumference, however we did find prospective observational studies to support the association between waist circumference and future all-cause mortality[16] and ischemic heart disease events.[17] A pooled analysis of 11 prospective cohort studies (n=650,386) with mean followup of 9 years reported a 7% increase in the risk of all-cause mortality in men (HR=1.07 [95% CI 1.06 to 1.08]) and 9% increase in women (HR=1.09 [95% CI 1.08 to 1.09]) associated with a 5 cm increment in waist circumference. We inverted these figures and calculated the decline in risk associated with a 2 cm reduction in men and a 1 cm reduction in women, consistent with our findings; the result was a 3% lower risk for men (HR=0.97 [95% CI 0.96 to 0.98]) and a 1% lower risk for women (HR=0.99 [95% CI 0.98 to 0.99]).[16] Similar calculations based on a pooled analysis of 6 prospective cohort studies from China and Australia (n=45,988) with a mean 6 years followup results in a 5% reduction in the risk of ischemic heart disease events (HR=0.95 [95% CI 0.95 to 0.98)] being associated with a 1.7 cm decrease in waist circumference.[17]

Diet

We found that dietary counseling was associated with decrease in percentage of energy from saturated fats and monounsaturated fats and had no statistically significant effect on the percentage of energy coming from polyunsaturated fats. Between-group differences included a decrease in 1.5 percent and 1.7 percent of total energy consumed in saturated fats and mono-unsaturated fats, respectively. We also found that dietary counseling increased the consumption of fruits and vegetable combined by 0.7 servings a day more than control groups and consumption of fiber increased by 1.4 grams per day more than control groups. Urinary sodium was also decreased by 17.9 mmol/L more in the intervention groups than the control groups. In addition, several trials improved overall indices of diet, and two reported increased adherence with the Mediterranean diet.

There is some observational data to support the benefits of a healthful diet on cardiovascular and all-cause mortality. A 2014 study meta-analysis of 95 cohort studies with up to 2 million participants found that an increase in fruit and vegetable consumption of 200 g/d was associated with an decreased relative risk of cardiovascular disease by 8 percent (RR, 0.92 [95% CI, 0.90 to 0.95]), strokes by 16% (RR, 0.84 [95% CI, 0.76 to 0.92]), and all-cause mortality by 10% (RR, 0.90 [95% CI, 0.87 to 0.93]).[18] However, 200 g/d is a considerably larger between-group effect than we found, which is more on the order of 30 g/day or less. A separate meta-analysis of 16 cohort studies that included over 800,000 individuals and 56,423 deaths found a 5 percent lower risk of all-cause mortality for an increment of one serving of fruit and vegetables per day (pooled HR=0.95 [95% CI 0.92 to 0.98]).[19]

Evidence also support increased fiber consumption. Incremental consumptions of 10 gram of dietary fiber per day has also been shown to decrease the all-cause mortality risk ratio by 11 percent [RR, 0.89 (95% CI 0.85 to 0.92)] according to a meta-analysis from 2014.[20] Again, however, this was a nearly 10 times larger change in fiber consumption than the between-group differences that was observed in the included studies.

The findings on intake of different types of dietary fat are less clear, although evidence suggest that a low-fat diet may not assist with weight loss or decrease CVD and cancer mortalities.[21-24] The results of a meta-analysis of two U.S.-based prospective cohort studies (the Nurses' Health Study and the Health Professionals Followup Study) of individuals without diabetes, cardiovascular disease and cancer at baseline found that a replacement of 5 percent of energy from saturated fats to polyunsaturated fats, monounsaturated fats, or whole grain carbohydrates was associated with a 25 (HR, 0.75 [95% CI, 0.67 to 0.84]), 15 (HR, 0.85 [95% CI, 0.74 to 0.97]), and 8 percent (HR, 0.91 [95% CI, 0.85 to 0.98]) reduction in coronary heart disease, respectively.[25] The reduction in saturated fat was substantially lower in the

included studies, and it was unlikely that these calories were replaced with MUFA or PUFA, since those also either declined or health steady in the included studies. A 2017 publication from the American Heart Association's review of the current evidence concluded that replacing saturated fats with unsaturated fats in lowers the incidences of cardiovascular disease,[26] however some disagreement in the field remains.[27] The U.S. Department of Health and Human Service has also began recommending substitution of saturated fats for poly- and monounsaturated fats.[28]

Physical Activity

Our analysis found that physical activity counseling was associated with statistically nonsignificant increases in physical activity of 9.1 minutes per week and 83 MET-minutes per week compared to the control group. We also found that 22 percent of individuals were able to meet the set physical activity recommendation (150 minutes of moderate-intensity or 75 minutes of vigorous physical activity per week) compared to the control. However, there was substantial level of heterogeneity in our pooled analysis for this outcome.

The broader body of observational and trial literature support the benefits of exercise in decreasing cardiovascular disease even at levels below the national standard. The Physical Activity Guidelines for Americans, second edition, reaffirmed the strong evidence to support the benefits of physical activity on all-cause mortality.[29] They recommend a minimum of 150 minutes of moderate intensity exercise or 75 minutes of vigorous-intensity exercise per week (approximately 500 to 1,000 MET-minutes/week). However, even physical activities below what is recommended show significant benefits,[29] and the current guide states that the is no threshold that must be exceeded before benefits begin to occur. Compared to no activity, activity below the recommended 450-MET-minutes/week reduced both cardiovascular death and all-cause mortality by 20 percent (HR, 0.80 [95% CI, 0.77 to 0.84]), HR, 0.80 [95% CI, 0.78 to 0.82] respectively) after adjusting for clinical and demographic characteristics, including BMI. Physical activity at the level of the national recommendation (500 to 1000 MET-minute/week) is associated with a 33 percent reduction in the risk of cardiovascular mortality (HR, 0.67 [95% CI, 0.65 to 0.70]) and all-cause mortality is reduced by 31 percent (HR, 0.69 [95% CI, 0.67 to 0.70]).[30] The benefits are observed regardless of whether the physical activity is recreational or non-recreational (e.g., housework, transportation and occupational).[31] The benefits of physical activities are generalizable across subpopulations of age, sex, race/ethnicity, BMI smoking and history of heart disease according to a Taiwanese prospective cohort study of more than 400,000 individuals. The study found that low levels of activity (90 min/week or 15/min/day) was associated with a 19 percent reduction in cardiovascular mortality (HR, 0.81 [95% CI, 0.71 to 0.93]) and a 14 percent reduction in risk of all-cause mortality (HR, 0.86 [95% CI, 0.81 to 0.91]). Furthermore, additional 15 minutes/day was associated with a 4 percent risk reduction in all-cause mortality (95% CI, 2.5 to 7.0).[32]

Large cross-sectional studies have associated better quality of life and perceived health status with physical activity regardless of BMI,[33, 34] while results of longitudinal analyses showed a mixture of substantial improvements in the range of quality-of-life domains,[35] and others showed limited impact.[36] The results of cross-sectional associations were not reproducible by longitudinal analysis, however.[37]

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
Ammerman, 2003[38] Fair	US Mixed	Dyslipidemia	Residents of rural areas, age 20 to 70, with untreated hypercholesterolemia	468	3, 6, 12 (75)	55 (20-70)	71	29 NR	HTN: 41 Dys: 100 PreDM: NR DM: 3 CVD: 10 Smoking: 21	% unemployed: 44 % education <high school: 30
Anderson, 1992[39] Fair	US Community	Dyslipidemia	Age 30 to 50 with moderate untreated hypercholesterolemia and without obesity or hypertension	177	4, 8, 12 (82)	41 (30-50)	40	NR 0	HTN: 0 Dys: 100 PreDM: NR DM: 0 CVD: 0 Smoking: 12	Mean education, years: 16
Anderssen, 1995[40] (Oslo Diet and Exercise Study (ODES)) Fair	Norway Community	Multiple risk factors	Age ≥40 with untreated elevated BP/hypertension and lipids, physically inactive and BMI >24	98	12 (97)	45 (41-50)	NR	29 100	HTN: NR Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: NR	NR
Appel, 2003[41](PREMIER) Good	US Mixed	Hypertension	Age ≥25 with untreated elevated BP/hypertension	810	6, 18 (94)	50 (≥25)	62	33 94	HTN: 38 Dys: 24 PreDM: NR DM: 0 CVD: 0 Smoking: 5	No. (%) ≤ High school: 74 (9) No. (%) some college: 476 (59) No. (%) some graduate school: 260 (32) No. (%) No. (%) $30-60k annual income: 256 (32) No. (%) >$60k annual income: 441 (54)
Appel, 2011[42] (POWER Hopkins (Practice Based	US Primary Health Care	Multiple risk factors	Age ≥21 with obesity and any of multiple risk factors	415	6, 12, 24 (95)	54 (≥21)	64	37 100	HTN: 76 Dys: 68 PreDM: NR DM: 23	Education, %: -HS grad or less, 10.6% -Some college, 30.1% -College grad, 59.3%

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Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
Opportunities for Weight Reduction)) Good									CVD: NR Smoking: NR	Household income, %: -$50,000-$99,000, 37.3% - ≥$100,000, 40.7% Employment status, %: -Employed, 75.2% -Retired, 15.7% -Other, 9.2% Insurance status: -Private, HMO, Medicare: 98.5% -Medicaid, uninsured: 1.5%
Applegate, 1992[43] Fair	US Community	Hypertension	Age 60 to 85 at ≥115% of ideal body weight, with hypertension	56	1, 2, 3, 4, 5, 6 (84)	64 (60-85)	55	NR 100	HTN: 100 Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: 13	Education (yrs): 12 Employment (Full time or part time): 30%
Arroll, 1995[44] Fair	New Zealand Mixed	Hypertension	Age 20 to 69 with treated hypertension and sedentary	208	3, 6 (87)	55 (20-69)	48	NR NR	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: NR	NR
Babazono, 2007[45] (PHPP) Fair	Japan Health Care	Multiple risk factors	Japanese adults with elevated BP, hypertension or prediabetes	99	4, 6, 12 (88)	64 (NR)	58	24 NR	HTN: 30 Dys: NR PreDM: NR DM: 17 CVD: NR Smoking: NR	NR
Beckmann, 1995[46] Fair	Norway NR	Hypertension	Men, age 40 to 56, with untreated mild-to-moderate hypertension	64	3, 6, 12 (100)	NR (40-56)	0	27 NR	HTN: 100 Dys: NR PreDM: NR DM: NR	NR

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Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
									CVD: NR Smoking: 22	
Bennett, 2012[47] (Be Fit, Be Well [POWER]) Good	US Health Care	Hypertension	Age ≥21 with obesity and treated hypertension	365	6, 12, 18, 24 (69)	55 (≥21)	68	37 100	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	Educational level, n (%) High school/GED, 109 (30) Some college/AD, 86 (24) ≥Bachelor's degree, 50 (14) Income, n (%) $10,000 to $25,000 to ≥$50 000, 56 (15) Employment, n (%) Employed, 192 (53) Unemployed, 50 (14) Retired, 43 (12) Disabled, 80 (22) Health insurance, n (%) Medicaid, 123 (34) Medicare, 75 (21) Private insurance, 137 (38) Other, 30 (8)
Bennett, 2018[48] (Track) Good	US Health Care	Multiple risk factors	Age 21 to 65 with obesity and any of multiple CVD risk factors	351	6, 12 (90)	51 (21-65)	68	36 100	HTN: 82 Dys: 55 PreDM: NR DM: 42 CVD: 0 Smoking: NR	Education: HS grad: 36% Some college or vocational: 40% 4-year college degree or higher: 10% Annual household income: 0-$11,999: 20% $12,000-$24,999: 31% $25,000-$34,999: 16% $35,000-$49,999: 13%

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
										≥$50,000: 7% Living under US poverty threshold: Below: 30% Borderline: 16% Above: 41% Current employment: Full- or part-time: 67% Unemployed: 31%
Beune, 2014[49] (Culturally Adapted Hypertension Education (CAHE)) Fair	The Netherlands Primary Health Care	Hypertension	Surinamese and Ghanaian immigrants, age ≥20, with hypertension	146	6 (95)	54 (≥20)	53	31 94	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	Education: Low: 50% Middle: 30% High: 19% Employment: Paid work: 64% Unpaid work: 1% Unemployed/disabled: 24% Retired: 11%
Blackford, 2016[50] (Albany Physical Activity and Nutrition (APAN)) Fair	Australia Health Care	Multiple risk factors	Age 50 to 69 with or at risk of metabolic syndrome	401	6 (78)	61 (50-69)	66	31 NR	HTN: NR Dys: NR PreDM: NR DM: 0 CVD: NR Smoking: 12	Employment: Full time: 46% Part time: 17% Unemployed: 4% Retired: 33% Education: Primary: 2% Secondary: 41% Technical/diploma: 32% University: 26%

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Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
Bloemberg, 1991[51] Fair	The Netherlands Other	Dyslipidemia	Men, age 30 to 60, with untreated dyslipidemia	80	6 (99)	47 (30-60)	0	26 NR	HTN: 0 Dys: 100 PreDM: NR DM: 0 CVD: 0 Smoking: NR	NR
Bo, 2007[52] Fair	Italy Primary Health Care	Multiple risk factors	Age 45 to 64 with metabolic syndrome	375	12 (89)	56 (45-64)	58	30 NR	HTN: 94 Dys: NR PreDM: 38 DM: 0 CVD: 0 Smoking: 22	Education level, %: - Primary, 79 - Secondary, 16 - University, 5
Bosworth, 2009[53] (Take Control of Your Blood pressure (TCYB)) Fair	US Primary Health Care	Hypertension	Adults with treated hypertension	478	12, 24 (76)	61 (NR)	64	32 NR	HTN: 100 Dys: NR PreDM: NR DM: 36 CVD: NR Smoking: 17	% completed ≤12 years education: 35 % employed: 40 % inadequate income: 19
Broekhuizen, 2012[54] (PRO-FIT) Fair	The Netherlands Other	Dyslipidemia	Age 18 to 70 with familial hypercholesterolemia	340	12 (94)	45 (18-70)	57	26 NR	HTN: NR Dys: 100 PreDM: NR DM: NR CVD: NR Smoking: 17	Education, %: - Low, 3 - Medium, 60 - High, 36
Bruckert, 2008[55] (PEGASE (Effect of an Education Program)) Fair	France Health Care	Dyslipidemia	Age ≥18 with elevated LDL and additional CVD risk factor (unless LDL very high)	640	6 (74)	57 (≥18)	40	NR NR	HTN: 34 Dys: 100 PreDM: NR DM: 9 CVD: 23 Smoking: 21	Education, %: - No education, 10 - HS grad, 14 - Tech school, 49 - Higher education, 24 Employed, %: 42 Retired,%: 47 Unemployed, %: 2

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Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
Burke, 2006[56] (ADAPT) Fair	Australia NR	Hypertension	Age 40 to 70 with treated hypertension and overweight or obese	241	16, 40 (80)	56 (40-70)	NR	30 100	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	NR
Chirinos, 2016[57] (Community Health and Risk-reduction for Metabolic Syndrome (CHARMS)) Fair	US Health Care	Multiple risk factors	Low-income adults, age 30 to 70, with metabolic syndrome and BMI ≥25	120	6, 12 (78)	52 (30-70)	56	NR 100	HTN: NR Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: NR	Education, mean: 13 years Income, %: - $20,000-$40,000: 22 - >$40,000: 4
Christian, 2011[58] Fair	US Primary Health Care	Multiple risk factors	Age 18 to 75 with BMI >25 and ≥2 components of the metabolic syndrome	279	12 (94)	50 (18-75)	68	34 100	HTN: NR Dys: NR PreDM: NR DM: 0 CVD: NR Smoking: NR	100% uninsured, Medicaid-eligible, or Medicare 60% at or below 100% of federal poverty level among entire patient population
Cicolini, 2014[59] Fair	Italy Primary Health Care	Hypertension	Adults with treated hypertension	203	3, 6 (98)	59 (NR)	NR	29 NR	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: 62	NR
Cochrane, 2012[60] Fair	UK Primary Health Care	Multiple risk factors	Age 35 to 74 with Framingham 10-year CVD risk ≥20%	601	12 (81)	64 (35-74)	11	28 NR	HTN: NR Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: 53	SES based on IMD deciles: - Deprived, n (%): 282 (48) - Intermediate, n (%): 189 (32) - More affluent, n (%): 112 (19)

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
Cohen, 1991[61] Fair	US Primary Health Care	Hypertension	Age 20 to 75 with BMI ≥27.8 and hypertension	30	6, 12 (100)	60 (20-75)	73	34 100	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	NR
Coleman, 2012[62] (Wisewoman California) Fair	US Health Care	Multiple risk factors	Low-income Hispanic females, age 40 to 64, with hypertension or hypercholesteremia	1093	12 (80)	52 (40-64)	100	32 90	HTN: 45 Dys: 56 PreDM: NR DM: 22 CVD: NR Smoking: 5	Education, %: Some HS, 10 ≥HS, 20
Delahanty, 2001[63] Good	US Primary Health Care	Dyslipidemia	Age 21 to 65 with untreated dyslipidemia	90	3, 6, 12 (97)	49 (21-65)	33	27 NR	HTN: NR Dys: 100 PreDM: NR DM: 0 CVD: NR Smoking: 8	% education < college grad: 33
Eakin, 2009[64] (Logan Healthy Living) Fair	Australia Primary Health Care	Multiple risk factors	Age ≥30 with diabetes or hypertension	434	4, 12, 18 (79)	58 (≥30)	61	31 NR	HTN: 86 Dys: NR PreDM: NR DM: 45 CVD: NR Smoking: 14	% ≥ high school graduate: 45 % retired: 36 % employed: 46
Edelman, 2006[65] Fair	US Primary Health Care	Multiple risk factors	Age ≥45 with one or more CVD risk factors	154	5, 10 (79)	53 (≥45)	80	34 NR	HTN: 38 Dys: NR PreDM: NR DM: 16 CVD: 0 Smoking: 10	Education, n (%): - completed college, 104 (68) Family income, n (%): - $40,000 to $59,999, 16 (10) - >$60,000, 85 (55)
Ellsworth, 2016[66] Fair	US NR	Multiple risk factors	Age ≥18 with any of multiple risk factors	184	12 (80)	61 (34-86)	58	31 85	HTN: 43 Dys: 33 PreDM: NR	NR

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Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
									DM: 24 CVD: 22 Smoking: NR	
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Spain Primary Health Care	Multiple risk factors	Men, age 55 to 80, and women, age 60 to 80, with any of multiple CVD risk factors, who did not score as unlikely to change according to the Stages of Change model	7447	12, 24, 36, 48, 60, 72 (93)	67 (55-80)	43	30 93	HTN: 83 Dys: 72 PreDM: NR DM: 49 CVD: 0 Smoking: 14	Employment status: Working: 13% Housewife: 32% Unemployed: 1% Retired: 52% Education: University graduate: 4% Some college: 4% Secondary education: 16% Primary education: 74% Illiterate: 2%
Fagerberg, 1998[68] (Risk Factor Intervention Study (RIS)) Good (KQ1); Fair (KQ2)	Sweden Mixed	Multiple risk factors	Men, age 50 to 72, with treated hypertension and any of high total cholesterol, diabetes, or current smoking	508	12, 40, 79 (94)	66 (50-72)	0	27 NR	HTN: 100 Dys: 74 PreDM: NR DM: 22 CVD: 13 Smoking: 29	NR
Gill, 2019 [69](Heartmatters Challenge - First Responders) Fair	US Other	Multiple risk factors	Adults, aged 18 to 65, with low HDL or high waist circumference	175	3, 6, 12 (78)	42 (18-65)	NR	32 NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	NR
Gill, 2019[70] (HealtheSteps) Fair	Canada Mixed	Multiple risk factors	Adults, aged 18 to 85 years, with BMI >25 kg/m2 and any of	118	6 (75)	58 (18-85)	79	31 100	HTN: 28 Dys: 28 PreDM: 16 DM: 15	Education, n (%): ≤High school, 35 (30) >High school, 83 (70)

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Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
			multiple risk factors						CVD: NR Smoking: 8	
Greaves, 2015[71] (Waste the Waist) Fair	UK Primary Health Care	Multiple risk factors	Age 40 to 74 with BMI ≥28 and ≥1 additional CV risk factor	108	4, 12 (89)	65 (40-74)	31	33 100	HTN: NR Dys: NR PreDM: 8 DM: 0 CVD: NR Smoking: NR	Education, n (%): - Up to age 16, 50 (46.3) - Up to age 18, 8 (7.4) - Some additional, 23 (21.3) - ≥Undergraduate, 27 (25.0) Area deprivation (Index of Multiple Deprivation [IMD] score): 11.9
Groeneveld, 2010[72] (Health Under Construction) Fair	The Netherlands Health Care	Multiple risk factors	Males in the construction industry, age 18 to 65, with higher than moderate (thresholds not defined) Framingham 10-yr CVD risk and any of multiple risk factors	816	6, 12 (72)	47 (18-65)	0	28 NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: 52	% blue-collar workers (performing the construction vs. white-collar workers involved in admin and supervision): 74
Hardcastle, 2008[73] Fair	UK Primary Health Care	Multiple risk factors	Age 18 to 65 with BMI ≥28, hypertension, or hypercholesterolemia	334	6, 18 (63)	50 (18-65)	67	34 99	HTN: 35 Dys: 57 PreDM: NR DM: NR CVD: NR Smoking: 16	NR
Harris, 2012[74] (Health Improvement and Prevention	Australia Health Care	Multiple risk factors	Age 40 to 55 with hypertension or dyslipidemia; age 56 to 64 with or	814	6, 12 (80)	NR (40-64)	57	29 56	HTN: 9 Dys: 88 PreDM: NR DM: 0	% employed: 68 % tertiary educated (college of technical and further education or university): 47

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
Study (HIPS)) Fair			without recorded risk factors						CVD: 0 Smoking: 13	% Socioeconomic Indexes for Areas score in lowest quintile: 2
Haufe, 2019[75] Fair	Germany Other	Multiple risk factors	Age >18 years with ≥3 of 5 components of metabolic syndrome	314	6 (87.3)	48 (>18)	14	33 NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	Type of work: Manual: 36% Office: 52% Unclassified: 12%
Hinderliter, 2014[76] (Exercise and Nutrition interventions for CardiOvasculaR hEalth (ENCORE)) Good	US Mixed	Hypertension	Age ≥35 with untreated above-normal blood pressure and BMI between 25 and 39.9	95	4,12 (86)	52 (≥35)	66	33 100	HTN: NR Dys: 27 PreDM: NR DM: 0 CVD: 0 Smoking: 8	Education: n (%) High school, 34 (36%) Completed college, 23 (24%) Income: n (%)
HPT, 1990[77] (Hypertension Prevention Trial (HPT)) Good	US Community	Hypertension	Age 25 to 49 with untreated high normal DBP	841	6, 12, 18, 24, 30, 36 (90)	39 (25-49)	35	27 75	HTN: 0 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: 17	College graduate, %: 54
Hyman, 1998[78] Fair	US Health Care	Dyslipidemia	Low-income patients, age 18 to 65, with untreated hypercholesterolemia	123	6 (80)	56 (18-65)	75	31 NR	HTN: NR Dys: 100 PreDM: NR DM: NR CVD: NR Smoking: NR	≤ High school education, %: 89 Income level ≤$1000/month, %: 78
Hyman, 2007[79] Fair	US Primary Health Care	Hypertension	Sedentary African Americans adults, age 45 to 60, with hypertension and current smoking	281	6, 18 (82)	53 (45-65)	67	32 NR	HTN: 100 Dys: NR PreDM: NR DM: 18	Recruited from facility that serves medically indigent, "most" patients ≤100% FPL

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
									CVD: 0 Smoking: 100	
Ives, 1993[80] (Rural Health Promotion Project (RHPP) Trial) Fair	US Community	Dyslipidemia	Residents of rural areas, age 65 to 79, with TC ≥240 mg/dL	1197	30 (77)	71 (65-79)	57	NR NR	HTN: 18 Dys: 100 PreDM: NR DM: 16 CVD: 20 Smoking: 12	Mean education, years: 11 Completed school; 60.1% completed HS or above Mean annual household income: $15,500
Johnston, 1995[81] Fair	Australia Health Care	Dyslipidemia	Adults with elevated total cholesterol	179	2, 6 (73)	57 (24-81)	NR	25 NR	HTN: NR Dys: 100 PreDM: NR DM: 0 CVD: 0 Smoking: NR	NR
Jones, 1999[82] (Hypertension Optimal Treatment (HOT)) Fair	US NR	Hypertension	Age 50 to 80 with BMI ≥27 and hypertension	112	6, 12,18, 24, 30 (91)	58 (50-80)	NR	34 100	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	NR
Kandula, 2015[83] (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	US Community	Multiple risk factors	Asian Indian or Pakistani immigrants, age 30 to 59, with at least one ASCVD risk factor	63	3, 6 (100)	50 (30-59)	64	30 NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: NR	Born outside of the US: 100% Limited English proficiency: 36%
Kanke, 2015[84] Fair	Japan Primary Health Care	Multiple risk factors	Age 30 to 69 with obesity (per Japanese cutpoints) and hypertension, dyslipidemia,	50	6, 12 (80)	55 (30-69)	36	28 100	HTN: 84 Dys: 38 PreDM: NR DM: 16 CVD: NR Smoking: 18	Education n (%): >HS: 14 (28.0%) ≥HS: 36 (72.0%)

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
			and/or type 2 diabetes							
Kastarinen, 2002[85] (Lifestyle Intervention against Hypertension in Eastern Finland (LIHEF)) Fair	Finland Primary Health Care	Hypertension	Age 25 to 74 with hypertension	715	12, 24 (83)	54 (25-74)	53	29 80	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: 4 Smoking: 8	NR
Keyserling, 1997[86] (Southeast Cholesterol Project) Fair	US Health Care	Dyslipidemia	Low-income adults, age 20 to 75, with elevated cholesterol	372	4, 7, 12, 24 (92)	56 (20-75)	67	NR NR	HTN: 60 Dys: 100 PreDM: NR DM: 0 CVD: 10 Smoking: 18	Education, mean grade: 11 Employed full-time, %: 36
Khanji, 2019[87] (HAPPY London) Good	UK Primary Health Care	Multiple risk factors	Age 40 to 74 with QRISK2 10-year CVD risk score ≥10%	402	6 (93.8)	65 (40-74)	37	28 NR	HTN: NR Dys: NR PreDM: NR DM: 14 CVD: 0 Smoking: 8	NR
Koelewijn-van Loon, 2009[88] (Improving Patient Adherence to Lifestyle Advice (IMPALA)) Fair	The Netherlands Primary Health Care	Multiple risk factors	Adults with one or more CVD risk factors	615	3, 12 (79)	57 (NR)	55	29 NR	HTN: 65 Dys: 43 PreDM: NR DM: 14 CVD: 0 Smoking: 26	SES level, n (%): -High, 134 (23) -Intermediate, 228 (39) -Low, 204 (35)
Kramer, 2018[89] (Healthy Lifestyle	US Community	Multiple risk factors	Age ≥18 with any of multiple risk factors	134	6 (92)	62 (28-88)	67	34 100	HTN: NR Dys: NR PreDM: NR	Median income for the three communities: $62,058

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
Project) Fair									DM: 0 CVD: NR Smoking: NR	$45,099 $38,811
Lakerveld, 2013[90] (HOORN) Fair	The Netherlands Primary Health Care	Multiple risk factors	Age 30 to 50 with any of multiple CVD risk factors	622	6, 12, 24 (81)	44 (30-50)	58	29 NR	HTN: NR Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: 21	% employed: 85 % below average income: 37 % average income: 18 % above average income: 30 % ≤ primary education: 23 % secondary education: 46 % college/university: 21
Langford, 1991[91] (Trial of Antihypertensive Interventions and Management (TAIM)) Fair	US Mixed	Hypertension	Age 21 to 65 at 110-160% of ideal body weight and untreated hypertension	878	6 (90)	49 (21-65)	44	NR 100	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: 16	% employed (FT or PT): 79 % education ≥college: 61
Lee, 2007[92] Fair	Taiwan Other	Hypertension	Older adults, age ≥60, with hypertension	202	6 (91)	71 (≥60)	42	25 NR	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: 22	Education level: 4-7 yrs: 39% >7 yrs: 18%
Liira, 2014[93] Fair	Finland Mixed	Multiple risk factors	Sedentary men, age 35 to 45, with at least 2 CVD risk factors	114	3, 12 (77)	40 (35-45)	0	NR NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	NR
Migneault, 2012[94] Fair	US Health Care	Hypertension	African-American adults, age ≥35,	337	4, 8, 12 (77)	56 (≥35)	70	34 NR	HTN: 100 Dys: NR PreDM: NR	Median household income: 10-20k/year % Employed full or part-time:

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
			with treated hypertension						DM: 38 CVD: 8 Smoking: NR	39.7 Education, mean years: 12.2
Moreau, 2001[95] Fair	US NR	Hypertension	Postmenopausal women, age 52 to 56, with borderline to stage 1 hypertension	24	3, 6 (100)	54 (53-55)	100	NR NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: 0	NR
Moy, 2001[96] Fair	US Health Care	Multiple risk factors	Siblings of persons with CHD onset prior to age 60, age 30 to 59, with elevated LDL, hypertension, or current smoking	235	24 (76)	46 (30-59)	48	29 NR	HTN: 57 Dys: 79 PreDM: NR DM: NR CVD: NR Smoking: 46	Education, mean years: 12
Muhlhauser, 1993[97] (Hypertension Treatment and Teaching Program (HTTP)) Fair	Germany Primary Health Care	Hypertension	Age 30 to 60 with hypertension	200	18 (80)	51 (30-60)	NR	NR NR	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	NR
Murphy, 2012[98] (National Exercise Referral Scheme (NERS)) Fair	UK Health Care	Multiple risk factors	Age >16 with ≥1 CHD risk factors or a mental health condition and sedentary	2160	12 (68)	52 (16-88)	66	NR NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	Welsh deprivation index: % low: 35 % mild: 34 % high: 31 Education beyond min school leaving age, %: 52.7 Employment: % Employed: 31

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
										% Retired: 34 % Housework: 19 % Other: 16 % Missing: 0
Neil, 1995[99] Fair	UK Primary Health Care	Dyslipidemia	European adults, age 35 to 64, with untreated hypercholesterolemia	309	6 (97)	55 (35-64)	47	26 59	HTN: NR Dys: 100 PreDM: NR DM: NR CVD: NR Smoking: 22	NR
Niiranen, 2014[100] Fair	Finland Primary Health Care	Hypertension	Age 35 to 74 with hypertension	229	12 (96)	62 (35-74)	50	28 NR	HTN: 100 Dys: 43 PreDM: NR DM: 11 CVD: NR Smoking: 11	>8 yrs education: 38%
Nolan, 2018[101] (Reducing Risk with E-based Support for Adherence to Lifestyle Change in Hypertension (REACH)) Fair	Canada Other	Hypertension	Age 35 to 74 with hypertension	264	4, 12 (74)	58 (35-74)	58	31 NR	HTN: 100 Dys: NR PreDM: NR DM: 7 CVD: 5 Smoking: 9	Mean years education: 16
Ogedegbe, 2014[102] (Counseling African Americans to Control Hypertension	US Health Care	Hypertension	Black adults, age ≥18, with treated, uncontrolled hypertension	1039	3, 6, 9, 12 (71)	56 (≥18)	72	33 86	HTN: 100 Dys: NR PreDM: NR DM: 36 CVD: 9 Smoking: 51	Education: ≤HS: 72% Some college: 26% Some graduate school: 2% Annual household income < $20k: 72%

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
(CAATCH)) Fair										Employment status: Unemployed: 11% Retired or homemaker: 55% Employed part time: 14% Employed full time: 20%
Reid, 2014[103] Fair	Canada Health Care	Multiple risk factors	Family members of patients with CAD with ≥1 modifiable risk factor	426	3, 12 (74)	52 (NR)	61	29 NR	HTN: NR Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: 9	Education, mean years: 14.7
Rodriguez, 2012[104] Fair	US Primary Health Care	Hypertension	Veterans, age ≥21, with treated uncontrolled hypertension	533	6, 12 (90)	66 (≥21)	1	30 NR	HTN: 100 Dys: 24 PreDM: NR DM: 44 CVD: 13 Smoking: 19	Employed full-time, %: 14 Employed (unspecified), %: 21 College graduate, %: 22 ≤High school graduate, %: 46
Rodriguez-Cristobal, 2012[105] Fair	Spain Primary Health Care	Multiple risk factors	Age 30 to 75, with elevated fibrinogen levels and estimated moderate or high Framingham CHD risk (thresholds not defined)	436	24 (69)	58 (30-75)	63	30 NR	HTN: 42 Dys: NR PreDM: NR DM: 14 CVD: 0 Smoking: 29	NR
Rosas, 2015[106] (Vivamos Activos Fair Oaks (VAFO)) Good	US Health Care	Multiple risk factors	Latino adults, age ≥18, with BMI 30-60 and 1 or more additional CHD risk factors	207	6, 12, 24 (84)	47 (≥18)	77	36 100	HTN: NR Dys: NR PreDM: NR DM: 43 CVD: NR Smoking: NR	Food insecure, %: 51 Education n (%): ≤8th grade: 140 (67.6%) Some HS: 24 (11.3%) ≥HS: 43 (20.8%)

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
										Employment status n (%) Employed: 97 (46.9%) Unemployed: 21 (10.1%) Not working: 89 (43.0%) Annual income n (%): < $10,000: 58 (28.0%) $10,000 - $20,000: 92 (44.4%) > $20,000: 56 (27.1%)
Rubinstein, 2016[107] Good	Argentina Mixed	Hypertension	Latino adults, age 30 to 60, with untreated prehypertension	212	12 (90)	43 (30-60)	54	29 NR	HTN: 0 Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: 19	Years education, mean: 11 Employment status: Employee: 42% Independent worker: 29% Housewife: 25% Other: 4% Income: First quintile: 9% Fifth quintile: 23%
Salisbury, 2016[108] Good	UK Primary Health Care	Multiple risk factors	Age 40 to 74 with 10 year CVD risk ≥20% and any of: SBP ≥140 mm Hg, BMI ≥30, or current smoking	641	6, 12 (91)	67 (40-74)	20	31 NR	HTN: NR Dys: NR PreDM: NR DM: 22 CVD: NR Smoking: 18	Employment status: Full time: 15% Part time: 11% Unemployed: 1% Unable to work: 2% Retired: 65% Homemaker: 1% Other: 4% College degree or higher: 22%

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
Schoenthaler, 2016[109] (Individual Motivational Interviewing - Therapeutic Lifestyle Changes (MINT-TLC)) Fair	US Primary Health Care	Hypertension	Black adults, age ≥18, with hypertension	194	1, 3, 6 (80)	57 (≥18)	50	33 NR	HTN: 100 Dys: NR PreDM: NR DM: 44 CVD: 14 Smoking: 18	Highest degree or level of education: < HS: 19% HS diploma/GED: 47% ≥ Some college: 34% Current employment status: Employed/self-employed: 27% Retiree: 20% On disability: 14% Unemployed/not working: 39% Annual income < $20k: 69%
Scott, 2018[110] Fair	UK Other	Multiple risk factors	Age ≥18 with any of multiple risk factors and completed previous exercise referral program	37	3, 6 (94)	59 (≥18)	43	NR 94	HTN: NR Dys: NR PreDM: NR DM: NR CVD: 6 Smoking: NR	Employment: Full-time: 6% Part-time: 17% Full-time caregiver: 6% Unemployed: 11% Incapacity benefit: 14% Retired: 46%
Soto Rodriguez, 2016[111] Fair	Spain Health Care	Multiple risk factors	Women, age 45 to 60, with any of diabetes, dyslipidemia, or hypertension	320	12 (72)	53 (45-60)	100	27 NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	NR
Stefanick, 1998[112] (Diet and Exercise for Elevated Risk (DEER)) Fair	US Mixed	Dyslipidemia	Postmenopausal women, age 45 to 64, and men, aged 30 to 64, with untreated dyslipidemia or	189	12 (98)	52 (30-64)	49	27 NR	HTN: NR Dys: 100 PreDM: NR DM: 0 CVD: 0 Smoking: NR	NR

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
			mildly elevated lipids							
Stevens, 2003[113] Fair	US Health Care	Dyslipidemia	Women, aged 40 to 70, with dyslipidemia	616	12 (87)	54 (40-70)	100	30 NR	HTN: NR Dys: 100 PreDM: NR DM: NR CVD: NR Smoking: NR	% college grad or more: 40
Svetkey, 2008[114] (Weight Loss Maintenance (WLM)) Good	US Mixed	Multiple risk factors	Age ≥25 with previous weight loss and pharmacologically treated for hypertension and/or dyslipidemia	1032	12, 18, 24, 30, 60 (95)	56 (28-83)	63	34 100	HTN: NR Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: NR	Household income/y: ≥$60,000: 57.4% Education: ≤Some college: 38.4% College degree: 61.6%
Svetkey, 2009[115] (Hypertension Improvement Project (HIP)) Fair	US Primary Health Care	Hypertension	Age ≥25 with hypertension	574	6, 18 (88)	60 (28-94)	61	32 NR	HTN: 97 Dys: 48 PreDM: NR DM: 30 CVD: 16 Smoking: 9	% % inadequate income: 15
Ter Bogt, 2009[116] (Groningen Overweight and Lifestyle (GOAL)) Good	The Netherlands Primary Health Care	Multiple risk factors	Age 40 to 70 with BMI 25-40 and hypertension or dyslipidemia	457	12, 36 (91)	56 (40-70)	52	30 100	HTN: 62 Dys: 39 PreDM: NR DM: 0 CVD: NR Smoking: 19	% low education: 32
Tiessen, 2012[117] (SPRING (Self-monitoring and Prevention of	The Netherlands Primary Health Care	Multiple risk factors	Age 50 to 75 with any of multiple CVD risk factors	201	12 (89)	65 (50-75)	31	28 NR	HTN: 76 Dys: 79 PreDM: NR DM: 0	% no education or primary education: 10 % lower secondary education: 42

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
RIsk Factors by Nurse practitioners in the region of Groningen)) Fair									CVD: 0 Smoking: 32	% higher secondary education: 27 % college or university: 22
Toft, 2008[118] (Inter99) Fair	Denmark Research Center	Multiple risk factors	Age 30 to 60 with any of multiple CVD risk factors	4053	12, 36, 60 (64)	47 (30-60)	51	27 NR	HTN: NR Dys: NR PreDM: NR DM: 11 CVD: NR Smoking: 59	% employed: 83 % no vocational education: 19
TOHP I CRG, 1992[119] (Trials of Hypertension Prevention Phase I (TOHP I)) Good	US Research Center	Hypertension	Overweight or obese adults age 30 to 54 with prehypertension	1224	3, 6, 12, 18, 192 (93)	43 (30-54)	28	28 100	HTN: 0 Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: 12	College graduates: 54% FT employment: 92%
TOHP II CRG, 1997[120] (Trial of Hypertension Prevention II (TOHP II)) Good	US Mixed	Hypertension	Age 30 to 54 with untreated prehypertension and 110 to 165% of ideal body weight	2382	6, 18, 36, 48 (88)	44 (30-54)	34	NR	HTN: 0 Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: 9	Education: Some college: 35% College graduate: 21% Postgraduate: 30% Employed full time: 88%
Tomson, 1995[121] Fair	Sweden Primary Health Care	Dyslipidemia	Age 25 to 54 with dyslipidemia	92	12 (83)	42 (25-54)	NR	25 NR	HTN: 0 Dys: 100 PreDM: NR DM: 0 CVD: 0 Smoking: 54	NR

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
van der Veen, 2002[122] (Nijmegen Family Practices Monitoring Project (NFPMP)) Fair	The Netherlands Primary Health Care	Dyslipidemia	Age 40 to 70 with dyslipidemia, high dietary fat intake, and hypertension or diabetes	143	6, 12 (91)	58 (40-70)	73	29 NR	HTN: 92 Dys: 100 PreDM: NR DM: 6 CVD: 0 Smoking: 22	Education, %: - Low, 68 - Intermediate, 19 - High, 14
van Keulen, 2011[123] (Vitalum) Fair	The Netherlands Primary Health Care	Hypertension	Age 45 to 70 with or without hypertension, not meeting Dutch diet and PA guidelines	1629	6, 11, 17 (74)	57 (45-70)	45	27 67	HTN: 52 Dys: NR PreDM: NR DM: 10 CVD: NR Smoking: 22	% low education: 54 % with paying job: 48
van Sluijs, 2005[124] (Physician-based Assessment and Counseling for Exercise (PACE)) Fair	The Netherlands Primary Health Care	Multiple risk factors	Age 18 to 70 with hypertension, hypercholesterolemia, or non-insulin dependent diabetes	358	2, 6, 12 (86)	56 (18-70)	49	29 NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: NR Smoking: 25	% low level of education: 36 % medium level of education: 43 % high level of education: 20 % employed full time: 30 % employed part time: 24 % unemployed: 46 (but average age is 55, unclear how many of these retired)
Viglione, 2019[125] (Goals for Eating and Moving (GEM)) Fair	US Primary Health Care	Multiple risk factors	Veterans, age 18 to 69, with obesity or overweight and multiple risk factors	45	3, 6, 12 (84.4)	54 (18-69)	33	NR NR	HTN: 40 Dys: 28 PreDM: NR DM: NR CVD: NR Smoking: NR	Annual household income: <$24,999: 27% $25,000-49,999: 29% $50,000-99,000: 31% $≥100,000: 9% Household food security: Food secure: 72% Food insecure: 21% Hunger: 7%

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
Voils, 2013[126] (CouPLES) Fair	US Primary Health Care	Dyslipidemia	Veterans with dyslipidemia and their spouses	255	6, 11 (89)	61 (NR)	NR	NR	HTN: NR Dys: 100 PreDM: NR DM: NR CVD: NR Smoking: NR	≤High School 24%; FT employment 41%
Wadden, 2011[127] (Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-UP)) Good	US Primary Health Care	Multiple risk factors	Age ≥21 with obesity and two or more CVD risk factors	261	6, 12, 18, 24 (85)	52 (≥21)	80	39 100	HTN: 71 Dys: 66 PreDM: NR DM: 21 CVD: 0 Smoking: 10	Education n (%): Less than HS: 5.7% HS: 19.9% Some college/associate's: 35.6% BA: 21.0% Graduate/professional degree: 17.6%
Whelton, 1998[128] (Trial of Nonpharmacologic Interventions in the Elderly (TONE)) Good	US Mixed	Hypertension	Age 60 to 80 with treated hypertension	975	36 (92)	66 (60-80)	48	29 NR	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: 5	No. (%) ≥11th grade: 107 (11) No. (%) College grad: 322 (33) No. (%) Unemployed: 29 (3) No. (%) Retired: 575 (59)
Wister, 2007[129] Good	Canada Mixed	Multiple risk factors	Age 45 to 64 with 10-yr CVD risk ≥10% based on Framingham risk score	315	12 (88)	55 (45-64)	58	32 NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: 13	NR
Wong, 2015[130] Good	Hong Kong Mixed	Hypertension	Age 40 to 70 with untreated newly-diagnosed Grade I hypertension	556	6, 12 (87)	55 (40-70)	51	24 NR	HTN: 100 Dys: NR PreDM: NR DM: 0	Employment: % unemployed: 43 % employed: 57

Appendix F Table 1. Population Characteristics

Author, year (Study name) Quality	Country Recruitment setting	Population risk focus	Population description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
									CVD: NR Smoking: 9	Monthly household income: % on comprehensive social security assistance: 2 % % $1290-2579: 24 % $2580-3869: 19 % $3870-5159: 18 % ≥$5160: 25 Education: % illiterate/kindergarten/primary: 19 % secondary: 64 % ≥undergraduate: 15 % other:
Wood, 2008[131] (EUROACTION) Fair	Europe (6 countries) Primary Health Care	Multiple risk factors	Age 50 to 80 with 10-yr SCORE CVD risk score ≥5%	2385	12 (85)	62 (50-80)	NR	NR	HTN: 63 Dys: 75 PreDM: NR DM: 30 CVD: 0 Smoking: 31	NR

Abbreviations: ASCVD = atherosclerotic cardiovascular disease; BMI = body mass index; CAD = coronary artery disease; CHD = coronary heart disease; CVD = cardiovascular disease; DBP = diastolic blood pressure; DM = diabetes mellitus; Dys = dyslipidemia; F/U = followup; FPL = federal poverty line; GED = general education diploma; HMO = health management organization; HS = high school; HTN = hypertension; LDL = low-density lipoprotein cholesterol; mg/dL = milligrams per deciliter; mm Hg; millimeters of mercury; N rand = number of participants randomized; No. = number; NR = not reported; PA = physical activity; PHPP = Patient-motivated Health Promotion Program; PREDIMED = Primary Prevention of Cardiovascular Disease with a Mediterranean Diet; PreDM = prediabetes mellitus; SBP = systolic blood pressure; TC = total cholesterol; yrs = years

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Ammerman, 2003[38] Fair	IG1	HD	7 sessions of dietary counseling (3 nurse sessions, 1 phone call, 3 nutritionist visits [if referred]) and 2 newsletters Total duration: 12 months	Total: 9 Interactive: 7 Other: 2 Est Tot Hr: 3.2 Category: Medium	Low-fat NR	Indiv	In-person Phone Print		None (No)	Nurse, nutritionist Health department	UC
Anderson, 1992[39] Fair	IG1	HD	10 60-min group dietary counseling sessions (high fiber diet) with 30-min individual dietitian consultation; 4 home visits (min NR); 12 monthly phone calls (min NR) Total duration: 12 months	Total: 26 Interactive: 26 Other: 0 Est Tot Hr: 20 Category: High	Low-fat Not promoted	Indiv Group	In-person Phone		None (No)	Dietitian, project staff NR, home	UC
Anderson, 1992[39] Fair	IG2	HD	10 60-min group dietary counseling sessions (AHA Diet) with 30-min individual dietitian consultation; 4 home visits (min NR); 12 monthly phone calls (min NR) Total duration: 12 months	Total: 26 Interactive: 26 Other: 0 Est Tot Hr: 20 Category: High	Low-fat Not promoted	Indiv Group	In-person Phone		None (No)	Dietitian, project staff NR, home	UC
Anderssen, 1995[40] (Oslo Diet and Exercise Study (ODES)) Fair	IG1	HD	3 individual sessions diet counseling Total duration: 9 months	Total: 3 Interactive: 3 Other: 0 Est Tot Hr: 1.5 Category: Medium	Low-fat Low sodium Promoted for all participants	Indiv Family	In-person		NR (NR)	NR	WL
Appel, 2003[41](PREMIER) Good	IG1	HD + PA	33 DASH diet and physical activity counseling, including 26 90-120 min group counseling sessionsand 7 30-60 min individual sessions using motivational interviewing Total duration: 18 months	Total: 33 Interactive: 33 Other: 0 Est Tot Hr: 59 Category: High	DASH Low sodium Promoted for subset of participants	Indiv Group	In-person Print	X	None (No)	Master's degree-level counselors (dietitians and health educators trained in behavioral methods) Clinical centers	UC
Appel, 2003[41](PREMIER	IG2	HD + PA	33 sessions of low sodium diet and physical activity	Total: 33 Interactive: 33	Low sodium Promoted for	Indiv Group	In-person Print	X	None (No)	Master's degree-level counselors	UC

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
) Good			counseling, including 26 90-120 min group counseling sessions and 7 30-60 min individual sessions using motivational interviewing Total duration: 18 months	Other: 0 Est Tot Hr: 59 Category: High	subset of participants					(dietitians and health educators trained in behavioral methods) Clinical centers	
Appel, 2011[42] (POWER Hopkins (Practice Based Opportunities for Weight Reduction)) Good	IG1	HD + PA	30 group counseling sessions (90 min), 12 individual counseling sessions (20 min), 15 phone sessions (20 min) + PCP counseling at routine visits, weekly web-based modules, and monthly e-mail messages Total duration: 24 months	Total: 58 Interactive: 58 Other: 0 Est Tot Hr: 54 Category: High	DASH Promoted for all participants	Indiv Group	In-person Tech-based Phone	X	Deliver part (NR)	Lifestyle coach Research clinic and home (web-based)	UC
Appel, 2011[42] (POWER Hopkins (Practice Based Opportunities for Weight Reduction)) Good	IG2	HD + PA	33 lifestyle behavioral coaching calls (20 min), weekly web-based modules, PCP counseling at routine visits Total duration: 24 months	Total: 34 Interactive: 34 Other: 0 Est Tot Hr: 11 Category: High	DASH Promoted for all participants	Indiv	Tech-based Phone	X	Deliver part (NR)	PCP, lifestyle coach Home (web-based)	UC
Applegate, 1992[43] Fair	IG1	HD + PA	12 group and 2 individual sessions of weight management, sodium restriction, and PA counseling Total duration: 6 months	Total: 14 Interactive: 14 Other: 0 Est Tot Hr: 13 Category: High	Low sodium Promoted for all participants	Indiv Group	In-person		None (No)	Registered dietitians Clinic	None
Arroll, 1995[44] Fair	IG1	HD + PA	Advised to exercise, reduce salt intake. Number/duration of sessions NR. Total duration: 6 months	Total: Interactive: Other: 0 Est Tot Hr: Category: Low	Low sodium NR	Indiv	In-person Print		NR (NR)	Research staff and GP "community setting"	Min
Arroll, 1995[44] Fair	IG2	PA	Advised to walk briskly 40mins, 3 days per week.	Total: Interactive:	NR	Indiv	In-person Print		NR (NR)	Research staff and GP	Min

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
			Number/duration of sessions NR Total duration: 6 months	Other: 0 Est Tot Hr: Category: Low						"community setting"	
Arroll, 1995[44] Fair	IG3	HD	Advised to decrease salt intake. Number/duration sessions NR. Total duration: 6 months	Total: Interactive: Other: 0 Est Tot Hr: Category: Low	Low sodium NR	Indiv	In-person Print		NR (NR)	Research staff and GP "community setting"	Min
Babazono, 2007[45] (PHPP) Fair	IG1	HD + PA	3 sessions of diet and physical activity counseling (length of sessions: NR), 1 at health center and 2 at home Total duration: 12 months	Total: 3 Interactive: 3 Other: 0 Est Tot Hr: 3 Category: Medium	NR	Indiv	In-person		None (No)	Dietitians, health exercise instructors, public health nurses Medical center, home visits	UC
Beckmann, 1995[46] Fair	IG1	HD	5 in-person individual dietary counseling sessions Total duration: 12 months	Total: 5 Interactive: 5 Other: 0 Est Tot Hr: 2.5 Category: Medium	Low-fat Low sodium Promoted for subset of participants	Indiv	In-person		None (No)	Nutritionist Outpatient clinic	WL
Bennett, 2012[47] (Be Fit, Be Well [POWER]) Good	IG1	HD + PA	18 tailored diet, physical activity and lifestyle counseling calls (20 min each); 12 optional group sessions; PCP endorsement message; and self-monitoring using study website or interactive voice response system Total duration: 24 months	Total: 31 Interactive: 30 Other: 0 Est Tot Hr: 18 Category: High	Promoted for all participants	Indiv Group	In-person Tech-based Phone Print	X	Deliver part (Yes)	Community health educator and PCP endorsement Home (web-based or print and phone) and community health center	UC
Bennett, 2018[48] (Track) Good	IG1	HD + PA	18 10-15 min telephone coaching sessions of diet and physical activity counseling, 3 PCP 2 min weight counseling visits, 52 2-3 min IVR calls Total duration: 12 months	Total: 73 Interactive: 21 Other: 0 Est Tot Hr: 5.4 Category: Medium	Promoted for all participants	Indiv	In-person Tech-based Phone Print	X	Deliver part (Yes)	PCP, dietitian, psychology graduate students Primary care and home (coaching calls)	UC

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Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Beune, 2014[49] (Culturally Adapted Hypertension Education (CAHE)) Fair	IG1	HD + PA	3 30-min sessions of medication and lifestyle counseling and culturally-specific written materials Total duration: 4.5 months	Total: 3 Interactive: 3 Other: 0 Est Tot Hr: 1.5 Category: Medium	NR	Indiv	In-person Print		None (Yes)	Practice Nurse Primary care	UC
Blackford, 2016[50] (Albany Physical Activity and Nutrition (APAN)) Fair	IG1	HD + PA	6 motivational interviewing telephone calls, 3 newsletters, and website access Total duration: 6 months	Total: 9 Interactive: 6 Other: 0 Est Tot Hr: 1.5 Category: Medium	NR	Indiv	Tech-based Phone Print	X	None (No)	Research assistants Home	WL
Bloemberg, 1991[51] Fair	IG1	HD	1 session of dietary counseling, 2 phone calls, and 5 mailers Total duration: 6 months	Total: 8 Interactive: 3 Other: 5 Est Tot Hr: 1 Category: Medium	Low-fat NR	Indiv	In-person Phone Print		None (No)	Dietitian NR	None
Bo, 2007[52] Fair	IG1	HD + PA	5 sessions of diet and physical activity counseling (1 60-min individual session and 4 60-min interactive group sessions) and printed materials Total duration: 12 months	Total: 5 Interactive: 5 Other: 0 Est Tot Hr: 5 Category: Medium	NR Promoted for subset of participants	Indiv Group	In-person Print		None (Yes)	Nutritionists, specialists in endocrinology, and internal medicine Assumed health clinic	UC
Bosworth, 2009[53] (Take Control of Your Blood pressure (TCYB)) Fair	IG1	HD + PA	12 16-min phone sessions of diet and physical activity counseling and self-administered blood pressure monitoring three times per week Total duration: 24 months	Total: 12 Interactive: 12 Other: 0 Est Tot Hr: 3.2 Category: Medium	DASH Low sodium Promoted for subset of participants	Indiv	Phone		None (No)	Nurse Home	UC
Bosworth, 2009[53] (Take Control of Your Blood	IG2	HD + PA	12 16-min phone sessions of diet and physical activity counseling Total duration: 24 months	Total: 12 Interactive: 12 Other: 0	DASH Low sodium Promoted for	Indiv	Phone		None (No)	Nurse Home	UC

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
pressure (TCYB)) Fair				Est Tot Hr: 3.2 Category: Medium	subset of participants						
Broekhuizen, 2012[54] (PRO-FIT) Fair	IG1	HD + PA	1 in-person individual lifestyle counseling session (time, NR), 5 (time, NR) counsellor-initiated booster phone calls, and access to computer-tailored PRO-FIT*advice Total duration: 11 months	Total: 6 Interactive: 6 Other: 0 Est Tot Hr: 2.2 Category: Medium	NR	Indiv	In-person Tech-based Phone	X	None (No)	Trained lifestyle coach Participants' home	UC
Bruckert, 2008[55] (PEGASE (Effect of an Education Program)) Fair	IG1	HD + PA	6 sessions of diet and physical activity counseling (4 45-min group sessions, 2 in-person individual sessions) and educational pamphlets Total duration: 6 months	Total: 6 Interactive: 6 Other: 0 Est Tot Hr: 4 Category: Medium	NR	Indiv Group	In-person Print		None (No)	Physician, nurse, nutritionist Medical centers specializing in CVD prevention	UC
Burke, 2006[56] (ADAPT) Fair	IG1	HD + PA	6 group sessions of diet and physical activity counseling accompanied by 5 printed modules and 4 newsletters Total duration: 16 months	Total: 10 Interactive: 6 Other: 4 Est Tot Hr: 6 Category: Medium	DASH Promoted for all participants	Indiv Group Family	In-person Phone Print		None (No)	Dietitian, program coordinators Medical center	AC
Chirinos, 2016[57] (Community Health and Risk-reduction for Metabolic Syndrome (CHARMS)) Fair	IG1	HD + PA	17 (90-min) diet and physical activity group counseling sessions Total duration: 12 months	Total: 17 Interactive: 17 Other: 0 Est Tot Hr: 25.5 Category: High	DPP Promoted for all participants	Group	In-person		None (No)	Master and doctoral level clinicians Research clinic	UC
Christian, 2011[58] Fair	IG1	HD + PA	2 computer assessments (10 min) and 2 physician motivational feedback sessions (15 min) Total duration: 6 months	Total: 4 Interactive: 2 Other: 0 Est Tot Hr: 0.8 Category: Medium	NR Promoted for all participants	Indiv	In-person Tech-based Print	X	Deliver all/most (Yes)	Computer expert system and PCP Community health center	UC

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Cicolini, 2014[59] Fair	IG1	HD + PA	1 60-min (NR type of session) educational session on healthy lifestyle and hypertension management; 26 weekly email messages; two booklets Total duration: 6 months	Total: 27 Interactive: 1 Other: 0 Est Tot Hr: 1 Category: Medium	Low sodium NR	Indiv	Tech-based Phone Print		None (NR)	Nurse care manager Home	UC
Cochrane, 2012[60] Fair	IG1	HD + PA	Health check plus 1 individual 45-60 min lifestyle counseling/motivational interviewing session with lifestyle coach, with additional maximum of 6 hours of support offered over 6 months. Total duration: 12 months	Total: 6 Interactive: 6 Other: 0 Est Tot Hr: 3.5 Category: Medium	NR Promoted for subset of participants	Indiv	In-person Phone	X	None (No)	Lifestyle coach Medical center	Min
Cohen, 1991[61] Fair	IG1	HD	12 monthly diet counseling visits with family practice resident Total duration: 12 months	Total: 12 Interactive: 12 Other: 0 Est Tot Hr: 6 Category: Medium	NR Promoted for all participants	Indiv	In-person		Deliver all/most (Yes)	Family practice resident Primary care	UC
Coleman, 2012[62] (Wisewoman California) Fair	IG1	HD + PA	3 in-person individual sessions of diet and physical activity counseling (averaged 50 min each), 3 phone calls and printed handouts Total duration: 6 months	Total: 6 Interactive: 6 Other: 0 Est Tot Hr: 3.2 Category: Medium	NR	Indiv	In-person Phone Print		None (No)	Bilingual (English/Spanish) community health workers (from same community as participants) medical center (4 sites)	UC
Delahanty, 2001[63] Good	IG1	HD + PA	6 individual sessions of diet and physical activity counseling Total duration: 6 months	Total: 4 Interactive: 4 Other: 0 Est Tot Hr: 4 Category: Medium	Low-fat Promoted for subset of participants	Indiv	In-person		Deliver part (Yes)	Registered dietitian Medical center	UC

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Eakin, 2009[64] (Logan Healthy Living) Fair	IG1	HD + PA	18 (average 18-min) sessions of diet and physical activity telephone counseling and 1 workbook Total duration: 12 months	Total: 19 Interactive: 18 Other: 1 Est Tot Hr: 5.4 Category: Medium	Low-fat NR	Indiv	Phone Print	X	None (No)	Graduate-level counselors Home	Min
Edelman, 2006[65] Fair	IG1	HD + PA	52 total sessions of diet, physical activity, and mind-body approaches to reduce CVD risk (28 120-min group sessions, 24 20-30 min individual sessions) Total duration: 10 months	Total: 52 Interactive: 52 Other: 0 Est Tot Hr: 68 Category: High	NR	Indiv Group	In-person Phone		None (No)	Master's level trained health coaches, nutritionists, physician, physician assistant Academic "integrative" medical center	UC
Ellsworth, 2016[66] Fair	IG1	HD + PA	22 diet and physical activity counseling sessions (1 240-min orientation session, 3 individual counseling sessions with each of registered dietitian, exercise physiologist, stress management instructor, and psychologist (time NR); 9 individual counseling sessions with integrative health coach (time NR)) Total duration: 12 months	Total: 22 Interactive: 22 Other: 0 Est Tot Hr: 20.5 Category: High	Mediter NR	Indiv	In-person		None (No)	Registered dietitian, exercise physiologist, stress management instructor, psychologist, and integrative health coach NR	UC
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet	IG1	HD	21 sessions of diet counseling (1 individual session with dietitian, 20 sessions with individual motivational interview and group session), print materials (shopping list,	Total: 21 Interactive: 21 Other: 0 Est Tot Hr: 30.5 Category: High	Mediter Not promoted	Indiv Group	In-person Print	X	None (No)	Registered dietitians Primary care centers, university health care centers, hospitals	Min

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
(PREDIMED)) Fair			weekly meal plans, recipes), and 20 15-liter allotments of extra-virgin olive oil Total duration: 60 months								
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	IG2	HD	21 sessions of diet counseling (1 individual session with dietitian, 20 sessions with individual motivational interview and group session), print materials (shopping list, weekly meal plans, recipes), and 20 quarterly allotments of mixed nuts (2700-3700g) Total duration: 60 months	Total: 21 Interactive: 21 Other: 0 Est Tot Hr: 30.5 Category: High	Mediter Not promoted	Indiv Group	In-person Print	X	None (No)	Registered dietitians Primary care centers, university health care centers, hospitals	Min
Fagerberg, 1998[68] (Risk Factor Intervention Study (RIS)) Good (KQ1) ; Fair (KQ2)	IG1	HD + PA	7 sessions of diet and physical activity counseling (1 group informational session, five weekly 2-hr group sessions, and 1 session individual followup). For smokers, an additional 6 smoking cessation sessions offered Total duration: 4 months	Total: 7 Interactive: 7 Other: 0 Est Tot Hr: 11.5 Category: High	Low-fat Promoted for subset of participants	Indiv Group Family	In-person		None (No)	Physician, nurses, and dietitian Hypertension outpatient clinic	UC
Gill, 2019[69] (Heartmatters Challenge - First Responders) Fair	IG1	HD + PA	30 20-min telephone lifestyle coaching Total duration: 12 months	Total: 30 Interactive: 30 Other: 0 Est Tot Hr: 10 Category: High	DASH Mediter Promoted for subset of participants	Indiv	Tech-based Phone		None (No)	Registered dietitian Home	Min
Gill, 2019[70] (HealtheSteps) Fair	IG1	HD + PA	4 in-person individual sessions of diet and physical activity counseling (4 35-min	Total: 4 Interactive: 4 Other: 0	NR	Indiv	In-person Tech-based		None (No)	Health coach Primary care community clinic sites	WL

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Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
			sessions), print materials, and health technology tools and resources (e.g., phone coaching, online HealtheSteps social network, smartphone app, HealtheSteps website) Total	Est Tot Hr: 2.3 Category: Medium			Phone Print				
Greaves, 2015[71] (Waste the Waist) Fair	IG1	HD + PA	4 2-hr group sessions of diet and physical activity counseling, 5 90-min group maintenance support sessions, and intervention handbook Total duration: 9 months	Total: 9 Interactive: 9 Other: 0 Est Tot Hr: 15.5 Category: High	Low-fat Promoted for all participants	Group	In-person Print	X	None (No)	Lifestyle coach Community	UC
Groeneveld, 2010[72] (Health Under Construction) Fair	IG1	HD + PA	7 sessions of diet and PA for weight loss or smoking counseling (4 45-60 min in-person counseling sessions and 3 15-30 min telephone counseling sessions) Total duration: 6 months	Total: 7 Interactive: 7 Other: 0 Est Tot Hr: 5.5 Category: Medium	Promoted for subset of participants	Indiv Family	In-person Phone Print	X	None (No)	Occupational physicians and occupational nurses in the role of lifestyle counselors Ocupational health clinic	UC
Hardcastle, 2008[73] Fair	IG1	HD + PA	1 20-30 min motivational interviewing session of diet and/or physical activity change and up to 4 optional 20-30 min MI sessions (average 2.0 sessions) Total duration: 6 months	Total: 2 Interactive: 2 Other: 0 Est Tot Hr: 1 Category: Medium	NR	Indiv	In-person Print	X	None (No)	Physical activity specialist and a registered dietician Primary care	UC
Harris, 2012[74] (Health Improvement and Prevention Study (HIPS)) Fair	IG1	HD + PA	1 brief session with PCP, then 2 individual sessions of diet and physical activity counseling and 6 90-min group counseling and physical activity	Total: 6 Interactive: 6 Other: 0 Est Tot Hr: 10.2 Category: High	Promoted for subset of participants	Indiv Group	In-person	X	Deliver all/most (Yes)	GP and practice nurse, dietitian or exercise physiologist, intervention officer Primary care	WL

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Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
			sessions Total duration: 12 months								
Haufe, 2019[75] Fair	IG1	HD + PA	6 sessions of physical activity counseling and 1 session of diet counseling Total duration: 6 months	Total: 7 Interactive: 7 Other: 0 Est Tot Hr: 3.5 Category: Medium	Not promoted	Indiv	Tech-based Phone		None (No)	Exercise scientist Community/home	WL
Hinderliter, 2014[76] (Exercise and Nutrition interventions for CardiOvasculaR hEalth (ENCORE)) Good	IG1	HD	4 in-person individual instructional sessions on diet and 14 (30-45 min) in-person group sessions of diet counseling Total duration: 4 months	Total: 18 Interactive: 18 Other: 0 Est Tot Hr: 11.5 Category: High	DASH Not promoted	Indiv Group	In-person		None (No)	Nutritionist Medical research center	UC
HPT, 1990[77] (Hypertension Prevention Trial (HPT)) Good	IG1	HD	28 60-min group dietary counseling sessions and 16 bimonthly newsletters Total duration: 36 months	Total: 28 Interactive: 28 Other: 0 Est Tot Hr: 28 Category: High	Low sodium Not promoted	Group	In-person Print		None (No)	Nutritionists and behavioral specialists Research clinic	None
HPT, 1990[77] (Hypertension Prevention Trial (HPT)) Good	IG2	HD	28 60-min group diet counseling sessions and 16 bimonthly newsletters Total duration: 36 months	Total: 28 Interactive: 28 Other: 0 Est Tot Hr: 28 Category: High	Low sodium Promoted for subset of participants	Group	In-person Print		None (No)	Nutritionists and behavioral specialists Research clinic	None
HPT, 1990[77] (Hypertension Prevention Trial (HPT)) Good	IG3	HD	28 60-min group weight loss counseling sessions and 16 bimonthly newsletters Total duration: 36 months	Total: 28 Interactive: 28 Other: 0 Est Tot Hr: 28 Category: High	NR Promoted for all participants	Group	In-person Print		None (No)	Nutritionists and behavioral specialists Research clinic	None
HPT, 1990[77] (Hypertension Prevention Trial (HPT)) Good	IG4	HD	28 60-min group weight loss and sodium reduction counseling sessions and 16 bimonthly newsletters Total duration: 36 months	Total: 28 Interactive: 28 Other: 0 Est Tot Hr: 28 Category: High	Low sodium Promoted for all participants	Group	In-person Print		None (No)	Nutritionists and behavioral specialists Research clinic	None

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Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Hyman, 1998[78] Fair	IG1	HD	4 60-min in-person classes of dietary education and behavioral changes, 12 mailed individualized diet questionnaires with feedback, 12 2-3 min interactive computer call Total duration: 6 months	Total: 28 Interactive: 16 Other: 12 Est Tot Hr: 4.6 Category: Medium	Low-fat NR	Indiv Group	In-person Phone Print		None (No)	Registered dietitian CHC	UC
Hyman, 2007[79] Fair	IG1	HD + PA	3 brief individual counseling sessions on smoking cessation, sodium reduction, and physical activity and 21 15-min motivational interviewing phone calls Total duration: 18 months	Total: 27 Interactive: 24 Other: 3 Est Tot Hr: 6 Category: Medium	Low sodium NR	Indiv	In-person Phone Print	X	None (No)	Health educator Primary care clinic, home (phone sessions)	Min
Hyman, 2007[79] Fair	IG2	HD + PA	3 brief individual counseling sessions on smoking cessation, sodium reduction, and physical activity and 21 15-min motivational interviewing phone calls Total duration: 18 months	Total: 27 Interactive: 24 Other: 3 Est Tot Hr: 6 Category: Medium	Low sodium NR	Indiv	In-person Phone Print	X	None (No)	Health educator Primary care clinic, home (phone sessions)	Min
Ives, 1993[80] (Rural Health Promotion Project (RHPP) Trial) Fair	IG1	HD + PA	5 visits of diet and physical activity counseling for cholesterol reduction Total duration: 12 months	Total: 5 Interactive: 5 Other: 0 Est Tot Hr: 2.5 Category: Medium	NR	Indiv	In-person		None (No)	Hospital staff Hospital	UC
Ives, 1993[80] (Rural Health Promotion Project (RHPP) Trial) Fair	IG2	HD + PA	5 visits of diet and physical activity counseling for cholesterol reduction Total duration: 12 months	Total: 5 Interactive: 5 Other: 0 Est Tot Hr: 2.5 Category: Medium	NR	Indiv	In-person		Deliver all/most (Yes)	PCP Primary care clinic	UC
Johnston, 1995[81] Fair	IG1	HD	3 90-min group sessions of diet counseling Total duration: 6 months	Total: 3 Interactive: 3 Other: 0	NR	Group	In-person Print		None (No)	Dietitian/nutritionist NR	UC

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Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
				Est Tot Hr: 4.5 Category: Medium							
Johnston, 1995[81] Fair	IG2	HD	3 in-person individual sessions of diet counseling Total duration: 6 months	Total: 3 Interactive: 3 Other: 0 Est Tot Hr: 1.5 Category: Medium	NR	Indiv	In-person Print		None (No)	Dietitian/nutritionist NR	UC
Jones, 1999[82] (Hypertension Optimal Treatment (HOT)) Fair	IG1	HD	2 in-person individual counseling sessions on diet and 11 in-person group support sessions Total duration: 30 months	Total: 13 Interactive: 13 Other: 0 Est Tot Hr: 12 Category: High	NR Promoted for all participants	Indiv Group	In-person		NR (No)	Registered dietitian NR	UC
Kandula, 2015[83] (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	IG1	HD + PA	6 60-90 min informational group classes about diet, physical activity, and stress reduction; 6 15-min individual telephone support calls, and 2 group gatherings involving culturally-relevant PA- and diet-related activities Total duration: 4 months	Total: 14 Interactive: 14 Other: 0 Est Tot Hr: 12.5 Category: High	NR Promoted for subset of participants	Indiv Group	In-person Phone	X	None (No)	Health educators Community (classes and melas), home (phone calls)	UC
Kanke, 2015[84] Fair	IG1	HD + PA	12 7-min sessions of weight loss, diet, and physical activity counseling (1 introductory session followed by 11 monthly or bimonthly routine consultations) Total duration: 12 months	Total: 12 Interactive: 12 Other: 0 Est Tot Hr: 1.4 Category: Medium	NR Promoted for all participants	Indiv	In-person Print		Deliver all/most (Yes)	PCP Primary care	Min
Kastarinen, 2002[85] (Lifestyle Intervention against Hypertension in Eastern Finland	IG1	HD + PA	7 individual sessions of individualized diet and physical activity counseling and 2 120-min group counseling sessions Total duration: 21 months	Total: 9 Interactive: 9 Other: 0 Est Tot Hr: 7.5 Category: High	Low sodium Promoted for subset of participants	Indiv Group	In-person		(Yes)	Public health nurses Primary health care center	UC

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Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
(LIHEF)) Fair											
Keyserling, 1997[86] (Southeast Cholesterol Project) Fair	IG1	HD	3 5-10 min in-person individual diet counseling visits with PCP, referral to 3 30-min in-person individual diet counseling with dietician, 1 mailing Total duration: 12 months	Total: 7 Interactive: 6 Other: 4 Est Tot Hr: 2 Category: Medium	NR	Indiv	In-person Print		Deliver all/most (Yes)	PCPs; dieticians; health educators Community and rural health centers, local health department, hospital outpatient services	UC
Khanji, 2019[87] (HAPPY London) Good	IG1	HD + PA	Diet and physical activity counseling (1 25-min physician-delivered counseling and instructional session and auto-generated personalized web-based counseling) Total duration: 6 months	Total: 1 Interactive: 1 Other: 0 Est Tot Hr: 0.4 Category: Low	Promoted for all participants	Indiv	In-person Tech-based		Deliver part (Yes)	Study physician Primary care, home	UC
Koelewijn-van Loon, 2009[88] (Improving Patient Adherence to Lifestyle Advice (IMPALA)) Fair	IG1	HD + PA	2 (15-20 min) in-person individual diet and physical activity counseling sessions with practice nurse, 1 (10-min) follow-up telephone call, and printed materials Total duration: 1 months	Total: 3 Interactive: 3 Other: 0 Est Tot Hr: 0.8 Category: Medium	NR	Indiv	In-person Phone Print	X	None (Yes)	Nurses General practice	UC
Kramer, 2018[89] (Healthy Lifestyle Project) Fair	IG1	HD + PA	Participant could choose between 16 (1-hr) group lifestyle counseling sessions or 12 (1-hr) individually-viewed lifestyle DVD sessions followed by brief telephone sessions (5-min); both handouts, self-monitoring logs, a	Total: 16 Interactive: 16 Other: 0 Est Tot Hr: 16 Category: High	DPP Promoted for all participants	Indiv Group	In-person Tech-based Phone Print		None (No)	Registered dietitians and exercise specialist Senior community centers	WL

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Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
			pedometer and exercise bands. Total duration: 6 months								
Lakerveld, 2013[90] (HOORN) Fair	IG1	HD + PA	Nine sessions of diet and physical activity counseling (6 30-min individual counseling sessions and 3 30-min booster phone calls) Total duration: 16 months	Total: 9 Interactive: 9 Other: 0 Est Tot Hr: 4.5 Category: Medium	NR	Indiv	In-person Phone	X	None (Yes)	Practice nurses Diabetes research center	UC
Langford, 1991[91] (Trial of Antihypertensive Interventions and Management (TAIM)) Fair	IG1	HD + PA	10 group sessions and 2 individual sessions of lifestyle counseling for weight loss and 6 individual BP medication management visits Total duration: 6 months	Total: 18 Interactive: 18 Other: 0 Est Tot Hr: 14 Category: High	NR Promoted for all participants	Indiv Group	In-person		NR (NR)	Nutritionists and therapists (nutritional intervention); NR (medical intervention) NR	Min
Langford, 1991[91] (Trial of Antihypertensive Interventions and Management (TAIM)) Fair	IG2	HD	10 group sessions and 2 individual sessions of nutrition counseling for reducing sodium intake and increasing potassium intake and 6 individual BP medication management visits Total duration: 6 months	Total: 18 Interactive: 18 Other: 0 Est Tot Hr: 14 Category: High	Low sodium Not promoted	Indiv Group	In-person		NR (NR)	Nutritionists and therapists (nutritional intervention); NR (medical intervention) NR	Min
Lee, 2007[92] Fair	IG1	PA	Median of 6 sessions of individual in-person and telephone physical activity counseling Total duration: 6 months	Total: 6 Interactive: 6 Other: 0 Est Tot Hr: 3 Category: Medium	NR	Indiv	In-person Phone		None (No)	Public health nurse Community centers, home	UC
Liira, 2014[93] Fair	IG1	HD + PA	1 90-min in-person diet and physical activity counseling session Total duration: 0.03 months	Total: 1 Interactive: 1 Other: 0 Est Tot Hr: 1.5 Category: Medium	NR	Indiv	In-person		None (No)	Public health nurses Primary care	UC

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Migneault, 2012[94] Fair	IG1	HD + PA	32 weekly 15-min automated phone sessions and one 20-min in-home health education session Total duration: 8 months	Total: 33 Interactive: 33 Other: 0 Est Tot Hr: 8.3 Category: High	Low-fat DASH Low sodium NR	Indiv	In-person Phone Print	X	Deliver part (Yes)	NA (automated phone system), PCP Home	Min
Moreau, 2001[95] Fair	IG1	PA	Instructions and pedometer provided for self-directed walking program Total duration: 6 months	Total: 0 Interactive: 0 Other: 0 Est Tot Hr: 0 Category: Low	NR	Indiv	In-person		NR (No)	NR Home	None
Moy, 2001[96] Fair	IG1	HD	13 sessions of individual and family dietary counseling (1 120-min sessions and 12 60-min sessions) Total duration: 24 months	Total: 13 Interactive: 13 Other: 0 Est Tot Hr: 14 Category: High	Low-fat NR	Indiv Family	In-person Phone		None (No)	Nurse NR	UC
Muhlhauser, 1993[97] (Hypertension Treatment and Teaching Program (HTTP)) Fair	IG1	HD + PA	4 60-90 min group counseling sessions on diet, exercise, and self-monitoring of blood pressure Total duration: 1 months	Total: 4 Interactive: 4 Other: 0 Est Tot Hr: 6 Category: Medium	NR	Group	In-person Print		Deliver part (Yes)	Physicians and practice staff Primary health care	Min
Murphy, 2012[98] (National Exercise Referral Scheme (NERS)) Fair	IG1	PA	3 individual in-person sessions of physical activity counseling with 2 telephone calls focused on relapse prevention and discounted access to 1-on-1 exercise instruction or group classes Total duration: 12 months	Total: 5 Interactive: 5 Other: 0 Est Tot Hr: 2 Category: Medium	NR	Indiv Group	In-person Phone	X	None (No)	Exercise professional Leisure centre, home (phone)	WL
Neil, 1995[99] Fair	IG1	HD	1 30-min in-person session of dietary counseling and 1 10-min in-person followup session Total duration: 2 months	Total: 2 Interactive: 2 Other: 0 Est Tot Hr: 0.7 Category: Medium	Low-fat Promoted for subset of participants	Indiv	In-person		None (No)	Dietitian General practice clinic	UC

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Neil, 1995[99] Fair	IG2	HD	1 30-min in-person session of dietary counseling and 1 10-min in-person followup session Total duration: 2 months	Total: 2 Interactive: 2 Other: 0 Est Tot Hr: 0.7 Category: Medium	Low-fat NR	Indiv	In-person		None (No)	Nurse General practice clinic	UC
Niiranen, 2014[100] Fair	IG1	HD + PA	3 sessions of diet and physical activity counseling (2 30-min individual counseling sessions and 1 60-min group session) and 5 PCP BP medication management calls that included individualized lifestyle advice. Total duration: 12 months	Total: 8 Interactive: 8 Other: 0 Est Tot Hr: 3.2 Category: Medium	Low sodium Promoted for subset of participants	Indiv Group	In-person Print		Deliver part (Yes)	PCPs and nurses Primary care, home	UC
Nolan, 2018[101] (Reducing Risk with E-based Support for Adherence to Lifestyle Change in Hypertension (REACH)) Fair	IG1	HD + PA	28 automated e-counseling sessions including videos on diet, exercise, and BP management; online handouts; and online monitoring forms Total duration: 12 months	Total: 28 Interactive: 0 Other: 0 Est Tot Hr: NA Category: High	NR	Indiv	Tech-based	X	None (No)	NA (counseling fully automated) Home	Min
Ogedegbe, 2014[102] (Counseling African Americans to Control Hypertension (CAATCH)) Fair	IG1	HD + PA	6 group sessions of diet and physical activity counseling, four interactive computerized educational modules, and home BP monitoring Total duration: 6 months	Total: 10 Interactive: 6 Other: 0 Est Tot Hr: 6 Category: Medium	DASH Low sodium Promoted for subset of participants	Indiv Group	In-person Tech-based	X	Deliver part (Yes)	Nutritionists, nurses, and health educators (from study and community health center), physicians Community health center	Min
Reid, 2014[103] Fair	IG1	HD + PA	17 sessions of diet and physical activity counseling (1 45-min in-person counseling session,	Total: 17 Interactive: 17 Other: 0	NR Promoted for subset of participants	Indiv	In-person Phone Print		None (No)	Health educators Tertiary care cardiac center	UC

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
			1 45-min phone counseling session, and 15 15-20 min phone counseling sessions) and print materials on smoking cessation, healthy eating, weight mgmt, and physical activity Total duration: 12 months	Est Tot Hr: 6.5 Category: High							
Rodriguez, 2012[104] Fair	IG1	HD + PA	6 monthly telephone sessions of diet, medication, and physical activity counseling individualized based on stage of change Total duration: 6 months	Total: 6 Interactive: 6 Other: 0 Est Tot Hr: 1.5 Category: Medium	Low-fat Low sodium NR	Indiv	Phone		None (No)	Counselors (Master's degree or higher in psychology or social work) Home	UC
Rodriguez-Cristobal, 2012[105] Fair	IG1	HD + PA	24 sessions of individual lifestyle counseling on diet, PA, and smoking cessation (12 physician-delivered in-person sessions and 12 psychologist follow-up calls) Total duration: 24 months	Total: 24 Interactive: 24 Other: 0 Est Tot Hr: 9 Category: High	NR Promoted for subset of participants	Indiv	In-person Phone		Deliver part (Yes)	Physician, psychologist Primary care	UC
Rosas, 2015[106] (Vivamos Activos Fair Oaks (VAFO)) Good	IG1	HD + PA	20 weight loss counseling sessions (15 120-min group sessions and 5 30-min individual counseling sessions), 7 home visits with community health workers, and take home items (pedometers, exercise CDs, and free weights) Total duration: 24 months	Total: 27 Interactive: 27 Other: 0 Est Tot Hr: 36 Category: High	DPP Promoted for all participants	Indiv Group	In-person	X	None (No)	Research staff & community health workers Community health center, home	UC
Rosas, 2015[106] (Vivamos Activos Fair Oaks	IG2	HD + PA	20 weight loss counseling sessions (15 120-min group sessions and 5 30-	Total: 20 Interactive: 20 Other: 0	DPP Promoted for	Indiv Group	In-person	X	None (No)	Research staff Community health center	UC

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
(VAFO)) Good			min individual counseling sessions) and take home items (pedometers, exercise CDs, and free weights) Total duration: 24 months	Est Tot Hr: 32.5 Category: High	all participants						
Rubinstein, 2016[107] Good	IG1	HD + PA	12 20-30 min telephone sessions of diet and physical activity counseling, 48 followup text messages, and an informational leaflet about healthy lifestyles Total duration: 12 months	Total: 60 Interactive: 12 Other: 0 Est Tot Hr: 6 Category: Medium	NR	Indiv	Tech-based Phone Print	X	None (No)	Nutritionists Home	None
Salisbury, 2016[108] Good	IG1	HD + PA	12 18-min telephone sessions of diet, physical activity, and blood pressure management counseling and access to a web-based behavior management program Total duration: 12 months	Total: 12 Interactive: 12 Other: 0 Est Tot Hr: 3.6 Category: Medium	NR Promoted for subset of participants	Indiv	Tech-based Phone	X	None (No)	Health advisors Home	UC
Schoenthaler, 2016[109] (Individual Motivational Interviewing - Therapeutic Lifestyle Changes (MINT-TLC)) Fair	IG1	HD + PA	13 sessions of diet and physical activity counseling (10 60-90 min group sessions and 3 30-min individual phone sessions) Total duration: 6 months	Total: 13 Interactive: 13 Other: 0 Est Tot Hr: 16.5 Category: High	Low-fat DASH Low sodium Promoted for subset of participants	Indiv Group	In-person Phone	X	None (No)	Health educators Hospital, home	Min
Scott, 2018[110] Fair	IG1	PA	7 sessions of physical activity counseling (2 1-hr in-person sessions and 5 15-30 min phone sessions) Total duration: 3 months	Total: 7 Interactive: 7 Other: 0 Est Tot Hr: 4.5 Category: Medium	NR	Indiv	In-person Phone	X	None (No)	PhD-level psychologist NR (in-person sessions), home (phone sessions)	UC

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Soto Rodriguez, 2016[111] Fair	IG1	HD	Three 90-min group sessions of CVD prevention counseling Total duration: 0.25 months	Total: 3 Interactive: 3 Other: 0 Est Tot Hr: 4.5 Category: Medium	Mediter NR	Group	In-person		NR (NR)	NR Health care	None
Stefanick, 1998[112] (Diet and Exercise for Elevated Risk (DEER)) Fair	IG1	HD	17 sessions of dietary counseling (1 individual session, eight 60-min group sessions, and 6-8 maintenance sessions) Total duration: 11 months	Total: 17 Interactive: 17 Other: 0 Est Tot Hr: 12.5 Category: High	Low-fat NR	Indiv Group	In-person Phone Print		None (No)	Registered dietitians Research clinic, home	None
Stevens, 2003[113] Fair	IG1	HD	2 45-min sessions of individual diet counseling (including 20-min computer assessment) and 2 10-min followup phone calls Total duration: 2 months	Total: 4 Interactive: 4 Other: 0 Est Tot Hr: 1.8 Category: Medium	Low-fat NR	Indiv	In-person Tech-based Phone Print	X	None (No)	Health counselors Research clinic	AC
Svetkey, 2008[114] (Weight Loss Maintenance (WLM)) Good	IG1	HD + PA	30 sessions of weight loss maintenance counseling (23 5-15 min phone sessions and 45-60 min individual in-person sessions); participants in extended followup received 4 in-person group sessions and an additional 29 5-15 min phone calls) Total duration: 60 months	Total: 30 Interactive: 30 Other: 0 Est Tot Hr: 12.8 Category: High	NR Promoted for all participants	Indiv Group	In-person Phone	X	None (No)	Research interventionist NR	Min
Svetkey, 2008[114] (Weight Loss Maintenance (WLM)) Good	IG2	HD + PA	Access to weight-loss maintenance support website, email reminders for weekly use for 30 months (median 107 log-ins) Total duration: 30 months	Total: 0 Interactive: 0 Other: 0 Est Tot Hr: 0 Category: High	NR Promoted for all participants	Indiv	Tech-based		None (No)	NA Home	Min

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Svetkey, 2009[115] (Hypertension Improvement Project (HIP)) Fair	IG1	HD + PA	Physicians received 2 45-min online training modules, a pocket reference card, and quarterly feedback reports. Patients received 20 weekly group sessions of diet and physical activity counseling followed by 12 monthly individual phone sessions Total duration: 18 months	Total: 39 Interactive: 32 Other: 4 Est Tot Hr: 24.5 Category: High	DASH Low sodium Promoted for subset of participants	Indiv Group	In-person Phone Print	X	Deliver part (Yes)	Behavioral interventionists and community health advisors, PCP Physician: Clinic, Patients: At or near participant's clinic site	UC
Svetkey, 2009[115] (Hypertension Improvement Project (HIP)) Fair	IG2	HD + PA	20 weekly group sessions of diet and physical activity counseling followed by 12 monthly individual phone sessions Total duration: 18 months	Total: 32 Interactive: 32 Other: 0 Est Tot Hr: 23 Category: High	DASH Low sodium Promoted for subset of participants	Indiv Group	In-person Phone Print	X	None (No)	Behavioral interventionists and community health advisors At or near participant's clinic site	UC
Svetkey, 2009[115] (Hypertension Improvement Project (HIP)) Fair	IG3	HD + PA	2 45-min online training modules, pocket reference care, and quarterly feedback reports (est. 5 x) Total duration: 18 months	Total: 7 Interactive: 0 Other: 0 Est Tot Hr: 1.5 Category: Medium	NR		Tech-based Print		Deliver all/most (Yes)	NA (Physicians trained) Clinic	UC
Ter Bogt, 2009[116] (Groningen Overweight and Lifestyle (GOAL)) Good	IG1	HD + PA	7 sessions of individual diet and physical activity counseling (1 GP session and 4 NP sessions) and 5 followup calls over 3 years (estimated 245 mins of contact in year 1) Total duration: 36 months	Total: 12 Interactive: 12 Other: 0 Est Tot Hr: 7.2 Category: High	NR Not promoted	Indiv	In-person Tech-based Phone		Deliver part (Yes)	General practitioner, nurse practitioner Primary care, home	UC
Tiessen, 2012[117] (SPRING (Self-monitoring and Prevention of RIsk Factors by Nurse	IG1	HD + PA	1 20-min individual session with nurse using motivational interviewing and 6-12 follow-up visits based on self-monitoring	Total: 5 Interactive: 5 Other: 0 Est Tot Hr: 2.1 Category: Medium	Promoted for subset of participants	Indiv	In-person	X	None (Yes)	Trained nurses Primary care	Min

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
practitioners in the region of Groningen)) Fair			feedback with the number of follow-up visits determined by the presence of risk factors Total duration: 12 months								
Toft, 2008[118] (Inter99) Fair	IG1	HD + PA	4 15-45 min individual sessions of smoking cessation/reduction and diet and physical activity counseling and 6 120-min group sessions of diet and physical activity counseling Total duration: 60 months	Total: 10 Interactive: 10 Other: 0 Est Tot Hr: 14 Category: High	Low-fat Low sodium Promoted for subset of participants	Indiv Group	In-person	X	None (No)	Doctors, nurses, and dietitians Research center	Min
TOHP I CRG, 1992[119] (Trials of Hypertension Prevention Phase I (TOHP I)) Good	IG1	HD	10 weekly 90-min sessions of sodium reduction counseling (8 group counseling sessions and 2 individual counseling sessions) and 16 monthly 90-min group or individual counseling sessions Total duration: 18 months	Total: 26 Interactive: 26 Other: 0 Est Tot Hr: 39 Category: High	Low sodium Not promoted	Indiv Group	In-person		None (No)	Registered dietitian and psychologist or exercise psychologist Research center	UC
TOHP I CRG, 1992[119] (Trials of Hypertension Prevention Phase I (TOHP I)) Good	IG2	HD + PA	30 sessions of diet and physical activity weight loss counseling (1 individual session and 29 group sessions) and optional individual check-in sessions Total duration: 18 months	Total: 30 Interactive: 30 Other: 0 Est Tot Hr: 36.5 Category: High	NR Promoted for all participants	Indiv Group	In-person		None (No)	Registered dietitian and psychologist or exercise psychologist Clinical center	UC
TOHP II CRG, 1997[120] (Trial of Hypertension Prevention II (TOHP II)) Good	IG1	HD + PA	57 weight loss and sodium reduction counseling sessions (1 individual introductory session, 14 90-min weekly group sessions, 6 90-min	Total: 57 Interactive: 57 Other: 0 Est Tot Hr: 48.5 Category: High	Low sodium Promoted for all participants	Indiv Group Family	In-person Phone Print		None (No)	Centrally trained staff (dietitians, psychologists, or health counselors) Research clinic	None

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
			biweekly group sessions and 3-6 "minimodules" consisting of up to 6 sessions each [36 available sessions], and optional participant-initiated individual counseling sessions) Total duration: 36 months								
TOHP II CRG, 1997[120] (Trial of Hypertension Prevention II (TOHP II)) Good	IG2	HD + PA	57 weight loss counseling sessions (1 individual introductory session, 14 90-min weekly group sessions, 6 90-min biweekly group sessions and 3-6 "minimodules" consisting of up to 6 sessions each [36 available sessions], and optional participant-initiated individual counseling sessions) Total duration: 36 months	Total: 57 Interactive: 57 Other: 0 Est Tot Hr: 48.5 Category: High	NR Promoted for all participants	Indiv Group Family	In-person Phone Print		None (No)	Centrally trained staff (dietitians, psychologists, or health counselors) Research clinic	None
TOHP II CRG, 1997[120] (Trial of Hypertension Prevention II (TOHP II)) Good	IG3	HD	53 sodium reduction counseling sessions (1 individual introductory session, 10 90-min weekly group sessions, 6 90-min biweekly group sessions and 3-6 "minimodules" consisting of up to 6 sessions each [36 available sessions], and optional participant-initiated individual counseling sessions) Total duration: 36 months	Total: 53 Interactive: 53 Other: 0 Est Tot Hr: 42.5 Category: High	Low sodium Not promoted	Indiv Group Family	In-person Phone Print		None (No)	Centrally trained staff (dietitians, psychologists, or health counselors) Research clinic	None

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Tomson, 1995[121] Fair	IG1	HD	6 sessions diet counseling, including 3 sessions with primary care physician and 3 sessions with dietician (1 individual, 1 with spouse, and 1 group session with trip to grocery store) Total duration: 12 months	Total: 6 Interactive: 6 Other: 0 Est Tot Hr: 3 Category: Medium	Low-fat Promoted for subset of participants	Indiv Group Family	In-person		Deliver part (Yes)	PCP, dietician Medical center	UC
van der Veen, 2002[122] (Nijmegen Family Practices Monitoring Project (NFPMP)) Fair	IG1	HD	Maximum of 3 10-min family physician nutrition counseling sessions with referral to dietician for 3 sessions (initial consultation of 30-40 mins and 10-15 mins for second and third consultation) Total duration: 2.5 months	Total: 6 Interactive: 6 Other: 0 Est Tot Hr: 1.7 Category: Medium	Low-fat Promoted for subset of participants	Indiv	In-person		Deliver all/most (Yes)	Family physician; dietician Family practice	UC
van Keulen, 2011[123] (Vitalum) Fair	IG1	HD + PA	4 20-min telephone-based sessions of diet and physical activity counseling Total duration: 10 months	Total: 4 Interactive: 4 Other: 0 Est Tot Hr: 1.3 Category: Medium	NR	Indiv	Phone	X	None (No)	Counselors (students of Health Education and Health Promotion, Mental Health Sciences, or Psychology) Home	UC
van Keulen, 2011[123] (Vitalum) Fair	IG2	HD + PA	2 20-min telephone-based sessions of diet and physical activity counseling and 2 tailored letters Total duration: 10 months	Total: 4 Interactive: 2 Other: 2 Est Tot Hr: 0.7 Category: Medium	NR	Indiv	Phone Print	X	None (No)	Counselors (students of Health Education and Health Promotion, Mental Health Sciences, or Psychology) Home	UC
van Keulen, 2011[123] (Vitalum) Fair	IG3	HD + PA	Four tailored letters addressing physical activity and consumption	Total: 4 Interactive: 0 Other: 4	NR	Indiv	Print		None (No)	NA Home	UC

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
			of fruits and vegetables Total duration: 10 months	Est Tot Hr: 0 Category: Low							
van Sluijs, 2005[124] (Physician-based Assessment and Counseling for Exercise (PACE)) Fair	IG1	PA	Two GP/NP sessions of physical activity counseling (10-min consultation followed by a counseling appointment) and two phone sessions with physical activity counselors Total duration: 2 months	Total: 4 Interactive: 4 Other: 0 Est Tot Hr: 0.8 Category: Medium	NR	Indiv	In-person Phone		Deliver part (Yes)	GP/NP and PA counselor Clinic, home (phone)	UC
Viglione, 2019[125] (Goals for Eating and Moving (GEM)) Fair	IG1	HD + PA	13 sessions of diet and physical activity counseling delivered by health coaches (1 60-min in-person counseling session and 12 25-min coaching calls) and an average of 2.3 counseling sessions with PCP Total duration: 12 months	Total: 15 Interactive: 15 Other: 0 Est Tot Hr: 6.6 Category: High	Promoted for all participants	Indiv	In-person Tech-based Phone Print	X	Deliver part (Yes)	Health coaches (trained students), PC team Primary care (baseline and PCP visits), home (calls)	UC
Voils, 2013[126] (CouPLES) Fair	IG1	HD + PA	9 phone counseling sessions for the patient and 9 phone counseling sessions for their spouse Total duration: 11 months	Total: 18 Interactive: 18 Other: 0 Est Tot Hr: 3.4 Category: Medium	NR	Indiv Family	Phone Print		None (No)	Research nurse Home	Min
Wadden, 2011[127] (Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-UP)) Good	IG1	HD + PA	32 sessions of diet and lifestyle counseling (8 5-7 min individual sessions with PCP and 24 10-15 min individual in-person and phone sessions with lifestyle coach) and printed handouts Total duration: 24 months	Total: 32 Interactive: 32 Other: 0 Est Tot Hr: 6.9 Category: High	DPP Promoted for all participants	Indiv	In-person Phone Print		Deliver part (Yes)	Medical assistant (lifestyle coach) and PCP Primary care	Min
Whelton, 1998[128] (Trial of	IG1	HD + PA	53 sessions of sodium reduction and weight loss	Total: 53 Interactive: 53	Low sodium Promoted for	Indiv Group	In-person		None (No)	Nutritionists and exercise counselors	Min

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Nonpharmacologic Interventions in the Elderly (TONE)) Good			counseling, including 7 individual and 46 group sessions. (Limited to pts with obesity) Total duration: 36 months	Other: 0 Est Tot Hr: 49.5 Category: High	all participants					Academic health center	
Whelton, 1998[128] (Trial of Nonpharmacologic Interventions in the Elderly (TONE)) Good	IG2	HD + PA	53 sessions of weight loss counseling, including 7 individual and 46 group sessions. (Limited to pts with obesity) Total duration: 36 months	Total: 53 Interactive: 53 Other: 0 Est Tot Hr: 49.5 Category: High	NR Promoted for all participants	Indiv Group	In-person		None (No)	Nutritionists and exercise counselors Academic health center	Min
Whelton, 1998[128] (Trial of Nonpharmacologic Interventions in the Elderly (TONE)) Good	IG3	HD	53 sessions of sodium reduction counseling, including 7 individual and 46 group sessions Total duration: 36 months	Total: 53 Interactive: 53 Other: 0 Est Tot Hr: 49.5 Category: High	Low sodium Promoted for subset of participants	Indiv Group	In-person		None (No)	Nutritionists and exercise counselors Academic health center	Min
Wister, 2007[129] Good	IG1	HD + PA	2 30-min phone sessions (4 additional 20-30 min sessions for smokers) and 3 mailings, targeting smoking, diet, physical activity, weight management and/or stress management Total duration: 12 months	Total: 5 Interactive: 2 Other: 1 Est Tot Hr: 1 Category: Medium	NR Promoted for subset of participants	Indiv	Phone Print	X	None (No)	Clinical lifestyle counselors (were also kinesiologists) Home	UC
Wong, 2015[130] Good	IG1	HD	1 3-5 min physician-delivered UC session and 1 25-min dietitian-delivered DASH diet counseling session Total duration: 0.03 months	Total: 2 Interactive: 2 Other: 0 Est Tot Hr: 0.5 Category: Low	Low-fat DASH Low sodium NR	Indiv	In-person Print		Deliver part (Yes)	Physician and dietitian Primary care	UC

Appendix F Table 2. Intervention Characteristics

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Format	Delivery	Motiv Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Wood, 2008[131] (EUROACTION) Fair	IG1	HD + PA	Individual nurse assessment with personal report card and family support pack plus 8 group workshops of diet, PA, and risk factor counseling Total duration: 4 months	Total: 8 Interactive: 8 Other: 0 Est Tot Hr: 8 Category: High	NR Promoted for subset of participants	Indiv Group Family	In-person	X	Deliver part (Yes)	Nurses; family doctors General practice center	UC

Abbreviations: AC = attention control; AHA = American Heart Association; DASH = Dietary Approaches to Stop Hypertension; DPP = Diabetes Prevention Program diet; Est Tot Hr = estimated total intervention contact hours; GP = general practitioner; HD = healthy diet only; HD = healthy diet and physical activity; IG = intervention group; Indiv = intervention delivered individually; Int arm = intervention arm; IVR = Interactive Voice Response; Mediter = Mediterranean diet; mgmt = management; Min = minimal intervention; min = minutes; Motiv Int = motivational interviewing; NR = not reported; PA = physical activity only; PCP = primary care provider; UC = usual care; WL = waitlist

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Ammerman, 2003[38] Fair	IG1	Participants received an intervention with 3 components: (1) Public health nurse-directed Food For Heart Program (FFHP) during three tailored counseling sessions, (2) referral to local nutritionist if lipids remained elevated at 3 month followup, and (3) a reinforcement program during the second half of the intervention (phone call, two newsletters focusing on seasonal tips for food preparation and strategies to enhance dietary change). The FFHP is a theory-based dietary assessment and tailored counseling program for lower income patients with high blood cholesterol who reside in the southeastern United States. The FFHP is initiated and guided by the Dietary Risk Assessment (DRA) instrument, a validated food frequency instrument. The primary nutritional goals of the FFHP are aimed to reduce consumption of foods high in saturated fat and increase fruit and vegetable intake and complex carbohydrates. The nurse provided structured, individually tailored dietary counseling with illustrated goal sheets, educational pamphlets and southern-style cookbooks. Behavior change recommendations were broken into small, achievable steps, and specific strategies were recommended that addressed barriers to dietary change. The DRA was used to monitor progress and facilitate reinforcement during a followup counseling session. Participants were also referred to a nutritionist for three counseling visits if their 3-month lipid levels remained above the NCEP cutpoints for nutritional counseling. Nutritionist reviewed progress, helped address problems related to dietary change, and worked with participants to set new goals.	HD only Total contact hrs: 3.25 Total duration: 12 months	Nurse, nutritionist Health department	Usual care: Nurses were instructed to provide counseling for high cholesterol as usual. Participants were instructed to see their physician if total cholesterol remained high.
Anderson, 1992[39] Fair	IG1	Participants attended 10-weekly 1- hour group sessions; and after each session 30-min individual session with dietitian to discuss dietary progress and set achievable goals. Each session followed recommended nutritional targets derived from the American Heart Association Phase II guidelines: 55% carbohydrate energy, 20% protein energy, 25% fat energy, ≤200 mg dietary cholesterol per day, and dietary fiber was 50 g. Individually tailored preplanned meal patterns with daily goal of 3 servings each of fruits and vegetables, 4 starches/breads (which always included 1 serving each of beans and a cereal), 2 low-fat dairy, ≤198.5 g lean meat, poultry or seafood, no egg yolks, fat servings based on energy content. Optional sweets and alcohol servings available. No additional recommendations regarding	HD only Total contact hrs: 20 Total duration: 12 months	Dietitian, project staff NR, home	Usual care: Participants were directed to maintain current dietary behaviors.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		modification of other risk-relevant behaviors (e.g., smoking, exercise). Encouraged to attend sessions with spouse/close friend; included demonstrations, problem solving, individual counseling (problems, questions about diet; goals). Home visits (4/year) by dietitian who provided further instruction and problem solving ; also dietitian made monthly phone calls to check progress and problem solve.			
Anderson, 1992[39] Fair	IG2	Participants attended 10-weekly 1- hour group sessions; and after each session 30-min individual session with dietitian. Each session followed recommended nutritional targets derived from the American Heart Association Phase II guidelines: 55% carbohydrate energy, 20% protein energy, 25% fat energy, ≤ 200 mg dietary cholesterol per day, 15 g fiber. Individually tailored preplanned meal patterns for daily pattern with 3 servings each of fruits and vegetables, 4 starches/breads, 2 low-fat dairy, ≤ 198.5 g lean meat, poultry or seafood, no egg yolks, fat servings based on energy content. Optional sweets and alcohol servings available. No additional recommendations regarding modification of other risk-relevant behaviors (e.g., smoking, exercise). Encouraged to attend sessions with spouse/close friend; included demonstrations, problem solving, individual counseling (problems, questions about diet; goals). Home visits (4/year) by dietitian who provided further instruction and problem solving; also dietitian made monthly phone calls to check progress and problem solve.	HD only Total contact hrs: 20 Total duration: 12 months	Dietitian, project staff NR, home	Usual care: Participants were directed to maintain current dietary behaviors.
Anderssen, 1995[40] (Oslo Diet and Exercise Study (ODES)) Fair	IG1	3 individual sessions diet counseling. Diet counseling was individualized and included spouse at the initial session, with additional sessions at 3 and 9 months followup without spouse. Diet messages were to decrease total calories, increase fish, reduce total and saturated fat, increase vegetables, and reduce sugar. Participants with elevated BP were advised to reduce salt. A target body weight reduction goal was set during counseling (typically 0.5 to 1 kg per month).	HD only Total contact hrs: 1.5 Total duration: 9 months	NR NR	Waitlist: Participants were offered dietary advice and physical training after 1 year. CG were told not to change their lifestyle during the trial but were advised against smoking.
Appel, 2003[41] (PREMIER) Good	IG1	Same goals as IG2 plus instruction and counseling on the Dietary Approaches to Stop Hypertension (DASH) diet. Goals related to DASH diet were: increased consumption of fruits and vegetables (9-12 servings/day) and low-fat dairy products (2-3 servings/d), and	HD + PA Total contact hrs: 59 Total duration: 18 months	Master's degree-level counselors (dietitians and health educators	Usual care: Interventionist discussed nonpharmacological

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		reduced intake of saturated fat (≤7% of energy) and total fat (≤25% of energy). To achieve weight loss, increased physical activity and reduced total energy intake was emphasized (as in IG2) but DASH intervention also emphasized substitution of fruits and vegetables for high-fat, high-calorie foods. In addition to food diaries, recording physical activity, and monitoring calorie and sodium intake (as with IG2), DASH intervention participants also monitored intake of fruits, vegetables, and dairy products and monitored their intake of fat. The individual 30-60 minute sessions focused on the participant's specific concerns, behavior change goals, and ways to maintain motivation during challenging situations. Interventionists used motivational enhancement techniques to assess the participant's current stage of change relative to dietary and physical activity behavior. Participants received individualized graphs of attendance, weight change, physical activity, and dietary goals to use as resources for goal setting and problem solving. The 90-120 minute group sessions were interactive, with group activities to foster problem solving, support, and program ownership. Behavior-change techniques (checking progress, problem solving, action planning, goal setting, and self-monitoring) occurred at each session. PA was incorporated into group sessions where participants exercised along with videos, took group walks, and watched demonstrations of stretching, weight training, and aerobics. Print materials contained information on physical activity, sodium, alcohol, weight loss, and DASH dietary recommendations The intervention was composed of 3 phases. The Intensive Phase I consisted of 3 months of weekly contacts (8 group and 3 individual). The Intermediate Phase II consisted of 3 months of biweekly contacts (6 group and 1 individual) and the Maintenance Phase III consisted of 12 months of monthly group sessions supplemented with 3 individual visits. The link provided for publicly available curriculum no longer works: http://www.kpchr.org/public/premier/intervention/		trained in behavioral methods) Clinical centers	factors that affect blood pressure (weight, sodium intake, physical activity, and the DASH diet) and provided printed educational materials. Counseling on behavior change not provided. Advice provided in two 30-minute individual sessions, 1 immediately after random assignment and 1 after 6-month data collection visit.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Appel, 2003[41] (PREMIER) Good	IG2	Participant goals were: (1) weight loss ≥15 lbs at 6 months for those with BMI ≥25, (2) ≥180 minutes/week moderate-intensity physical activity, (3) daily intake ≤2400 mg dietary sodium, and (4) daily intake ≤1 oz alcohol (2 drinks) for men and ½ oz of alcohol (1 drink) for women. No goals for fruit, vegetable, or dairy intake; saturated fat goal ≤10%, total fat goal ≤30% of energy. To achieve weight loss, increased physical activity and reduced total energy intake was emphasized. Participants kept food diaries, recorded physical activity, and monitored calorie and sodium intake. The individual 30-60 minute sessions focused on the participant's specific concerns, behavior change goals, and ways to maintain motivation during challenging situations. Interventionists used motivational enhancement techniques to assess the participant's current stage of change relative to dietary and physical activity behavior. Participants received individualized graphs of attendance, weight change, physical activity, and dietary goals to use as resources for goal setting and problem solving. The 90-120 minute group sessions were interactive, with group activities to foster problem solving, support, and program ownership. Behavior-change techniques (checking progress, problem solving, action planning, goal setting, and self-monitoring) occurred at each session. Physical activity was incorporated into group sessions where participants exercised along with videos, took group walks, and watched demonstrations of stretching, weight training, and aerobics. Print materials contained information on physical activity, sodium, alcohol, and weight loss. The intervention was composed of 3 phases. The Intensive Phase I consisted of 3 months of weekly contacts (8 group and 3 individual). The Intermediate Phase II consisted of 3 months of biweekly contacts (6 group and 1 individual) and the Maintenance Phase III consisted of 12 months of monthly group sessions supplemented with 3 individual visits. The link provided for publicly available curriculum no longer works: http://www.kpchr.org/public/premier/intervention/	HD + PA Total contact hrs: 59 Total duration: 18 months	Master's degree-level counselors (dietitians and health educators trained in behavioral methods) Clinical centers	Usual care: Interventionist discussed nonpharmacological factors that affect blood pressure (weight, sodium intake, physical activity, and the DASH diet) and provided printed educational materials. Counseling on behavior change not provided. Advice provided in two 30-minute individual sessions, 1 immediately after random assignment and 1 after 6-month data collection visit.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Appel, 2011[42] (POWER Hopkins (Practice Based Opportunities for Weight Reduction)) Good	IG1	30 group counseling sessions, 12 individual counseling sessions, 15 phone sessions, and PCP counseling at routine visits, including weekly web-based modules and monthly e-mail messages. Intervention focused on behavioral self-management approaches designed to help participants set weight-related goals, self-monitor weight and weight-related behaviors, increase self-efficacy and support, and solve problems. Motivational interviewing was the primary approach to interactions with participants. Participants were encouraged to lose 5% of their weight within 6 months and maintain reduced weight through end of study at 2 years. Participants were encouraged to log on to the study-specific Web site weekly that contained learning modules and opportunities for self-monitoring of weight, calorie intake, and exercise. Monthly e-mail messages were sent to provide tailored feedback. In addition, participants received in-person contact with lifestyle coaches to encourage completing web-based module and reinforce key behaviors. In-person support included weekly contact in months 1-3 (9 group sessions plus 3 individual sessions), monthly contact in months 4-6 (1 group session plus 2 individual sessions), and two monthly contacts in months 7-24 (1 group and 1 individual session [in-person or via phone per month). Group sessions were 90 minutes and individual and telephone calls were approximately 20 minutes. At routine medical visits, PCP encouraged participant to actively engage in the intervention and reviewed one-page report on patients' weight-loss progress at routine office visits.	HD + PA Total contact hrs: 54 Total duration: 24 months	Lifestyle coach Research clinic and home (web-based)	Usual care: At randomization, participant met with a weight-loss coach for brief orientation to the static website and, if desired, after participant's 24-month follow up visit, can meet again to discuss weight management guidelines. Received NHLBI "Aim for a Healthy Weight" brochure and a list of recommended Web sites promoting weight loss.
Appel, 2011[42] (POWER Hopkins (Practice Based Opportunities for Weight Reduction)) Good	IG2	33 lifestyle behavioral coaching calls, weekly web-based modules, and PCP counseling at routine visits. Intervention focused on behavioral self-management approaches designed to help participants set weight-related goals, self-monitor weight and weight-related behaviors, increase self-efficacy and support, and solve problems. Motivational interviewing was the primary approach to interactions with participants. Participants were encouraged to lose 5% of their weight within 6 months and maintain reduced weight through end of study at 2 years. Participants were encouraged to log on to the study-specific Web site weekly that contained learning modules and opportunities for self-monitoring of weight, calorie intake, and exercise. Monthly e-mail messages were sent to provide tailored	HD + PA Total contact hrs: 11 Total duration: 24 months	PCP, lifestyle coach Home (web-based)	Usual care: At randomization, participant met with a weight-loss coach for brief orientation to the static website and, if desired, after participant's 24-month follow up visit, can meet again to discuss weight management guidelines. Received

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		feedback. In the first 3 months, participants received 12 weekly coaching calls with lifestyle coaches to encourage completing web-based module and reinforce key behaviors. In months 7-24, monthly coaching calls were received. Telephone calls were approximately 20 minutes. At routine medical visits, PCP encouraged participant to actively engage in the intervention.			NHLBI "Aim for a Healthy Weight" brochure and a list of recommended Web sites promoting weight loss.
Applegate, 1992[43] Fair	IG1	12 group and 2 individual sessions of weight management, sodium restriction, and PA counseling. Weight loss goal of 4.5 kg and individualized calorie restrictions (for women, no less than 1200 calories per day and no less than 1500 calories per day for men). Sodium consumption goal was 1400 mg daily and PA goal was 120 minutes/week (4 30-minute sessions of slow walking per week). Participants self-monitored sodium, calories, and minutes of PA; food records were reviewed each week and returned to participants with suggestions for improvement. Anti-HTN meds withdrawn at start of intervention.	HD + PA Total contact hrs: 13 Total duration: 6 months	Registered dietitians Clinic	No advice: Received no treatment; if DBP exceeded 105 mm Hg, participants were placed on meds and removed from trial. At the end of the trial, any participant with DBP >90 mm Hg placed on open-label medication
Arroll, 1995[44] Fair	IG1	Exercise and salt interventions: Advised to walk 40mins 3 times per week, 1 page pamphlet, general article on BP/salt reduction, book containing salt content of common foods. Number and duration of sessions NR, but state that "The interventions were very simple and based on written and verbal information that could be easily used in a primary care setting. There was no intensive dietary advice…" All participants kept a weekly diary tracking injuries or health problems and medication compliance.	HD + PA Total contact hrs: NR Total duration: 6 months	Research staff and GP "community setting"	Minimal intervention: Usual care; weekly diary of health problems and medication changes.
Arroll, 1995[44] Fair	IG2	Participants advised to walk briskly for 40 minutes 3 days a week. A plan to build up to this amount of exercise was determined by the patient's doctor. Number and duration of sessions NR, but state that "The interventions were very simple and based on written and verbal information that could be easily used in a primary care setting. There was no intensive dietary advice…" All participants kept a weekly diary tracking injuries or health problems and medication compliance.	PA only Total contact hrs: NR Total duration: 6 months	Research staff and GP "community setting"	Minimal intervention: Usual care; weekly diary of health problems and medication changes.
Arroll, 1995[44] Fair	IG3	Participants advised to decrease their use of high salt foods and added salt when cooking and eating. Each person received a simple pamphlet, a general article about salt and BP, and an in depth book	HD only Total contact hrs: NR Total duration: 6 months	Research staff and GP	Minimal intervention: Usual care; weekly diary of health

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		with information about salt content of common foods. Number and duration of sessions NR, but state that "The interventions were very simple and based on written and verbal information that could be easily used in a primary care setting. There was no intensive dietary advice…" All participants kept a weekly diary tracking injuries or health problems and medication compliance.		"community setting"	problems and medication changes.
Babazono, 2007[45] (PHPP) Fair	IG1	Team encouraged patients to set their own goals & to select lifestyle improvements that they were interested in making; choose and prioritize physical activity to achieve goals; provided advice about how to achieve the goals set using "Stages of change" challenge cards. Problem solving for ways to achieve goals, or discussion about changing goals when appropriate, was a part of sessions. The primary goals of the intervention were to physical activity and vegetable intake, but other dietary goals were also listed on the "challenge cards, such as decreasing salty foods, oily foods, sugar, and alcohol, and increasing tofu intake, increasing time for meals, and eating more slowly.	HD + PA Total contact hrs: 3 Total duration: 12 months	Dietitians, health exercise instructors, public health nurses Medical center, home visits	Usual care: Asked to return to the medical center 1 month after baseline assessments, where they received results and were given instructions on how to enhance physical activity via leaflets only.
Beckmann, 1995[46] Fair	IG1	Participants were instructed to lower their sodium intake (e.g., not adding salt at table or while cooking, avoiding sodium-rich foods, processed food; bake own bread, use oil, salt-free margarine and increase use of fruits and vegetables) and provided with a free 2-week supply of unsalted foods with aim to reduce average daily sodium intake to 30 mmol/d. Following the two weeks of food provision, participants aimed to achieve an average daily sodium intake of 100 mmol/d. After 3 months, participants with elevated BMI ($\geq$27 kg/m^2) or total cholesterol (>50th percentile) received advice to reduce body weight and reduce saturated and increase intake of polyunsaturated dietary fat.	HD only Total contact hrs: 2.5 Total duration: 12 months	Nutritionist Outpatient clinic	Waitlist: At 12 months, participants were given dietary advice similar to that given to the intervention group.
Bennett, 2012[47] (Be Fit, Be Well [POWER]) Good	IG1	18 tailored diet, physical activity and lifestyle counseling calls (20 min each); 12 optional group sessions; PCP endorsement message; and self-monitoring using study website or interactive voice response system. Participants were prescribed 3 tailored goals for modifying obesogenic lifestyle behaviors with new goals selected at subsequent 13-week intervals. For the duration of the study, participants maintained a hypertension medication adherence goal. Participants	HD + PA Total contact hrs: 18 Total duration: 24 months	Community health educator and PCP endorsement Home (web-based or print and phone) and	Usual care: Received NHLBI self-help booklet, "Aim for a Healthy Weight."

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		self-monitored behavioral goals via the study website or printed logs which were then entered into an interactive voice response system. Trained community health educators delivered monthly 15-20-min telephone counseling calls in the first year and bimonthly during the second year (18 telephone calls total) that covered data from self-monitoring, problem solving and behavioral skills training. Twelve optional bimonthly group sessions were also offered including interactive skills training and a physical activity component (e.g., group walk), and promoting social support for behavioral change. PCP delivered at least 1 brief, standardized message about the importance of intervention participation. Participants were provided behavior change "prescription" that included PCP's electronic signature, as well as tailored information on community resources (e.g., public parks, walking groups, and farmers' market) and received a walking kit with a pedometer.		community health center	
Bennett, 2018[48] (Track) Good	IG1	Weight-loss intervention informed by social cognitive theory, and had a weight loss goal of 7% weight reduction. The Track intervention contained five components: (1) tailored physical activity- and diet-related behavioral goals; (2) self-monitoring of behavioral goals via interactive voice response (IVR) phone calls and SMS text messages with automated, tailored feedback; (3) daily self-weighing via a cellular connected scale; (4) skills training materials in print and video; (5) 18 weight loss counseling 10-15 min coaching calls (weekly for calls 1-4; biweekly for calls 5-10; and monthly for calls 11-18), during which registered dietitians and psychology graduate students (i) reviewed self-monitoring data (behavioral goals and daily weights) and reinforced its importance, (ii) discussed barrier reduction strategies, (iii) delivered skills training content, and (iv) discussed community resources; and (6) brief PCP-delivered weight-loss counseling at medical visits. To facilitate PCP counseling, regular participant progress reports were delivered to PCPs through the EHR that include the participant's status on behavioral change goals, weight change data, and feedback regarding the participant's adherence to self-monitoring. Clinicians are alerted to their updates through pop-ups that display upon opening an intervention participant's EHR. PCPs also received quarterly reports with feedback on their individual counseling rates. PCPs also	HD + PA Total contact hrs: 5.4 Total duration: 12 months	PCP, dietitian, psychology graduate students Primary care and home (coaching calls)	Usual care: Participants received current standard of care offered by their primary care providers, as well as self-help materials (NHLBI "Aim for a Healthy Weight") and a collated list of community resources for healthful eating, physical activity, and weight management. Participants also received quarterly newsletters that included seasonal-related health tips, and financial and safety information.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		received annual in-service trainings and period presentations at staff meetings showing clinic-level data. Four individualized behavior change goals were selected among 24 dietary and PA goals, rotating every 8 weeks, based on a self-administered survey. Each person was assigned their top 3 goals based on a computer algorithm, and plus a rotating 4th goal which was the same for all participants. The 4th goal also changed every 8 weeks and were: (1) "no red zone foods" [red zone foods are commonly eaten high-calorie foods and beverages (sodas, sweet teas, desserts, potato chips, pizza, hamburgers) that the participant typically eats 3 times per week or more], (2) practice portion control, (3) walk 7000-10000 steps per day.			
Beune, 2014[49] (Culturally Adapted Hypertension Education (CAHE)) Fair	IG1	Participants received three 30-minute culturally-appropriate hypertension education (CAHE) sessions adapting the "5As" model (ask, assess, advise, assist, arrange) over a period of 4.5 months, conducted by a trained practice nurse. During the first session, the PN educated the participant about hypertension and discussed hypertension treatment goals for the next 3 months, as well as potential barriers/facilitators in achieving treatment goals. During the second and third sessions, the PN discussed with the participant their experiences of culturally-specific barriers/enables in achieving their hypertension treatment goals, such as medication use and lifestyle changes. PNs also discussed the participant's current BP measurement; self-reported medication and lifestyle adherence; goals for the next 3 months; potential barriers/facilitators in achieving treatment goals; and feasible steps needed to maintain/achieve treatment goals. In addition to the CAHE sessions, participants received culturally-specific, educational written material, and if necessary, referrals to neighborhood facilities (e.g., walking clubs or health food stores) that could help Surinamese and Ghanaian patients adopt healthier lifestyles.	HD + PA Total contact hrs: 1.5 Total duration: 4.5 months	Practice Nurse Primary care	Usual care: Participants received standard hypertension care and education following the recommendations in the Dutch clinical guidelines.
Blackford, 2016[50] (Albany Physical Activity and Nutrition	IG1	As part of a 6-month home-based intervention, participants received a package designed to educate, motivate, and support improvement in nutrition and physical activity through goal setting. The program empowers individuals to self-manage and monitor their health behaviors and weight, emphasizing the importance of regular self-	HD + PA Total contact hrs: 1.5 Total duration: 6 months	Research assistants Home	Waitlist: Participants received the intervention after completing post-test data collection.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
(APAN)) Fair		weighing. The package contained a booklet, exercise chart, calendar, resistance bands, and nutrition panel wallet cards. The educational materials provide illustrations and tips on how to perform exercises safely. The PA component will use accelerometers to measure PA at baseline and posttest for the IG group only, with graphical feedback provided to participants at baseline. A resistance band was provided for strength training exercises. The nutrition component consists of suggested meal plans, recipes, and tips on healthy eating, encouraging a higher consumption of fruits and vegetables and fiber while reducing intake of fat and sugar. The package materials were adapted from PANS study materials for a rural context. The booklet had materials based on the Australian Dietary Guidelines and Australia's Physical Activity and Sedentary Behavior Guidelines, which participants used to set their diet and PA goals for the duration of the intervention. The calendar was used to support goal setting by providing a resource for their planning and recording their PA and eating habits and supplemented the program booklet as a quick and convenient reference. In addition to the package materials, participants received 6 motivational telephone calls (weeks 3, 6, 12, 18, and 24) utilizing strategies such as empathy, shared decision-making, and reflective listening and followup emails from research assistants, which were used to support goal setting and use of the program resources. Participants chose their own goals. Participants had the option to contact the research assistant they had been allocated to throughout the course of the intervention. Participants also received a bimonthly newsletter and had access to a website that included diet and PA information and links, a blog for program news and updates, and a daily and weekly progress tracker to PA, diet behaviors, and weight.			
Bloemberg, 1991[51] Fair	IG1	Participants received individualized dietary advice based on their habitual food intake and the "Guidelines for a Healthy Diet" of Netherlands Nutrition Council. The aim of the advice was to lower plasma total cholesterol level without lowering the HDL cholesterol level. With the aid of a study-created computer program, the study dietitian examined data on participant baseline habitual food intake and checked the effect of changes on the energy and nutrient content. The computer program was also able to estimate the expected	HD only Total contact hrs: 1 Total duration: 6 months	Dietitian NR	No advice: Did not receive any advice to improve diet during the study period.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		decrease of plasma total cholesterol level due to changes in fatty acid and cholesterol content of their diet. The aim of the dietary advice was to reduce total cholesterol by 1 mmol/L. One week after examination, dietitian counseled participants on their diet and tried to convince them to adhere to their advice. In addition, participants received an average of two telephone calls in which the dietitian inquired about possible problems related to their dietary advice. Five mailers with information on healthy diets were sent to participants.			
Bo, 2007[52] Fair	IG1	Trained interventionists delivered the following: 1 individual session prescribing diet tailored to participants' current weight and dietary intake (normo- or hypocaloric); general dietary recommendations about cooking, reducing fat, sugar, and salt intake, and tips for dining out; discussion about behavior modifications; written recommendations for physical activity; a brief written guide on behavioral change; a copy of the food pyramid; explanations about the benefits of using diet and exercise to control metabolic abnormalities; and individualized diet and physical activity goals; and 4 group sessions for each different topics: food composition; portion control, strategies for dining out; and physical activity benefits. In addition, PCP delivered a brief general healthy lifestyle advice according to their usual practice to participants in both groups.	HD + PA Total contact hrs: 5 Total duration: 12 months	Nutritionists, specialists in endocrinology, and internal medicine Assumed health clinic	Usual care: General information on the importance of a healthy lifestyle was given from participants' physicians according to their usual practice.
Bosworth, 2009[53] (Take Control of Your Blood pressure (TCYB)) Fair	IG1	Participants received a tailored behavioral self-management intervention, delivered by one nurse via bi-monthly telephone calls. Information was presented in an easily understood format with a readability score of 9th grade or less. Factors targeted in calls were: perceived risk for HTN, memory, literacy, social support, patients' relationships with their healthcare provider, and side effects of medication. The intervention also focused on improving adherence to the DASH diet, weight loss, reduced sodium intake, regular moderate intensity PA, smoking cessation, and moderation of alcohol intake. Each encounter included a core group of modules potentially implemented during each call and additional modules activated at specific intervals. In addition to the dietary and PA counseling calls, participants received a blood pressure monitor, which they were trained to self-administer 3 times weekly on separate days at the	HD + PA Total contact hrs: 3.2 Total duration: 24 months	Nurse Home	Usual care: Participants received usual hypertension care from their primary care provider.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		same time of day. The trial nurse was not aware of home monitored BP values, but participants asked to maintain and turn in BP logs.			
Bosworth, 2009[53] (Take Control of Your Blood pressure (TCYB)) Fair	IG2	Participants received a tailored behavioral self-management intervention, delivered by one nurse via bi-monthly telephone calls. Information was presented in an easily understood format with a readability score of 9th grade or less. Factors targeted in calls were: perceived risk for HTN, memory, literacy, social support, patients' relationships with their healthcare provider, and side effects of medication. The intervention also focused on improving adherence to the DASH diet, weight loss, reduced sodium intake, regular moderate intensity PA, smoking cessation, and moderation of alcohol intake. Each encounter included a core group of modules potentially implemented during each call and additional modules activated at specific intervals.	HD + PA Total contact hrs: 3.2 Total duration: 24 months	Nurse Home	Usual care: Participants received usual hypertension care from their primary care provider.
Broekhuizen, 2012[54] (PRO-FIT) Fair	IG1	A combination of tailored web-based advice (PRO-FIT*advice) and one face-to-face counselling complemented with 1 to 5 telephone booster sessions (PRO-FIT*coach). The goal was to: 1) improve awareness of the cardiovascular disease risk through an increase of specific knowledge, cues to action and change in risk perception, 2) improve motivation with respect to healthy behavior through an increase of specific knowledge and a change in attitude, self-efficacy and social influences, 3) adopt and maintain a healthier lifestyle, specifically with regard to physical activity, saturated fat intake, fruit and vegetables intake, smoking and compliance to statin therapy, and 4) lower the level of LDL-C and other biological CVD risk indicators and thereby reducing the CVD risk. Thus, the intervention was a personalized health counseling intervention that included the use of a website on CVD risk communication and how to change these risks; and access to online PRO-FIT advice account, which had tailored advice regarding positive behaviors such as food intake, smoking, and compliance to statin therapy, presented according to the individual participants risk profile; and a lifestyle coach who delivered personal feedback and worked with participants to make action plans using motivational interviewing techniques.	HD + PA Total contact hrs: 2.25 Total duration: 11 months	Trained lifestyle coach Participants' home	Usual care: Usual care (no intervention)
Bruckert, 2008[55] (PEGASE (Effect of an Education	IG1	Assessment and six counseling for healthy diet and physical activity (4 45-min group sessions, 2 in-person individual sessions). Sessions focused on three stages: increasing awareness on CVD risks, start	HD + PA Total contact hrs: 4 Total duration: 6 months	Physician, nurse, nutritionist Medical centers	Usual care: Physicians received no training;

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Program)) Fair		action, maintain action. Group sessions included self-reflection on risks and threats to health, physical activity & healthy diet education, and information on cholesterol management and barriers to drug adherence, plus written materials. Educational messages were reinforced during individual sessions, along with focusing on translating individual goals into small, achievable steps and actions related to healthy behaviors.		specializing in CVD prevention	patients received usual care
Burke, 2006[56] (ADAPT) Fair	IG1	6 group workshops with printed materials for behavioral self-management of nutrition, physical activity and weight loss with emphasis on barriers, costs and benefits of a healthy lifestyle, goal setting, and time management. The DASH diet was the model for dietary advice with the following goals: sodium intake <2 g per day, increased intake of fruit, vegetables, and low-fat dairy, reduced intake of total and saturated fats, sweets, and sugary drinks; eating ≥4 fish meals per week; participating in ≥30 min of physical activity most days and increasing incidental activity; weight loss of ≥5%; reduced alcohol (consuming ≤2 drinks per day), and smoking cessation. Social support was encouraged by allowing a partner, relative, or friend to accompany participants during group sessions and involving them in grocery shopping, meal prep, and physical activity. Diet and physical activity calendars were used to track behaviors. Individual counselling sessions with dietician or program coordinator were offered, but few participated (5 individuals attended with 2 sessions each). A newsletter was issued every 3 months. Participants with 24-hr ambulatory BP <130/85 mm Hg at the end of 4 months had anti-HTN medications withdrawn; these participants then measured their BP using a home monitor with regular phone contact with study facilitators to report results of home-monitored BP.	HD + PA Total contact hrs: 6 Total duration: 16 months	Dietitian, program coordinators Medical center	Attention control: Usual care; publications from the National Heart Foundation of Australia & the Health Department of Australia; attention control with 4 seminars on topics unrelated to ADAPT were held as well.
Chirinos, 2016[57] (Community Health and Risk-reduction for Metabolic Syndrome (CHARMS)) Fair	IG1	17 (90-min) diet and physical activity group counseling sessions. Intervention was DPP-based and tailored to population by Spanish translation of materials, delivery in English or Spanish according to individual language preferences, and culturally relevant examples and dietary recommendations. Intervention had a 3-month core curriculum of eight sessions (four weekly and four bi-weekly) followed by a maintenance phase with 9-monthly sessions. Calorie goals were set based on participant's baseline weight; however,	HD + PA Total contact hrs: 25.5 Total duration: 12 months	Master and doctoral level clinicians Research clinic	Usual care: At baseline and 6 months, received detailed description of their lab values and met with a medical provider for lifestyle modification advice, which is recommended

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		participants were not prescribed a structured dietary program. Unsupervised exercise, which consisted of brisk walking, was initiated at week 1, starting with four 15-min weekly sessions, increasing progressively to five 30-min weekly sessions by week 5. Dietary and exercise goals were aligned to national recommendations. Participants were asked to record their food intake in food logs and wear a pedometer for at least one week prior to each sessions. Sessions targeted a broad range of material related to diet, physical activity and psychosocial well-being.			management of the metabolic syndrome.
Christian, 2011[58] Fair	IG1	Patients completed a computer-based assessment of their motivational readiness to increase physical activity and make dietary changes just before a usual care visit. The assessment (<10 minutes) solicited information on usual dietary habits, weight-management history, and awareness of the role of diet and exercise in the prevention of diabetes. Upon completion of the assessment, the computer system generated a tailored report providing feedback addressing participant-identified barriers to improving their physical activity and diet. The purpose of this feedback was to enhance participants' motivation to increase PA and reduce caloric intake; to identify potential barriers to making lifestyle changes, and to provide tailored counseling suggestions to enhance readiness, decision-making, and self-efficacy. Before the baseline clinic visit, participants read their report and listed 2-3 dietary and/or PA self-management goals they want to achieve and were also given a 30-page planning guide that provided general supplemental information on preventing diabetes and achieving goals. The computer expert system also generated a companion report for the patient's physician, which consisted of a less than 1-page bulleted summary of the findings from the patient's assessment and provided the physician with patient-specific counseling recommendations based on an MI approach. Participants reassessed goals at 6 months and again reviewed their goal sheet with their physician, who reinforced patients' goals.	HD + PA Total contact hrs: 0.83 Total duration: 6 months	Computer expert system and PCP Community health center	Usual care: Given a packet of health education materials addressing diabetes, diet, and exercise before completing their usual care visit
Cicolini, 2014[59] Fair	IG1	1 60-minute educational session on healthy lifestyle and hypertension management; 26 weekly email messages and phone calls; and two booklets. For 6 months, participants received weekly emails containing a reminder program on the compliance with	HD + PA Total contact hrs: 1 Total duration: 6 months	Nurse care manager Home	Usual care: Received 1-hour educational session on healthy lifestyle and

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		healthy lifestyle. And, in case of no read receipt, nurse care manage phoned participants to press for reading. The attached program to the emails contained recommendations on healthy lifestyle, including a diet high in vegetables and low in salt, saturated fat intake and cholesterol, moderate aerobic exercise, smoking cessation and/or replacement with nicotine/bupropion, moderate alcohol consumption, blood pressure self-monitoring (with instructions) and medication adherence.			hypertension management.
Cochrane, 2012[60] Fair	IG1	Health check plus 1 individual 45-60 minute lifestyle counseling/motivational interviewing session with lifestyle coach. The coach offered an additional maximum of 6 hours of support over 6 months and a final review at 12 months; subsequent contacts could be face-to-face, by telephone, or text message based on patient preference. Initial consultation session was used to discuss, develop, and negotiate a personalized health improvement plan and lifestyle improvement priorities identified by the patient. Referrals to free support sessions were offered, including PA sessions (free 20-week program), weight management support (free Weight Watchers vouchers), cooking and eating and positive thinking sessions, and access to smoking cessation support. Primary care toolkit publicly available at: https://www.healthcheck.nhs.uk/	HD + PA Total contact hrs: 3.5 Total duration: 12 months	Lifestyle coach Medical center	Minimal intervention: NHS health check plus usual general practice care, including medication or treatment for raised BP and/or cholesterol and newly diagnosed diabetes and referral to smoking cessation services, but did not receive additional lifestyle support. May have received lifestyle advice from the GP team.
Cohen, 1991[61] Fair	IG1	12 monthly diet counseling visits with family practice resident. The goal of the dietary advice was to reduce the caloric content of the diet without radically changing the patient's lifestyle; suggested diets were not specifically intended to be salt-reducing. At the initial visit, the resident reviewed the patient's diet using a questionnaire. Information was provided about the calorie content of foods and suggestions for changes made as appropriate. Patients were encouraged to use a diet history sheet to evaluate and modify diet. At each visit the patient's weight was recorded and any weight change noted, and dietary analysis and advice repeated. Short-term goals were set for the patient to meet by the next visit. The amount of weight gained or lost at each visit was used as feedback.	HD only Total contact hrs: 6 Total duration: 12 months	Family practice resident Primary care	Usual care: Physicians received no special instructions or materials. Participants received usual care; physicians could provide or refer participants for dietary advice. Participants were instructed about the importance of blood pressure control.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		Management of the patient's hypertension medication was left to the PCP.			
Coleman, 2012[62] (Wisewoman California) Fair	IG1	Three individual tailored counseling sessions (averaged 50 min) for healthy diet and physical activity; comprised of assessment, tailored feedback, collaborative goal setting, identifying strategies for overcoming barriers, and outlining small, achievable steps. Emphasis on self-efficacy, self-monitoring, reinforcement, readiness for change, and the importance of social support. Delivered in language of choice. Visual aids and hands on tools used (e.g. food models showing appropriate portions) along with a curriculum binder. Community health workers followed up via telephone in between sessions to encourage healthy behaviors, give referrals to health education classes (e.g. smoking cessation, nutrition, physical activity), and give appointment reminders. Received the same access to usual care and incentives (e.g. tote bags, water bottles, transportation tokens, grocery store vouchers) during assessments and sessions.	HD + PA Total contact hrs: 3.25 Total duration: 6 months	Bilingual (English/Spanish) community health workers (from same community as participants) medical center (4 sites)	Usual care: Usual care for elevated blood pressure and cholesterol. May have included brief healthy behavior education, healthy lifestyle handouts (general, related to hypertension/hyperlipidemia), and/or referral to education classes. Received incentives during assessments.
Delahanty, 2001[63] Good	IG1	Participants received cholesterol lowering nutritional counseling and treatment according to NCEP-based cholesterol lowering protocol (e.g., progressively reducing intake of saturated fat and cholesterol and to promote weight loss for participants who are overweight by eliminating excess total calories and increasing physical activity). Participants were required to meet with a registered dietitian for a minimum of 2 to 3 visits over a 2- to 3-month period (average 90-min/session, range 60-140 min, average of 2.5 sessions), followed by an additional 2-3 visit over the next 3 months of lipids were not in the target range, average 30 min/session, average of 1.5 sessions). The number of visits each participant received was based on an assessment of each volunteer's eating habits, lifestyle, capabilities, and motivation for change, in addition to usual care from PCPs.	HD + PA Total contact hrs: 4 Total duration: 6 months	Registered dietitian Medical center	Usual care: Participants received usual care and were instructed not to use lipid-lowering drugs or to seek additional dietary counseling.
Eakin, 2009[64] (Logan Healthy Living) Fair	IG1	The intervention was delivered over 18 months with 18 phone calls (10 over 12-month implementation period and 8 over 8-month maintenance period), during which participants received counseling with motivational interviewing techniques to promote healthy diet and physical activity. Participants were also mailed a detailed workbook, pedometer, self-monitoring form, and a stretch band prior to the first counseling call. During the counseling calls, participants	HD + PA Total contact hrs: 5.4 Total duration: 12 months	Graduate-level counselors Home	Minimal intervention: After each assessment, participants received a brief and tailored letter with feedback on their results. They also received generic

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		were guided through a series of steps, beginning with a detailed assessment of their current physical activity and dietary behaviors, followed by feedback on their health behaviors in relation to national recommendations. The feedback highlighted the discrepancy between their health goals and current health behaviors. Participants set collaborative goals for PA and dietary change with their telephone counselor, which was incorporated into a behaviorally-specific action plan specifying exactly what was to be done and when. Discussions included barriers and supports to behavior change, confidence in ability to change, and problem-solving as needed. Other components covered included goal setting, problem-solving, self-rewards, social support, positive self-talk, relapse, and action plans. Counseling followed the 4As approach: assessment, advice, assistance, and arranging followup. Participants were encouraged to meet the Australian dietary recommendations (5 servings/day of vegetables, 2 servings/day of fruit,			brochures on a variety of health topics, including physical activity and diet, and a project newsletter with general health tips.
Edelman, 2006[65] Fair	IG1	52 total sessions of diet, physical activity, and mind-body approaches to reduce CVD risk (2 individual in-person sessions providing feedback on CVD risk assessment results, 28 120-min group sessions, 20 20-30 min phone calls, and 2 individual nutrition counseling sessions). Baseline CVD risk assessment using “Know Your Number” with individualized feedback at baseline and 5-months from physician or physician assistant. With support of health coach, participants prioritized 1-3 goals for behavior change, and new goals were added once previous goals were achieved. Group sessions included mind-body approaches to self-care, nutrition education, physical activity education, and strategies for behavior change such as goal-setting, communication skills, and relapse prevention. Every two weeks, participants had individual telephone sessions (20-30 min) with their coach to reinforce group session techniques, to clarify priorities and set or update goals, and enhance motivation. Participants had 2 opportunities to meet with a nutritionist for individualized support and recommendations.	HD + PA Total contact hrs: 68 Total duration: 10 months	Master's level trained health coaches, nutritionists, physician, physician assistant Academic "integrative" medical center	Usual care: The group received a mailed report including their health assessment and baseline blood test results.
Ellsworth, 2016[66] Fair	IG1	Participants first received a 3-month therapeutic education and lifestyle workshop in which they developed individualized lifestyle plans to reduce metabolic risk. Lifestyle plans focused on a Mediterranean-style diet that included moderate carbohydrate and	HD + PA Total contact hrs: 20.5 Total duration: 12 months	Registered dietitian, exercise physiologist, stress	Usual care: Participants received standard care from their PCPs, but did not participate in

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		animal/vegetable fat, weight loss, strength and endurance, and stress reduction. Participants first attended a 4-h orientation that outlined objectives, requirements and expectations and then met individually with a registered dietitian, exercise physiologist, stress management instructor and psychologist to learn effective strategies for integrating healthy changes into their current lifestyle. Subjects met monthly with each specialty provider to receive reinforcement for implementing recommended lifestyle changes and guidance for maintaining success on their own. Over the next 9 months, participants received additional instruction for integrating healthy behaviors into daily life through monthly contact with an integrative health coach.		management instructor, psychologist, and integrative health coach NR	any component of the lifestyle programs or receive any advice or counseling beyond routine care information regarding healthy lifestyle behaviors.
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	IG1	Following randomization, all participants met with a dietitian to complete a questionnaire regarding adherence to the Mediterranean diet and discussed individual recommendations for changes to their diet in order to achieve a personalized goal depending on group assignment. The dietitian provided reasons to adopt a Mediterranean diet, highlighting the advantages of following this diet rather than the risks of not adhering to it, and transmitting a positive message emphasizing the benefits for the high CV risk of the participants. The dietitian personalized the message by adapting it to the participant's clinical condition, preferences, and beliefs. The visit ended with an agreement to participate in the group session, which was scheduled in the next 1-2 weeks. The group sessions were facilitated by the dietitians and were scheduled regularly and attended by ≤20 participants per session. During the group sessions, the dietitian gave an informative talk regarding dietary goals, description and clarification of written materials (descriptions of 4 to 5 foods typical of the high-olive oil dietary pattern), a quantitative 1-week shopping list of food items according to the season of the year, a weekly plan of meals (with detailed menus) corresponding to the shopping list, and the recipes for preparing the meals of the suggested menus), allotments of supplemental foods (15-liter supply of extra-virgin olive oil), and an agreement to participate in the next visit 3 months later. The individual motivational interviews included three steps: assessment, intervention, and future directions. Interventionists	HD only Total contact hrs: 30.5 Total duration: 60 months	Registered dietitians Primary care centers, university health care centers, hospitals	Minimal intervention: During the first three years, participants received one dietary counseling session with a dietitian at baseline and an annual leaflet explaining the low-fat diet. Thereafter, participants had quarterly individual and group sessions with the delivery of food descriptions, shopping lists, meal plans and recipes (adapted to the low-fat diet) in such a way that the intensity of the intervention was similar to that of the Mediterranean diet groups, except for the provision of free

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		emphasized the holistic approach to lifestyle change in order to tailor the intervention to nutritional assessment and individual needs, encourage adherence to the MedDiet, transmit a sense of empowerment, and, importantly, feel a self-reward for each upward step in the 14-point MedDiet score. The focus was shifted from changing portion sizes to changing frequency of intake or to changes in cooking methods. Accomplishments in the previous months, even if minor, are considered as support to provide further empowerment and self-reward. The general guidelines to follow the Mediterranean diet included: a) abundant use of olive oil for cooking and dressing dishes; b) consumption of ≥2 daily servings of vegetables (at least one of them as fresh vegetables in a salad), discounting side dishes; c) ≥2-3 daily servings of fresh fruits (including natural juices); d) ≥3 weekly servings of legumes; e) ≥ 3 weekly servings of fish or seafood (at least one serving of fatty fish); f) ≥1 weekly serving of nuts or seeds; g) select white meats (poultry without skin or rabbit) instead of red meats or processed meats (burgers, sausages); h) cook regularly (at least twice a week) with tomato, garlic and onion adding other aromatic herbs, and dress vegetables, pasta, rice and other dishes with tomato, garlic and onion. Participants were encouraged to eliminate or limit the consumption of food products high in saturated fat, simple carbohydrates, and sugar. The dietitians insisted that two main meals per day should be eaten (seated at a table, lasting more than 20 minutes). For usual drinkers, the dietitian's advice was to use wine as the main source of alcohol (maximum 300 ml, 1-3 glasses of wine per day) Interventionists applied common cognitive behavioral techniques, including goal setting, self-monitoring, feedback and reinforcement, self-efficacy enhancement, incentives, problem solving, relapse prevention, and motivational interviewing in individual and group sessions. Measurable realistic goals easily identifiable by the participant and attainable in specified time frames were set.			supplemental olive oil or nuts.
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a	IG2	Following randomization, all participants met with a dietitian to complete a questionnaire regarding adherence to the Mediterranean diet and discussed individual recommendations for changes to their diet in order to achieve a personalized goal depending on group assignment. The dietitian provided reasons to adopt a Mediterranean	HD only Total contact hrs: 30.5 Total duration: 60 months	Registered dietitians Primary care centers, university health	Minimal intervention: During the first three years, participants received one dietary counseling session with

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Mediterranean Diet (PREDIMED)) Fair		diet, highlighting the advantages of following this diet rather than the risks of not adhering to it, and transmitting a positive message emphasizing the benefits for the high CV risk of the participants. The dietitian personalized the message by adapting it to the participant's clinical condition, preferences, and beliefs. The visit ended with an agreement to participate in the group session, which was scheduled in the next 1-2 weeks. The group sessions were facilitated by the dietitians and were scheduled regularly and attended by ≤20 participants per session. During the group sessions, the dietitian gave an informative talk regarding dietary goals, description and clarification of written materials (descriptions of 4 to 5 foods typical of the high-nut dietary pattern), a quantitative 1-week shopping list of food items according to the season of the year, a weekly plan of meals (with detailed menus) corresponding to the shopping list, and the recipes for preparing the meals of the suggested menus), allotments of supplemental foods (3-month supply of nuts consisting of 1350 g walnuts, 675 g hazelnuts, 675 g hazelnuts [additional 1000 g packs of mixed nuts provided to each family unit]), and an agreement to participate in the next visit 3 months later. The individual motivational interviews and group sessions were repeated every 3 months with the same content. Each visit included three steps: assessment, intervention, and future directions. The general guidelines to follow the Mediterranean diet included: a) abundant use of olive oil for cooking and dressing dishes; b) consumption of ≥2 daily servings of vegetables (at least one of them as fresh vegetables in a salad), discounting side dishes; c) ≥2-3 daily servings of fresh fruits (including natural juices); d) ≥3 weekly servings of legumes; e) ≥ 3 weekly servings of fish or seafood (at least one serving of fatty fish); f) ≥1 weekly serving of nuts or seeds; g) select white meats (poultry without skin or rabbit) instead of red meats or processed meats (burgers, sausages); h) cook regularly (at least twice a week) with tomato, garlic and onion adding other aromatic herbs, and dress vegetables, pasta, rice and other dishes with tomato, garlic and onion. Participants were encouraged to eliminate or limit the consumption of food products high in saturated fat, simple carbohydrates, and sugar. The dietitians insisted that two main meals per day should be eaten (seated at a table, lasting more		care centers, hospitals	a dietitian at baseline and an annual leaflet explaining the low-fat diet. Thereafter, participants had quarterly individual and group sessions with the delivery of food descriptions, shopping lists, meal plans and recipes (adapted to the low-fat diet) in such a way that the intensity of the intervention was similar to that of the Mediterranean diet groups, except for the provision of free supplemental olive oil or nuts.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		than 20 minutes). For usual drinkers, the dietitian's advice was to use wine as the main source of alcohol (maximum 300 ml, 1-3 glasses of wine per day). Interventionists applied common cognitive behavioral techniques, including goal setting, self-monitoring, feedback and reinforcement, self-efficacy enhancement, incentives, problem solving, relapse prevention, and motivational interviewing in individual and group sessions. Measurable realistic goals easily identifiable by the participant and attainable in specified time frames were set.			
Fagerberg, 1998[68] (Risk Factor Intervention Study (RIS)) Good (KQ1); Fair (KQ2)	IG1	Aims to reduce total cholesterol to <6.0 mmol/L, help current smokers quit, prevent nonsmokers from starting, reduce hemoglobin A1c to <6.0% in those with diabetes, and lower DBP to <90 mm Hg. Dietary advice was consistent with NCEP guidelines. After an initial informational group meeting, weekly group lessons for 5 weeks for 10-20 patients (and spouses) to change eating habits. Basic nutrition, purchase and preparation of food discussed using a slide series, a specially developed textbook and food/beverage exhibition. Overweight patients set a weight goal and restriction of alcohol intake encouraged for high consumers. Those with diabetes taught self-monitoring of glucose. Information provided about physical activity. At 4 months, individual follow-up visit with nurse to discuss results and further changes in dietary habits. Smoking cessation program consisting of 1 physician visit and weekly 1-hour group sessions were offered to smokers. Sessions included discussion of smoking habits, symptoms and diseases secondary to nicotine usage, psychological and social factors, and motivation for quitting. Nicotine gum was offered. At the 6 month visit, physicians started treatment with lipid lowering drugs and diabetes drugs if TC and/or HbA1c goals were not met.	HD + PA Total contact hrs: 11.5 Total duration: 4 months	Physician, nurses, and dietitian Hypertension outpatient clinic	Usual care: Usual care. Primary care provider treated hypercholesterolemia, diabetes, and smoking according to normal practice. Similar to IG, goal was to reduce DBP to <90 mm Hg so that differences in endpoint rates were not attributable to difference in BP.
Gill, 2019[69] (Heartmatters Challenge - First Responders) Fair	IG1	Personalized diet and exercise plan via an online portal based on combination of laboratory results and personal references; lifestyle plans reviewed during telephone coaching with registerd dietitians and online tools for tracking diet, exercise, and weight, including gamification apps to promote participaton. Recommended carbohydrate intakes 30% to 60%, saturated fat intake 5% to 10% with no more than 7% for known CVD or LDL-C ≥160 mg/dL, and total calorie intake set to facilitate health weight as determined by	HD + PA Total contact hrs: 10 Total duration: 12 months	Registered dietitian Home	Minimal intervention: Completed 3-day food journals prior to each blood draw at FUP timepoints.

Appendix F Table 3. Detailed Intervention Descriptions

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		waist to height ratio. Carbohydrates recommendation were based on the severity of metabolic syndrome, and promoted unrefined natural sources such as vegetables, legumes, fruits, low-fat dairy, and whole grains. Dietary cholesterol was limited to 300 mg/dL, or 200 mg/dL for subjects with CVD, LDL ≥160 mg/dL or abnormally high cholesterol absorption. A 30% reduction in total energy intake was recommended to those requiring weight loss. Online food journals were reviewed during 20-minute one-on-one telephone lifestyle coaching sessions.			
Gill, 2019[70] (HealtheSteps) Fair	IG1	4 in-person individual sessions of diet and physical activity counseling (4 35-min sessions), print materials, and health technology tools and resources (e.g., phone coaching, online HealtheSteps social network, smartphone app, HealtheSteps website). Participants received 'Eating Well with Canada's Food Guide' and the 'Canadian Physical Activity Guidelines for Adults' and met with their coach to set their exercise (moderate to vigorous intensity), physical activity (steps/day) and healthy eating prescriptions and discuss strategies to achieve their goals. Specifically, sessions were personalized to the participant focusing on setting S.M.A.R.T. (specific, measurable, attainable, realistic, and timely) goals. For the exercise prescription, participants completed a validated Step and Exercise Prescription providing a personalized target heart rate to measure and assist participants meeting their personal recommendations for moderate to vigorous activity. Coaches also discussed and encouraged strategies with participants on how to increase the amount of time that they spent exercising at their target heart rate. For the physical activity prescription, participants used a pedometer to record their average daily step count for 1 week (baseline). A paper chart was used to guide participants to incrementally increase their step count up to 10,000 steps per day. For aiding in further reducing sedentary behaviour, participants were instructed to reduce their sitting time in addition to increasing their step count daily. Lastly, a heathy eating prescription was planned so that the participant would increase (or decrease) their intake of fruits and vegetables, fats, carbohydrates and protein until they met the recommendations set out by Health Canada through Eating Well with Canada's Food Guide.	HD + PA Total contact hrs: 2.3 Total duration: 6 months	Health coach Primary care community clinic sites	Waitlist: At allocation, participants were provided with copies of 'Eating Well with Canada's Food Guide' and the 'Canadian Physical Activity Guidelines for Adults'.

Appendix F Table 3. Detailed Intervention Descriptions

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Greaves, 2015[71] (Waste the Waist) Fair	IG1	Four 2-hr group-based sessions in the first month to support initial behavioral change then five 90-min maintenance support sessions at 1.5, 2, 4, 6, and 9 months. Goals included increasing PA, reducing intake of total and saturated fat, increasing fiber intake, and other dietary changes to achieve 5% weight loss, although specific goals were chosen by each participant. Participants were invited to bring along a partner if they wished. Each session comprised a series of short sections to elicit and exchange ideas (e.g., about the importance of exercise, risks of excess weight, healthy eating etc.), learn key facts about diet and physical activity and skills of action/coping planning, self-monitoring and problem-solving. Early sessions focused on the skills and information required to adopt a new behavior, and later sessions introduced discussions more relevant to the maintenance of behavior, such as dealing with stress and challenging situations, and how to maintain motivation if weight loss 'plateaus'. Sessions also encouraged emotional self-regulation, and included a cognitive behavioral therapy technique for impulse control. The main focus of sessions was to equip participants with a better understanding of what a healthy lifestyle is and it is importance, as well as to encourage them towards the continued use of self-regulatory activities (goal-setting, self-monitoring of behavior and weight, reviewing progress, problem-solving and review of goals) and to help them to better understand the process of behavior change over the long term. At the start and end of each session participants were reminded of the program's two key messages designed to encourage sustainable lifestyle change; (i) small changes can make a big difference to their weight and your health, and (ii) aim for a lifestyle that is both healthy and enjoyable (make changes that they can live with). Participants were provided with a handbook including information for reference, and were given tasks each week; these usually included implementing action plans set during session time.	HD + PA Total contact hrs: 15.5 Total duration: 9 months	Lifestyle coach Community	Usual care: Brief advice from usual PCP care. Received standard pack of written information on cardiovascular risk and the effects of diet and physical activity on such risk. After 12 months, participants were offered condense (two sessions) version of the intervention.
Groeneveld, 2010[72] (Health Under Construction) Fair	IG1	Participants received a 6-month motivational interviewing (MI) intervention led by occupational physicians and occupational nurses trained to be lifestyle counselors. Using MI, the counselors guided participants through the process of becoming aware of their CVD risk, changing their behavior, and maintaining the changed behavior	HD + PA Total contact hrs: 5.5 Total duration: 6 months	Occupational physicians and occupational nurses in the role of lifestyle	Usual care: Participants received usual care in which an occupational physician (OP) informed them of their

Appendix F Table 3. Detailed Intervention Descriptions

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		delivered in three 45-60 minute in-person counseling sessions and four 15-30 minute telephone counseling sessions. Participants' wives or partners were invited to accompany them to the in-person sessions. During the first in-person session, the counselor explained the goals and procedure of the intervention and discussed the participant's knowledge about CVD risk factors and health consequences, their personal risk profile, current lifestyle, and family history. Also during the first session, participants were offered two types of interventions: (1) Energy balance - Both diet and PA were addressed. Depending on the current PA and dietary behavior of the participant, the focus was on both diet and daily PA; (2) smoking cessation. After choosing the intervention type, pros and cons of behavior change, and willingness, readiness, and perceived confidence in the ability to change were discussed. Last, the participant set long- and short-term goals, and formulated implementation intentions. In subsequent sessions, progress and barriers were discussed and short-term goals could be adjusted. No specific weight loss advice was given. In addition to the in-person and telephone sessions, counselors provided several brochures to each participant containing educational materials on lifestyle risk factors for CVD, smoking cessation, PA, healthy diet, and dietary guidelines of the Dutch Nutrition Center. Participants were also provided a leaflet describing products high in saturated fat and low-fat alternatives, a leaflet with caloric values of common food products, and a brochure with recipes for healthy meals.		counselors Occupational health clinic	CVD risk profile in person or by mail. In some cases the OP provided brochures about CVD risk factors and/or lifestyle. The OP could provide advice on the participant's lifestyle or refer them to a general practitioner, depending on the seriousness of the risk and the OP's usual practice.
Hardcastle, 2008[73] Fair	IG1	1 motivational interviewing session of diet and/or physical activity counseling (20-30 mins) with up to 4 optional MI sessions offered over the following 6 months (20-30 mins per session); average 2.0 sessions attended. MI sessions conducted by a registered dietician and/or physical activity specialist. Stage-matched motivational interviewing approach in which the focus on diet or physical activity depended on the participant's priorities and readiness to change. Techniques included agenda setting, exploring pros and cons, exploring concerns/building confidence, providing information, asking key questions, and negotiating a change plan. Standard leaflet about exercise and nutrition provided at baseline assessment.	HD + PA Total contact hrs: 1 Total duration: 6 months	Physical activity specialist and a registered dietician Primary care	Usual care: Standard leaflet about exercise and nutrition provided at baseline assessment; included food and activity quiz which advice depending on score.

Appendix F Table 3. Detailed Intervention Descriptions

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Harris, 2012[74] (Health Improvement and Prevention Study (HIPS)) Fair	IG1	This brief intervention with the PCP was modeled on the 5As framework (ask, advise, assess, assist, arrange). At the patient's health-check visit, the GP and practice nurse reviewed behavioral and physiological risk factors and provided brief lifestyle counseling. Patients were referred to the lifestyle-modification program if they were found to be at high risk, defined as including one or more of the following characteristics: (1) a history of gestational diabetes mellitus, or impaired glucose tolerance or impaired fasting glycemia; (2) hypertension (blood pressure [BP] ≥140/90 mm/Hg on two occasions) or already treated for hypertension; (3) dyslipidemia (any of: TC >4.5 mmol/L, LDL >2.5 mmol/L, TG >2.0 mmol/L, or already treated for dyslipidemia); (4) overweight (BMI ≥kg/m^2); (5) waist circumference >102 cm in males or >88 cm in females; (6) current smoker. The lifestyle program included an initial visit with a dietitian or exercise physiologist for an assessment and individual goal setting, followed by attendance at a group education program, "CHANGE for HIPS", adapted from the patient education component of the Counterweight program. This comprised four 1.5-hour sessions over the first 3 months and a further two follow-up sessions at 6 and 9 months. Group sessions included education, physical activity (20–30 minutes of walking or resistance exercise) and self-management strategies (goal setting, self-monitoring, developing practical skills and problem solving) aimed at promoting positive dietary and physical activity changes and weight loss. Patients were encouraged to keep a food and physical activity diary and use a pedometer between sessions.	HD + PA Total contact hrs: 10.25 Total duration: 12 months	GP and practice nurse, dietitian or exercise physiologist, intervention officer Primary care	Waitlist: After 12 months of usual care, control practices were offered to join intervention.
Haufe, 2019[75] Fair	IG1	6 sessions of physical activity counseling and 1 session of diet counseling. Based on data from initial exercise tests, activity questionnaires, and medical history, the intervention group received counseling with recommendations aimed to perform 150 min of moderately intense physical activity per week with individualized heart rate goals provided based on results of treadmill test. Participants were also instructed to maintain a high level of daily activity and were provided tips for their daily routine, including information on potential training facilities at their home and at the workplace. Activity monitors were also provided, and participants were instructed to download the monitor's smartphone application	HD + PA Total contact hrs: 3.5 Total duration: 6 months	Exercise scientist Community/home	Waitlist: Participants were instructed to maintain their current lifestyle and were offered the intervention following the completion of the study.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		and to wear the monitors throughout the duration of the intervention. The smartphone application provided general information about the study, individual training goals, recommended heart rates for endurance activities, tips for increased physical activity in everyday life, and the exercise scientist's contact information. The exercise scientist monitored participants' physical activity levels using data from the application and provided feedback and adaptations to their further training schedule during monthly meetings. Participants were free to contact the exercise scientist by telephone or email at any time with questions. Adherence to the goal of 150 min of activity per week was assessed from self-started activities using the provided activity monitor. In addition to the exercise intervention, participants received nutritional counseling, which provided background information on healthy food choices based on general recommendations issued by the German Society for Nutrition.			
Hinderliter, 2014[76] (Exercise and Nutrition interventions for CardiOvasculaRhEalth (ENCORE)) Good	IG1	4 in-person individual instructional sessions on diet and 14 (30-45 min) group sessions of diet counseling. Intervention began with 2 week controlled feeding period followed by 14 weekly 30-45 minute small group sessions with nutritionist. Participants were asked not to exercise or attempt to lose weight. During controlled feeding period, provided study meals were isocaloric to prevent weight gain or loss and participant met twice weekly with nutritionist to learn about the DASH dietary pattern. Following feeding period, participants instructed to maintain DASH diet on their own. The goal of weekly group counseling sessions was to assist participants in learning how to buy and prepare appropriate foods, to enhance motivation to choose to eat those foods, and to overcome obstacles to following the diet. Participants weighed each week to monitor weight and make adjustments in the recommended servings so that weight would remain stable during the intervention period.	HD only Total contact hrs: 11.5 Total duration: 4 months	Nutritionist Medical research center	Usual care: Asked to maintain their usual dietary and exercise habits
HPT, 1990[77] (Hypertension Prevention Trial (HPT)) Good	IG1	28 60-min group diet counseling sessions and 16 bimonthly newsletters: The HPT dietary intervention consisted of two phases: initial and maintenance. The initial phase consisted of 12 group sessions held during a 4-month period. Participants were given a goal to increase potassium intake to approximately 3,900 mg or more per day and reduce daily sodium intake to approximately 1,600 mg or less per day. Participants received counseling related to meal	HD only Total contact hrs: 28 Total duration: 36 months	Nutritionists and behavioral specialists Research clinic	No advice: No dietary counseling

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		planning and preparation, food purchasing, and label reading to assist them in making the required changes. Participants were asked to complete daily food records for the basis to encourage participants to make further changes or to maintain their dietary changes. Behavioral strategies included: (1) setting realistic daily and weekly goals for diet change; (2) assessing your diet at regular intervals to track your progress; (3) rewarding yourself for adhering to your diet; (4) Planning ahead, especially for meals away from home; (5) discussing your diet with family and friends and enlisting their help; (6) asking, when eating out, what is being served and request modifications as needed; (7) recognizing negative moods and thoughts that interfere with diet adherence and practicing a positive attitude; and (8) analyzing causes of recurrent dietary mistakes and taking steps to minimize them. Other specific content included building motivation, social eating strategies, assertiveness, problem solving, food cues, maintenance/relapse prevention strategies. The maintenance phase followed the initial phase and continued to the end of the study. It consisted of group sessions every second month. Participants who did not attend the group sessions were contacted by telephone and were provided a makeup with an individual session. The telephone contact included a qualitative assessment of the participant's dietary compliance based on self-report. Throughout the maintenance phase, participants also received a bimonthly newsletter containing relevant dietary information and recipes.			
HPT, 1990[77] (Hypertension Prevention Trial (HPT)) Good	IG2	28 60-min group diet counseling sessions and 16 bimonthly newsletters: The HPT dietary intervention consisted of two phases: initial and maintenance. The initial phase consisted of 12 group sessions held during a 4-month period. Participants were given a goal to reduce daily sodium intake to approximately 1,600 mg or less per day (individual goal: urine sodium excretion ≤70 mmol/d). Participants received counseling related to meal planning and preparation, food purchasing, and label reading to assist them in making the required changes. Participants were asked to complete daily food records for the basis to encourage participants to make further changes or to maintain their dietary changes. Same behavioral	HD only Total contact hrs: 28 Total duration: 36 months	Nutritionists and behavioral specialists Research clinic	No advice: No dietary counseling

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		components as IG1. The maintenance phase followed the initial phase and continued to the end of the study. It consisted of group sessions every second month. Participants who did not attend the group sessions were contacted by telephone and were provided a makeup with an individual session. The telephone contact included a qualitative assessment of the participant's dietary compliance based on self-report. Throughout the maintenance phase, participants also received a bimonthly newsletter containing relevant dietary information and recipes.			
HPT, 1990[77] (Hypertension Prevention Trial (HPT)) Good	IG3	28 60-min group diet counseling sessions and 16 bimonthly newsletters: The HPT dietary intervention consisted of two phases: initial and maintenance. The initial phase consisted of 12 group sessions held during a 4-month period. Participants were given a goal to reduce their weight by 5% through calorie restriction. Participants received counseling related to meal planning and preparation, food purchasing, and label reading to assist them in making the required changes. Participants were asked to complete daily food records for the basis to encourage participants to make further changes or to maintain their dietary changes. Same behavioral components as IG1. The maintenance phase followed the initial phase and continued to the end of the study. It consisted of group sessions every second month. Participants who did not attend the group sessions were contacted by telephone and were provided a makeup with an individual session. The telephone contact included a qualitative assessment of the participant's dietary compliance based on self-report. Throughout the maintenance phase, participants also received a bimonthly newsletter containing relevant dietary information and recipes.	HD only Total contact hrs: 28 Total duration: 36 months	Nutritionists and behavioral specialists Research clinic	No advice: No dietary counseling
HPT, 1990[77] (Hypertension Prevention Trial (HPT)) Good	IG4	28 60-min group diet counseling sessions and 16 bimonthly newsletters: The HPT dietary intervention consisted of two phases: initial and maintenance. The initial phase consisted of 12 group sessions held during a 4-month period. Participants were given a goal to reduce their weight by 5% through calorie restriction and reduce daily sodium intake to approximately 1,600 mg or less per day.	HD only Total contact hrs: 28 Total duration: 36 months	Nutritionists and behavioral specialists Research clinic	No advice: No dietary counseling

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		Participants received counseling related to meal planning and preparation, food purchasing, and label reading to assist them in making the required changes. Participants were asked to complete daily food records for the basis to encourage participants to make further changes or to maintain their dietary changes. Same behavioral components as IG1. The maintenance phase followed the initial phase and continued to the end of the study. It consisted of group sessions every second month. Participants who did not attend the group sessions were contacted by telephone and were provided a makeup with an individual session. The telephone contact included a qualitative assessment of the participant's dietary compliance based on self-report. Throughout the maintenance phase, participants also received a bimonthly newsletter containing relevant dietary information and recipes.			
Hyman, 1998[78] Fair	IG1	Patients were offered and encouraged to use multi-modal counseling: up to 12 mailed dietary questionnaires with individualized mailed feedback, up to 12 computer-interactive phone calls, and 4-weekly 1-hr classes. All three components of counseling encouraged to make dietary changes to reduce cholesterol levels. Intervention focused on improving practical skills like reading labels, eating out, modifying recipes and self-monitoring, while being practical for primary care. Phone calls included 1 to 4 questions asking about recent dietary behaviors, goals, intentions, or nutritional knowledge, and received an appropriate pre-recorded message. Class components included videos featuring practical skills to reduce fat and cholesterol intake and included cooking and tasting, recipe modification, role playing to restaurant ordering and dealing with pressure to eat high-fat meals.	HD only Total contact hrs: 4.59999990463257 Total duration: 6 months	Registered dietitian CHC	Usual care: Usual care by primary care physician, hypercholesterolemic patients could be referred to clinic registered dieticians. After trial, offered the series of classes (waitlist control)
Hyman, 2007[79] Fair	IG1	Simultaneous counseling addressed smoking cessation, sodium reduction, and increasing PA during each of 3 brief individual in-clinic counseling sessions held every 6 months. Each counseling visit was followed by 7 15-minute motivational interviewing telephone counseling sessions scheduled 2, 4, 6, 8, 12, 16, and 20 weeks later. Participants also received home-based instructional materials including a printed manual and motivational videotape. Primary goals for target areas included: stop smoking, reduce sodium levels	HD + PA Total contact hrs: 6 Total duration: 18 months	Health educator Primary care clinic, home (phone sessions)	Minimal intervention: Brief educational session on 3 target behaviors (smoking cessation, sodium intake reduction, increased physical activity). Postcards

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		to 10,000 per week) where were all measured objectively. After each 6-month measurement visit, a postcard was mailed to participants to report how their measures compared to goals.			mailed after each 6-month measurement to report how measures compared to goals.
Hyman, 2007[79] Fair	IG2	Sequential counseling addressed 1 behavior change at a time (smoking cessation, sodium reduction, or increasing PA) during each of 3 brief individual in-clinic counseling sessions held every 6 months. Each counseling visit was followed by 7 15-minute motivational interviewing telephone counseling sessions scheduled 2, 4, 6, 8, 12, 16, and 20 weeks later. Participants also received home-based instructional materials including a printed manual and motivational videotape. Primary goals for target areas included: stop smoking, reduce sodium levels to 10,000 per week) where were all measured objectively. After each 6-month measurement visit, a postcard was mailed to participants to report how their measures compared to goals.	HD + PA Total contact hrs: 6 Total duration: 18 months	Health educator Primary care clinic, home (phone sessions)	Minimal intervention: Brief educational session on 3 target behaviors (smoking cessation, sodium intake reduction, increased physical activity). Postcards mailed after each 6-month measurement to report how measures compared to goals.
Ives, 1993[80] (Rural Health Promotion Project (RHPP) Trial) Fair	IG1	5 visits of diet and physical activity counseling. Health Risk Appraisal and review of risk factors identified by the appraisal. Participants received 5 vouchers redeemable for cholesterol-lowering program which were presented at each visit. There was no specified content or structure to the visits; providers were given training and education in nonpharmacological methods for cholesterol reduction and offered potential program content but the intervention was not controlled. Interventionist training covered government and professional society recommendations (AHA, NHLBI, NCEP) for lowering cholesterol.	HD + PA Total contact hrs: 2.5 Total duration: 12 months	Hospital staff Hospital	Usual care: Usual care; completed Health Risk Appraisal but results were not reviewed and not offered vouchers for screening or health education
Ives, 1993[80] (Rural Health Promotion Project (RHPP) Trial) Fair	IG2	5 visits of diet and physical activity counseling. Health Risk Appraisal and review of risk factors identified by the appraisal. Participants received 5 vouchers redeemable for cholesterol-lowering program which were presented at each visit. There was no specified content or structure to the visits; providers were given training and education in nonpharmacological methods for cholesterol reduction and offered potential program content but the intervention was not controlled. Clinicians at primary care sites could refer their eligible participants to the hospital for the intervention rather than conducting it in their own offices.	HD + PA Total contact hrs: 2.5 Total duration: 12 months	PCP Primary care clinic	Usual care: Usual care; completed Health Risk Appraisal but results were not reviewed and not offered vouchers for screening or health education

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Johnston, 1995[81] Fair	IG1	3 90-min group sessions of diet counseling in groups of 2 to 6. Content included source and function of dietary cholesterol, risk associated with high cholesterol intake, debunking of dietary misconceptions, advice for eating out, and benefits of exercise. Partners invited to attend. At study entry, all patients completed a simple health questionnaire which included basic info on diet and exercise; received verbal advice (~3 minutes) and a pamphlet about diet modification, cooking methods and physical exercise.	HD only Total contact hrs: 4.5 Total duration: 6 months	Dietitian/nutritionist NR	Usual care: All patients completed a simple health questionnaire which included basic info on diet and exercise; received verbal advice (~3 mins) and a pamphlet about diet modification, cooking methods and physical exercise. No further counseling. Incidental queries from the subjects were answered briefly on their return to clinic.
Johnston, 1995[81] Fair	IG2	3 in-person individual sessions of diet counseling. Content included detailed diet history, food planning, cooking methods, recipe modification, shopping for food and exercise. At study entry, all patients completed a simple health questionnaire which included basic info on diet and exercise; received verbal advice (~3 mins) and a pamphlet about diet modification, cooking methods and physical exercise.	HD only Total contact hrs: 1.5 Total duration: 6 months	Dietitian/nutritionist NR	Usual care: All patients completed a simple health questionnaire which included basic info on diet and exercise; received verbal advice (~3 mins) and a pamphlet about diet modification, cooking methods and physical exercise. No further counseling. Incidental queries from the subjects were answered briefly on their return to clinic.
Jones, 1999[82] (Hypertension Optimal Treatment	IG1	2 in-person individual counseling sessions on diet and 11 in-person group support sessions. Intervention began with two individual counseling sessions on food selection and preparation and establishment of weight reduction goals. Total caloric restriction and reduction of fat intake were the only methods used for weight	HD only Total contact hrs: 12 Total duration: 30 months	Registered dietitian NR	Usual care: Research nurse informed participants to lose weight but no

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Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
(HOT)) Fair		reduction. Six group support sessions in first 3 months and then every 3 to 6 months for duration of the study. Participants were not counseled to exercise.			counseling or group support provided.
Kandula, 2015[83] (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	IG1	After randomization, all participants were given a primary care referral by CBO staff. Following the primary care referral, participants received a 16-week lifestyle intervention that included group classes, experiential activities, behavior change counseling, and telephone support. The 60-90 minute group classes were held weekly for 6 weeks. Each class covered a different topic (#1: What is Heart Disease and Understanding Your Risk Factors; #2: How to Get More Exercise; #3: Eat Less Fat and Salt; #4: Enjoy Fruits, Vegetables, & Grains; #5: Maintain A Healthy Weight; #6: Taking Care of Stress and Tension). During the classes, participants watched a video pertaining to the class topic, followed by a discussion, experiential activities, goal-setting, and closing review. Participants were taught about national physical activity guidelines (e.g. 150 minutes of moderate intensity physical activity per week) and diet (e.g. 7 servings of fruits and vegetables per day) recommendations and were encouraged to set a realistic goal based on their current behaviors using the recommendations as a guide. Individual telephone support started after the group classes ended and ran to 10 weeks, biweekly and then monthly (6 total calls). The 15-min phone counseling used a motivational interviewing framework to focus on self-reflection, behavior goals, and problem-solving. In addition to the group classes and phone support calls, participants had to option to attend 4 heart healthy "melas" (festive gatherings) over the course of 12 months that incorporated culturally-salient activities (yoga, healthy cooking with a South Asian chef, aerobic exercise that built on South Asian folk dance, and competitions with prices), which were designed to reinforce healthy behaviors and increase group cohesion and support. Melas were offered over 12 months to capture multiple intervention group cohorts, we assumed only two of the melas occurred prior to the final (6 month) followup for any given intervention cohort.	HD + PA Total contact hrs: 12.5 Total duration: 4 months	Health educators Community (classes and melas), home (phone calls)	Usual care: After randomization, all participants were given a primary care referral by CBO staff. In addition to the primary care referral, participants received their baseline screening results and monthly mailing of National Heart, Lung, and Blood Institute's print education materials on heart disease, diet, exercise, and weight (translated into Hindi and Urdu by academic and CBO staff). Participants were advised to followup with their PCP for further advice.
Kanke, 2015[84] Fair	IG1	12 7-min sessions of diet and physical activity counseling (1 introductory session followed by 11 monthly or bimonthly routine consultations). At the first consultation, the PCP counseled	HD + PA Total contact hrs: 1.4	PCP Primary care	Minimal intervention: Participants received same initial

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		participants on their ideal body weight (BMI 22 kg/m^2) and weight reduction target (5% of baseline body weight), as well as the positive effect of weight reduction for the participant's specific disease (dyslipidemia, hypertension, or T2DM). In addition to the counseling, the PCP provided participants with an informational leaflet. Following the first consultation, participants received routine consultations every 1 or 2 months for the participant's specific disease based on the Japanese guidelines. During these visits, the PCP questioned the participant on key lifestyle factors for weight reduction (i.e., eating, exercising, and weight monitoring) and provided the participant with information on the standard lifestyle changes: (1) reduce calorie intake to 25 kcal/kg ideal body weight/day; (2) eat a well-balanced diet (calorie balance: protein, 10-15%; fat, 20-25%; carbohydrate, 60%); (3) exercise for 20-30 min at least 3 times per week. The physician advice focused on weight reduction adjusted to each participant's circumstances and lifestyle. Participants were weighed at all consultations.	Total duration: 12 months		intervention as IG1 at first consultation and usual care was provided at subsequent (every 1-2 month) consultations. The physician was not required to measure body weight or discuss weight reduction at every consultation.
Kastarinen, 2002[85] (Lifestyle Intervention against Hypertension in Eastern Finland (LIHEF)) Fair	IG1	7 individual sessions of individualized diet and physical activity counseling and 2 120-minute group counseling sessions. Intervention goals were to achieve a normal weight (BMI <25 kg/m^2), sodium intake <5 g daily, <2 alcoholic drinks per day, moderate intensity exercise ≥3 times per week for 30 minutes, and to stop smoking if a smoker. During individual counseling visits with nurses, participants were instructed to change health behaviors on the basis of their individual situation. At each counseling visit, BP and weight were measured and the values, as well as changes in lifestyle factors to be reached before the next study visit, were written down in a followup card. The 2 120-minute group sessions focused on advice targeting reduction of salt intake and overweight.	HD + PA Total contact hrs: 7.5 Total duration: 21 months	Public health nurses Primary health care center	Usual care: Participants were instructed to see their primary care providers according to usual care practice.
Keyserling, 1997[86] (Southeast Cholesterol Project) Fair	IG1	3 5-10 min in-person individual diet counseling visits with PCP and referral to 3 30-min in-person individual diet counseling with dietician and 1 reinforcement mailing. Diet counseling was based on the Food for Heart Program which consisted of a Dietary Risk Assessment (DRA), a color and number-coded educational strategy corresponding to the DRA to guide clinician counseling without requiring extensive knowledge of behavior-change theory or food composition, and easy-to-read illustrated patient educational	HD only Total contact hrs: 2 Total duration: 12 months	PCPs; dieticians; health educators Community and rural health centers, local health department, hospital	Usual care: Usual care clinicians were advised to manage their patient's hypercholesterolemia according to usual practices.

Appendix F Table 3. Detailed Intervention Descriptions

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		materials that are culturally and regionally specific to the population. Includes identification of major sources of saturated fat and cholesterol and rates the atherogenicity of individual foods, weekly consumption for each food or preparation practice. If LDL-C remained elevated at 4 months, participants were referred to dietician or health educator for up to 3 30-minute sessions where the Food for Heart Program materials were used in greater depth along with other materials as appropriate. If LDL remained elevated at 7 months, the clinician received a prompt (a letter) to consider initiation of drug therapy. A mailing was sent to participants with recipes and health tips at 7 months.		outpatient services	
Khanji, 2019[87] (HAPPY London) Good	IG1	Diet and physical activity counseling (1 25-min physician-delivered counseling and instructional session and auto-generated personalized web-based counseling). At baseline participants received a 10-15 min physician-delivered personalized face-to-face counseling session on suboptimal lifestyle and cardiovascular risk factors based on guideline recommendations. The counseling was based on a lifestyle questionnaire and baseline measurements, and included advice on factors including blood pressure, cholesterol, glucose readings, smoking, weight, physical activity, fruit and vegetable intake, alcohol intake, and stress. During the same visit, participants received instructions on how to use the website for the HAPPY London web-based tool (5-10 min). The web-based tool provided a personalized score for the participant's lifestyle, 10-year risk score, and tailored advice and information specifically for the participant's relevant suboptimal risk factors. Ideal targets were highlighted as goals and updated during the 3 and 6-month visits. Additional regular email reminders were sent to encourage achievement of goals.	HD + PA Total contact hrs: 0.42 Total duration: 6 months	Study physician Primary care, home	Usual care: Participants received a 10-15 min physician-delivered personalized face-to-face counseling session on suboptimal lifestyle and cardiovascular risk factors based on guideline recommendations during the baseline visit. The counseling was based on a lifestyle questionnaire and baseline measurements, and included advice on factors including blood pressure, cholesterol, glucose readings, smoking, weight, physical activity, fruit and vegetable intake, alcohol intake, and stress.

Appendix F Table 3. Detailed Intervention Descriptions

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Koelewijn-van Loon, 2009[88] (Improving Patient Adherence to Lifestyle Advice (IMPALA)) Fair	IG1	2 (15-20 min) in-person individual diet and physical activity counseling sessions with practice nurse, 1 (10-min) follow-up telephone call, and printed materials. During the first meeting with the practice nurse, a risk communication tool was used with patients to explain 10-year CVD mortality risk. Options for risk reduction were presented to patients with increased risk and a decision aid was provided for review at home. During the second meeting approximately 2 weeks later, the nurse asked questions about the decision aid and asked the patient what they wanted to discuss with the help of an agenda-setting chart. Nurses guided patients in formulating personal goals for lifestyle change, focusing on one or more of smoking, physical exercise, dietary behavior (fruits and vegetables, fat intake), alcohol consumption, and adherence to medical treatment. A follow-up phone call using motivational interviewing was made approximately 2 weeks later to explore the importance of the lifestyle goal, increase patient confidence, and refer to local facilities as necessary.	HD + PA Total contact hrs: 0.83 Total duration: 1 months	Nurses General practice	Usual care: Patients received usual care after risk assessment step. [Nurses received a 2-hour training session on risk assessment.]
Kramer, 2018[89] (Healthy Lifestyle Project) Fair	IG1	Participant could choose between 16 (1-hr) group lifestyle counseling sessions or 12 (1-hr) individually-viewed lifestyle DVD sessions followed by brief telephone sessions (5-min); both options included health-related handouts, self-monitoring logs, a fat and calorie counter, a pedometer and exercise bands. DVD sessions were made available to participants who missed a group session. Intervention was DPP-based and adapted to a group format with goals to achieve and maintain 7% weight loss and safely and progressively increase to 150 min/wk of moderately intense PA. Participants who chose face-to-face group delivery attended 12 weekly 1-hour sessions; followed by biweekly and then monthly meetings. Participants who chose the DVD watched 1 session each week for 12 weeks and received a brief weekly telephone call to assess weight and PA and ascertain understanding of the program content; these participants were also invited to attend monthly group meetings.	HD + PA Total contact hrs: 16 Total duration: 6 months	Registered dietitians and exercise specialist Senior community centers	Waitlist: Received periodic health-related handouts via mail; will begin intervention in 6 months.
Lakerveld, 2013[90] (HOORN) Fair	IG1	Participants received a cognitive behavioral program, which combined several elements of both the theory of planned behavior & self-regulation. The intervention was provided by practice nurses in the participating general practices and consisted of six individual 30-	HD + PA Total contact hrs: 4.5 Total duration: 16 months	Practice nurses Diabetes research center	Usual care: Participants received written information about their risk of developing

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		min counseling sessions followed by three monthly booster sessions by phone over the period of one year. The counseling techniques included motivational interviewing and problem-solving treatment, with development of SMART goals and implementation plans. The aim of counseling was to increase motivation & ability to change dietary (fruit, vegetable, fiber, alcohol consumption, saturated fat), PA, & smoking behaviors (participants chose which behavior[s] they wanted to focus on). Motivational interviewing & problem-solving treatment were used to help patients find solutions to overcoming barriers & increase perceived control.			T2DM and CVD, and existing brochures containing health guidelines regarding physical activity, a healthy diet, and how to stop smoking. Patients with SBP >160 mm Hg and/or hypercholesterolemia (>8 mmol/L) were referred to their GP for additional medication.
Langford, 1991[91] (Trial of Antihypertensive Interventions and Management (TAIM)) Fair	IG1	10 group sessions and 2 individual sessions of lifestyle counseling for weight loss and 6 individual BP medication management visits. Participants additionally randomized to either a diuretic (chlorthalidone 25 mg), a beta-blocker (atenolol 50 mg), or a placebo, as well as counseling for weight loss, consisting of 10 weekly group sessions followed by individual sessions every 6-12 weeks. The weight loss goal was a reduction of 10% of baseline weight or 4.54 kg. In addition, participants had monthly BP management clinical visits, which included (1) blood pressure and weight measurements; (2) review of interim history and symptoms, treatment status, compliance; and (3) dispensing of study drugs. Participants who failed to achieve adequate blood pressure control were stepped up to additional therapy at 6 months or sooner if emergency failure criteria were met. The additional step-up therapy included either 25 mg chlorthalidone or 50 mg atenolol for placebo failures; combined 25 mg chlorthalidone-50 mg atenolol therapy was given to the chlorthalidone or atenolol failures. Medication was increased during the first 6 months if DBP was ≥100 mm Hg for three visits at 2-wk intervals, ≥105 mm Hg at two visits a week apart; or ≥115 mm Hg at any visit. If the additional step-up therapy did not adequately control DBP, open-label therapy (antihypertensive medication) was used.	HD + PA Total contact hrs: 14 Total duration: 6 months	Nutritionists and therapists (nutritional intervention); NR (medical intervention) NR	Minimal intervention: No further nutritional counseling beyond the initial explanation of the allocation and general consultation provided to all participants. Participants additionally randomized to either a diuretic (chlorthalidone 25 mg), a beta-blocker (atenolol 50 mg), or a placebo. In addition, participants had monthly BP management clinical visits, which included (1) blood pressure and weight measurements; (2) review of interim history and symptoms, treatment status,

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
					compliance; and (3) dispensing of study drugs. Participants who failed to achieve adequate blood pressure control were stepped up to additional therapy at 6 months or sooner if emergency failure criteria were met. The additional step-up therapy included either 25 mg chlorthalidone or 50 mg atenolol for placebo failures; combined 25 mg chlorthalidone-50 mg atenolol therapy was given to the chlorthalidone or atenolol failures. Medication was increased during the first 6 months if DBP was ≥100 mm Hg for three visits at 2-wk intervals, ≥105 mm Hg at two visits a week apart; or ≥115 mm Hg at any visit. If the additional step-up therapy did not adequately control DBP, open-label therapy

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
					(antihypertensive medication) was used.
Langford, 1991[91] (Trial of Antihypertensive Interventions and Management (TAIM)) Fair	IG2	10 group sessions and 2 individual sessions of nutrition counseling for reducing sodium intake and increasing potassium intake and 6 individual BP medication management visits. Participants additionally randomized to either a diuretic (chlorthalidone 25 mg), a beta-blocker (atenolol 50 mg), or a placebo, as well as nutritional counseling for reducing sodium intake and increasing potassium intake, consisting of 10 weekly group sessions followed by individual sessions every 6-12 weeks. Sodium and potassium goals were individualized by weight and ranged from 52-100 mmol/day for sodium (average 87 mmol/day), and from 62-115 mmol/day for potassium (average 103 mmol/day). In addition, participants had monthly BP management clinical visits, which included (1) blood pressure and weight measurements; (2) review of interim history and symptoms, treatment status, compliance; and (3) dispensing of study drugs. Participants who failed to achieve adequate blood pressure control were stepped up to additional therapy at 6 months or sooner if emergency failure criteria were met. The additional step-up therapy included either 25 mg chlorthalidone or 50 mg atenolol for placebo failures; combined 25 mg chlorthalidone-50 mg atenolol therapy was given to the chlorthalidone or atenolol failures. Medication was increased during the first 6 months if DBP was ≥100 mm Hg for three visits at 2-wk intervals, ≥105 mm Hg at two visits a week apart; or ≥115 mm Hg at any visit. If the additional step-up therapy did not adequately control DBP, open-label therapy (antihypertensive medication) was used.	HD only Total contact hrs: 14 Total duration: 6 months	Nutritionists and therapists (nutritional intervention); NR (medical intervention) NR	Minimal intervention: No further nutritional counseling beyond the initial explanation of the allocation and general consultation provided to all participants. Participants additionally randomized to either a diuretic (chlorthalidone 25 mg), a beta-blocker (atenolol 50 mg), or a placebo. In addition, participants had monthly BP management clinical visits, which included (1) blood pressure and weight measurements; (2) review of interim history and symptoms, treatment status, compliance; and (3) dispensing of study drugs. Participants who failed to achieve adequate blood pressure control were stepped up to additional therapy at 6 months or sooner if emergency failure criteria were met. The

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
					additional step-up therapy included either 25 mg chlorthalidone or 50 mg atenolol for placebo failures; combined 25 mg chlorthalidone-50 mg atenolol therapy was given to the chlorthalidone or atenolol failures. Medication was increased during the first 6 months if DBP was ≥100 mm Hg for three visits at 2-wk intervals, ≥105 mm Hg at two visits a week apart; or ≥115 mm Hg at any visit. If the additional step-up therapy did not adequately control DBP, open-label therapy (antihypertensive medication) was used.
Lee, 2007[92] Fair	IG1	Median of 6 sessions of individual in-person and telephone physical activity counseling. Six-month community-based walking intervention delivered by a public health nurse. The intervention involved a series of regular individual contacts, provided through telephone and face-to-face visits in both local community activity centers and participants' homes according to their preference. The first intervention contact occurred within one month of randomization. The primary aim of the intervention was to increase the frequency and time participants spent walking. Participants were provided with a pedometer, walking log, and advice about regular	PA only Total contact hrs: 3 Total duration: 6 months	Public health nurse Community centers, home	Usual care: Participants received usual primary health care involving self-initiated contact with health services as required.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		walking based on established PA guidelines. The intervention was individualized according to each participant's baseline exercise stage of change. Content areas for discussion for each participant varied, but mainly included perceived benefits of increased walking, ideas for overcoming perceived barriers and sharing practical information gleaned from others about pleasant walking routes and pedometer usage. More frequent contacts were arranged during the first three months of the intervention period in order to facilitate and reinforce regular walking and less frequently during the last three months.			
Liira, 2014[93] Fair	IG1	Participants received a one-time 90-minute health promotion check-up delivered by a public health nurse. The nurse used a type 2 diabetes risk assessment form (produced by the Finnish Diabetes Association) and a cardiovascular risk assessment (produced by the Finnish Heart Association). The intervention included an assessment of individual risks, dietary habits, physical activity, and a motivational talk about those health habits. If participants had elevated blood sugar, total cholesterol >7.0 mmol/L, uncontrolled hypertension, or another reason for medical assessment, the nurse referred them to a physician for consideration of medication. In addition to the intervention, participants received usual care at a municipal public primary care unit where, if necessary, they were referred to a PCP.	HD + PA Total contact hrs: 1.5 Total duration: 0.03 months	Public health nurses Primary care	Usual care: Participants received usual care at a municipal public primary care unit where, if necessary, they were referred to a PCP. Participants were offered the health counseling intervention after the study period.
Migneault, 2012[94] Fair	IG1	Prior to randomization, participants had an in-home visit for health education, which consisted of a 75-page resource manual that described hypertension, listed dietary recommendations, heart healthy food recipes, and local resources for exercise, and provided information to support antihypertensive medication adherence. In addition to the resource manual, all participants received a 20-minute education session based on the content of the manual and were given a pedometer and digital weight scale. Following randomization, a Telephone-Linked Care- automated system delivered three tailored behavior intervention modules using social-cognitive theory, transtheoretical model of behavioral change, and motivational interviewing. The intervention was culturally tailored, both matching intervention materials and messages to include familiar or preferred people, places, languages, music, food locations, and clothing and incorporating cultural values, social, historical, and psychological	HD + PA Total contact hrs: 8.3 Total duration: 8 months	NA (automated phone system), PCP Home	Minimal intervention: Prior to randomization, participants had an in-home visit for health education, which consisted of a 75-page resource manual that described hypertension, listed dietary recommendations, heart healthy food recipes, and local resources for exercise, and provided information to support

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		forces relevant to African American populations. The first three calls introduced targeted behaviors, how they help with blood pressure control, and oriented users to the system. Subsequent calls were modules on medication adherence (8 calls), physical activity (12 calls), and diet (9 calls, covering fruits and vegetables, fiber, sodium, and fat). Each call consisted of a (1) introduction; (2) section for reporting health information collected on study-issued home measurement devices (pedometers, sphygmomanometers, weight scales); (3) theory-based interactive education and counseling on the targeted behavior. The physical activity module focused on increasing moderate or greater intensity physical activity. The diet module focused on fruits/vegetables, fiber, sodium, and fat and intended to promote the Dietary Approaches to Stop Hypertension (DASH) diet. Participants and their primary care providers received printouts of their tracked health behaviors, which were sent at the beginning and end of each of the three behavioral modules and were designed to reinforce the intervention.			antihypertensive medication adherence. In addition to the resource manual, participants received a 20-minute education session based on the content of the manual and were given a pedometer and digital weight scale.
Moreau, 2001[95] Fair	IG1	Participants were given a pedometer to wear throughout the day for a 1- to 2-wk period before beginning the 24-wk walking program in order to document preintervention daily lifestyle walking activity. Participants wore the pedometer on their belt or waistband as soon as they awoke in the morning, removed it before going to bed each night, and recorded the number of steps they accumulated each day. Participants were provided with a target number of steps that could lead to a 3-km increase in daily walking. The target steps were added onto their baseline step value to prevent a decline in their current daily lifestyle activity. Initially, all women were prescribed a distance of 1.4 km per day above their baseline walking during week 1. Distance was then increased by 0.5 km per day until the desired walking distance was achieved by the third week. Participants were instructed to walk at a self-selected comfortable pace and were allowed to accumulate their steps in whatever pattern best fit their lifestyle. Other than walking, subjects were asked not to make any changes in their current lifestyle activities.	PA only Total contact hrs: 0 Total duration: 6 months	NR Home	No advice: Participants were given a pedometer to wear throughout the day for a 1- to 2-wk period before beginning the 24-wk walking program in order to document preintervention daily lifestyle walking activity. Participants were asked not to change daily activity and subsequently wore a pedometer 1 wk each month to document their walking.
Moy, 2001[96] Fair	IG1	Participants received individualized instructions to lower fat intake (based on Adult Treatment Panel III guidelines), focusing on total fat	HD only Total contact hrs: 14	Nurse NR	Usual care: Participants received usual care

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		consumption and daily monitoring (usually a goal <40 g total fat). Participants were initially given a total "fat allowance" based on their intake at baseline and were taught how to read food labels, use fat counter to monitor and record total daily fat intake. Self-monitoring logs were used to record daily fat intake. Participants were seen individually and with family members every 6-8 weeks to reinforce the diet, evaluate dietary compliance, and measure lipids. Physicians were asked to explicitly not to manage dietary interventions as recommended based on results and feedback from baseline screening. At each visit, a dietary fat screening instrument was used to identify potential problems. Counseling was individualized based on initial dietary habits, lifestyles, and progress.	Total duration: 24 months		from a primary care physician. Physicians received patient-specific recommendations from results and feedback from the baseline screening for risk factor management on three occasions.
Muhlhauser, 1993[97] (Hypertension Treatment and Teaching Program (HTTP)) Fair	IG1	Participants received 4 consecutive weekly group 60-90 min counseling sessions, for groups of 4-6 participants. The objectives of the intervention were: assumption of greater responsibility for disease management, including blood pressure self-monitoring and treatment decision making; confirming the diagnosis of hypertension and treatment using at home blood pressure monitoring; and emphasis on non-pharmacological treatments. The first session focused on group discussions and patients were provided with blood pressure monitors and logbooks. During the second session, blood pressure monitoring and logbooks were assessed, as well as strategies for achieving blood pressure control (including dietary and physical activity recommendations; details of dietary advice NR). The last two sessions began with a presentation and discussion about participants' experiences with nutrition, weight change, and blood pressure self-monitoring. Participants discussed their experiences and fears related to the side effects of antihypertensive drug therapy during the third session. Information leaflets about drugs currently used by the participants were discussed, as well as possibilities of avoiding side effects of blood pressure lowering therapy. Participants following non-drug treatment regimens were encouraged to try to reduce the dosages of their antihypertensive drugs. If indicated, drug therapy was started by the physician at the end of the third session. During the fourth session, the effects of antihypertensive drug therapy on blood pressure control was discussed, as well as psychological aspects and smoking.	HD + PA Total contact hrs: 6 Total duration: 1 months	Physicians and practice staff Primary health care	Minimal intervention: Physicians and staff at CG practices received the same training on BP measurement as those in IG practices but did not deliver HTTP intervention. Additionally, 20 patients at each CG site had their medical files marked with a red dot to remind clinic staff to take BP, weight, and medication information at each visit.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Murphy, 2012[98] (National Exercise Referral Scheme (NERS)) Fair	IG1	3 individual in-person sessions of physical activity counseling with 2 telephone calls focused on relapse prevention and discounted access to 1-on-1 exercise instruction or group classes. The initial consultation with the exercise professional included a lifestyle questionnaire, health check, motivational interview and physical activity goal setting using patient-centered approach, and introduction to leisure centers (sporting/community centers). The primary goal was to achieve 30 min of moderate physical activity on ≥5 days/week. Participants were given discounted access to 1-on-1 exercise instruction or group classes (£1 per session). Two telephone followups were made at 4 weeks and 8 months to review goals and prevent relapse. At 16 weeks, an individual consultation included review of goals, motivational interview, health check, lifestyle questionnaire, and advice on continuing with exercise after the program. At 12 months, a program review was held with a repeat of the health check and a fitness stop test.	PA only Total contact hrs: 2 Total duration: 12 months	Exercise professional Leisure center, home (phone)	Waitlist: Usual care and a leaflet highlighting the benefits of exercise and including a website address listing locations of local leisure facilities.
Neil, 1995[99] Fair	IG1	Participants attended a 30-minute appointment with a dietitian the general practice at which a standard diet history was taken and participants were given individual advice on their dietary habits and weight. Participants were advised to reduce the percentage of total dietary energy from fat to 30% or less; consume up to 10% of energy from saturated, monounsaturated, and polyunsaturated fatty acids; 50-60% energy derived from carbohydrates, protein 10-20%; daily intake of <300 mg cholesterol; 35 g fiber. Participants met with the dietitian at a 10-minute followup appointment where further dietary advice was given.	HD only Total contact hrs: 0.67 Total duration: 2 months	Dietitian General practice clinic	Usual care: Participants received a pamphlet containing dietary guidance consistent with advice provided by dietitian. Additional written advice was provided after 2 months.
Neil, 1995[99] Fair	IG2	Participants attended a 30-minute individual appointment with the study nurse at which they were advised to make changes in food intake to reduce the amount of total and saturated fat; increase amount of dietary fiber and complex carbohydrates. Habitual diet was estimated by prescored food frequency questionnaire that combined groups of food with similar nutrient content and dietary use and assigned each group a score proportional to the fat or fiber content of standard portion size. The total score and pattern of individual food sources used to suggest specific changes in food choices. Participants met with the nurse at a 10-minute followup appointment where further dietary advice was given.	HD only Total contact hrs: 0.67 Total duration: 2 months	Nurse General practice clinic	Usual care: Participants received a pamphlet containing dietary guidance consistent with advice provided by dietitian. Additional written advice was provided after 2 months.

Appendix F Table 3. Detailed Intervention Descriptions

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Niiranen, 2014[100] Fair	IG1	3 sessions of diet and physical activity counseling (2 30-min individual counseling sessions and 1 60-min group session) and 5 PCP BP medication management calls that included individualized lifestyle advice. Lifestyle guidance from nurse during two 30-min individual counseling sessions held at 4-week intervals and at a 60-min group session of 10-12 participants held 4 weeks later. In addition, written instructions were distributed to the participants. During the counseling sessions, participants were instructed to avoid added salt, use low-salt food ingredients, increase intake of fruits, vegetables, and berries, favor unsaturated fat over saturated fat, use low-fat dairy products, eat fish for 1–2 meals per week, exercise at least 3 hours per week, lose weight if necessary, and use no more than moderate amounts of alcohol. The lifestyle goals were: (i) BMI 5% among the obese (body mass index ≥30 kg/m^2); (ii) >180 minutes per week of moderate-intensity physical activity; (iii) daily intake of 3/3.5 grams of dietary potassium for women/men; (v) smoking cessation; (vi) 1% of daily energy intake from omega-3 fatty acids; and (viii) daily intake of ≤3 drinks of alcohol for men and ≤2 drinks for women. In addition to the lifestyle counseling, the participants' antihypertensive treatment was guided by systematic home BP measurements. The target BP was home BP <135/83 mm Hg. Participants self-measured their BP at 0, 3, 6, 9, and 12 months and additionally 1 month after any changes in their medication. The BP readings were mailed to the treating physician, and the participant was contacted by phone. During the calls, results of the participant's lifestyle questionnaire (on exercise, nutrition, alcohol use, and smoking; administered at 0, 3, 6, 9, and 12 months) were examined at the same time, and lifestyle guidance was given. Face-to-face PCP appointments were scheduled if deemed necessary, and if home BP was greater than the target pressure, the drug therapy was intensified. Physicians had free choice of which medications to use, but they had been educated on rational drug choices and combinations.	HD + PA Total contact hrs: 3.25 Total duration: 12 months	PCPs and nurses Primary care, home	Usual care: No intervention was offered to patients or staff at the control site. No contact between the control group and the study organization occurred between the baseline examinations and the follow-up examinations at 12 months, and hypertension treatment continued according to conventional practice.
Nolan, 2018[101] (Reducing Risk with E-based Support for	IG1	Participants were contacted by email weekly for months 1 to 4, biweekly for months 5 to 8, and monthly for months 9 to 12. Each email contained an e-link to lifestyle counseling activities including videos, online handouts, and monitoring forms to help participants	HD + PA Total contact hrs: Total duration: 12 months	NA (counseling fully automated) Home	Minimal intervention: Participants received the same amount of automated emails as

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Adherence to Lifestyle Change in Hypertension (REACH)) Fair		with blood pressure management. Initially, participants assessed their stage of readiness to adhere to self-care according to the Transtheoretical Model. Then they selected their behavior change priority from a list that included exercise, diet, smoke-free living, and adherence to antihypertensive medications. Motivational components helped participants by validating their initial stage of readiness, build their readiness by guiding them to select a goal that matched their readiness stage, reinforcing their active and collaborative role in the intervention, and helping them resolve ambivalence for change by linking their behavior change goal to a salient personal priority. For participants with elevated readiness, cognitive-behavioral strategies reinforced their efficacy for initiating and sustaining change by (1) educating them about how to set manageable behavioral goals for self-care adherence, (2) outlining progressive steps in the change plan for self-care, (3) facilitating performance-based feedback with self-monitoring tools for BP and self-care behavior, (4) providing rewarding feedback about progress in initiating or sustaining behavior change, (5) maintaining virtual peer support and positive behavioral modeling via video material, and (6) reviewing guidelines to manage stress to sustain therapeutic change in self-care. The 14 intervention videos developed for the e-counseling sessions included (1) expert-type presentations with self-help guidelines for adhering to self-care behavior; (2) an unscripted discussion among peers that provided positive role modeling and guidance as they spoke about how heart healthy living was connected to their personal priorities and how they managed barriers to change; and (3) dramatic vignettes that reflected and validated participant experiences as fictional characters learned to accept the diagnosis of hypertension and then as they planned and carried out lifestyle changes with the support of a healthcare professional or peer.			intervention group participants, but were instead linked to publicly available content on self-help skills for managing BP from the resource section of the Blood Pressure Action Plan of the Heart and Stroke Foundation of Canada. Participants were also permitted to log into the Heart and Stroke Foundation website to access heart healthy recipes, as well as e-tools and self-monitoring forms to track BP and changes in self-care behaviors.
Ogedegbe, 2014[102] (Counseling African Americans to Control Hypertension	IG1	Intervention comprising three components: (1) interactive computerized self-paced programmed instruction (4 modules) for educating patients about the causes, complications and treatment of HTN; expected side effects of medications, and methods for adoption of lifestyle changes; (2) home BP monitoring; and (3) individual and group behavioral counseling sessions on the adoption of lifestyle modifications conducted by trained study staff, community health	HD + PA Total contact hrs: 6 Total duration: 6 months	Nutritionists, nurses, and health educators (from study and community health center), physicians	Minimal intervention: Participants received a single HTN patient education session plus printed versions of the NHLBI patient education material,

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
(CAATCH)) Fair		center dieticians and health educators. The content of the computer tutorial is based on two NHLBI publications, “Your Guide to Lowering Blood Pressure” and “Facts about the DASH Eating Plan”. The tutorial is broken down into several modules that are written at an appropriate reading level. The computer program gives patients control of the pace of learning and they are asked questions on the material and given feedback to verify their understanding of the material. For home BP monitoring, participants received an automated home BP monitor and instructions on its use. Participants were encouraged to record their weekly BP readings (twice daily, three times per week) in a diary that they brought with them to each study visit. The behavioral counseling involved six monthly group behavioral counseling sessions on adoption of recommended lifestyle modifications conducted by trained community health center staff and/or study staff (nutritionists, nurses, and health educators). Behavior change strategies involved motivational interviewing, goal setting, problem solving, stimulus control, cognitive strategies, and self-monitoring. The specific behavior goals set in collaboration with the patients included dietary changes, weight loss, reduction of sodium intake, increased physical activity, moderation of alcohol intake, and adherence to prescribed BP medications. In addition to the patient intervention, their primary care providers received monthly onsite continuing medical education based on the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure guidelines; HTN case rounds; and quarterly chart audits of their patient office BP readings. They were also provided quarterly feedback on the values of their patient's home BP readings, which were obtained from the patient diaries.		Community health center	"Your Guide to Lowering Blood Pressure" and "Facts about the DASH Eating Plan". Primary care providers received print versions of the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure guidelines.
Reid, 2014[103] Fair	IG1	The heart health intervention included feedback about the results of the baseline and 3 month assessments; goal setting; 17 counseling sessions with a health educator; and the communication of reports and recommendations to the participant's PCP. Counseling sessions occurred weekly for the first 12 weeks, and then at weeks 16, 20, 26, 39, and 52. The first 2 counseling sessions were 45-min; the remaining 15 were 15-20-min long. All counseling sessions were delivered via phone except for the second counseling session, which	HD + PA Total contact hrs: 6.5 Total duration: 12 months	Health educators Tertiary care cardiac center	Usual care: Participants received printed materials about smoking cessation, healthy eating, weight management, and physical activity. A report was sent to their

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		was delivered in-person. During the first two sessions, participants received feedback about their risk levels relative to recommendations. The health educators helped participants set goals for reducing their risks and create action plans. An assessment summary and indications for the participant's medical care were mailed to their PCP. Medical care was suggested if the participant's BP or lipid levels exceeded threshold values (BP >140/90 mm Hg; LDL-C >2.0 mmol/L and Framingham Risk Score (FRS) 20%; LDL-C 3.5 mmol/L and FRS 10-19%; or LDL-C >5.0 mmol/L and FRS <10%). Participants received printed materials about smoking cessation, healthy eating, weight management, and physical activity. During sessions 3-12, 16, 20, 26, 39, and 52, the health educators engaged participants in a dialog about progress toward their goals and recommended strategies to overcome any barriers. During the week 16 session, participants received results from their 3 month assessment. The summary of this assessment and recommendations for medical care were mailed to the participant's PCP.			PCP if the critical thresholds for BP or lipids were exceeded.
Rodriguez, 2012[104] Fair	IG1	6 monthly telephone sessions of diet, medication, and physical activity counseling individualized based on stage of change. Stage of change, decisional balance, and self-efficacy was evaluated at each session for diet, physical activity, and medication adherence, and a computer system was used to deliver standardized interventions. Calls covered problem solving; tips and information for each behavior; and review of a medication log (participants used a calendar to track medication use). Diet counseling focused on low sodium and total fat intake, high intake of fruits and vegetables and low or nonfat dairy products.	HD + PA Total contact hrs: 1.5 Total duration: 6 months	Counselors (Master's degree or higher in psychology or social work) Home	Usual care: Participated in in-person assessment visits only
Rodriguez-Cristobal, 2012[105] Fair	IG1	24 sessions of individual lifestyle counseling on diet, PA, and smoking cessation (12 physician-delivered in-person sessions and 12 psychologist follow-up calls). Psychologists made phone calls to remind intervention group of upcoming physician visits (every 2 months) and to provide encouragement about maintaining lifestyle changes. Participants who smoked were motivated to give up smoking and received clear and tailored advice as well as medication when indicated. For physical activity, participants received advice to start, maintain, or increase their current level of physical activity. Participants with overweight or obesity (BMI 25-30 and ≥30 kg/m^2,	HD + PA Total contact hrs: 9 Total duration: 24 months	Physician, psychologist Primary care	Usual care: Participants received standard advice from their physician about their lifestyle (diet, physical activity, smoking cessation) according to current practice guidelines.

Appendix F Table 3. Detailed Intervention Descriptions

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		respectively) received advice on gradual weight loss (0.51 kg per week) and maintaining a healthy diet after healthy weight achieved with the objective of achieving a BMI 20-25 kg/m^2. Participants with hypertension received dietary and pharmacological treatment according to guidelines with the objective of achieving BP <7%.			
Rosas, 2015[106] (Vivamos Activos Fair Oaks (VAFO)) Good	IG1	Participants received a case management intervention based on DPP and Heart to Heart trial tailored to local population plus home visits by community health workers. Intervention consisted of 12 group sessions (2 hrs) and 4 individual (30 min) sessions in the intensive phase (12 months) followed by 3 group sessions and 1 individual session in the maintenance phase (months 13-24). Key intervention components included motivational interviewing, building self-management and goal setting skills, proving hands-on cooking and physical activity demonstrations, fostering self-efficacy, leveraging group-based social support, identifying community resources, and coordinating with primary care providers. Take-home items included pedometers, exercise CDs, and free weights. Individual sessions focused on individualized goal setting based on the patient's stage of behavior change, problem solving, medical and social service referrals. Participants also received 5 community health worker (CHW) home visits in the intensive phase and 2 CHW visits in the maintenance phase. Visits were semi-structured to allow the CHW to facilitate behavioral changes relevant to participant and their household, family, and neighborhood (e.g., navigating an obesogenic environment, fostering family support, enhancing participant success in food negotiations, mapping out neighborhood walking routes, using participant-taken photos of food/PA as triggers for goal setting and problem-solving.	HD + PA Total contact hrs: 36 Total duration: 24 months	Research staff & community health workers Community health center, home	Usual care: Routine primary care follow-ups with potential for referral to lifestyle counseling within a specialized diabetes clinic.
Rosas, 2015[106] (Vivamos Activos Fair Oaks (VAFO)) Good	IG2	Participants received a case management intervention based on DPP and Heart to Heart trial tailored to the local population. The intervention consisted of 12 group sessions (2 hrs) and 4 individual (30 min) sessions in the intensive phase (12 months) followed by 3 group sessions and 1 individual session in the maintenance phase (months 13-24). Key intervention components included motivational interviewing, building self-management and goal setting skills, proving hands-on cooking and physical activity demonstrations, fostering self-efficacy, leveraging group-based social support,	HD + PA Total contact hrs: 32.5 Total duration: 24 months	Research staff Community health center	Usual care: Routine primary care follow-ups with potential for referral to lifestyle counseling within a specialized diabetes clinic.

Appendix F Table 3. Detailed Intervention Descriptions

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		identifying community resources, and coordinating with primary care providers. Take-home items included pedometers, exercise CDs, and free weights. Individual sessions focused on individualized goal setting based on the patient's stage of behavior change, problem solving, medical and social service referrals.			
Rubinstein, 2016[107] Good	IG1	12 20-30 min telephone sessions of diet and physical activity counseling, 48 followup text messages, and an informational leaflet about healthy lifestyles. After a short introductory call, each participant received monthly motivational interviewing calls to their personal mobile phone by a trained nutritionist over 12 months. Each call focused on one of four target behaviors (reduction of dietary sodium intake, reduction of high-fat and high-sugar food intake, increase in fruit and vegetable intake, and promotion of physical activity). Each participant's readiness to change a specified behavior was assessed by the caller, and the conversation was tailored to that behavior. Only one behavior change target, agreed to by the participant, was addressed in each call, but each of the four behaviors had to be discussed in the first four calls. For the remaining eight calls, participants could choose to discuss any of the four target behaviors, a strategy based on the motivational interviewing principle of autonomy support. Each call was followed by a weekly text message with contents related to the target behaviors and readiness to change that had been addressed in the previous call. Up to five text messages were sent per month. The information obtained during the calls was entered into a web-based platform to customize the set of weekly text messages delivered to the participant in the following month. In addition to the calls and text messages, participants received a leaflet with written information about the adoption of healthy lifestyles.	HD + PA Total contact hrs: 6 Total duration: 12 months	Nutritionists Home	No advice: Participants received a leaflet with written information about the adoption of healthy lifestyles. No further information was provided.
Salisbury, 2016[108] Good	IG1	In addition to usual NHS care, participants received support from the Healthlines service, which is a multifaceted intervention incorporating a range of strategies to address the various components of the TECH conceptual model. The conceptual model emphasizes self-management (including using established approaches such as goal-setting, self-monitoring, information-sharing, decision-making, relapse prevention and regular review), optimization of treatment (particularly titration of medications following protocols),	HD + PA Total contact hrs: 3.6 Total duration: 12 months	Health advisors Home	Usual care: Participants continued to receive care normally provided by the NHS (management of CVD risk factors by primary care clinicians, including, in some

Appendix F Table 3. Detailed Intervention Descriptions

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		coordination of care between providers, and methods designed to enhance engagement of patients and GP. The intervention was based around regular telephone calls form a health advisor, supported by patient-specific tailored algorithms and standardized scripts generated through a computerized behavioral management program. The program included the following series of modules: knowledge about CVD risk and healthy lifestyles; review of drugs and side effects; optimization of drugs for BP lowering; home BP monitoring; review of statins; support for drug adherence; smoking and nicotine replacement therapy; healthy eating; weight loss and Orlistat; alcohol use; and exercise. The standardized scripts generated by the software were based on principles of behavior change (e.g., stimulus control, problem solving, cognitive restructuring, and goal setting). During the first call, health advisors discussed with participants their health needs and agreed on specific goal. Thereafter, participants received one call monthly for one year. Participants were also provided with access to a Healthlines web portal where they could obtain further information about CVD, access other online resources, request a call-back from Healthlines staff, see copies of letters sent to their GP, and use a BP monitoring system. Participants with baseline SBP ≥140 mm Hg were offered a validated home BP monitor by their practice nurse, requested to take their BP twice daily for the first week and weekly thereafter, and to upload their readings to the Healthlines portal. Using these readings, participants were automatically advised by the portal whether their BP was too high or too low. At each telephone contact, health advisors reviewed average BP meetings, and participants with above target readings were instructed to see their doctor to review their treatment. Advisors sent an email to the GP, attaching details of the participant's recent BP readings and a summary of guidelines from NICE about recommended steps for intensifying treatment.			cases, referral to community services for advice about smoking cessation and weight management).
Schoenthaler, 2016[109] (Individual Motivational Interviewing - Therapeutic	IG1	13 sessions of diet and physical activity counseling (10 60-90 minute group sessions and 3 30-min individual phone sessions). In addition to standard treatment recommendations as determined by their physicians, participants received an intervention based on established clinical practice guidelines for prevention and treatment of hypertension, which recommends weight loss (if overweight),	HD + PA Total contact hrs: 16.5 Total duration: 6 months	Health educators Hospital, home	Minimal intervention: In addition to standard treatment recommendations as determined by their physicians, participants

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Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Lifestyle Changes (MINT-TLC)) Fair		regular physical activity, limiting and/or reducing sodium and alcohol intake, and eating a low-fat diet that is rich in fruit and vegetables. Stress management and medication adherence were also addressed. Participants attended 10 weekly classes over 12 weeks (intensive phase) followed by monthly, individual telephone-based motivational interviewing sessions for 3 months (maintenance phase). The intensive phase involved 60-90 minute group classes conducted by health educators, focusing on developing skills, goal-setting and generating strategies for behavior change as well as support for relapse prevention. Each session followed a similar structure and included the following components: 1) Overview of HTN and antihypertensive medications; 2) DASH eating plan 3) Goal setting and healthy living diaries; 4) Serving sizes, portion control and food labels (with emphasis on sodium monitoring); 5) Physical activity; 6) Building skills for meal planning and shopping; 7) Recipe modification and eating away from the home; 8) Stress Management; 9) Eating triggers and mindful eating; and 10) Planning for lasting change. The monthly 30-minute individual telephone-based sessions were also conducted by health educators with the purpose of helping participants focus on problem-solving, goal setting, and prevention of relapse with regard to each of the therapeutic lifestyle changes adopted during the intensive phase. The sessions focused on tailoring the intervention strategies to the participant's individual needs and consisted of: 1) assessing the participant's motivation and confidence in engaging in a given behavior; 2) eliciting barriers and concerns about adoption of each lifestyle modification; 3) summarizing in a non-threatening manner the pros and cons of the participant's concerns; 4) providing a menu of options to the patient based on the nature of the barriers elicited by the patient; 5) assessing each participant's values and goals. Each session ended with a global summary of what was discussed and a clarification of an agreed upon action plan.			received a 30-minute individual counseling session on lifestyle modification, as well as content on stress management and medication adherence. Participants also received printed versions of the MINT-TLC intervention material.
Scott, 2018[110] Fair	IG1	7 sessions of physical activity counseling (2 1-hr in-person sessions and 5 15-30 minute phone sessions). In-person sessions occurred at weeks 1 and 12 and telephone sessions were delivered in weeks 2-4, 6, and 8. During the sessions, eight theory-derived determinants were targeted: PA outcome expectations, PA outcome experiences, PA	PA only Total contact hrs: 4.5 Total duration: 3 months	PhD-level psychologist NR (in-person sessions), home (phone sessions)	Usual care: Participants received usual care and no additional PA support throughout the study. Usual care

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		outcome expectations–experiences discrepancy, values, exercise barrier self-efficacy, social support and coping skills. MI was the underpinning counseling approach used to influence motivation, self-efficacy and discrepancies/ambivalence. A toolkit of 36 cognitive behavioral techniques derived from a taxonomy and a previous study were tailored to the individual. These included: providing information on consequences of behavior in general and to the individual; providing information about others' approval; goal setting (behavior); goal setting (outcome); action planning; setting graded tasks; prompt review of behavioral goals; prompt review of outcome goals; prompt rewards contingent on effort or progress toward behavior; providing rewards contingent on successful behavior; shaping; prompt generalization of a target behavior; prompt self-monitoring of behavior; prompt self-monitoring of behavioral outcome; prompting focus on past success; providing feedback on performance; providing information on where and when to perform the behavior; providing instruction on how to perform the behavior; model/demonstrate the behavior; teach to use prompt cues; environmental restructuring; behavioral contract; prompt practice; use of follow-up prompts; facilitating social comparison; plan social support/social change; prompt identification as role mode/position advocate; prompt anticipated regret; fear arousal; prompt self-talk; prompt use of imagery; relapse prevention/coping planning; and stress management/emotional control training.			participants received a one-hour feedback session on questionnaire results after the study ended.
Soto Rodriguez, 2016[111] Fair	IG1	Three 90-min interactive group educational workshops on the prevention of CVD, recommending the adoption and maintenance of healthy habits that favor a change in lifestyle. The importance of following a Mediterranean diet was emphasized, reducing consumption of saturated fats, sugar and alcohol, and increasing consumption of plant foods and foods rich in polyunsaturated fats. The three workshops were held over one week in groups of 15 participants.	HD only Total contact hrs: 4.5 Total duration: 0.25 months	NR Health care	No advice: Participants received a brochure mailed to their address with the information on the same subjects covered in the intervention group.
Stefanick, 1998[112] (Diet and Exercise for Elevated Risk	IG1	Dietary recommendations, based on the goals of the NCEP Step 2 diet (less than 30 percent total fat, less than 7 percent saturated fat, and less than 200 mg of cholesterol per day), were presented to the subjects by registered dietitians. Participants entered a 12-week adoption phase in which an individualized counseling session was	HD only Total contact hrs: 12.5 Total duration: 11 months	Registered dietitians Research clinic, home	No advice: Participants were instructed to maintain usual diet and exercise.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
(DEER)) Fair		followed by eight one-hour, mixed-sex group lessons on replacing dietary sources of saturated fat with complex carbohydrates, low-fat dairy foods, and other alternatives, including lean meats. Weight loss was not emphasized in the group sessions, which averaged 15 persons per group. A six-to-eight-month maintenance phase consisted of monthly contacts with study dietitians, by mail or telephone or in group or private meetings.			
Stevens, 2003[113] Fair	IG1	2 45-min sessions of individual diet counseling (including 20-min computer assessment) and 2 10-min followup phone calls. The intervention combined motivational interviewing, problem-solving and social cognitive theory strategies. The first session described the overall goals: reduction in dietary fat and increased consumption of fruits, vegetables, and whole grains. Feedback was provided on baseline fat, fruit, and vegetable consumption relative to goals and participants were asked to select one or two goals for the first session. If dietary fat was selected, then a 20-minute touch-screen computer-assisted assessment provided feedback on fat intake and other dietary patterns based upon the modified Fat and Fiber Behavior Questionnaire. Participants then answered questions about their personal barriers to dietary change and were helped to select tailored strategies to address those barriers. An automated touch-screen program produced a personalized printout which the interventionist then reviewed with the participant. The participant took the printout with them in addition to nutrition education materials. Participants not selecting dietary fat at the first session received an individually tailored counseling session focused on increasing consumption of fruits, vegetables, and whole grains. At the second visit 2–3 weeks later, participants reported on their progress toward achieving their goals. If they had not selected dietary fat as a target in the first intervention session, they then completed the automated program described above. Those who completed the automated program in the first session were encouraged to focus on increasing fruit and vegetable consumption. The focus was on the parts of their personal eating pattern they were most willing to change, and on the barriers encountered. During this session, participants had made commitments to work on several dietary changes and identified personally tailored behavior change	HD only Total contact hrs: 1.83 Total duration: 2 months	Health counselors Research clinic	Attention control: Participants received an intervention focused on breast self-exam, which included a 9 minute American Cancer Society video, self-help pamphlets, barriers-based problem solving counseling regarding interest and motivation for conducting regular breast self-exam.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		strategies for each. Two 5- to 10-min calls after the second session provided ongoing support and checks on participants' behavior change plans.			
Svetkey, 2008[114] (Weight Loss Maintenance (WLM)) Good	IG1	All participants had successfully lost ≥4 kg in phase 1 of a 6-month nonrandomized initial weight loss intervention prior to enrollment. Phase 2, the maintenance portion, included monthly 5-15 minute phone sessions and every 4th month, a 45-60 individual face-to-face contact. Each contact began with self-reported or measured weight (for face-to-face contacts), review of progress, number of days a food diary was kept, frequency of weighing, average minutes of exercise, progress on additional goals and action plans, and problem-solving. Contacts provided opportunities to discuss barriers to weight loss maintenance and plans to overcome those barriers. The intervention reinforced key theoretical constructs (motivation, support, problem solving, relapse prevention). Participants were encouraged to continue adherence to the recommended dietary pattern and to increase moderate physical activity to at least 225 min per week. Phase 3: At 30 months, 3 of 4 sites started an extended followup period for an additional 30 months. The extended intervention consisted of 4 weekly group sessions followed by monthly phone contacts that followed the same general content as in Phase 2. 98 of participants from IG1 were re-randomized to ongoing contact, 98 participants from IG1 were randomized to no contact, and 47 participants were not re-randomized (19.3% of participants from IG1 at participating sites opted-out of extended F/U; 11.4% of participants from CG at participating sites opted out of phase 3). In the extended F/U, the IG participants randomized to further contact vs no contact showed no differences so were combined in the analysis.	HD + PA Total contact hrs: 12.75 Total duration: 60 months	Research interventionist NR	Minimal intervention: Printed lifestyle guidelines with diet and physical activity recommendations at randomization and met briefly with a study interventionist after 12-month data collection visit.
Svetkey, 2008[114] (Weight Loss Maintenance (WLM)) Good	IG2	Unlimited access to a website designed to support weight loss maintenance and were encouraged to log in at least once per week. Participants were required to record their weight upon logging into the website. The website provided a number of intervention elements, including social support using a bulletin board feature, record-keeping tools, tracking options, accountability, diet and exercise information, and tailored feedback. The website also	HD + PA Total contact hrs: 0 Total duration: 30 months	NA Home	Minimal intervention: Printed lifestyle guidelines with diet and physical activity recommendations at randomization and met briefly with a study

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		included interactive training modules that addressed problem solving and motivation. If participants missed a self-scheduled contact, they were sent an email reminder that was repeated after another week of no contact. If there was no response to the 2 email prompts, participants received 2 weekly automated telephone calls. If participants didn't log into the website after that, they were contacted by study staff, who encouraged them to return to the website. IG2 participants were not part of the phase 3 extended F/U.			interventionist after 12-month data collection visit.
Svetkey, 2009[115] (Hypertension Improvement Project (HIP)) Fair	IG1	Participants received both the physician intervention (MD-I) and the patient intervention (Pt-I). For the MD-I, physicians received two 45-minute online training modules (Continuing Medical Education) aimed at Joint National Committee-7 guidelines and lifestyle modification for blood pressure control. An evaluation and treatment algorithm summarizing the major Joint National Committee-7 guidelines and formatted as a decision tree (laminated, color-coded, pocket-sized) was provided to each physician. Assessment and quarterly feedback was provided to physicians on their adherence to guidelines, including lifestyle counseling that assessed the proportion of patients with hypertension whose blood pressure was controlled, proportion not at goal, the proportion that received lifestyle counseling, the proportion with diabetes or chronic kidney disease who were at goal blood pressure and prescribed a thiazide diuretic or angiotensin-converting enzyme inhibitor/angiotensin receptor blocker, and comparisons of physicians with peers. For the Pt-I, patients received an intervention consisting of 20 weekly group sessions followed by 12 monthly phone contacts. The weekly group sessions focused on behavior change using the following strategies: frequent contact, group interaction and social support, goal setting and self-monitoring, identification of barriers and problem solving, and motivational interviewing. The behavior goals of Pt-I included weight loss if overweight, the Dietary Approaches to Stop Hypertension (DASH) dietary pattern, increased moderate-to-vigorous physical activity, reduced sodium intake, and moderation of alcohol intake. In addition, the intervention promoted adherence to antihypertensive medication regimen. Participants kept records of dietary intake, physical activity, and medication use. The group	HD + PA Total contact hrs: 24.5 Total duration: 18 months	Behavioral interventionists and community health advisors, PCP Physician: Clinic, Patients: At or near participant's clinic site	Usual care: Participants had a brief PC visit after randomization during which they received advice and brochures on lifestyle modification for blood pressure control consistent with Joint National Committee-7.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		sessions and the participant manual emphasized diet, physical activity, and changing behaviors. Community health advisors attended and helped to lead group sessions and also provided one-on-one monthly telephone counseling during and after the group session period.			
Svetkey, 2009[115] (Hypertension Improvement Project (HIP)) Fair	IG2	Participants received an intervention consisting of 20 weekly group sessions followed by 12 monthly phone contacts. The weekly group sessions focused on behavior change using the following strategies: frequent contact, group interaction and social support, goal setting and self-monitoring, identification of barriers and problem solving, and motivational interviewing. The behavior goals of Pt-I included weight loss if overweight, the Dietary Approaches to Stop Hypertension (DASH) dietary pattern, increased moderate-to-vigorous physical activity, reduced sodium intake, and moderation of alcohol intake. In addition, the intervention promoted adherence to antihypertensive medication regimen. Participants kept records of dietary intake, physical activity, and medication use. The group sessions and the participant manual emphasized diet, physical activity, and changing behaviors. Community health advisors attended and helped to lead group sessions and also provided one-on-one monthly telephone counseling during and after the group session period.	HD + PA Total contact hrs: 23 Total duration: 18 months	Behavioral interventionists and community health advisors At or near participant's clinic site	Usual care: Participants had a brief PC visit after randomization during which they received advice and brochures on lifestyle modification for blood pressure control consistent with Joint National Committee-7.
Svetkey, 2009[115] (Hypertension Improvement Project (HIP)) Fair	IG3	Physicians received two 45-minute online training modules (Continuing Medical Education) aimed at Joint National Committee-7 guidelines and lifestyle modification for blood pressure control. An evaluation and treatment algorithm summarizing the major Joint National Committee-7 guidelines and formatted as a decision tree (laminated, color-coded, pocket-sized) was provided to each physician. Assessment and quarterly feedback was provided to physicians on their adherence to guidelines, including lifestyle counseling that assessed the proportion of patients with hypertension whose blood pressure was controlled, proportion not at goal, the proportion that received lifestyle counseling, the proportion with diabetes or chronic kidney disease who were at goal blood pressure and prescribed a thiazide diuretic or angiotensin-converting enzyme inhibitor/angiotensin receptor blocker, and comparisons of physicians with peers.	HD + PA Total contact hrs: 1.5 Total duration: 18 months	NA (Physicians trained) Clinic	Usual care: Participants had a brief PC visit after randomization during which they received advice and brochures on lifestyle modification for blood pressure control consistent with Joint National Committee-7.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Ter Bogt, 2009[116] (Groningen Overweight and Lifestyle (GOAL)) Good	IG1	Participants completed a lifestyle questionnaire and had at least one visit with their general practitioner (GP) to discuss results of the baseline assessment and start treatment according to the GP's guidelines. Participants then received nurse-practitioner (NP)-led physical activity and healthy diet counseling consisting of individual sessions focused on self-awareness, lifestyle education, individual motivation, and goal-setting. During the four individual sessions, the NP was guided by a standardized computer program that contained instructions on lifestyle counseling defined by international guidelines and allowed data entry of the measurements. The aim of the intervention was to achieve persistent lifestyle changes and prevent weight gain. Participants developed a tailored treatment plan based on goals. Ongoing evaluation of goals by nurse practitioners during sessions; modification of goals, as needed, as well as possible referral to dietician. Diet was assessed via food diaries and physical activity was measured using pedometers. Following the in-person sessions, the NP called participants to give them feedback on their lifestyle by critiquing their food diary, physical activity (pedometer), baseline questionnaires, and discussed finishing their treatment plan. During the second and third year, participants had one individual session with the NP and received two feedback phone calls per year.	HD + PA Total contact hrs: 7.25 Total duration: 36 months	General practitioner, nurse practitioner Primary care, home	Usual care: Participants were offered one GP consultation to discuss the results of their baseline measurements and thereafter received usual care by a GP according to national GP guidelines.
Tiessen, 2012[117] (SPRING (Self-monitoring and Prevention of RIsk Factors by Nurse practitioners in the region of Groningen)) Fair	IG1	1 20-minute individual session with practice nurse using motivational interviewing and 6-12 follow-up visits with the number of follow-up visits determined by the presence of risk factors. Follow-up visits based on self-monitoring results (pedometer, scale, BP device). The first session was based on SCORE risk assessment, present risk factors and corresponding treatment goals. The number, length, and interval of follow-up visits was tailored to participants risk factors and the order in which risk factors were addressed depended on the participant's preference and stage of change. Quitting smoking was the first treatment goal if applicable. Adapted motivational interviewing was used to help participants recognize and change unhealthy behavior. Overweight participants received a food diary, home weight scale, step diary, and pedometer, and were followed up three times at monthly intervals followed by 3-monthly intervals. Participants with low physical activity received a step diary and pedometer and were followed up three times at monthly intervals	HD + PA Total contact hrs: 2.13 Total duration: 12 months	Trained nurses Primary care	Minimal intervention: 1 20-minute individual session with nurse using motivational interviewing. The first session was based on SCORE risk assessment, present risk factors and corresponding treatment goals. Standard information leaflets were given to participants based on overweight, smoking, and physical activity

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		followed by 3-monthly intervals. Participants with hypertension received home blood pressure monitoring and medication with monthly follow-up. Participants with dyslipidemia received medication and follow-up at three-month intervals. Participants with current smoking were followed up monthly until planned date of quitting, and after that at increasing intervals. Any medication adjustments were made by nurse under supervision of GP.			status. More counseling or referral for these risk factors given only on patient's request. After the initial visit, participants had follow-up visits based on the Dutch HTN and hypercholesterolemia guidelines if these risk factors were present.
Toft, 2008[118] (Inter99) Fair	IG1	Participants were offered three types of counseling: a smoking cessation course, a smoking reduction course, and a course on diet and physical activity counseling. Dietary recommendations included reducing fat intake (to 30% of energy/day); at least 300 g fish per week; at least 600 g fruit and vegetables (diabetics advised to limit fruit to maximum 3 pieces/day) per day; increase consumption of complex carbohydrates and dietary fiber; limit alcohol intake to 14/21 [F/M] units/week; limit salt consumption for participants with high blood pressure; and limit energy consumption for obese participants. For physical activity, participants were advised to engage in at least 30 min of moderate physical activity per day. Recommendations were adjusted over the 5-year intervention period, but were generally consistent over time. The choice of group depended on risk factors and the preference of the individual. Those who were not ready to decide whether or not they wanted to participate in group counseling were encouraged to consider the invitation and were contacted by mail after 3 months and offered participation in a group. Relatives of participants were offered to participate in 1 of the meetings. After 1 and 3 years, individuals still fulfilling high-risk criteria were again offered group counseling. Groups were led by a nurse or dietitian and included didactic and open-ended discussion and participants committing to specific diet and PA goals; dietary and physical activity advice mirrored advice in individual sessions. In group sessions, the general physical activity aim was to achieve small positive changes in physical activity in everyday life.	HD + PA Total contact hrs: 14 Total duration: 60 months	Doctors, nurses, and dietitians Research center	Minimal intervention: Assessment and individual counseling at baseline, 1, 3, and 5 years. Based on a personal risk assessment, each participant received an individual 'lifestyle counseling talk' focusing on smoking, PA, diet and alcohol. Counseling addressed all individuals who smoked, had 14 drinks/week for women and >21 for men. Written materials provided as appropriate. Overall goal was to achieve small but sustained dietary changes. Specifically, decreasing total SF intake, substituting SF for

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		Participants also received same health assessment and 45-min (baseline) or 15-min (years 1,3,5) individual counseling session provided to control participants.			unsaturated fat, and increasing intake of F/V and fish. Participants advised to aim for 4 hours/week PA (some papers report 30 mins/day); only minimal counseling time spent on PA. Participants were re-invited after 1 and 3 years for risk assessment and counseling and at 5 years for a short finishing lifestyle counseling.
TOHP I CRG, 1992[119] (Trials of Hypertension Prevention Phase I (TOHP I)) Good	IG1	The intervention consisted of group educational sessions supplemented by individual counseling. Demonstrations and practice were incorporated into each meeting. There was a 3-month initial (intensive) period consisting of 10 weekly sessions (8 group and 2 individual) lasting 90 minutes each. Interventions focused on shopping, cooking, and food selection behaviors aimed at reducing sodium intake. The individual sessions focused on a goal to reduce 24-hour sodium intake to 60 mmol (1400 mg). Food diaries were provided to participants and used to facilitate self-monitoring of sodium intake; intervention staff reviewed and commented on food diaries. 16 followup sessions offered after intensive intervention. Followup was implemented to provide continued information, support, and counseling through telephone, mail and at minimum, bimonthly in-person group or individual meetings (90 minutes each) throughout the trial. Participants were guided through a behavioral change process that focused on action goals and implementation steps specific to social, emotional, or practical problems encountered in sodium reduction. Group meetings included discussions to generate peer support and	HD only Total contact hrs: 39 Total duration: 18 months	Registered dietitian and psychologist or exercise psychologist Research center	Usual care: Participants received usual care.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		share effective strategies for achieving sodium-related behavior changes. Additional motivational strategies included special presentations about the importance of and rationale for the study and incentives in the form of food products and cooking demonstrations, and as some sites, contests (low-sodium "cook-offs") or door prizes at group meetings.			
TOHP I CRG, 1992[119] (Trials of Hypertension Prevention Phase I (TOHP I)) Good	IG2	Participants attended an individual counseling session followed by 14 weekly 90 minute group sessions (intensive phase), which were followed by monthly group meetings (extended intervention). Sessions presented information basic nutrition, social eating, self-management techniques, exercise demonstrations, supervised exercise, and relapse prevention. Participants reviewed progress and made plans for the next week. During the extended intervention participants had the option of monthly group sessions, group weigh-in session, individual weigh-in sessions, and individual counseling sessions according to individual needs. Food diaries were kept for the first 14 weeks and reviewed by nutrition staff who provided comments. Participants were asked to make a moderate reduction in total energy intake with the goal of achieving gradual weight loss not to exceed 0.9 kg (2 lb) a week with intake to not to fall below 1200 kcal. After reaching weight loss goal they were asked to adjust intake to maintain weight. Participants were encouraged maintain a graph of weight change from baseline and record daily exercise time as a bar graph. Participants were encouraged to increase activity, principally through walking at least 20 minutes 3 times per week. As intervention progressed, they were asked to adopt moderate exercise of 4 to 5 days per week between 30-45 minutes with an intensity of 40-55% of heart rate reserve. Behavioral self-management strategies employed included setting reasonable short-term goals, formulating specific plans of action to achieve these goals, developing reinforcement and social support for each major element of the plan, keeping records to assess progress, and regularly evaluating and modifying action plans. Small group sessions took place at every group where participants shared their goals and progress and worked on/problem-solved specific and	HD + PA Total contact hrs: 36.5 Total duration: 18 months	Registered dietitian and psychologist or exercise psychologist Clinical center	Usual care: Participants received usual care.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		detailed goals for the following week. Relapse prevention was also discussed and strategies developed.			
TOHP II CRG, 1997[120] (Trial of Hypertension Prevention II (TOHP II)) Good	IG1	57 weight loss and sodium reduction counseling sessions (1 individual introductory session, 14 90-min weekly group sessions, 6 90-min biweekly group sessions and 3-6 "minimodules" consisting of up to 6 sessions each [36 available sessions], and optional participant-initiated individual counseling sessions. Goal was to achieve ≥4.5 kg weight loss and mean sodium intake of ≤80 mmol/L with the aim to achieve goals during initial 6 months and to maintain goal thereafter. Behavioral objectives for weight loss intervention emphasized reducing caloric intake by decreasing consumption of excess fat, sugar, and alcohol and included daily food diaries and encouragement of moderately increasing physical activity. The physical activity goal was to gradually increase moderate intensity activity to 30-45 min per day, four to five days per week. Intervention was delivered in four phases. The pre-intensive phase consisted of one individual counseling session to prevent weight gain prior to initiation of group sessions. The intensive phase followed with 14 weekly 90-min group meetings led by dietitians or health educators and focused on core knowledge and skills for weight loss and sodium reduction. After the 14-week intensive phase, the transitional phase consisted of participants attending 6 biweekly group meetings and then monthly group meetings. Beginning in the 18th month, participants were offered optional individual counseling sessions and special group sessions focused on selected weight loss and sodium reduction topics. The program covered behavioral self-management, nutrition education, information on PA, social support, self-monitoring (food diaries and graphs of PA), goal-setting with action plans, strategies for situations that trigger problem eating.	HD + PA Total contact hrs: 48.5 Total duration: 36 months	Centrally trained staff (dietitians, psychologists, or health counselors) Research clinic	No advice: Assessment only, received no further intervention.
TOHP II CRG, 1997[120] (Trial of Hypertension Prevention II (TOHP II)) Good	IG2	57 weight loss counseling sessions (1 individual introductory session, 14 90-min weekly group sessions, 6 90-min biweekly group sessions and 3-6 "minimodules" consisting of up to 6 sessions each [36 available sessions], and optional participant-initiated individual counseling sessions). Goal was to achieve ≥4.5 kg weight loss with the aim to achieve goal during initial 6 months and to maintain goal thereafter. Behavioral objectives for weight loss intervention emphasized reducing caloric intake by decreasing consumption of	HD + PA Total contact hrs: 48.5 Total duration: 36 months	Centrally trained staff (dietitians, psychologists, or health counselors) Research clinic	No advice: Assessment only, received no further intervention.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		excess fat, sugar, and alcohol and included daily food diaries and encouragement of moderately increasing physical activity. The physical activity goal was to gradually increase moderate intensity activity to 30-45 min per day, four to five days per week. Intervention was delivered in four phases. The pre-intensive phase consisted of one individual counseling session to prevent weight gain prior to initiation of group sessions. The intensive phase followed with 14 weekly 90-min group meetings led by dietitians or health educators and focused on core knowledge and skills for weight loss. After the 14-week intensive phase, the transitional phase consisted of participants attending 6 biweekly group meetings and then monthly group meetings. Beginning in the 18th month, participants were offered optional individual counseling sessions and special group sessions focused on selected weight loss topics. The program covered behavioral self-management, nutrition education, information on PA, social support, self-monitoring (food diaries and graphs of PA), goal-setting with action plans, strategies for situations that trigger problem eating.			
TOHP II CRG, 1997[120] (Trial of Hypertension Prevention II (TOHP II)) Good	IG3	53 sodium reduction counseling sessions (1 individual introductory session, 10 90-min weekly group sessions, 6 90-min biweekly group sessions and 3-6 "minimodules" consisting of up to 6 sessions each [36 available sessions], and optional participant-initiated individual counseling sessions). The group goal was average sodium intake ≤80 mmol/24h, and the individual goal was sodium intake ≤70 mmol/24h with the aim to achieve goals during initial 6 months and to maintain goal thereafter. Intervention focused on identifying sodium content of foods, preparing lower sodium foods, modifying recipes, and making lower sodium food selections at and between meals and when eating out; taste-testing, making small, progressive sodium intake changes; alternatives to high-sodium eating behaviors; general behavioral modification and relapse prevention techniques, including self-monitoring of sodium intake; and feedback on food records and urinary sodium excretion. Intervention was delivered in four phases. The pre-intensive phase consisted of one individual counseling session. During this phase, the primary goal was to provide participants with core knowledge and behavioral skills necessary to make and maintain reductions in sodium intake. The intensive phase	HD only Total contact hrs: 42.5 Total duration: 36 months	Centrally trained staff (dietitians, psychologists, or health counselors) Research clinic	No advice: Assessment only, received no further intervention.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		followed with 10 weekly 90-min group meetings led by dietitians or health educators and focused on core knowledge and skills for reducing dietary sodium. After the 10-week intensive phase, the transitional phase consisted of participants attending 6 biweekly group meetings and then monthly group meetings. A transitional phase consisting of 4 monthly sessions was designed to prevent relapse and to ease transition from weekly to less frequent contacts. The final extended phase was to maintain participants' behavior changes. As a routine, this included 1 to 2 monthly contacts and a series of 3 to 6 refresher sessions that was offered on intervention-related topics to promote contact and adherence with the intervention.			
Tomson, 1995[121] Fair	IG1	6 sessions diet counseling, including 3 sessions with primary care physician and 3 sessions with dietician (1 individual, 1 with spouse, and 1 group session with trip to grocery store). Counseling intervention aimed at non-pharmacological management of high cholesterol. The first session with the dietician involved a diet history and individualized suggestions for dietary modification based on the 'Step I' diet, which recommended: total fat <30% of calories, ratio of polyunsaturated fat to saturated fat of 1.0, dietary cholesterol <200 mg/day, and caloric restriction to achieve desirable weight. Spouses were invited to the second dietician session, and the third dietician session was a small group trip to the grocery store to learn how to identify low-fat and high-fiber foods.	HD only Total contact hrs: 3 Total duration: 12 months	PCP, dietician Medical center	Usual care: Results of screening were communicated to participant by letter from GP explaining that cholesterol values were too high and therapy is to modify diet. A booklet with diet information was sent with the letter and dietary recommendations based on the patient's weight were included. For those who were overweight: increase fiber and decrease fat intake to 30% of total daily calories. For those of healthy weight: focus on switching to mono and polyunsaturated fats. If participant had to visit

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
					health center for other reasons during the intervention period, there was no restriction on discussion of hypercholesterolemia.
van der Veen, 2002[122] (Nijmegen Family Practices Monitoring Project (NFPMP)) Fair	IG1	Maximum of 3 10-minute family physician nutrition counseling sessions with referral to dietician for 3 sessions (initial consultation of 30-40 minutes and 10-15 minutes for second and third consultation). Stages-of-change-based intervention with content tailored to participant's stage; the intervention stopped if no progress was made to the next stage or relapse to former stage. Participants in the precontemplation stage received feedback on baseline dietary intake, lipids, and anthropometry as well as a counseling session focused on raising awareness of dietary behavior and a fill-in-at-home worksheet. Participants in the contemplation stage were given feedback on baseline measures and a counseling session focused on motivation to change dietary behavior and a list of food substitutions. Participants in the action stage received feedback on baseline measures and counseling session focused on practical behavior changes for reducing saturated fat and increasing unsaturated fat, and advised to reduce total energy and total fat if high in body weight. Additional counseling sessions in the action stage included discussion of progress and barriers, discussion of results of second measurements, and expectations.	HD only Total contact hrs: 1.7 Total duration: 2.5 months	Family physician; dietician Family practice	Usual care: No details provided
van Keulen, 2011[123] (Vitalum) Fair	IG1	Participants received four 20-minute telephone calls based on motivational interviewing on physical activity, and fruit/vegetable consumption. During each call, the counselor assessed the participant's current behaviors and progress, summarized the participant's behavior based on a participant profile generated from a questionnaire; discussed public health guidelines related to participant's health behaviors; assessed and enhanced motivation and self-efficacy for behavior change; assessed readiness to change. Half of the participants in each group received pedometers at week 29 (along with instructions to gradually increase their number of steps to 10,000 per day) and the remainder received one after the last followup.	HD + PA Total contact hrs: 1.3 Total duration: 10 months	Counselors (students of Health Education and Health Promotion, Mental Health Sciences, or Psychology) Home	Usual care: After the intervention period, participants received one tailored letter addressing physical activity and fruit/vegetable consumption based on results from previous followup questionnaire.

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Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
van Keulen, 2011[123] (Vitalum) Fair	IG2	Participants received both tailored print communication and two 20-minute telephone-based motivational interviewing calls. One letter and 1 call focused on physical activity; the other two focused on fruit/veggie consumption. Half of the participants in each group received pedometers at week 29 (along with instructions to gradually increase their number of steps to 10,000 per day) and the remainder received one after the last followup.	HD + PA Total contact hrs: 0.67 Total duration: 10 months	Counselors (students of Health Education and Health Promotion, Mental Health Sciences, or Psychology) Home	Usual care: After the intervention period, participants received one tailored letter addressing physical activity and fruit/vegetable consumption based on results from previous followup questionnaire.
van Keulen, 2011[123] (Vitalum) Fair	IG3	Participants received four tailored letters based on baseline and followup survey data (variables included current behavior, awareness, age, gender, stage of change, attitude, self-efficacy expectations, and action plans): letters 1 & 3 focused on physical activity (3-6 pages) and letters 2 & 4 focused on fruit and vegetable consumption (4-6 pages). Letters included feedback on the targeted behavior and stage-matched advice to change behavior. Letters 3 and 4 reinforced tailored feedback on behavioral progress based on intermediate survey data. Half of the participants in each group received pedometers at week 29 (along with instructions to gradually increase their number of steps to 10,000 per day) and the remainder received one after the last followup.	HD + PA Total contact hrs: 0 Total duration: 10 months	NA Home	Usual care: After the intervention period, participants received one tailored letter addressing physical activity and fruit/vegetable consumption based on results from previous followup questionnaire.
van Sluijs, 2005[124] (Physician-based Assessment and Counseling for Exercise (PACE)) Fair	IG1	Participants had 2 visits with their provider and 2 "booster" followup phone calls with a PACE counselor. At the initial visit patients met with their general practitioner or nurse practitioner for a 10-minute consultation to discuss the patients' medical condition(s), to offer advice about becoming more physically active, and to assess their stage of change for physical activity, using the PACE physical activity program materials, which included a stage-specific protocol to guide the clinician. The goal of PACE intervention was to "promote long-term participation in regular physical activity by altering social and psychological factors known to influence physical activity, such as social support, increased self-efficacy, reduced perceived barriers, and increased awareness of the benefits of physical activity ". After initial visit, 1 follow-up visit with provider (4 weeks), where they focused on stage-specific protocols and checked in on participant progress. At 4 wk visit physical activity	PA only Total contact hrs: 0.83 Total duration: 2 months	GP/NP and PA counselor Clinic, home (phone)	Usual care: GPs discussed patient's current level of physical activity and, as appropriate, encouraged patient to become more active. Standard text on physical activity promotion was provided.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		counselors offered new counseling protocol for those who had either progressed or regressed through stages of change. PACE physical activity counselors (separate from general practitioner/nurse practitioner) provided 2 "booster" phone call consultations (2 and 8 weeks after initial provider visit), to offer support and resolve possible problems or questions.			
Viglione, 2019[125] (Goals for Eating and Moving (GEM)) Fair	IG1	13 sessions of diet and physical activity counseling delivered by health coaches (1 60-min in-person counseling session and 12 25-min coaching calls) and an average of 2.3 counseling sessions with PCP. Participants attended an hour-long baseline visit with a health coach, in which the health coach provided an overview of the tablet-delivered GEM tool, as well as instructions for using the pedometer and food/physical activity diary. Health coaches also used the baseline visit to counsel participants, using motivational interviewing techniques, to explore motivation and barriers for losing weight, increasing physical activity, and making dietary changes. Participants were encouraged to attend MOVE! Sessions (weight management program comprised of support and skill-building lessons focused on self-monitoring, diet, physical activity, and weight loss for veterans seen at the VA). Participants used the GEM tool at baseline to answer a series of questions and complete a goal-setting algorithm, which the tool used to generate tailored educational materials (SMART goal worksheets, standardized MOVE! Handouts, information on health resources, GEM summary report), which were given to participants in a binder as a personalized care plan. Following the baseline visit, participants received up to 12 25-minute coaching calls in which health coaches reminded them to use food records and pedometers three days prior to each coaching session. Health coaches documented their encounters in the participant's medical record with a note to generate a clinical reminder for the PCP. PCPs were trained on the GEM tool, supporting participant goals and addressing barriers, the role of the health coach, and the electronic clinical reminders. PCPs were asked to discuss goal and address barriers, communicate with health coaches, and document weight loss counseling.	HD + PA Total contact hrs: 6.6 Total duration: 12 months	Health coaches (trained students), PC team Primary care (baseline and PCP visits), home (calls)	Usual care: Participants received a printed flyer about MOVE! and a "VA Healthy Living" brochure from a health coach. The pamphlet covered screening tests and immunizations, stress management, tobacco and alcohol use, and physical activity. Handouts encouraged participants to discuss goals with their PCPs.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Voils, 2013[126] (CouPLES) Fair	IG1	9 phone counseling sessions for the patient and 9 phone counseling sessions for their spouse. Patient phone sessions addressed goal-setting and problem solving and the topic was selected by the patient at the beginning of the call from among: diet, physical activity, patient-physician communication, and medication adherence. In the first session, patients and spouses received information about hypercholesterolemia and an overview of self-management principles. Spouses also received an orientation on strategies to support patient goal achievement. Subsequent phone sessions allowed each patient to choose a behavior on which to focus and set their own goals and action plans according to what they felt they could accomplish. Spouse calls occurred within one week of patient calls and included a review of patients' success in meeting previous goals; spouses were asked to create a behavior plan for supporting achievement of new goals. For diet and physical activity goals, spouses were asked if they planned to make the same changes that patients planned to make. Patients selected diet for 51% of calls and physical activity for 49% of calls. Spouses agreed to make the same changes as patients in 97% of calls in which the patient sets dietary change goals and 65% of calls in which the patient set exercise goals. The patient–physician communication topic was only selected for 2 calls, and the medication management topic was never selected.	HD + PA Total contact hrs: 3.5 Total duration: 11 months	Research nurse Home	Minimal intervention: Clinical management of lipid disorders using Adult Treatment Panel III guidelines. Reminders for physicians were embedded in 11 emails, electronic medical records, and performance measures. Emails emphasized the use of lipid lowering medications. Physicians also had access to 2 referral clinics: a subspecialty lipid clinic for difficult to manage cases and a subspecialty risk factor management clinic that enrolled high-risk patients whose LDL-C was above goal. These clinics provided lifestyle behavior counseling, medication management, and followup.
Wadden, 2011[127] (Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-UP)) Good	IG1	Participants whose weight was less than 113.4 kg were prescribed a balanced diet of 1200 to 1500 kcal per day (1500 to 1800 kcal per day for participants who weighed 113.4 or more), which consisted of approximately 15 to 20% kcal from protein, 20 to 35% kcal from fat, and the remainder from carbohydrates. All participants were instructed to gradually increase their PA to 180 min/week and were given a pedometer, a calorie-counting book, and handouts from Aim for a Healthy Weight. Attended quarterly 10-15 min PCP visits, at	HD + PA Total contact hrs: 6.9 Total duration: 24 months	Medical assistant (lifestyle coach) and PCP Primary care	Minimal intervention: Participants attended eight quarterly 5-7 min PCP visits to review their weight change and to discuss information in the Aim for a Healthy Weight

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		which they reviewed their health status and were provided handouts from Aim for a Healthy Weight. In addition, participants attended monthly visits with a medical assistant (referred to as lifestyle coach [LC]), who delivered abbreviated DPP treatment. Participants attended 14 LC visits in year 1, followed by 12 LC visits in year 2. During month 1, this included 2 counseling visits to learn how record food and calorie intake in diaries provided. Visits began with a weigh-in and then a review of food intake, PA and other goals prescribed in monthly handouts. In year 2, they were permitted, every other month, to complete counseling visits by telephone (although <5% of visits were made by telephone). The intervention views participants as active problem solvers who are capable of regulating their affect, behavior, and cognition. Self-monitoring is used to identify times, places, emotions, people, and events associated with eating (or exercising) appropriately or inappropriately. Goal setting is facilitated by specifying behaviors to be adapted and when, where, how, and with whom they will be performed. Behavior change is reinforced by increased self-efficacy, by the inherent rewards in reaching a goal (i.e., weight loss or improved fitness), by social support (including encouragement from medical personnel) or by the use of external rewards. The intervention will include other traditional lifestyle modification topics (e.g., challenging negative thoughts, obtaining social support), most of which will be accompanied by a homework assignment to be completed before the next visit with the Lifestyle Coach. An important behavior will be having participants weigh themselves at least once a week and record their weight. Participants who do not have access to a scale for weekly weigh-ins will be provided an inexpensive bathroom scale.			handouts. Same dietary and PA goals as IG.
Whelton, 1998[128] (Trial of Nonpharmacologic Interventions in the Elderly	IG1	(Limited to patients with obesity) 25 sessions of individual and group counseling over 8 months, followed by 28 monthly maintenance sessions, focused on reducing dietary sodium intake to ≤1800 mg per day and achieving weight loss of ≥10 lbs. Weight loss was to be achieved by a caloric deficit from both dietary restriction and increased physical activity. Withdrawal of antihypertensive	HD + PA Total contact hrs: 49.5 Total duration: 36 months	Nutritionists and exercise counselors Academic health center	Minimal intervention: Usual care groups received no study-related counseling in lifestyle change techniques but were

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
(TONE)) Good		medication was a goal for all participants and was initiated 3 months after the first group counseling session. Counseling interventionists provided information using both centrally and locally prepared materials, motivated participants to make and sustain long-term lifestyle changes, monitored individual and group progress at frequent intervals, and helped participants customize intervention to meet individual needs. Centrally prepared materials included food counters, scorekeepers, manuals, and audiovisual aides. Intervention consisted of 3 phases (intensive, extended, and maintenance). Primary goal during intensive phase was to provide core knowledge and behavior skills necessary to achieve and maintain reductions in sodium reduction and body weight. During extended phase, focus was on problem solving and relapse prevention. During maintenance phase, continued attempts were made to maintain or re-engage participant interest in the intervention. Telephone and mail contacts are suggested in the protocol during the maintenance phase without specific details provided.			invited to meetings on topics unrelated to diet, physical activity, and cardiovascular disease.
Whelton, 1998[128] (Trial of Nonpharmacologic Interventions in the Elderly (TONE)) Good	IG2	(Limited to patients with obesity) 25 sessions of individual and group counseling over 8 months, followed by 28 monthly maintenance sessions, focused on achieving weight loss of ≥10 lbs. Weight loss was to be achieved by a caloric deficit from both dietary restriction and increased physical activity. Withdrawal of antihypertensive medication was a goal for all participants and was initiated 3 months after the first group counseling session. Counseling interventionists provided information using both centrally and locally prepared materials, motivated participants to make and sustain long-term lifestyle changes, monitored individual and group progress at frequent intervals, and helped participants customize intervention to meet individual needs. Centrally prepared materials included food counters, scorekeepers, manuals, and audiovisual aides. Weight loss group received information on techniques and group practice in safe low-level exercise. Intervention consisted of 3 phases (intensive, extended, and maintenance). Primary goal during intensive phase was to provide core knowledge and behavior skills necessary to achieve and maintain reductions in body weight. During extended phase, focus was on problem solving and relapse prevention. During maintenance phase, continued attempts were made to maintain or re-	HD + PA Total contact hrs: 49.5 Total duration: 36 months	Nutritionists and exercise counselors Academic health center	Minimal intervention: Usual care groups received no study-related counseling in lifestyle change techniques but were invited to meetings on topics unrelated to diet, physical activity, and cardiovascular disease.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		engage participant interest in the intervention. Telephone and mail contacts are suggested in the protocol during the maintenance phase without specific details provided.			
Whelton, 1998[128] (Trial of Nonpharmacologic Interventions in the Elderly (TONE)) Good	IG3	25 sessions of individual and group counseling over 8 months focused on reducing dietary sodium intake to ≤1800 mg per day, followed by 28 monthly maintenance sessions. Withdrawal of antihypertensive medication was a goal for all participants and was initiated 3 months after the first group counseling session. Counseling interventionists provided information using both centrally and locally prepared materials, motivated participants to make and sustain long-term lifestyle changes, monitored individual and group progress at frequent intervals, and helped participants customize intervention to meet individual needs. Centrally prepared materials included food counters, scorekeepers, manuals, and audiovisual aides. Intervention consisted of 3 phases (intensive, extended, and maintenance). Primary goal during intensive phase was to provide core knowledge and behavior skills necessary to achieve and maintain reductions in sodium and body weight. During extended phase, focus was on problem solving and relapse prevention. During maintenance phase, continued attempts were made to maintain or re-engage participant interest in the intervention. Telephone and mail contacts are suggested in the protocol during the maintenance phase without specific details provided.	HD only Total contact hrs: 49.5 Total duration: 36 months	Nutritionists and exercise counselors Academic health center	Minimal intervention: Usual care groups received no study-related counseling in lifestyle change techniques but were invited to meetings on topics unrelated to diet, physical activity, and cardiovascular disease.
Wister, 2007[129] Good	IG1	2 30-minute phone sessions (4 additional 20-30 minute sessions for smokers) of diet and physical activity counseling and 3 mailings. The mailing consisted of an initial report card with CVD risk profile and mailings of counseling summaries and educational materials after each phone session. The report card was sent to the participant and primary care provider, with the participant's risk profile. The Framingham risk score was used to calculate global CVD risk. The first phone session occurred about 10 days after receiving their risk profile, followed by another phone session approximately 6 months later. A letter grading system (A, B, C, D, F) was developed for the risk scores, which guided recommendations. Smoking was considered top priority for lifestyle counseling, followed by physical activity, dietary habits, weight management and stress. Counselors addressed the areas where the grade was lowest first and	HD + PA Total contact hrs: 1 Total duration: 12 months	Clinical lifestyle counselors (were also kinesiologists) Home	Usual care: Participants received usual care from their physicians, based on their own determination of the need for visits.

Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		comparisons with previous report cards were discussed with the participant to set new goals. Smokers prepared to quit received additional 20- to 30-minute sessions at 2, 4, 8 and 12 weeks according to US and Canadian guidelines. Summaries of each counseling session and supporting evidence-based educational materials were mailed to the participants.			
Wong, 2015[130] Good	IG1	1 3-5 min physician-delivered usual care session and 1 25-min dietitian-delivered DASH diet counseling session. Usual care consisted of a 3-5 minute physician-delivered counseling session based on a standard pamphlet for hypertensive patients used in all public primary care clinics in Hong Kong. Participants were educated on (i) the definition and nature of hypertension; (ii) the diagnosis of Grade 1 hypertension with its associated complications; (iii) causes of hypertension; the clinical tests needed for annual assessment; and (iv) non-pharmacological approaches to control BP (i.e., smoking cessation, reduction in alcohol use, maintenance of body weight, regular PA, balanced diet [low salt and low fat], and adequate rest). The DASH diet counseling session was delivered by a dietitian and included information about the nature of DASH, benefits, major components, and individualized meal plan tailored to Chinese culture. Participants were encouraged to achieve individualized DASH diet goals, with regard to higher intake of fruits (4–5 serves/day) and vegetables (4–5 serves/day), low-fat dairy products (2–3 serves/day), lean meats, poultry, and fish (≤6 serves/day), and nuts, seeds, and legumes (4–5 serves/week), while limiting the intake of sweets and added sugars (≤5 serves/week), and fats and oils (2–3 serves/day). Practical tips for decreasing salt intake were also emphasized, and participants were given an educational pamphlet on the DASH diet. Dietician checked all patients for comprehension of DASH advice offered and provided clarification to hose with inquires.	HD only Total contact hrs: 0.5 Total duration: 0.03 months	Physician and dietitian Primary care	Usual care: Participants received usual care consisting of a 3-5 minute physician-delivered counseling session based on a standard pamphlet for hypertensive patients used in all public primary care clinics in Hong Kong. Participants were educated on (i) the definition and nature of hypertension; (ii) the diagnosis of Grade 1 hypertension with its associated complications; (iii) causes of hypertension; the clinical tests needed for annual assessment; and (iv) non-pharmacological approaches to control BP (i.e., smoking cessation, reduction in alcohol use, maintenance of body weight, regular PA, balanced diet [low salt

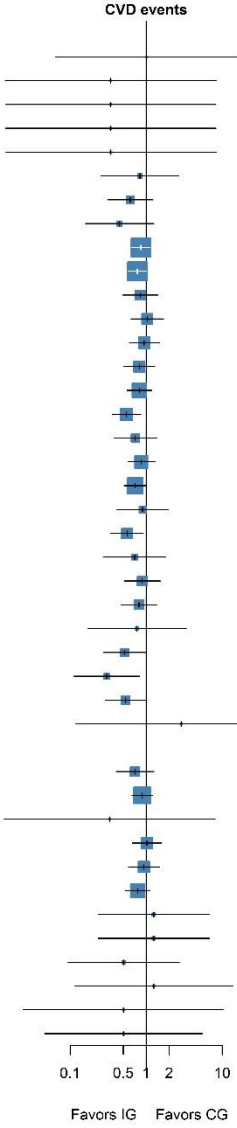
Appendix F Table 3. Detailed Intervention Descriptions

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
					and low fat], and adequate rest). No advice was given on the DASH diet.
Wood, 2008[131] (EUROACTION) Fair	IG1	Individual nurse assessment with personal report card and family support pack plus 8 group workshops of diet, PA, and risk factor counseling. Motivational interviewing, stages of change, and family support were used to help participants and their partners achieve risk factor and lifestyle targets which included: not smoking, saturated fat 400 g/day, fish >20 g/day, oily fish >3 times/week, alcohol < 6.1 mmol/L (good glycemic control in diabetics); those with BMI >25 kg/m^2 had a goal to reduce weight by 5% in 1 year. A pedometer was used to motivate PA. Nurse monitored BP, lipids, and glucose and reviewed results with physicians to treat to targets. Nurses educated families about medications to improve adherence.	HD + PA Total contact hrs: 8 Total duration: 4 months	Nurses; family doctors General practice center	Usual care: Centers randomized to usual care were informed that they would be audited. No other details reported.

Abbreviations: DPP = Diabetes Prevention Program; F/U = followup; g = grams; GP = general practitioner; HD = healthy diet only; HD + PA = healthy diet and physical activity; HDL = high-density lipoprotein cholesterol; hrs = hours; HTN = hypertension; IG = intervention group; Int arm = intervention arm; kg = kilograms; kg/m^2 = kilograms per meter squared; LDL = low-density lipoprotein cholesterol; mg = milligrams; MI = motivational interviewing; min = minutes; ml = milliliters; mm Hg = millimeters of mercury; mmol/L = millimoles per liter; NCEP = National Cholesterol Education Program; NHLBI = National Heart, Lung, and Blood Institute; NHS = National Health Service (UK); NR = not reported; PA = physical activity only; PCP = primary care provider; PN = practice nurse; TC = total cholesterol; TG = triglycerides; wk = week

Appendix G Figure 1. All CVD Events by Study

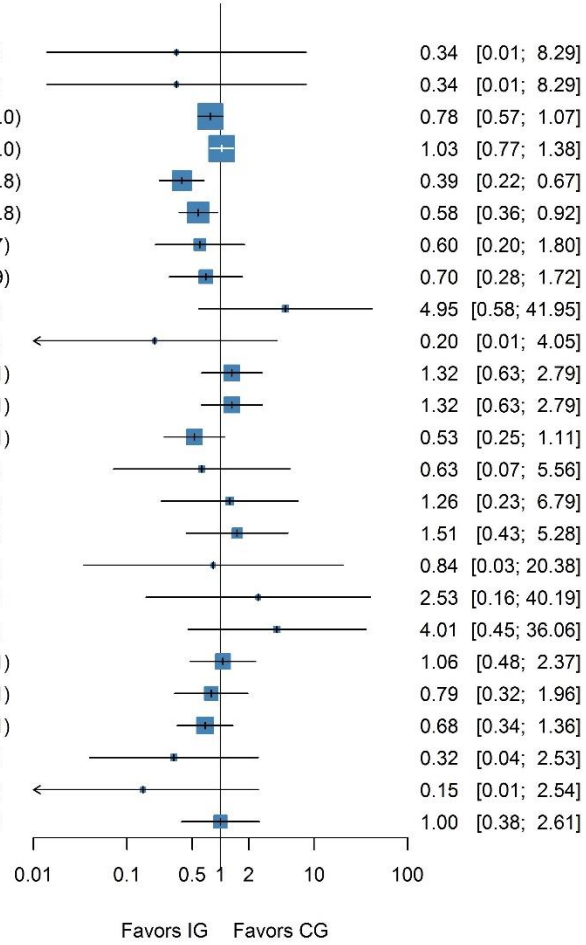
Study	Int arm	Population risk focus	Timepoint (months)	Outcome	IG n/N (%)	CG n/N (%)	RR	95% CI
Appel, 2003	IG1	Hypertension	6	MI	1/269 (0.4)	1/273 (0.4)	1.01	[0.06; 16.02]
Appel, 2003	IG2	Hypertension	6	MI	0/268 (0.0)	1/273 (0.4)	0.34	[0.01; 8.29]
Appel, 2003	IG1	Hypertension	6	Stroke	0/269 (0.0)	1/273 (0.4)	0.34	[0.01; 8.29]
Appel, 2003	IG2	Hypertension	6	Stroke	0/268 (0.0)	1/273 (0.4)	0.34	[0.01; 8.29]
Bennett, 2012	IG1	Hypertension	24	CVD events	0/180 (0.0)	1/185 (0.5)	0.34	[0.01; 8.37]
Bennett, 2018	IG1	Multiple risk factors	12	CVD events	5/176 (2.8)	6/175 (3.4)	0.83	[0.26; 2.68]
Bo, 2007	IG1	Multiple risk factors	108	CVD events	12/169 (7.1)	19/166 (11.4)	0.62	[0.31; 1.23]
Bo, 2007	IG1	Multiple risk factors	108	CVD Mortality	5/169 (3.0)	11/166 (6.6)	0.44	[0.16; 1.26]
Estruch, 2018	IG1	Multiple risk factors	60	CVD events	96/2543 (3.8)	109/2450 (4.4)	0.85	[0.65; 1.12]
Estruch, 2018	IG2	Multiple risk factors	60	CVD events	83/2454 (3.4)	109/2450 (4.4)	0.76	[0.58; 1.00]
Estruch, 2018	IG1	Multiple risk factors	60	CVD Mortality	26/2543 (1.0)	30/2450 (1.2)	0.84	[0.49; 1.42]
Estruch, 2018	IG2	Multiple risk factors	60	CVD Mortality	31/2454 (1.3)	30/2450 (1.2)	1.03	[0.63; 1.68]
Estruch, 2018	IG1	Multiple risk factors	60	MI	37/2543 (1.5)	38/2450 (1.6)	0.94	[0.60; 1.48]
Estruch, 2018	IG2	Multiple risk factors	60	MI	31/2454 (1.3)	38/2450 (1.6)	0.81	[0.51; 1.30]
Estruch, 2018	IG1	Multiple risk factors	60	Stroke	49/2543 (1.9)	58/2450 (2.4)	0.81	[0.56; 1.18]
Estruch, 2018	IG2	Multiple risk factors	60	Stroke	32/2454 (1.3)	58/2450 (2.4)	0.55	[0.36; 0.84]
Fagerberg, 1998	IG1	Multiple risk factors	79	Coronary deaths	17/253 (6.7)	23/255 (9.0)	0.72	[0.38; 1.37]
Fagerberg, 1998	IG1	Multiple risk factors	79	Coronary events	44/253 (17.4)	50/255 (19.6)	0.86	[0.57; 1.30]
Fagerberg, 1998	IG1	Multiple risk factors	79	CVD events	63/253 (24.9)	84/255 (32.9)	0.71	[0.51; 0.99]
Fagerberg, 1998	IG1	Multiple risk factors	40	CVD Mortality	12/253 (4.7)	13/255 (5.1)	0.90	[0.41; 1.96]
Fagerberg, 1998	IG1	Multiple risk factors	79	CVD Mortality	24/253 (9.5)	42/255 (16.5)	0.56	[0.34; 0.91]
Fagerberg, 1998	IG1	Multiple risk factors	79	MI fatal	7/253 (2.8)	10/255 (3.9)	0.70	[0.28; 1.81]
Fagerberg, 1998	IG1	Multiple risk factors	79	MI nonfatal	22/253 (8.7)	25/255 (9.8)	0.89	[0.51; 1.54]
Fagerberg, 1998	IG1	Multiple risk factors	40	MI	18/253 (7.1)	22/255 (8.6)	0.80	[0.46; 1.39]
Fagerberg, 1998	IG1	Multiple risk factors	79	Stroke fatal	3/253 (1.2)	4/255 (1.6)	0.76	[0.17; 3.35]
Fagerberg, 1998	IG1	Multiple risk factors	79	Stroke nonfatal	13/253 (5.1)	25/255 (9.8)	0.52	[0.27; 1.00]
Fagerberg, 1998	IG1	Multiple risk factors	40	Stroke	5/253 (2.0)	17/255 (6.7)	0.30	[0.11; 0.82]
Fagerberg, 1998	IG1	Multiple risk factors	79	Stroke	16/253 (6.3)	29/255 (11.4)	0.53	[0.29; 0.98]
Haufe, 2019	IG1	Multiple risk factors	6	MI nonfatal	1/160 (0.6)	0/154 (0.0)	2.89	[0.12; 70.44]
Hinderliter, 2014	IG1	Hypertension	12	CVD events	0/46 (0.0)	0/49 (0.0)		
TOHP I CRG, 1992	IG1	Hypertension	192	CVD events	17/231 (7.4)	32/311 (10.3)	0.71	[0.40; 1.26]
TOHP II CRG, 1997	IG0	Hypertension	192	CVD events	71/938 (7.6)	80/935 (8.6)	0.89	[0.65; 1.21]
Wadden, 2011	IG1	Multiple risk factors	24	MI	0/131 (0.0)	1/130 (0.8)	0.33	[0.01; 8.04]
Whelton, 1998	IG1	Hypertension	36	CVD events	23/147 (15.6)	57/371 (15.4)	1.02	[0.65; 1.60]
Whelton, 1998	IG2	Hypertension	36	CVD events	21/147 (14.3)	57/371 (15.4)	0.93	[0.58; 1.49]
Whelton, 1998	IG3	Hypertension	36	CVD events	44/370 (11.9)	57/371 (15.4)	0.77	[0.53; 1.12]
Whelton, 1998	IG1	Hypertension	36	MI nonfatal	2/147 (1.4)	4/371 (1.1)	1.26	[0.23; 6.79]
Whelton, 1998	IG2	Hypertension	36	MI nonfatal	2/147 (1.4)	4/371 (1.1)	1.26	[0.23; 6.79]
Whelton, 1998	IG3	Hypertension	36	MI nonfatal	2/370 (0.5)	4/371 (1.1)	0.50	[0.09; 2.71]
Whelton, 1998	IG1	Hypertension	36	Stroke nonfatal	1/147 (0.7)	2/371 (0.5)	1.26	[0.12; 13.75]
Whelton, 1998	IG2	Hypertension	36	Stroke nonfatal	0/147 (0.0)	2/371 (0.5)	0.50	[0.02; 10.46]
Whelton, 1998	IG3	Hypertension	36	Stroke nonfatal	1/370 (0.3)	2/371 (0.5)	0.50	[0.05; 5.48]



Abbreviations: CG = control group; CI = confidence interval; CVD = cardiovascular disease; IG = intervention group; Int arm = intervention arm; MI = myocardial infarction; RR = risk ratio; TOHP I CRG = The Trials of Hypertension Prevention – Phase I Collaborative Research Group; TOHP II CRG = The Trials of Hypertension Prevention – Phase II Collaborative Research Group

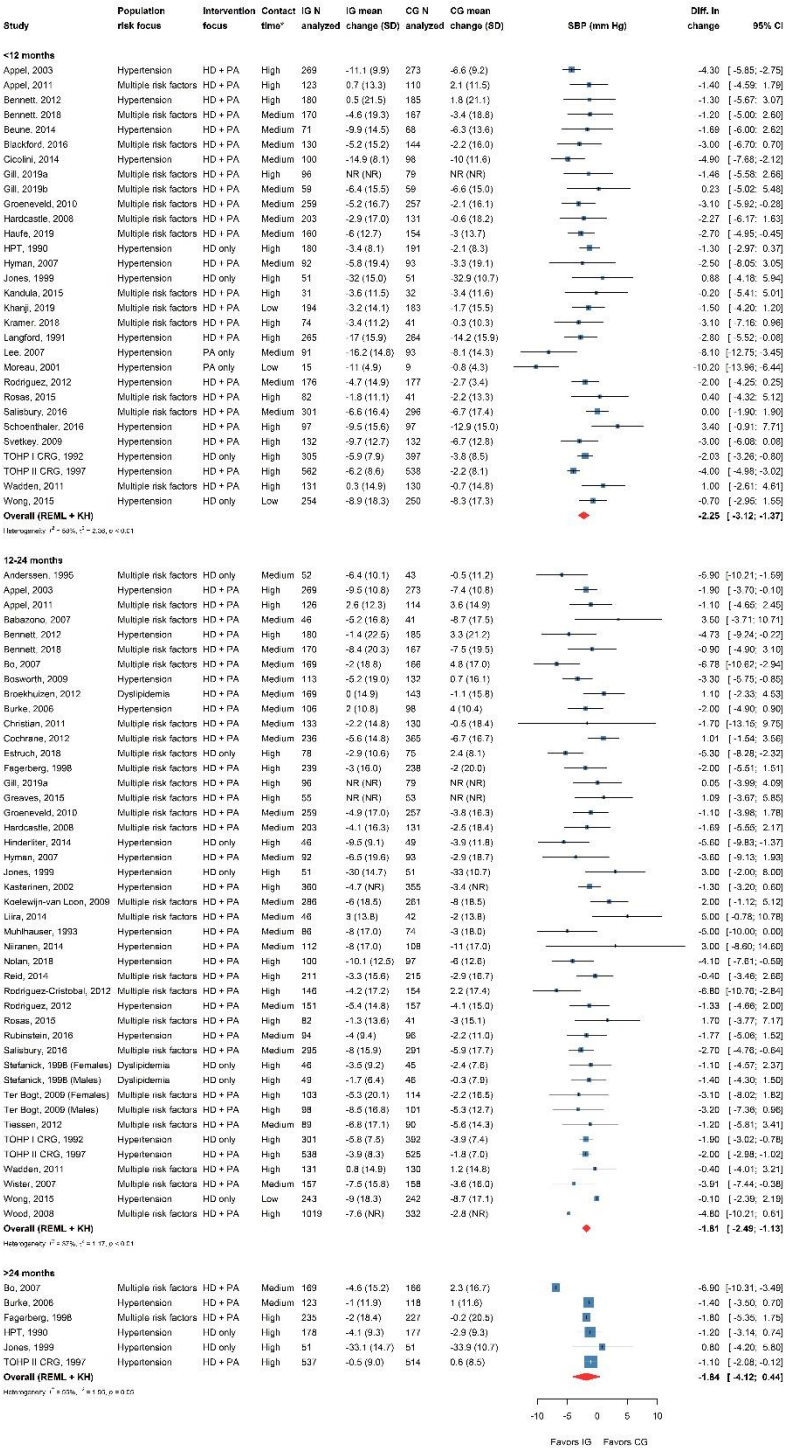
Appendix G Figure 2. Other CVD Events by Study

Study	Int arm	Population risk focus	Timepoint (months)	Outcome	IG n/N (%)	CG n/N (%)	RR	95% CI
Appel, 2003	IG1	Hypertension	6	Transient Ischemic Attack	0/269 (0.0)	1/273 (0.4)	0.34	[0.01; 8.29]
Appel, 2003	IG2	Hypertension	6	Transient Ischemic Attack	0/268 (0.0)	1/273 (0.4)	0.34	[0.01; 8.29]
Estruch, 2018	IG1	Multiple risk factors	72	Arrhythmia	72/2292 (3.1)	89/2203 (4.0)	0.78	[0.57; 1.07]
Estruch, 2018	IG2	Multiple risk factors	72	Arrhythmia	92/2210 (4.2)	89/2203 (4.0)	1.03	[0.77; 1.38]
Estruch, 2018	IG1	Multiple risk factors	60	Incident PAD	18/2539 (0.7)	45/2444 (1.8)	0.39	[0.22; 0.67]
Estruch, 2018	IG2	Multiple risk factors	60	Incident PAD	26/2452 (1.1)	45/2444 (1.8)	0.58	[0.36; 0.92]
Fagerberg, 1998	IG1	Multiple risk factors	40	Angina	7/253 (2.8)	12/255 (4.7)	0.60	[0.20; 1.80]
Fagerberg, 1998	IG1	Multiple risk factors	40	Claudication	7/253 (2.8)	10/255 (3.9)	0.70	[0.28; 1.72]
Wadden, 2011	IG1	Multiple risk factors	24	Angina	5/131 (3.8)	1/130 (0.8)	4.95	[0.58; 41.95]
Wadden, 2011	IG1	Multiple risk factors	24	Congestive Heart Failure	0/131 (0.0)	2/130 (1.5)	0.20	[0.01; 4.05]
Whelton, 1998	IG1	Hypertension	36	Angina	10/147 (6.8)	19/371 (5.1)	1.32	[0.63; 2.79]
Whelton, 1998	IG2	Hypertension	36	Angina	10/147 (6.8)	19/371 (5.1)	1.32	[0.63; 2.79]
Whelton, 1998	IG3	Hypertension	36	Angina	10/370 (2.7)	19/371 (5.1)	0.53	[0.25; 1.11]
Whelton, 1998	IG1	Hypertension	36	Arrhythmia	1/147 (0.7)	4/371 (1.1)	0.63	[0.07; 5.56]
Whelton, 1998	IG2	Hypertension	36	Arrhythmia	2/147 (1.4)	4/371 (1.1)	1.26	[0.23; 6.79]
Whelton, 1998	IG3	Hypertension	36	Arrhythmia	6/370 (1.6)	4/371 (1.1)	1.51	[0.43; 5.28]
Whelton, 1998	IG1	Hypertension	36	Congestive Heart Failure	0/147 (0.0)	1/371 (0.3)	0.84	[0.03; 20.38]
Whelton, 1998	IG2	Hypertension	36	Congestive Heart Failure	1/147 (0.7)	1/371 (0.3)	2.53	[0.16; 40.19]
Whelton, 1998	IG3	Hypertension	36	Congestive Heart Failure	4/370 (1.1)	1/371 (0.3)	4.01	[0.45; 36.06]
Whelton, 1998	IG1	Hypertension	36	Other CVD events	8/147 (5.4)	19/371 (5.1)	1.06	[0.48; 2.37]
Whelton, 1998	IG2	Hypertension	36	Other CVD events	6/147 (4.1)	19/371 (5.1)	0.79	[0.32; 1.96]
Whelton, 1998	IG3	Hypertension	36	Other CVD events	13/370 (3.5)	19/371 (5.1)	0.68	[0.34; 1.36]
Whelton, 1998	IG1	Hypertension	36	Transient Ischemic Attack	1/147 (0.7)	8/371 (2.2)	0.32	[0.04; 2.53]
Whelton, 1998	IG2	Hypertension	36	Transient Ischemic Attack	0/147 (0.0)	8/371 (2.2)	0.15	[0.01; 2.54]
Whelton, 1998	IG3	Hypertension	36	Transient Ischemic Attack	8/370 (2.2)	8/371 (2.2)	1.00	[0.38; 2.61]



Abbreviations: CG = control group; CI = confidence interval; CVD = cardiovascular disease; IG = intervention group; Int arm = intervention arm; PAD = peripheral artery disease; RR = risk ratio

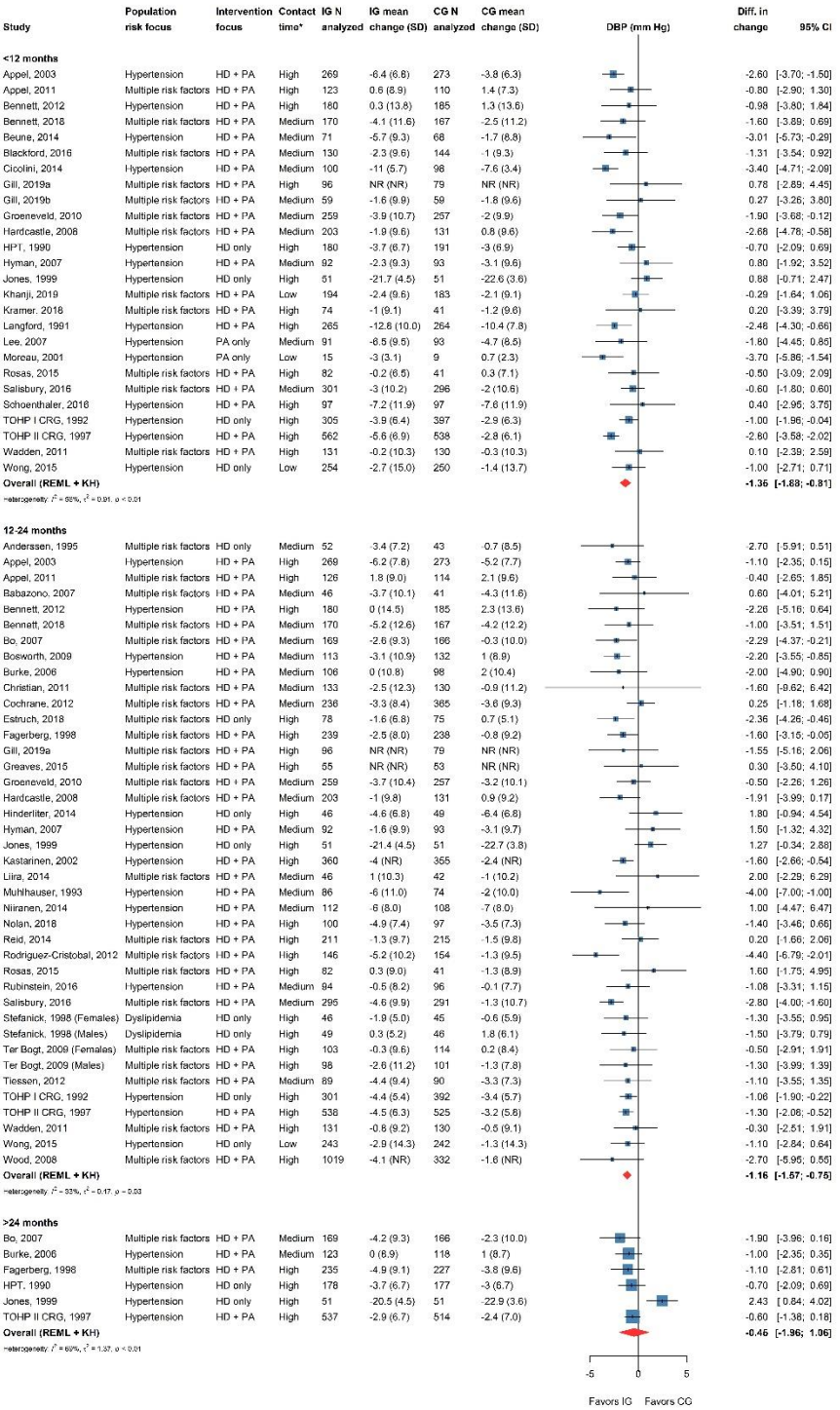
Appendix G Figure 3. Systolic Blood Pressure by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; HPT = Hypertension Prevention Trial; KH = Knapp-Hartung adjustment; mm Hg = millimeters of mercury; REML = restricted maximum likelihood; SBP = systolic blood pressure; SD = standard deviation; TOHP I CRG = The Trials of Hypertension Prevention – Phase I Collaborative Research Group; TOHP II CRG = The Trials of Hypertension Prevention – Phase II Collaborative Research Group

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

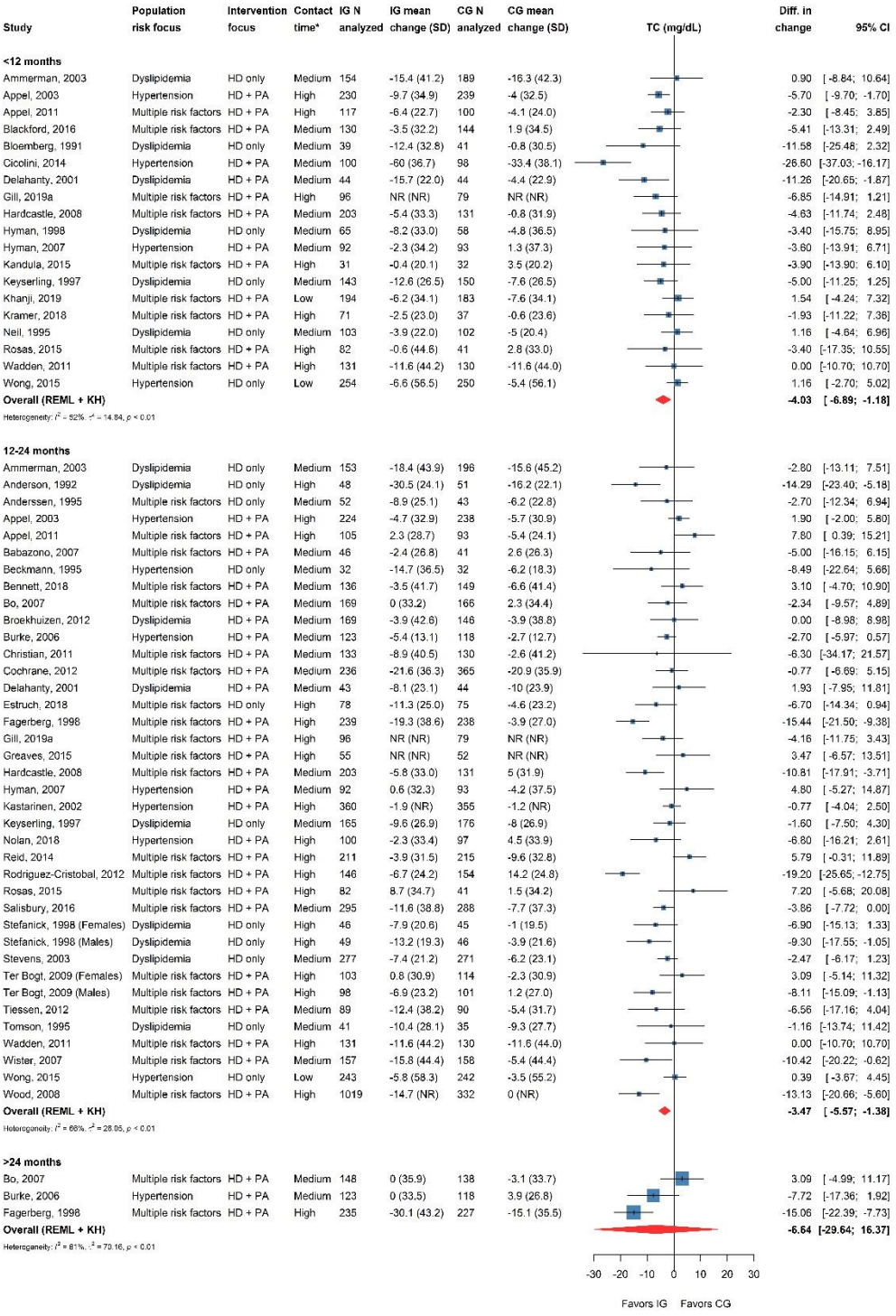
Appendix G Figure 4. Diastolic Blood Pressure by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; DBP = diastolic blood pressure; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; HPT = Hypertension Prevention Trial; KH = Knapp-Hartung adjustment; mm Hg = millimeters of mercury; REML = restricted maximum likelihood; SD = standard deviation; TOHP I CRG = The Trials of Hypertension Prevention – Phase I Collaborative Research Group; TOHP II CRG = The Trials of Hypertension Prevention – Phase II Collaborative Research Group

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

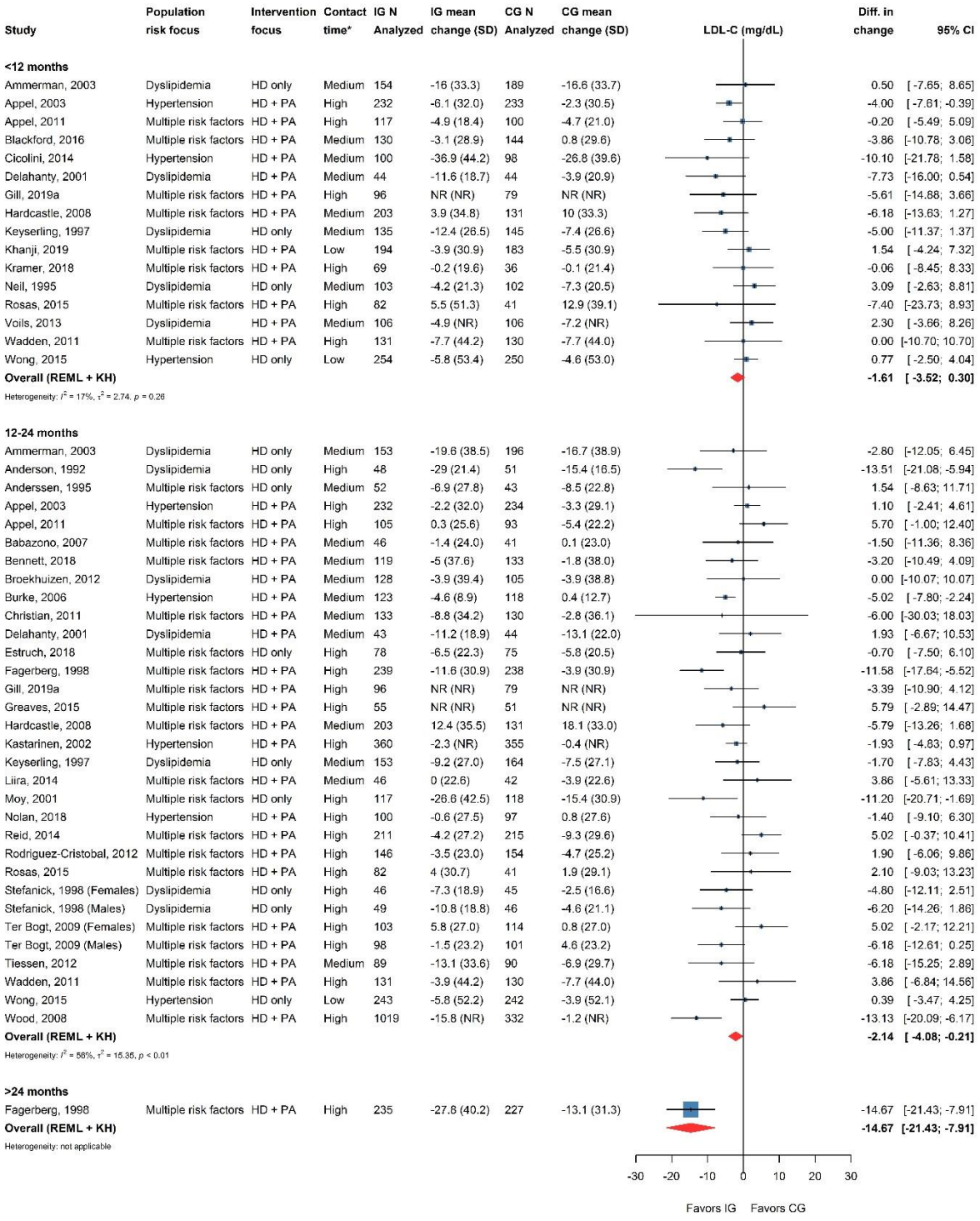
Appendix G Figure 5. Total Cholesterol by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; mg/dL = milligrams per deciliter; NR = not reported; REML = restricted maximum likelihood; SD = standard deviation; TC = total cholesterol

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

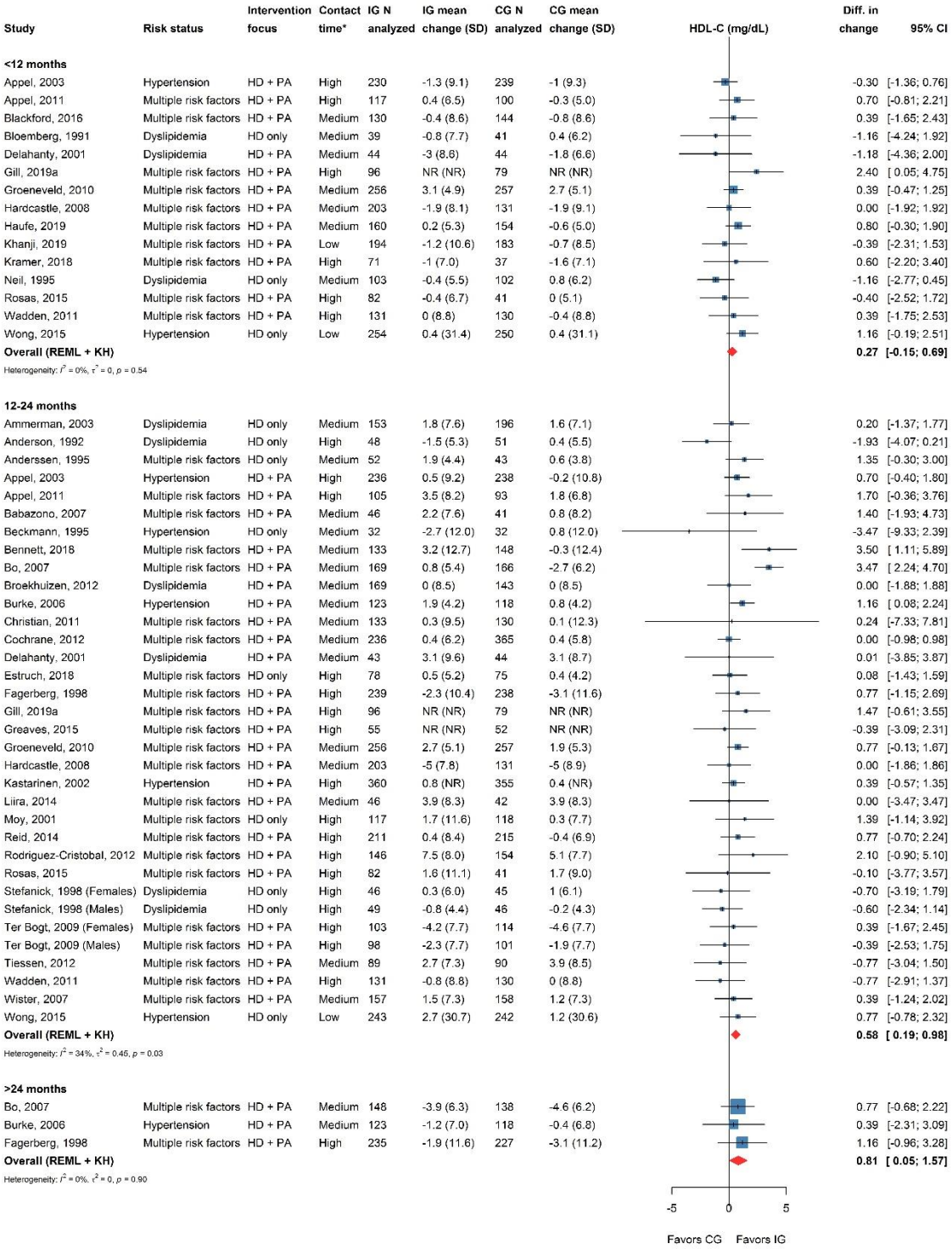
Appendix G Figure 6. LDL Cholesterol by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; LDL-C = low-density lipoprotein cholesterol; mg/dL = milligrams per deciliter; NR = not reported; REML = restricted maximum likelihood; SD = standard deviation

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

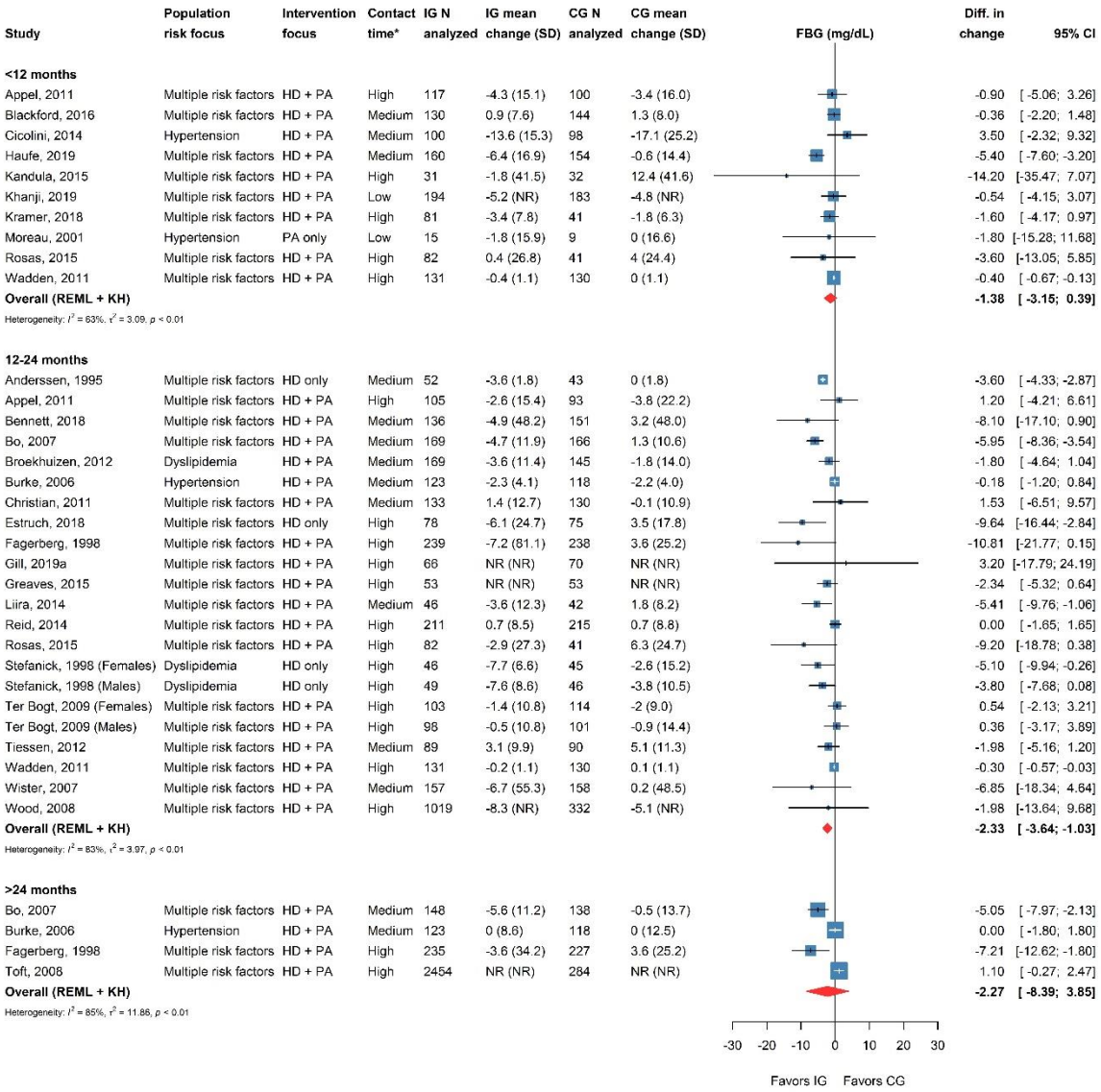
Appendix G Figure 7. HDL Cholesterol by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; HDL-C = low-density lipoprotein cholesterol; KH = Knapp-Hartung adjustment; mg/dL = milligrams per deciliter; REML = restricted maximum likelihood; SD = standard deviation

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

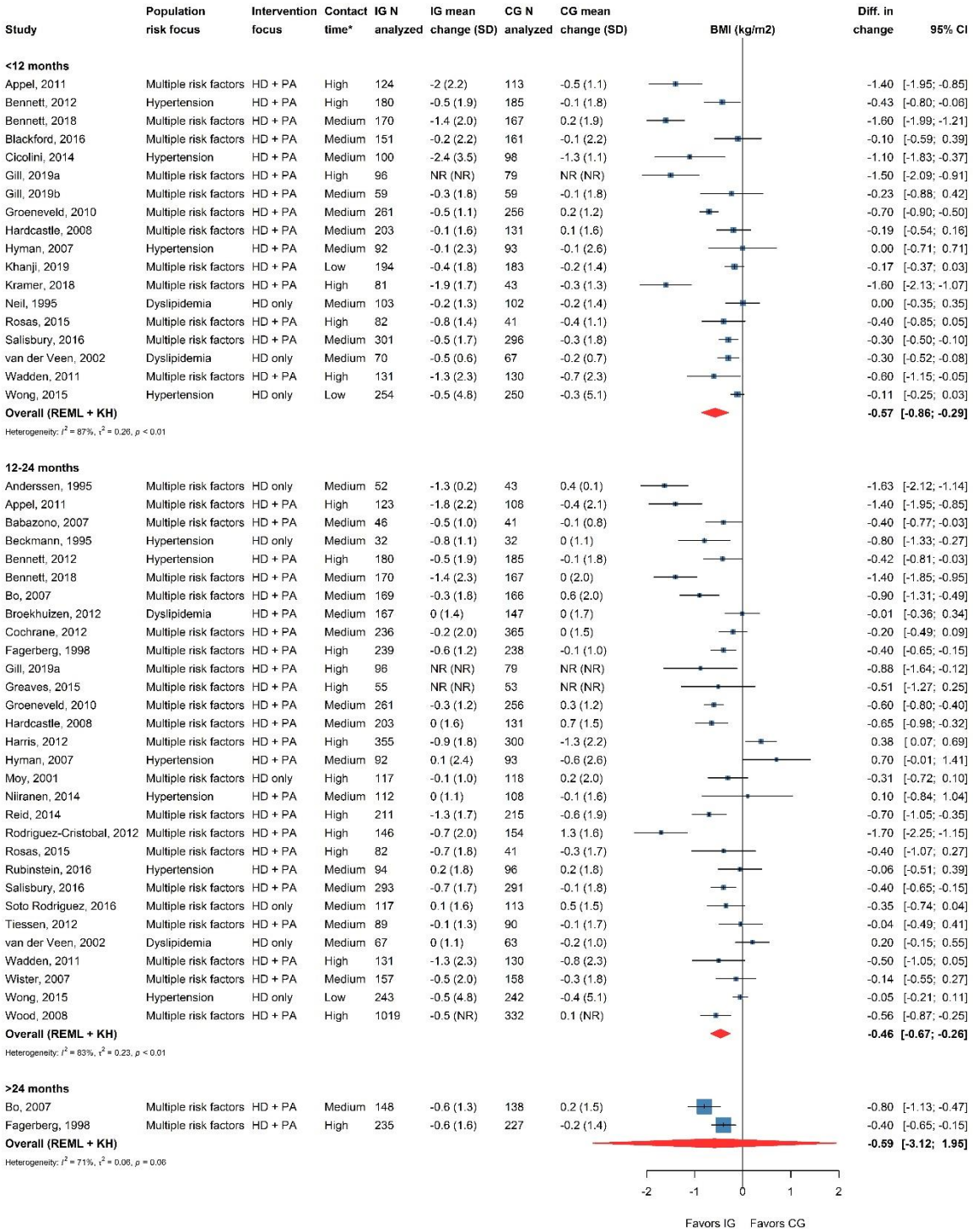
Appendix G Figure 8. Fasting Blood Glucose by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; FBG = fasting blood glucose; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; mg/dL = milligrams per deciliter; NR = not reported; REML = restricted maximum likelihood; SD = standard deviation

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

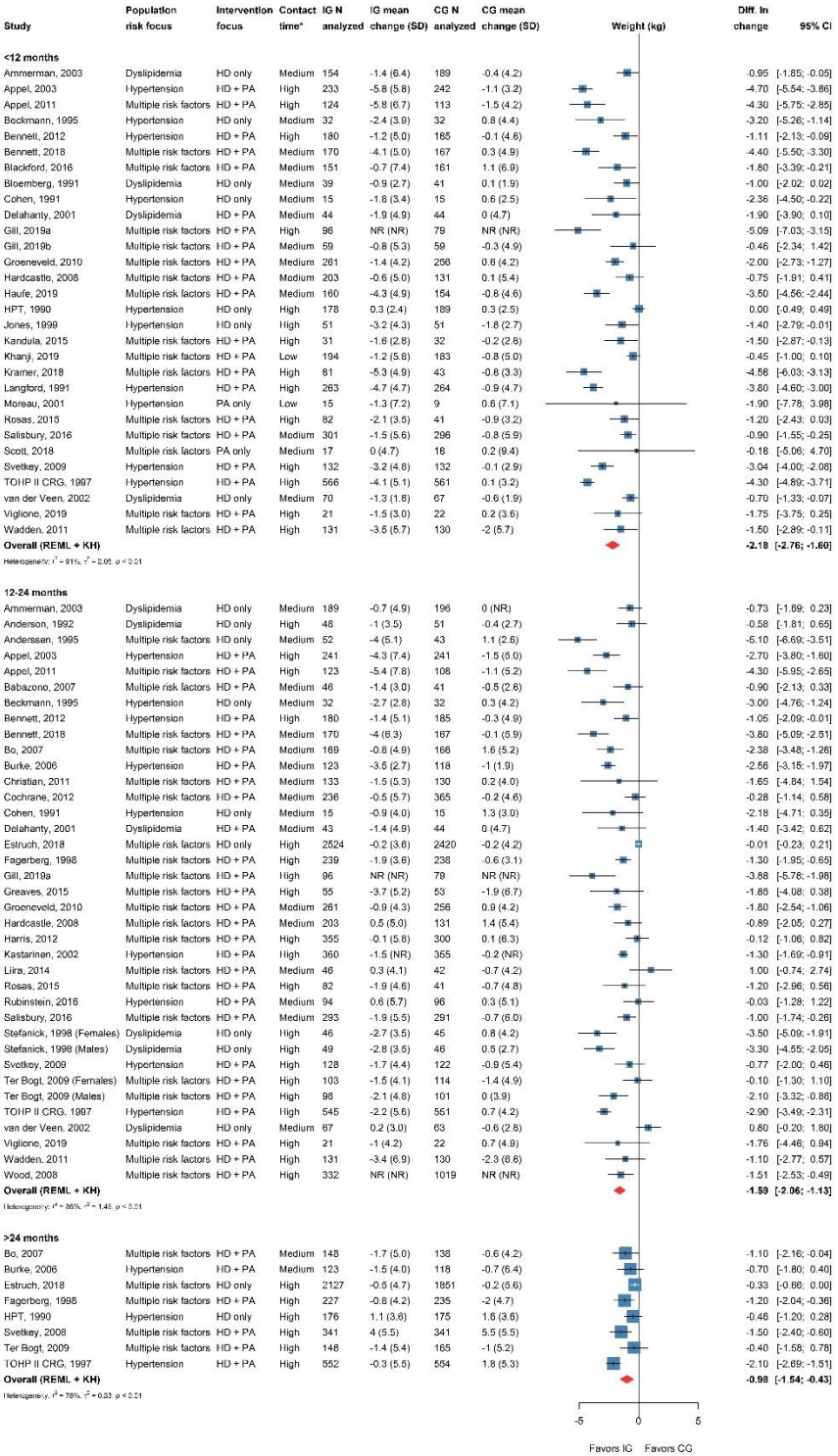
Appendix G Figure 9. Body Mass Index by Study and Followup Category



Abbreviations: BMI = body mass index; CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; kg/m^2 = kilograms per meter squared; KH = Knapp-Hartung adjustment; NR = not reported; REML = restricted maximum likelihood; SD = standard deviation

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

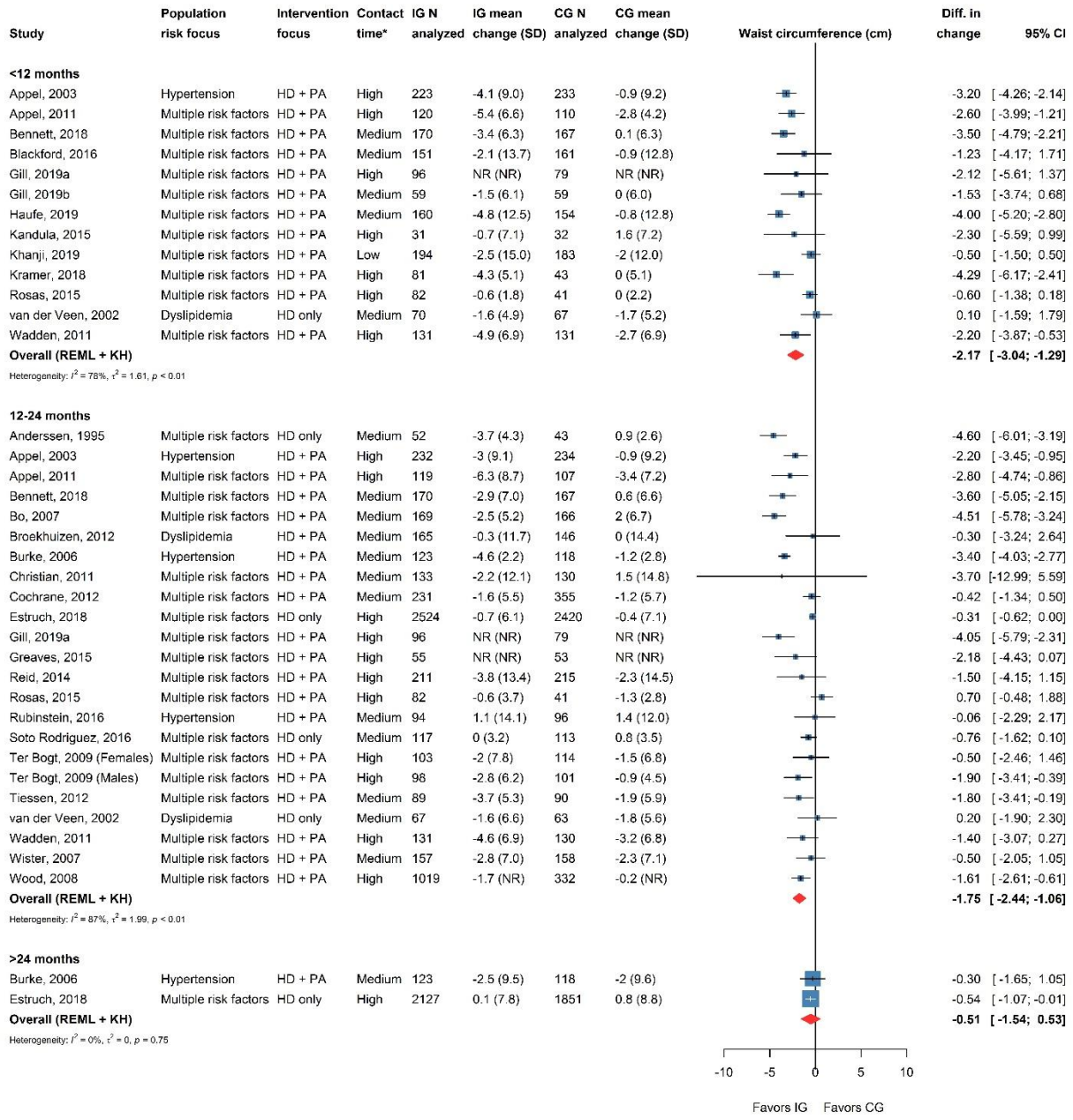
Appendix G Figure 10. Weight by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; kg = kilograms; KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; SD = standard deviation

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

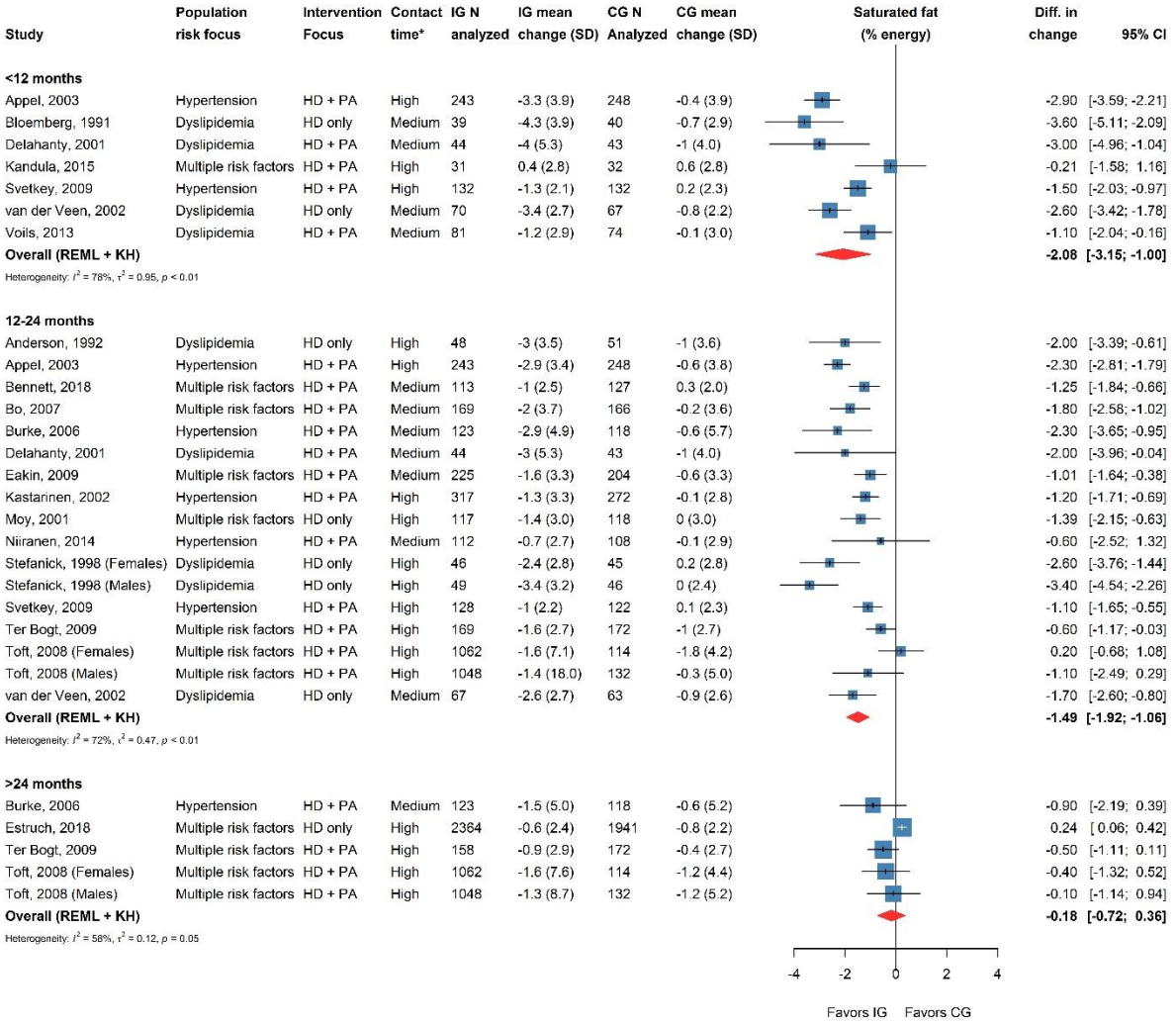
Appendix G Figure 11. Waist Circumference by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; cm = centimeters; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; NR = not reported; REML = restricted maximum likelihood; SD = standard deviation

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

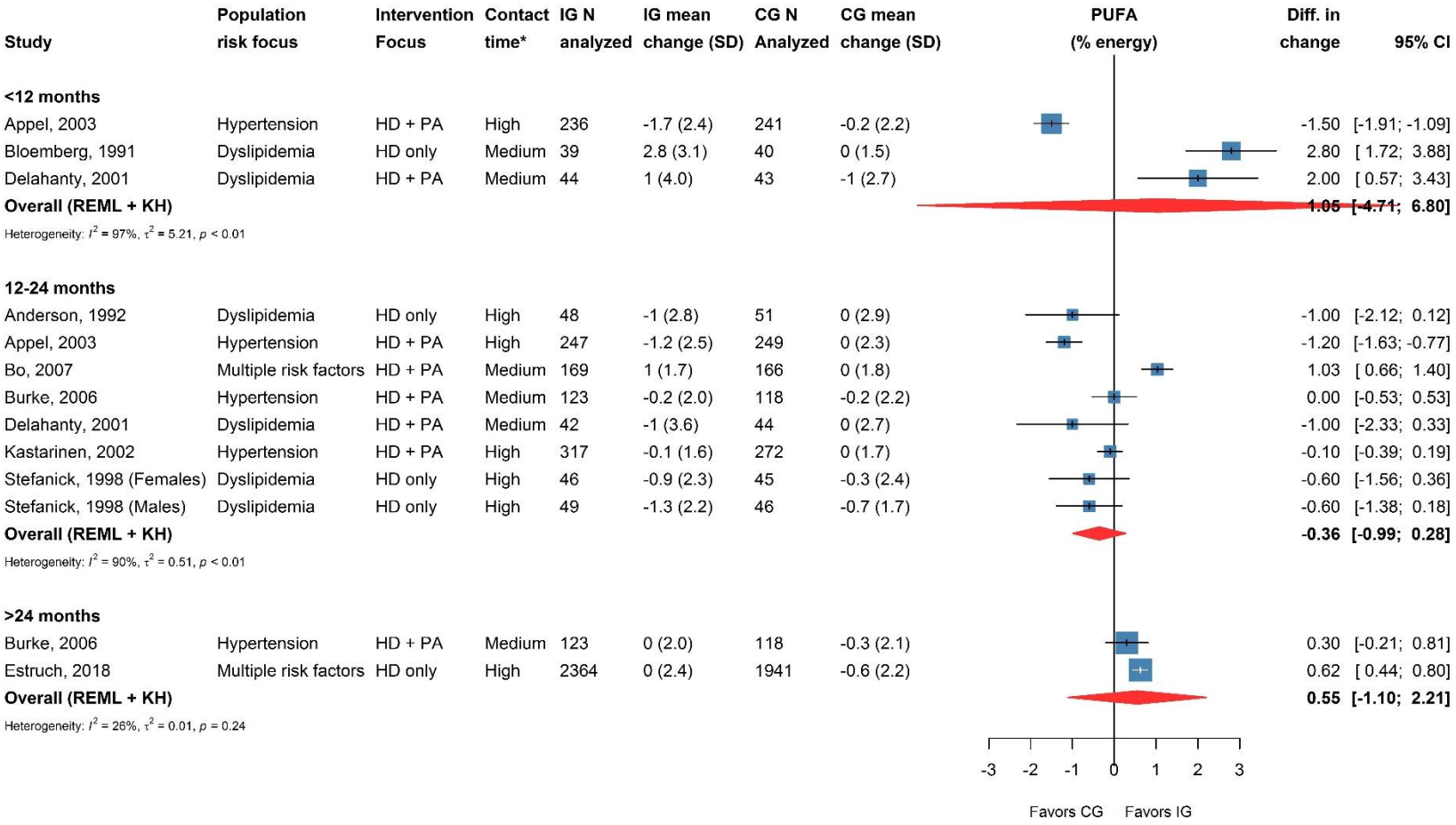
Appendix G Figure 12. Saturated Fat by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; SD = standard deviation

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

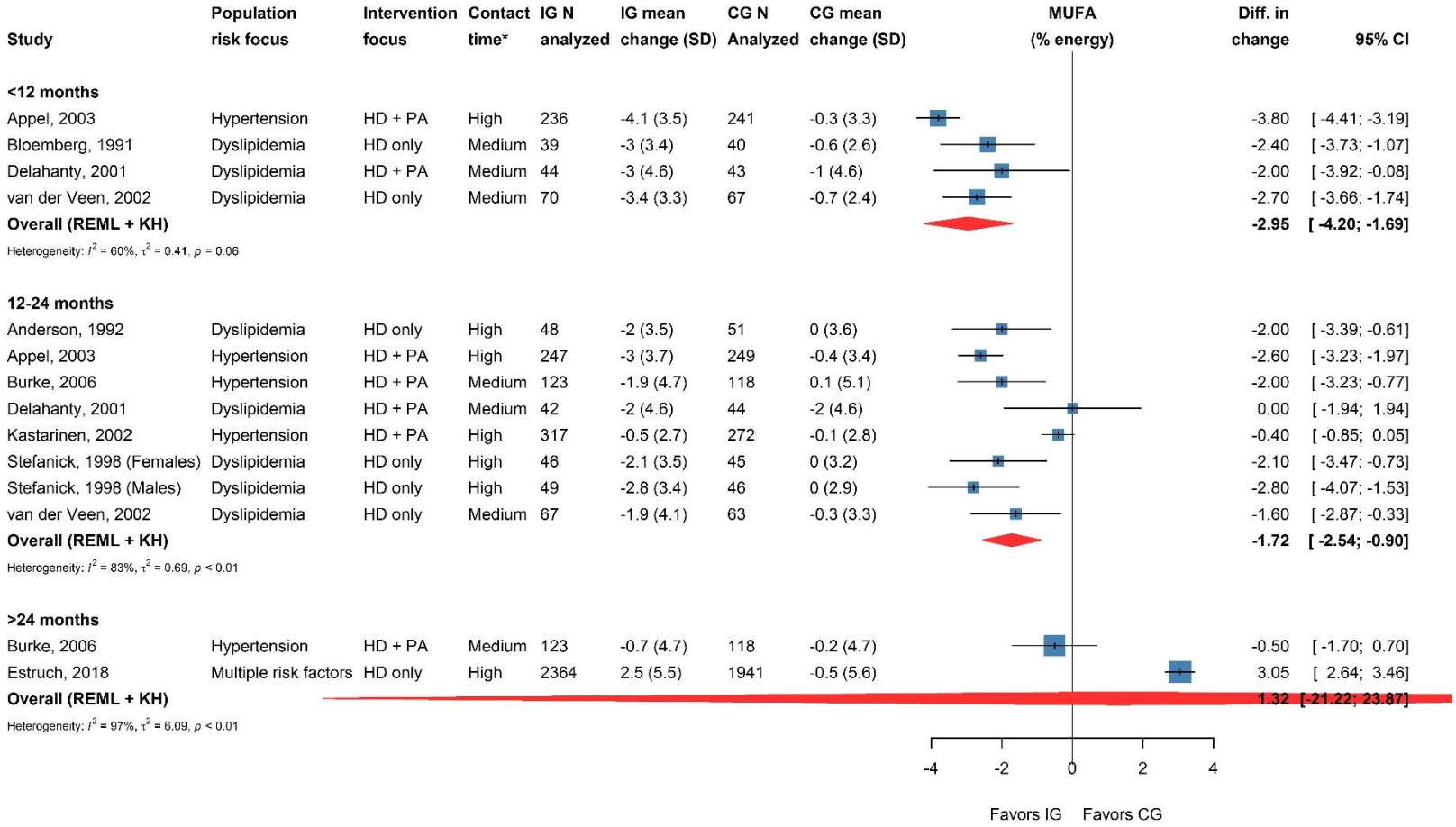
Appendix G Figure 13. Polyunsaturated Fat by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; PUFA = polyunsaturated fatty acids; REML = restricted maximum likelihood; SD = standard deviation

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

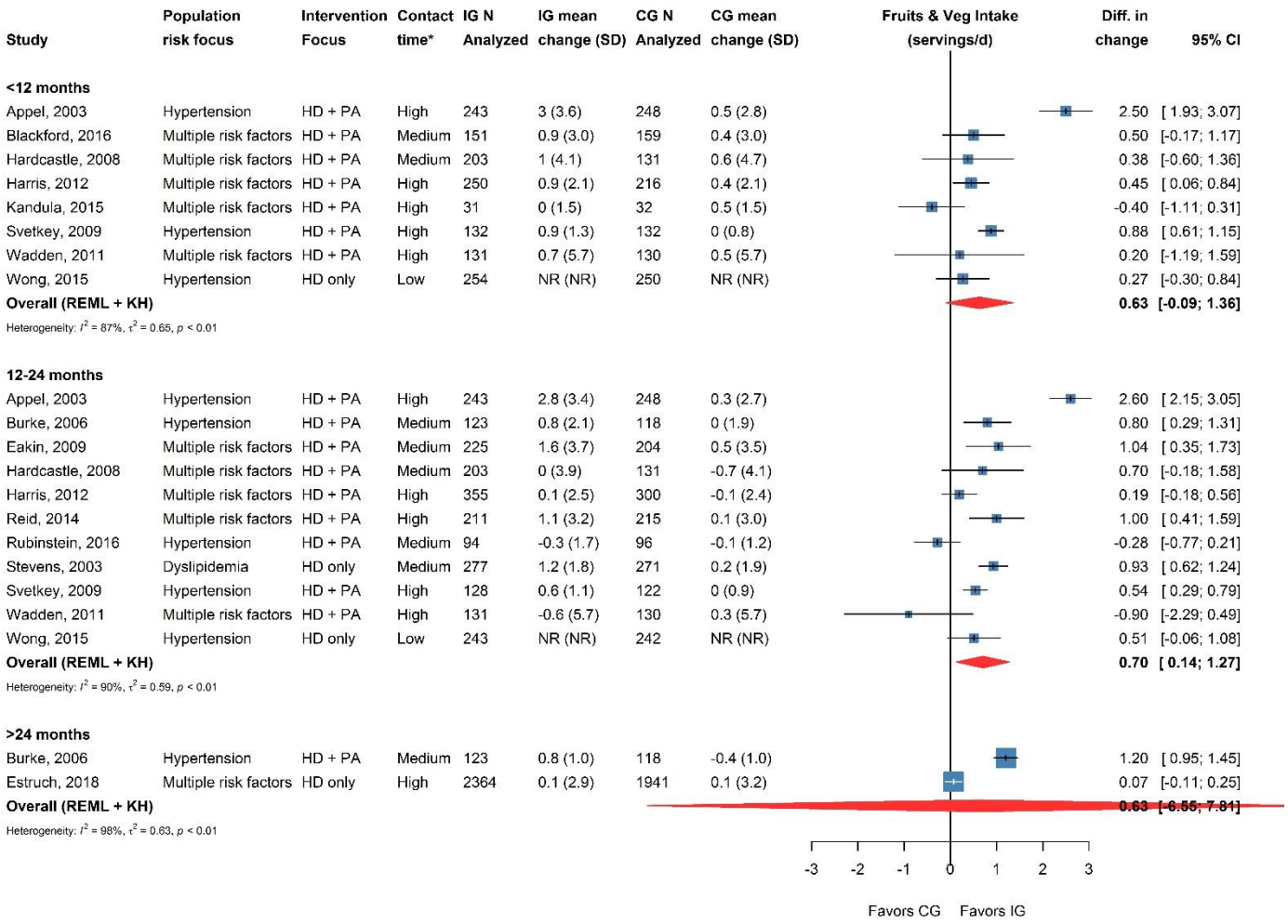
Appendix G Figure 14. Monounsaturated Fat by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; MUFA = monounsaturated fatty acids; REML = restricted maximum likelihood; SD = standard deviation

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

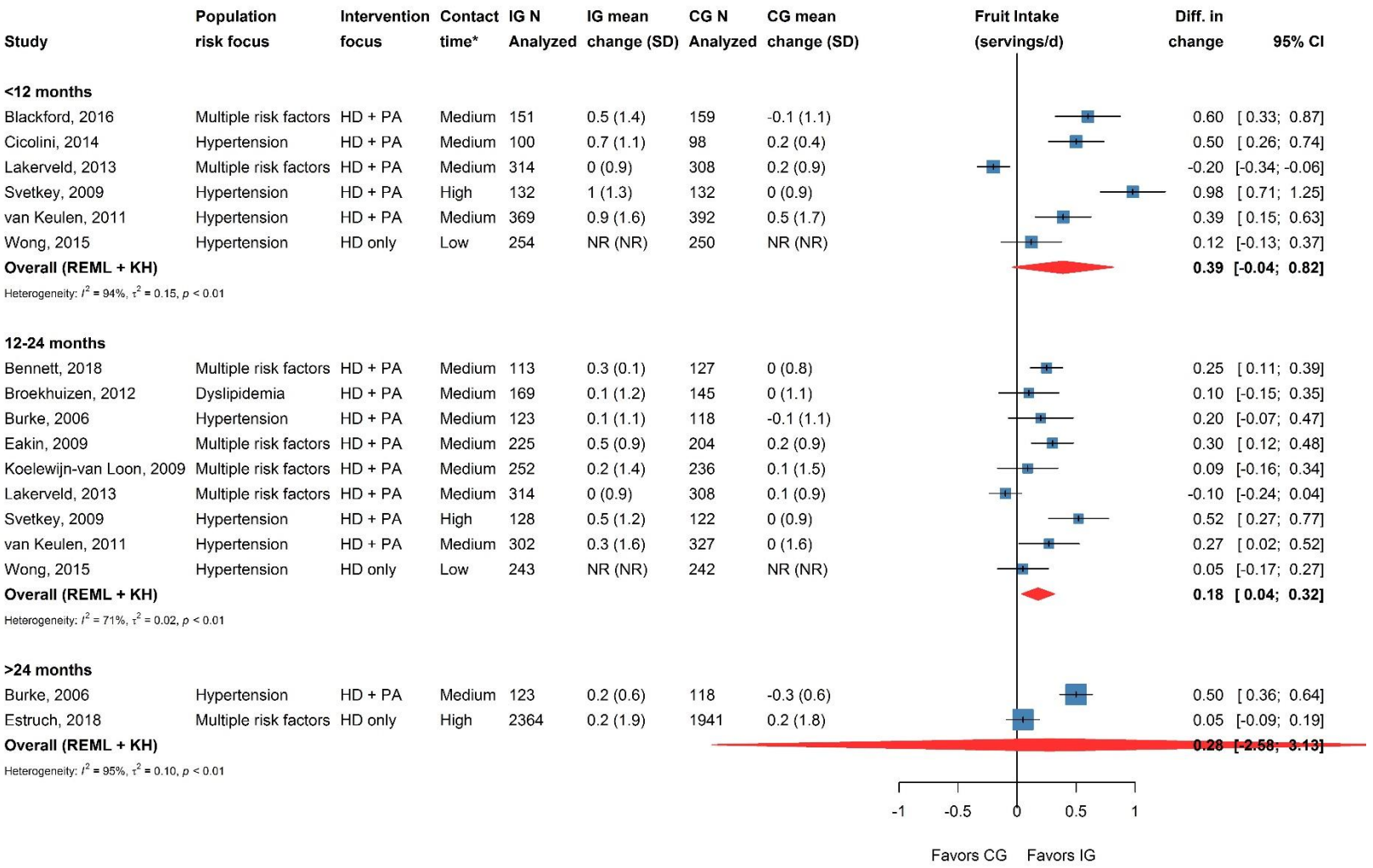
Appendix G Figure 15. Fruit and Vegetable Intake by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; FUP = followup timepoint; HD = healthy diet; HD + PA = healthy diet and physical activity; IG = intervention group; KH = Knapp-Hartung adjustment; NR = not reported; REML = restricted maximum likelihood; SD = standard deviation; servings/d = servings per day

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Appendix G Figure 16. Fruit Intake by Study and Followup Category

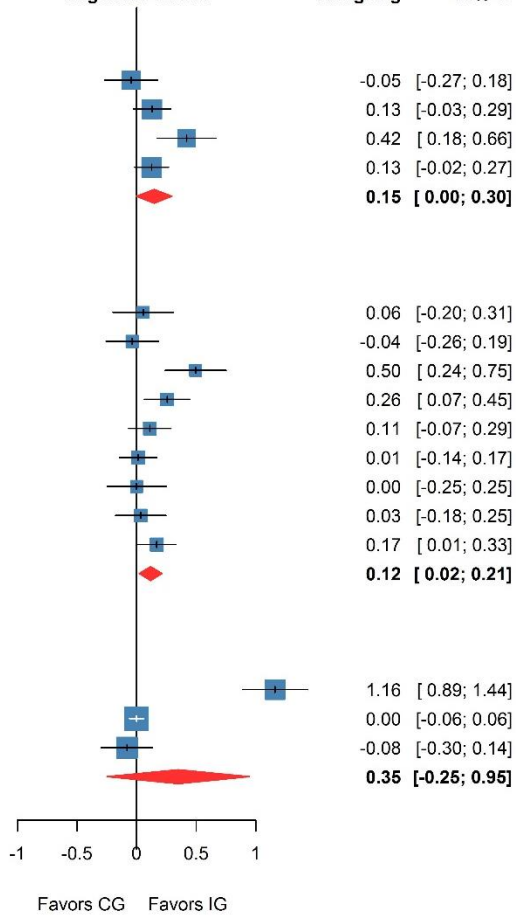


Abbreviations: CG = control group; CI = confidence interval; FUP = followup timepoint; g/day = grams per day; HD = healthy diet; HD + PA = healthy diet and physical activity; IG = intervention group; KH = Knapp-Hartung adjustment; NR = not reported; REML = restricted maximum likelihood; SD = standard deviation; servings/d = servings per day

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Appendix G Figure 17. Vegetable Intake by Study and Followup Category

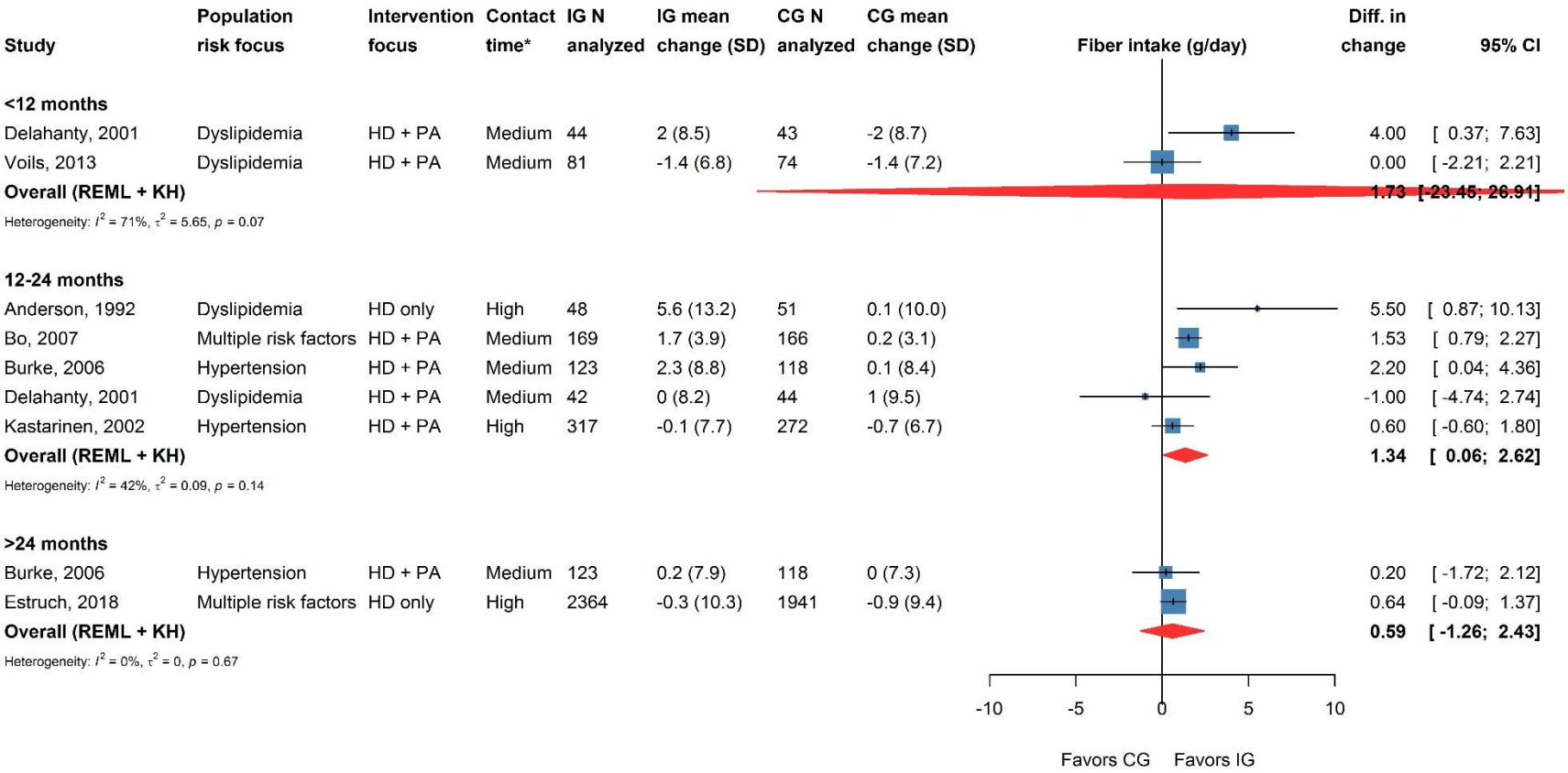
Study	Population risk focus	Intervention focus	Contact time*	Unit	IG N Analyzed	IG mean change (SD)	CG N Analyzed	CG mean change (SD)	Hedges g	95% CI
<12 months										
Blackford, 2016	Multiple risk factors	HD + PA	Medium	servings/d	151	0.4 (2.1)	159	0.5 (2.2)	-0.05	[-0.27; 0.18]
Lakerveld, 2013	Multiple risk factors	HD + PA	Medium	g/day	314	13 (109.8)	308	1 (69.5)	0.13	[-0.03; 0.29]
Svetkey, 2009	Hypertension	HD + PA	High	servings/d	132	1 (2.5)	132	0.1 (1.7)	0.42	[0.18; 0.66]
van Keulen, 2011	Hypertension	HD + PA	Medium	g/day	369	26 (78.2)	392	16 (80.0)	0.13	[-0.02; 0.27]
Overall (REML + KH)									**0.15**	**[0.00; 0.30]**
Heterogeneity: I^2 = 62%, τ^2 = 0.01, p = 0.05										
12-24 months										
Bennett, 2018	Multiple risk factors	HD + PA	Medium	servings/d	113	0.2 (1.8)	127	0.1 (1.8)	0.06	[-0.20; 0.31]
Broekhuizen, 2012	Dyslipidemia	HD + PA	Medium	g/day	169	9.4 (76.2)	146	12.2 (77.5)	-0.04	[-0.26; 0.19]
Burke, 2006	Hypertension	HD + PA	Medium	servings/d	123	0.7 (1.3)	118	0.1 (1.1)	0.50	[0.24; 0.75]
Eakin, 2009	Multiple risk factors	HD + PA	Medium	servings/d	225	1.1 (3.2)	204	0.3 (3.0)	0.26	[0.07; 0.45]
Koelewijn-van Loon, 2009	Multiple risk factors	HD + PA	Medium	Tbsp/d	252	0.3 (1.7)	236	0.1 (1.9)	0.11	[-0.07; 0.29]
Lakerveld, 2013	Multiple risk factors	HD + PA	Medium	g/day	314	8 (72.2)	308	7 (81.9)	0.01	[-0.14; 0.17]
Svetkey, 2009	Hypertension	HD + PA	High	servings/d	128	0.3 (2.5)	122	0.3 (2.5)	0.00	[-0.25; 0.25]
Ter Bogt, 2009	Multiple risk factors	HD + PA	High	g/day	169	16.1 (65.0)	172	13.6 (77.9)	0.03	[-0.18; 0.25]
van Keulen, 2011	Hypertension	HD + PA	Medium	g/day	302	11 (84.7)	327	-3 (80.5)	0.17	[0.01; 0.33]
Overall (REML + KH)									**0.12**	**[0.02; 0.21]**
Heterogeneity: I^2 = 50%, τ^2 = 0.01, p = 0.04										
>24 months										
Burke, 2006	Hypertension	HD + PA	Medium	servings/d	123	0.6 (0.6)	118	-0.1 (0.6)	1.16	[0.89; 1.44]
Estruch, 2018	Multiple risk factors	HD only	High	servings/d	2364	-0.1 (1.5)	1941	-0.1 (1.9)	0.00	[-0.06; 0.06]
Ter Bogt, 2009	Multiple risk factors	HD + PA	High	g/day	158	11.7 (74.1)	172	18.2 (86.7)	-0.08	[-0.30; 0.14]
Overall (REML + KH)									**0.35**	**[-0.25; 0.95]**
Heterogeneity: I^2 = 97%, τ^2 = 0.27, p < 0.01										



Abbreviations: CG = control group; CI = confidence interval; FUP = followup timepoint; g/day = grams per day; HD = healthy diet; HD + PA = healthy diet and physical activity; IG = intervention group; KH = Knapp-Hartung adjustment; NR = not reported; REML = restricted maximum likelihood; SD = standard deviation; servings/d = servings per day; Tbsp/day = tablespoons per day

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

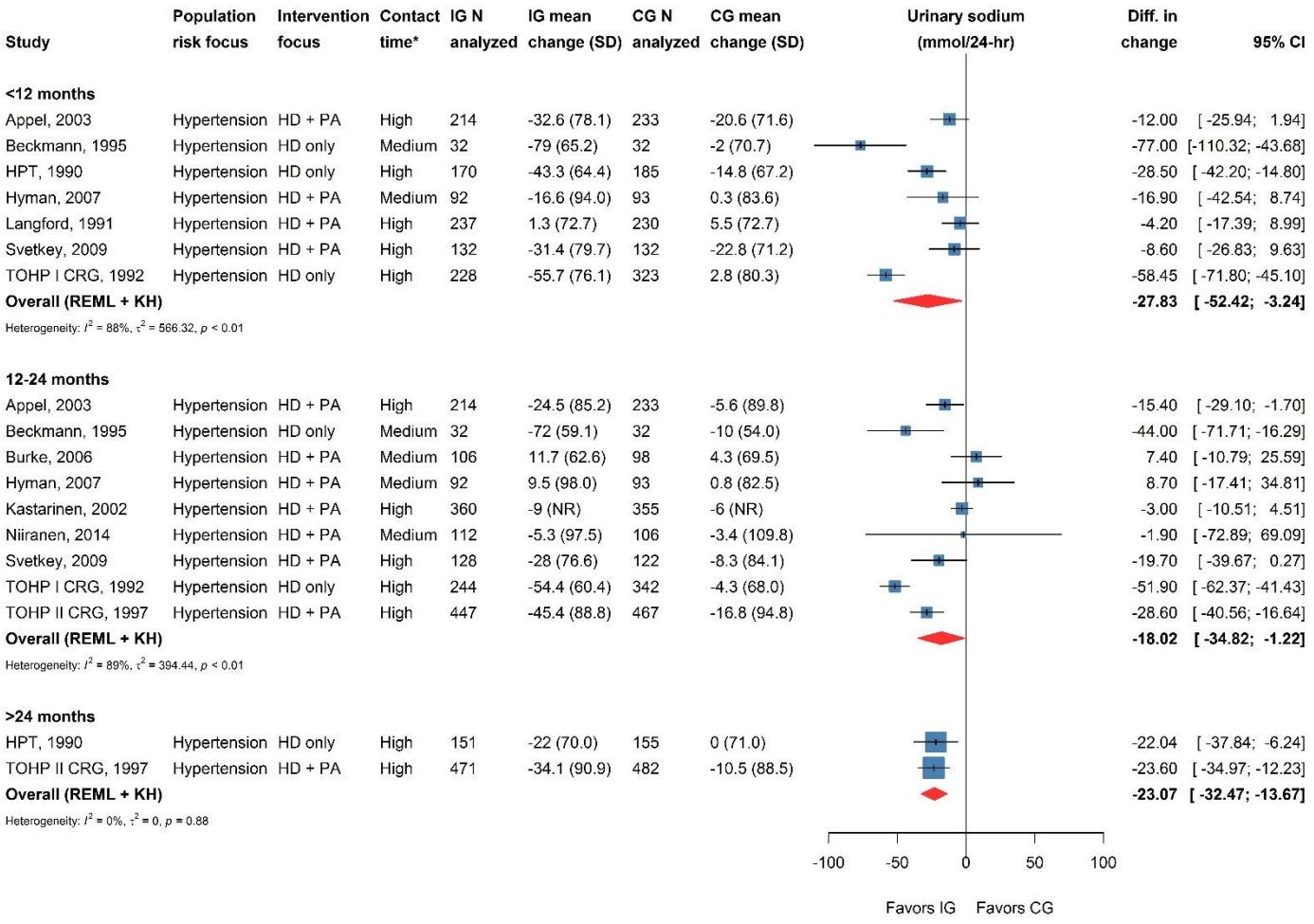
Appendix G Figure 18. Fiber Intake by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; FUP = followup timepoint; g/day = grams per day; HD = healthy diet; HD + PA = healthy diet and physical activity; IG = intervention group; KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; SD = standard deviation

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Appendix G Figure 19. Urinary Sodium by Study and Followup Category



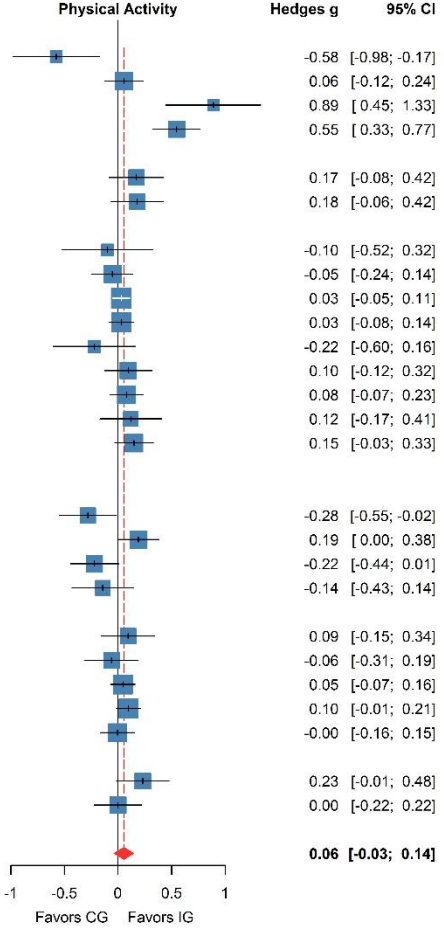
Abbreviations: CG = control group; CI = confidence interval; FUP = followup timepoint; HD = healthy diet; HD + PA = healthy diet and physical activity; IG = intervention group; KH = Knapp-Hartung adjustment; mmol/24-hr = millimoles per 24 hours; REML = restricted maximum likelihood; SD = standard deviation

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Appendix G Figure 20. Physical Activity at 12 to 24 Months' Followup

Study	Intervention focus	Contact time*	Outcome	Unit	IG N Analyzed	IG mean change (SD)	CG N Analyzed	CG mean change (SD)	BG p-value	Hedges g	95% CI
Anderson, 1992	HD only	High	Total energy expenditure	kJ/kg/d	48	0.1 (16.9)	51	13.7 (28.2)	<0.05	-0.58	[-0.98; -0.17]
Appel, 2003	HD + PA	High	Total PA	kcal/kg	240	0.8 (3.4)	242	0.6 (3.6)	NSD	0.06	[-0.12; 0.24]
Babazono, 2007	HD + PA	Medium	Total PA	steps/d	46	3028 (3993.2)	41	-381 (3558.7)	≤0.001	0.89	[0.45; 1.33]
Bo, 2007	HD + PA	Medium	Total PA	MET-min/wk	169	283.8 (724.3)	166	-15.6 (260.3)	<0.001	0.55	[0.33; 0.77]
Broekhuizen, 2012	HD + PA	Medium	Moderate to vigorous intensity PA	min/wk	171	79 (NR)	146	64.9 (NR)	NSD		
Burke, 2006	HD + PA	Medium	Moderate to vigorous intensity PA	min/wk	123	41 (124.5)	118	20 (119.2)	0.185	0.17	[-0.08; 0.42]
Christian, 2011	HD + PA	Medium	Total PA	MET-min/wk	133	288.8 (659.0)	130	112.3 (1216.4)	0.07	0.18	[-0.06; 0.42]
Cochrane, 2012	HD + PA	Medium	Total PA	score	236	0.1 (NR)	365	0.2 (NR)	NSD		
Delahanty, 2001	HD + PA	Medium	Total PA	min/wk	43	29 (115.9)	44	43 (160.3)	NSD	-0.10	[-0.52; 0.32]
Eakin, 2009	HD + PA	Medium	Moderate to vigorous intensity PA	min/wk	225	71.2 (213.0)	204	82.2 (213.0)	0.589	-0.05	[-0.24; 0.14]
Estruch, 2018 (w/ METS)	HD only	High	Leisure PA	MET-min/wk	1236	133 (1946.2)	1094	77 (1890.0)	NSD	0.03	[-0.05; 0.11]
Estruch, 2018 (w/o METS)	HD only	High	Leisure PA	MET-min/wk	663	126 (1977.1)	594	63 (1871.4)	NSD	0.03	[-0.08; 0.14]
Greaves, 2015	HD + PA	High	Moderate to vigorous intensity PA	min/wk	53	-3.6 (104.2)	53	22.9 (131.7)	0.291	-0.22	[-0.60; 0.16]
Hardcastle, 2008	HD + PA	Medium	Total PA	MET-min/wk	203	1299.6 (2977.6)	131	993.5 (3470.0)	NSD	0.10	[-0.12; 0.32]
Harris, 2012	HD + PA	High	PA score	score	355	0.9 (2.5)	300	0.7 (2.5)	0.005	0.08	[-0.07; 0.23]
Hyman, 2007	HD + PA	Medium	Total PA	steps/d	92	127 (2813.7)	93	-284.5 (3906.7)	NSD	0.12	[-0.17; 0.41]
Koelewijn-van Loon, 2009	HD + PA	Medium	Moderate to vigorous intensity PA	min/wk	252	55 (352.9)	236	2 (355.4)	0.74	0.15	[-0.03; 0.33]
Lakerveld, 2013	HD + PA	Medium	Vigorous intensity PA	MET-min/wk	314	NR (NR)	308	NR (NR)	NSD		
Migneault, 2012	HD + PA	High	Moderate to vigorous intensity PA	min/wk	169	-21.3 (NR)	168	7.3 (NR)	NSD		
Niiranen, 2014	HD + PA	Medium	Leisure PA	MJ/d	112	0 (0.4)	108	0.1 (0.3)	0.15	-0.28	[-0.55; -0.02]
Reid, 2014	HD + PA	High	Total PA	min/wk	211	50.8 (113.5)	215	29.9 (104.7)	0.03	0.19	[0.00; 0.38]
Rodriguez, 2012	HD + PA	Medium	Total PA	min/wk	151	-60.6 (412.7)	155	31.2 (420.7)	NSD	-0.22	[-0.44; 0.01]
Rubinstein, 2016	HD + PA	Medium	Total PA	MET-min/wk	94	-348.9 (1345.5)	96	-188.5 (842.2)	0.22	-0.14	[-0.43; 0.14]
Salisbury, 2016	HD + PA	Medium	PA score	score	297	NR (NR)	294	NR (NR)	0.003		
Svetkey, 2009	HD + PA	High	Moderate to vigorous intensity PA	min/wk	128	-0.7 (112.3)	122	-13 (145.7)	NSD	0.09	[-0.15; 0.34]
Ter Bogt, 2009	HD + PA	High	Total PA	MET-min/wk	120	-126 (997.6)	129	-68 (909.8)	0.52	-0.06	[-0.31; 0.19]
Toft, 2008 (Males)	HD + PA	High	Moderate to vigorous intensity PA	min/wk	2965	-2.5 (359.4)	337	-18.9 (361.6)	NSD	0.05	[-0.07; 0.16]
Toft, 2008 (Females)	HD + PA	High	Moderate to vigorous intensity PA	min/wk	3126	-1.8 (380.2)	356	-38.8 (358.5)	NSD	0.10	[-0.01; 0.21]
van Keulen, 2011	HD + PA	Medium	Moderate intensity PA	min/wk	302	44.4 (255.0)	327	45.6 (249.2)	NSD	-0.00	[-0.16; 0.15]
van Sluijs, 2005	PA only	Medium	Moderate intensity energy expenditure	min/wk	171	NR (NR)	187	NR (NR)	0.38		
Wadden, 2011	HD + PA	High	Moderate to vigorous intensity PA	kcal/wk	131	415.4 (2060.2)	130	-70.4 (2120.7)	0.037	0.23	[-0.01; 0.48]
Wister, 2007	HD + PA	Medium	PA score	score	157	0.2 (1.5)	158	0.2 (1.5)	NSD	0.00	[-0.22; 0.22]
Overall (REML + KH)										**0.06**	**[-0.03; 0.14]**

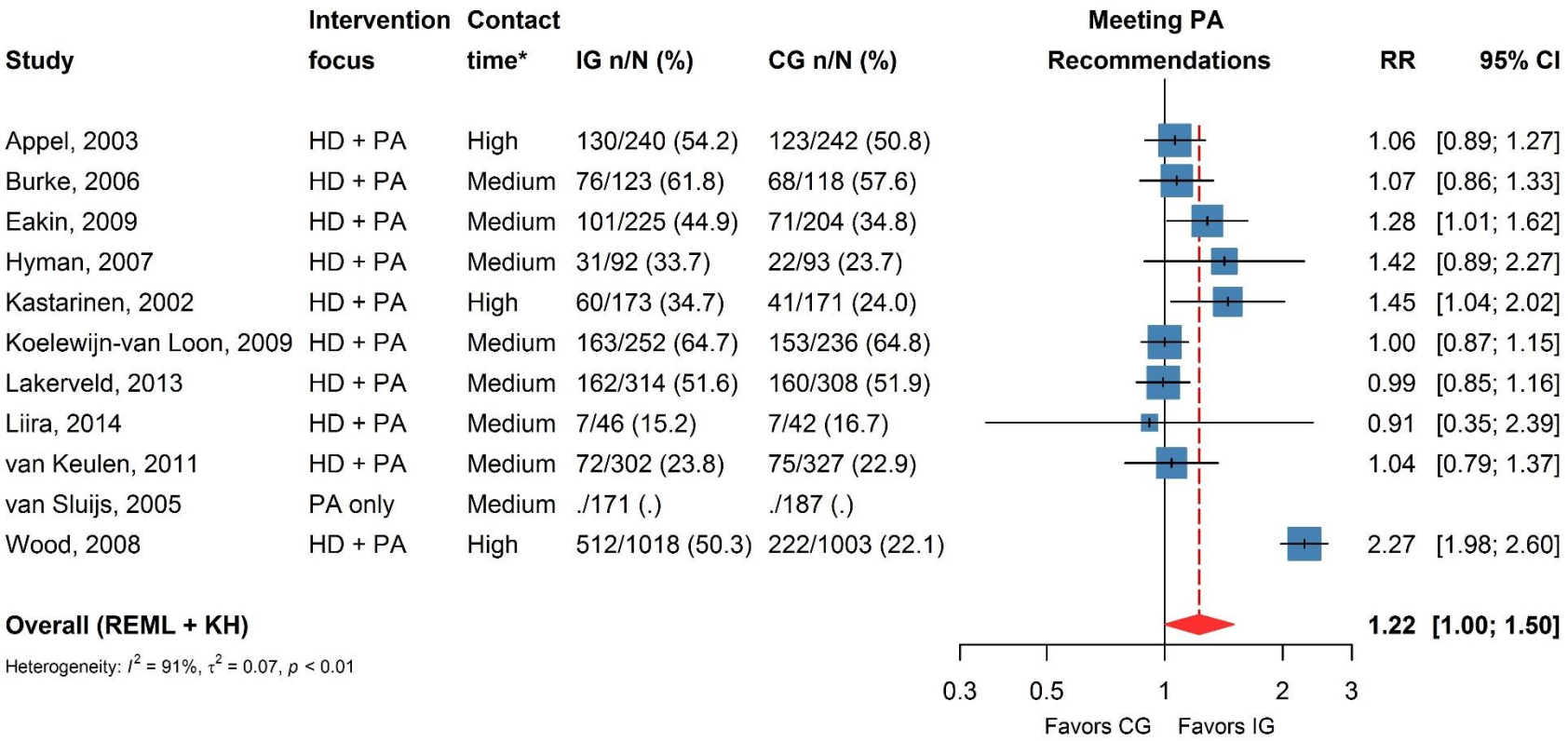
Heterogeneity: $I^2 = 64\%$, $\tau^2 = 0.02$, $p < 0.01$



Abbreviations: BG = between-group; CG = control group; CI = confidence interval; FUP = followup timepoint; HD = healthy diet; HD + PA = healthy diet and physical activity; IG = intervention group; KH = Knapp-Hartung adjustment; kcal/kg = kilocalories per kilogram; kcal/wk = kilocalories per week; kJ/kg/d = kilojoules per kilogram per day; MET-min/wk = metabolic equivalent of task minutes per week; METS = metabolic syndrome; min/wk = minutes per week; NR = not reported; NSD = no statistically significant difference; PA = physical activity; REML = restricted maximum likelihood; steps/d = steps per day

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Appendix G Figure 21. Physical Activity, Meeting Recommendations



Abbreviations: CG = control group; CI = confidence interval; FUP = followup timepoint; HD = healthy diet; HD + PA = healthy diet and physical activity; IG = intervention group; KH = Knapp-Hartung adjustment; PA = physical activity; REML = restricted maximum likelihood; RR = risk ratio

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Appendix H Table 1. CVD Events + CVD Mortality (KQ1)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Appel, 2003[41] (PREMIER) Good	HTN	High HD + PA	Myocardial Infarction	IG1	6	1/269 (0.4)	1/273 (0.4)	1.01 (0.06 to 16.14), NR
	HTN	High HD + PA	Myocardial Infarction	IG2	6	0/268 (0.0)	1/273 (0.4)	0.34 (0.01 to 8.30), NR
	HTN	High HD + PA	Stroke	IG1	6	0/269 (0.0)	1/273 (0.4)	0.34 (0.01 to 8.27), NR
	HTN	High HD + PA	Stroke	IG2	6	0/268 (0.0)	1/273 (0.4)	0.34 (0.01 to 8.30), NR
	HTN	High HD + PA	Transient Ischemic Attack	IG1	6	0/269 (0.0)	1/273 (0.4)	0.34 (0.01 to 8.27), NR
	HTN	High HD + PA	Transient Ischemic Attack	IG2	6	0/268 (0.0)	1/273 (0.4)	0.34 (0.01 to 8.30), NR
Bennett, 2012[47] (Be Fit, Be Well [POWER]) Good	HTN	High HD + PA	CVD events	IG1	24	0/180 (0.0)	1/185 (0.5)	0.34 (0.01 to 8.35), NR
Bennett, 2018[48] (Track) Good	Multiple	Medium HD + PA	CVD events	IG1	12	5/176 (2.8)	6/175 (3.4)	0.83 (0.26 to 2.67), NR
Bo, 2007[52] Fair	Multiple	Medium HD + PA	CVD events	IG1	108	12/169 (7.1)	19/166 (11.4)	HR=0.60 (0.29 to 1.24), 0.17
	Multiple	Medium HD + PA	CVD Mortality	IG1	108	5/169 (3.0)	11/166 (6.6)	HR=0.42 (0.15 to 1.23), 0.11
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	Arrhythmia	IG1	72	72/2292 (3.1)	89/2203 (4.0)	HR=0.62 (0.44 to 0.85), <0.05
	Multiple	High HD only	Arrhythmia	IG2	72	92/2210 (4.2)	89/2203 (4.0)	HR=0.86 (0.63 to 1.17), NSD
	Multiple	High HD only	CVD events	IG1	60	96/2543 (3.8)	109/2450 (4.4)	HR=0.69 (0.53 to 0.91), <0.05
	Multiple	High HD only	CVD events	IG2	60	83/2454 (3.4)	109/2450 (4.4)	HR=0.72 (0.54 to 0.95), <0.05
	Multiple	High HD only	CVD Mortality	IG1	60	26/2543 (1.0)	30/2450 (1.2)	HR=0.62 (0.36 to 1.06), NSD
	Multiple	High HD only	CVD Mortality	IG2	60	31/2454 (1.3)	30/2450 (1.2)	HR=1.02 (0.63 to 1.67), NSD
	Multiple	High HD only	Myocardial Infarction	IG1	60	37/2543 (1.5)	38/2450 (1.6)	HR=0.82 (0.52 to 1.30), NSD
	Multiple	High HD only	Myocardial Infarction	IG2	60	31/2454 (1.3)	38/2450 (1.6)	HR=0.76 (0.47 to 1.25), NSD

Appendix H Table 1. CVD Events + CVD Mortality (KQ1)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
	Multiple	High HD only	Stroke	IG1	60	49/2543 (1.9)	58/2450 (2.4)	HR=0.65 (0.44 to 0.95), <0.05
	Multiple	High HD only	Stroke	IG2	60	32/2454 (1.3)	58/2450 (2.4)	HR=0.54 (0.35 to 0.82), <0.05
Fagerberg, 1998[68] (Risk Factor Intervention Study (RIS)) Good (KQ1); Fair (KQ2)	Multiple	High HD + PA	Angina	IG1	40	7/253 (2.8)	12/255 (4.7)	0.60 (0.20 to 1.80), 0.36
	Multiple	High HD + PA	Claudication	IG1	40	7/253 (2.8)	10/255 (3.9)	0.70 (0.30 to 1.80), 0.63
	Multiple	High HD + PA	Coronary deaths	IG1	79	17/253 (6.7)	23/255 (9.0)	0.72 (0.39 to 1.40), NSD
	Multiple	High HD + PA	Coronary events	IG1	79	44/253 (17.4)	50/255 (19.6)	0.86 (0.57 to 1.28), NSD
	Multiple	High HD + PA	CVD events	IG1	79	63/253 (24.9)	84/255 (32.9)	0.71 (0.51 to 0.99), 0.041
	Multiple	High HD + PA	CVD Mortality	IG1	40	12/253 (4.7)	13/255 (5.1)	0.90 (0.40 to 1.90), 0.98
	Multiple	High HD + PA	CVD Mortality	IG1	79	24/253 (9.5)	42/255 (16.5)	0.56 (0.34 to 0.92), 0.021
	Multiple	High HD + PA	Myocardial Infarction	IG1	40	18/253 (7.1)	22/255 (8.6)	0.80 (0.50 to 1.50), 0.64
	Multiple	High HD + PA	Myocardial Infarction fatal	IG1	79	7/253 (2.8)	10/255 (3.9)	0.71 (0.27 to 1.82), NR
	Multiple	High HD + PA	Myocardial Infarction nonfatal	IG1	79	22/253 (8.7)	25/255 (9.8)	0.89 (0.51 to 1.53), NR
	Multiple	High HD + PA	Stroke	IG1	40	5/253 (2.0)	17/255 (6.7)	0.30 (0.11 to 0.81), 0.017
	Multiple	High HD + PA	Stroke	IG1	79	16/253 (6.3)	29/255 (11.4)	0.53 (0.29 to 0.97), <0.05
	Multiple	High HD + PA	Stroke fatal	IG1	79	3/253 (1.2)	4/255 (1.6)	0.76 (0.17 to 3.34), NR
	Multiple	High HD + PA	Stroke nonfatal	IG1	79	13/253 (5.1)	25/255 (9.8)	0.52 (0.27 to 1.00), NR
Haufe, 2019[75] Fair	Multiple	Medium HD + PA	MI nonfatal	IG1	6	1/160 (0.6)	0/154 (0.0)	2.89 (0.12 to 70.36), NS

Appendix H Table 1. CVD Events + CVD Mortality (KQ1)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Hinderliter, 2014[76] (Exercise and Nutrition interventions for CardiOvasculaR hEalth (ENCORE)) Good	HTN	High HD only	CVD events	IG1	12	0/46 (0.0)	0/49 (0.0)	NR, NSD
TOHP I CRG, 1992[119] (Trials of Hypertension Prevention Phase I (TOHP I)) Good	HTN	High HD only	CVD events	IG1	192	17/231 (7.4)	32/311 (10.3)	HR=0.48 (0.25 to 0.92), 0.027
Wadden, 2011[127] (Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-UP)) Good	Multiple	High HD + PA	Angina	IG1	24	5/131 (3.8)	1/130 (0.8)	4.96 (0.59 to 41.89), NR
	Multiple	High HD + PA	Congestive Heart Failure	IG1	24	0/131 (0.0)	2/130 (1.5)	0.20 (0.01 to 4.09), NR
	Multiple	High HD + PA	Myocardial Infarction	IG1	24	0/131 (0.0)	1/130 (0.8)	0.33 (0.01 to 8.05), NR
	Multiple	High HD + PA	Transient Ischemic Attack	IG1	24	0/131 (0.0)	0/130 (0.0)	NR, NSD
	HTN	High HD + PA	Angina	IG1	36	10/147 (6.8)	19/371 (5.1)	1.33 (0.63 to 2.79), NR
	HTN	High HD + PA	Angina	IG2	36	10/147 (6.8)	19/371 (5.1)	1.33 (0.63 to 2.79), NR
	HTN	High HD only	Angina	IG3	36	10/370 (2.7)	19/371 (5.1)	0.53 (0.25 to 1.12), NR
	HTN	High HD + PA	Arrhythmia	IG1	36	1/147 (0.7)	4/371 (1.1)	0.63 (0.07 to 5.60), NR
	HTN	High HD + PA	Arrhythmia	IG2	36	2/147 (1.4)	4/371 (1.1)	1.26 (0.23 to 6.82), NR
	HTN	High HD only	Arrhythmia	IG3	36	6/370 (1.6)	4/371 (1.1)	1.50 (0.43 to 5.29), NR
	HTN	High HD + PA	Congestive Heart Failure	IG1	36	0/147 (0.0)	1/371 (0.3)	0.84 (0.03 to 20.45), NR
	HTN	High HD + PA	Congestive Heart Failure	IG2	36	1/147 (0.7)	1/371 (0.3)	2.52 (0.16 to 40.08), NR
	HTN	High HD only	Congestive Heart Failure	IG3	36	4/370 (1.1)	1/371 (0.3)	4.01 (0.45 to 35.71), NR

Appendix H Table 1. CVD Events + CVD Mortality (KQ1)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
	HTN	High HD + PA	CVD events	IG1	36	23/147 (15.6)	57/371 (15.4)	1.02 (0.65 to 1.59), NR
	HTN	High HD + PA	CVD events	IG2	36	21/147 (14.3)	57/371 (15.4)	0.93 (0.59 to 1.48), NR
	HTN	High HD only	CVD events	IG3	36	44/370 (11.9)	57/371 (15.4)	0.77 (0.54 to 1.12), NR
	HTN	High HD + PA	Myocardial Infarction nonfatal	IG1	36	2/147 (1.4)	4/371 (1.1)	1.26 (0.23 to 6.82), NR
	HTN	High HD + PA	Myocardial Infarction nonfatal	IG2	36	2/147 (1.4)	4/371 (1.1)	1.26 (0.23 to 6.82), NR
	HTN	High HD only	Myocardial Infarction nonfatal	IG3	36	2/370 (0.5)	4/371 (1.1)	0.50 (0.09 to 2.72), NR
	HTN	High HD + PA	Other CVD events	IG1	36	8/147 (5.4)	19/371 (5.1)	1.06 (0.48 to 2.37), NR
	HTN	High HD + PA	Other CVD events	IG2	36	6/147 (4.1)	19/371 (5.1)	0.80 (0.32 to 1.96), NR
	HTN	High HD only	Other CVD events	IG3	36	13/370 (3.5)	19/371 (5.1)	0.69 (0.34 to 1.37), NR
	HTN	High HD + PA	Stroke nonfatal	IG1	36	1/147 (0.7)	2/371 (0.5)	1.26 (0.12 to 13.81), NR
	HTN	High HD + PA	Stroke nonfatal	IG2	36	0/147 (0.0)	2/371 (0.5)	0.50 (0.02 to 10.41), NR
	HTN	High HD only	Stroke nonfatal	IG3	36	1/370 (0.3)	2/371 (0.5)	0.50 (0.05 to 5.51), NR
	HTN	High HD + PA	Transient Ischemic Attack	IG1	36	1/147 (0.7)	8/371 (2.2)	0.32 (0.04 to 2.50), NR
	HTN	High HD + PA	Transient Ischemic Attack	IG2	36	0/147 (0.0)	8/371 (2.2)	0.15 (0.01 to 2.55), NR
	HTN	High HD only	Transient Ischemic Attack	IG3	36	8/370 (2.2)	8/371 (2.2)	1.00 (0.38 to 2.64), NR

Abbreviations: CG = control group; CI = confidence interval; CVD = cardiovascular disease; Dys = dyslipidemia; F/U = followup timepoint; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; HR = hazard ratio; IG = intervention group; Int arm = intervention arm; KQ = key question; NR = not reported; NSD = no statistically significantly difference; RR = risk ratio

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

†Risk ratio unless otherwise specified

Appendix H Table 2. All-Cause Mortality (KQ1)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Appel, 2011[42] (POWER Hopkins (Practice Based Opportunities for Weight Reduction)) Good	Multiple	High HD + PA	IG1	24	0/138 (0.0)	0/138 (0.0)	NR, NSD
	Multiple	High HD + PA	IG2	24	0/139 (0.0)	0/138 (0.0)	NR, NSD
Bennett, 2018[48] (Track) Good	Multiple	Medium HD + PA	IG1	12	1/176 (0.6)	0/175 (0.0)	2.98 (0.12 to 72.73), NSD
Bo, 2007[52] Fair	Multiple	Medium HD + PA	IG1	108	21/169 (12.4)	28/166 (16.9)	HR=0.71 (0.40 to 1.26), 0.24
Bosworth, 2009[53] (Take Control of Your Blood pressure (TCYB)) Fair	HTN	Medium HD + PA	IG1	24	2/159 (1.3)	5/159 (3.1)	0.40 (0.08 to 2.03), NSD
	HTN	Medium HD + PA	IG2	24	5/160 (3.1)	5/159 (3.1)	0.99 (0.29 to 3.37), NSD
Eakin, 2009[64] (Logan Healthy Living) Fair	Multiple	Medium HD + PA	IG1	18	3/231 (1.3)	2/208 (1.0)	1.35 (0.23 to 8.00), NSD
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	IG1	60	118/2543 (4.6)	114/2450 (4.7)	HR=0.90 (0.69 to 1.18), NSD
	Multiple	High HD only	IG2	60	116/2454 (4.7)	114/2450 (4.7)	HR=1.12 (0.86 to 1.47), NSD
Fagerberg, 1998[68] (Risk Factor Intervention Study (RIS)) Good (KQ1); Fair (KQ2)	Multiple	High HD + PA	IG1	12	5/253 (2.0)	6/255 (2.4)	0.84 (0.26 to 2.72), NSD
	Multiple	High HD + PA	IG1	40	14/253 (5.5)	21/255 (8.2)	0.70 (0.40 to 1.30), 0.3
	Multiple	High HD + PA	IG1	79	41/253 (16.2)	64/255 (25.1)	0.62 (0.42 to 0.92), 0.016
Greaves, 2015[71] (Waste the Waist) Fair	Multiple	High HD + PA	IG1	12	2/55 (3.6)	0/53 (0.0)	4.82 (0.24 to 98.13), NSD
HPT, 1990[77] (Hypertension Prevention Trial (HPT)) Good	HTN	High HD only	IG1	36	1/195 (0.5)	1/196 (0.5)	1.01 (0.06 to 15.96), NSD
	HTN	High HD only	IG2	36	1/196 (0.5)	1/196 (0.5)	1.00 (0.06 to 15.87), NSD

Appendix H Table 2. All-Cause Mortality (KQ1)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
	HTN	High HD only	IG3	36	0/125 (0.0)	1/196 (0.5)	0.52 (0.02 to 12.69), NSD
	HTN	High HD only	IG4	36	1/129 (0.8)	1/196 (0.5)	1.52 (0.10 to 24.08), NSD
Kandula, 2015[83] (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	Multiple	High HD + PA	IG1	6	0/31 (0.0)	0/32 (0.0)	NR, NSD
Keyserling, 1997[86] (Southeast Cholesterol Project) Fair	Dys	Medium HD only	IG1	12	2/184 (1.1)	0/188 (0.0)	5.11 (0.25 to 105.68), NR
	Dys	Medium HD only	IG1	24	4/184 (2.2)	1/188 (0.5)	4.09 (0.46 to 36.22), NR
Niiranen, 2014[100] Fair	HTN	Medium HD + PA	IG1	12	1/117 (0.9)	0/112 (0.0)	NR, NSD
Ogedegbe, 2014[102] (Counseling African Americans to Control Hypertension (CAATCH)) Fair	HTN	Medium HD + PA	IG1	12	8/529 (1.5)	3/510 (0.6)	2.57 (0.69 to 9.64), 0.22
Rosas, 2015[106] (Vivamos Activos Fair Oaks (VAFO)) Good	Multiple	High HD + PA	IG1	24	0/82 (0.0)	0/41 (0.0)	NR, NSD
	Multiple	High HD + PA	IG2	24	0/84 (0.0)	0/41 (0.0)	NR, NSD
Salisbury, 2016[108] Good	Multiple	Medium HD + PA	IG1	12	0/325 (0.0)	2/316 (0.6)	0.19 (0.01 to 4.03), NSD
Svetkey, 2008[114] (Weight Loss Maintenance (WLM)) Good	Multiple	High HD + PA	IG1	30	1/342 (0.3)	1/342 (0.3)	1.00 (0.06 to 15.92), NSD
	Multiple	High HD + PA	IG2	30	1/348 (0.3)	1/342 (0.3)	0.98 (0.06 to 15.65), NSD
	Multiple	High HD + PA	IG1	60	3/244 (1.2)	1/247 (0.4)	3.04 (0.32 to 28.99), NR
TOHP I CRG, 1992[119] (Trials of Hypertension Prevention Phase I	HTN	High HD only	IG1	18	0/327 (0.0)	1/417 (0.2)	0.42 (0.02 to 10.39), NSD
	HTN	High HD + PA	IG2	18	1/308 (0.3)	1/256 (0.4)	0.83 (0.05 to 13.22), NSD

Appendix H Table 2. All-Cause Mortality (KQ1)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
(TOHP I)) Good	HTN	High HD only	IG1	180	10/327 (3.1)	14/417 (3.4)	HR=0.76 (0.33 to 1.74), 0.52
TOHP II CRG, 1997[120] (Trial of Hypertension Prevention II (TOHP II)) Good	HTN	High HD + PA	IG1	48	2/597 (0.3)	2/596 (0.3)	1.00 (0.14 to 7.06), NSD
	HTN	High HD + PA	IG2	48	5/595 (0.8)	2/596 (0.3)	2.50 (0.49 to 12.86), NSD
	HTN	High HD only	IG3	48	3/594 (0.5)	2/596 (0.3)	1.51 (0.25 to 8.97), NSD

Abbreviations: CG = control group; CI = confidence interval; Dys = dyslipidemia; F/U = followup timepoint; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; HR = hazard ratio; IG = intervention group; Int arm = intervention arm; KQ = key question; NR = not reported; NSD = no statistically significantly difference; PREDIMED = Primary Prevention of Cardiovascular Disease with a Mediterranean Diet; RR = risk ratio

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

†Risk ratio unless otherwise specified

Appendix H Table 3. Patient-Reported Measures of Subjective Well-Being (KQ1)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Appel, 2003[41] (PREMIER) Good	HTN	High HD + PA	SF-36 Bodily pain	IG1	6	219	53.8 (7.4)	0.1 (7.4)	219	54.6 (5.92)	-0.5 (7.4)	0.60 (-0.79 to 1.99), NSD
	HTN	High HD + PA	SF-36 Bodily pain	IG2	6	221	54.2 (5.95)	0.4 (7.43)	219	54.6 (5.92)	-0.5 (7.4)	0.90 (-0.49 to 2.29), NSD
	HTN	High HD + PA	SF-36 Bodily pain	IG1	18	219	53.8 (7.4)	0.6 (7.4)	219	54.6 (5.92)	0 (7.4)	0.60 (-0.79 to 1.99), NSD
	HTN	High HD + PA	SF-36 Bodily pain	IG2	18	221	54.2 (5.95)	-0.7 (7.43)	219	54.6 (5.92)	0 (7.4)	-0.70 (-2.09 to 0.69), NSD
	HTN	High HD + PA	SF-36 General health problems	IG1	6	219	50.5 (7.4)	0.9 (7.4)	219	51.7 (7.4)	-1 (7.4)	1.90 (0.51 to 3.29), <0.05
	HTN	High HD + PA	SF-36 General health problems	IG2	6	221	50.8 (7.43)	0.1 (7.43)	219	51.7 (7.4)	-1 (7.4)	1.10 (-0.29 to 2.49), NSD
	HTN	High HD + PA	SF-36 General health problems	IG1	18	219	50.5 (7.4)	1.3 (7.4)	219	51.7 (7.4)	-1.3 (7.4)	2.60 (1.21 to 3.99), <0.05
	HTN	High HD + PA	SF-36 General health problems	IG2	18	221	50.8 (7.43)	0.1 (7.43)	219	51.7 (7.4)	-1.3 (7.4)	1.40 (0.01 to 2.79), <0.1
	HTN	High HD + PA	SF-36 General mental health	IG1	6	219	52.4 (7.4)	0.4 (7.4)	219	53.5 (7.4)	-0.2 (7.4)	0.60 (-0.79 to 1.99), NSD
	HTN	High HD + PA	SF-36 General mental health	IG2	6	221	52.7 (7.43)	-0.2 (7.43)	219	53.5 (7.4)	-0.2 (7.4)	0.00 (-1.39 to 1.39), NSD
	HTN	High HD + PA	SF-36 General mental health	IG1	18	219	52.4 (7.4)	0.1 (7.4)	219	53.5 (7.4)	0.2 (7.4)	-0.10 (-1.49 to 1.29), NSD
	HTN	High HD + PA	SF-36 General mental health	IG2	18	221	52.7 (7.43)	-0.3 (7.43)	219	53.5 (7.4)	0.2 (7.4)	-0.50 (-1.89 to 0.89), NSD
	HTN	High HD + PA	SF-36 MCS	IG1	6	219	51.5 (8.88)	0.9 (8.88)	219	52.6 (7.4)	0.1 (8.88)	0.80 (-0.86 to 2.46), <0.1
	HTN	High HD + PA	SF-36 MCS	IG2	6	221	52 (7.43)	-1 (8.92)	219	52.6 (7.4)	0.1 (8.88)	-1.10 (-2.76 to 0.56), NSD
	HTN	High HD + PA	SF-36 MCS	IG1	18	219	51.5 (8.88)	0.2 (8.88)	219	52.6 (7.4)	0.1 (8.88)	0.10 (-1.56 to 1.76), NSD
	HTN	High HD + PA	SF-36 MCS	IG2	18	221	52 (7.43)	-0.3 (8.92)	219	52.6 (7.4)	0.1 (8.88)	-0.40 (-2.06 to 1.26), NSD
	HTN	High HD + PA	SF-36 PCS	IG1	6	219	52 (7.4)	0.2 (7.4)	219	52.3 (5.92)	-1 (7.4)	1.20 (-0.19 to 2.59), NSD
	HTN	High HD + PA	SF-36 PCS	IG2	6	221	51.8 (5.95)	0.8 (7.43)	219	52.3 (5.92)	-1 (7.4)	1.80 (0.41 to 3.19), <0.05

Appendix H Table 3. Patient-Reported Measures of Subjective Well-Being (KQ1)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	High HD + PA	SF-36 PCS	IG1	18	219	52 (7.4)	0.5 (7.4)	219	52.3 (5.92)	-0.6 (7.4)	1.10 (-0.29 to 2.49), NSD
Appel, 2003[41] (PREMIER) Good	HTN	High HD + PA	SF-36 PCS	IG2	18	221	51.8 (5.95)	0.1 (7.43)	219	52.3 (5.92)	-0.6 (7.4)	0.70 (-0.69 to 2.09), NSD
	HTN	High HD + PA	SF-36 Physical functioning	IG1	6	219	52 (5.92)	0.8 (7.4)	219	52.1 (5.92)	-0.8 (7.4)	1.60 (0.21 to 2.99), <0.1
	HTN	High HD + PA	SF-36 Physical functioning	IG2	6	221	51.9 (5.95)	0 (7.43)	219	52.1 (5.92)	-0.8 (7.4)	0.80 (-0.59 to 2.19), NSD
	HTN	High HD + PA	SF-36 Physical functioning	IG1	18	219	52 (5.92)	0.3 (7.4)	219	52.1 (5.92)	-0.4 (7.4)	0.70 (-0.69 to 2.09), NSD
	HTN	High HD + PA	SF-36 Physical functioning	IG2	18	221	51.9 (5.95)	0 (7.43)	219	52.1 (5.92)	-0.4 (7.4)	0.40 (-0.99 to 1.79), NSD
	HTN	High HD + PA	SF-36 Role limitations - emotional	IG1	6	219	51.6 (8.88)	0.5 (8.88)	219	52.3 (7.4)	0.9 (8.88)	-0.40 (-2.06 to 1.26), NSD
	HTN	High HD + PA	SF-36 Role limitations - emotional	IG2	6	221	52.2 (7.43)	-1.5 (8.92)	219	52.3 (7.4)	0.9 (8.88)	-2.40 (-4.06 to -0.74), <0.05
	HTN	High HD + PA	SF-36 Role limitations - emotional	IG1	18	219	51.6 (8.88)	0 (10.36)	219	52.3 (7.4)	0.3 (10.36)	-0.30 (-2.24 to 1.64), NSD
	HTN	High HD + PA	SF-36 Role limitations - emotional	IG2	18	221	52.2 (7.43)	-0.3 (10.41)	219	52.3 (7.4)	0.3 (10.36)	-0.60 (-2.54 to 1.34), NSD
	HTN	High HD + PA	SF-36 Role limitations - physical	IG1	6	219	51.9 (7.4)	-0.6 (8.88)	219	52 (7.4)	0 (8.88)	-0.60 (-2.26 to 1.06), NSD
	HTN	High HD + PA	SF-36 Role limitations - physical	IG2	6	221	51.3 (7.43)	0.7 (8.92)	219	52 (7.4)	0 (8.88)	0.70 (-0.96 to 2.36), NSD
	HTN	High HD + PA	SF-36 Role limitations - physical	IG1	18	219	51.9 (7.4)	-0.4 (10.36)	219	52 (7.4)	0 (10.36)	-0.40 (-2.34 to 1.54), NSD

Appendix H Table 3. Patient-Reported Measures of Subjective Well-Being (KQ1)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	High HD + PA	SF-36 Role limitations - physical	IG2	18	221	51.3 (7.43)	0.4 (10.41)	219	52 (7.4)	0 (10.36)	0.40 (-1.54 to 2.34), NSD
	HTN	High HD + PA	SF-36 Social functioning	IG1	6	219	52.9 (7.4)	0.6 (8.88)	219	53.2 (7.4)	-0.3 (8.88)	0.90 (-0.76 to 2.56), NSD
	HTN	High HD + PA	SF-36 Social functioning	IG2	6	221	53.2 (7.43)	-0.2 (8.92)	219	53.2 (7.4)	-0.3 (8.88)	0.10 (-1.56 to 1.76), NSD
	HTN	High HD + PA	SF-36 Social functioning	IG1	18	219	52.9 (7.4)	0.3 (10.36)	219	53.2 (7.4)	0.4 (10.36)	-0.10 (-2.04 to 1.84), NSD
Appel, 2003[41] (PREMIER) Good	HTN	High HD + PA	SF-36 Social functioning	IG2	18	221	53.2 (7.43)	-0.7 (10.41)	219	53.2 (7.4)	0.4 (10.36)	-1.10 (-3.04 to 0.84), NSD
	HTN	High HD + PA	SF-36 Vitality	IG1	6	219	49.7 (8.88)	1.7 (8.88)	219	51.2 (8.88)	-1.9 (8.88)	3.60 (1.94 to 5.26), <0.05
	HTN	High HD + PA	SF-36 Vitality	IG2	6	221	49.7 (8.92)	0.1 (8.92)	219	51.2 (8.88)	-1.9 (8.88)	2.00 (0.34 to 3.66), <0.05
	HTN	High HD + PA	SF-36 Vitality	IG1	18	219	49.7 (8.88)	0.6 (8.88)	219	51.2 (8.88)	-1.2 (8.88)	1.80 (0.14 to 3.46), <0.1
	HTN	High HD + PA	SF-36 Vitality	IG2	18	221	49.7 (8.92)	0.7 (8.92)	219	51.2 (8.88)	-1.2 (8.88)	1.90 (0.24 to 3.56), <0.05
Appel, 2011[42] (POWER Hopkins (Practice Based Opportunities for Weight Reduction)) Good	Multiple	High HD + PA	SF-12 MCS	IG1	24	100	52.16 (9.6)	-0.5 (7.6)	88	51.06 (8.71)	0.62 (8.91)	-1.12 (-3.52 to 1.27), NSD
	Multiple	High HD + PA	SF-12 MCS	IG2	24	115	52.53 (7.4)	-1.07 (7.29)	88	51.06 (8.71)	0.62 (8.91)	-1.70 (-3.99 to 0.60), NSD
	Multiple	High HD + PA	SF-12 PCS	IG1	24	100	47.06 (8.92)	2.23 (7.5)	88	46.83 (7.95)	-0.29 (9.1)	2.52 (0.11 to 4.93), <0.05
	Multiple	High HD + PA	SF-12 PCS	IG2	24	115	47.53 (8.42)	1.16 (8.26)	88	46.83 (7.95)	-0.29 (9.1)	1.45 (-0.99 to 3.90), NSD
Babazono, 2007[45] (PHPP) Fair	Multiple	HD + PA	GHQ-30	IG1	12	46	4.4 (4.1)	-1.3 (3.8)	41	4 (3.3)	0 (3.83)	-1.30 (-2.91 to 0.31), NSD
Bruckert, 2008[55] (PEGASE (Effect of an Education	Dys	Medium HD + PA	SF-36 Bodily pain	IG1	6	221	NR (NR)	2.76 (NR)	188	NR (NR)	-0.95 (NR)	NR, NSD
	Dys	Medium HD + PA	SF-36 General health problems	IG1	6	221	NR (NR)	2.81 (NR)	188	NR (NR)	-0.64 (NR)	NR, NSD

Appendix H Table 3. Patient-Reported Measures of Subjective Well-Being (KQ1)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Program)) Fair	Dys	Medium HD + PA	SF-36 General mental health	IG1	6	221	NR (NR)	1.79 (NR)	188	NR (NR)	0.13 (NR)	NR, NSD
	Dys	Medium HD + PA	SF-36 MCS	IG1	6	221	NR (NR)	0.53 (NR)	188	NR (NR)	0.69 (NR)	NR, NSD
	Dys	Medium HD + PA	SF-36 PCS	IG1	6	221	NR (NR)	2.57 (NR)	188	NR (NR)	-0.5 (NR)	NR, NSD
	Dys	Medium HD + PA	SF-36 Physical functioning	IG1	6	221	NR (NR)	6.72 (NR)	188	NR (NR)	-0.63 (NR)	NR, NSD
	Dys	Medium HD + PA	SF-36 Role limitations – emotional	IG1	6	221	NR (NR)	2.22 (NR)	188	NR (NR)	3.55 (NR)	NR, NSD
	Dys	Medium HD + PA	SF-36 Role limitations - physical	IG1	6	221	NR (NR)	7.91 (NR)	188	NR (NR)	1.08 (NR)	NR, NSD
Bruckert, 2008[55] (PEGASE (Effect of an Education Program)) Fair	Dys	Medium HD + PA	SF-36 Social functioning	IG1	6	221	NR (NR)	2.09 (NR)	188	NR (NR)	0.73 (NR)	NR, NSD
	Dys	Medium HD + PA	SF-36 Vitality	IG1	6	221	NR (NR)	3.43 (NR)	188	NR (NR)	-1.47 (NR)	NR, NSD
Fagerberg, 1998[68] (Risk Factor Intervention Study (RIS)) Good (KQ1); Fair (KQ2)	Multiple	High HD + PA	MSEP – Contentment (No. deteriorated)	IG1	40	176	NA	28 (15.9)		NA	24 (15.3)	RR=1.04 (0.63 to 1.72)
	Multiple	High HD + PA	MSEP – Contentment (No. improved)	IG1	40	176	NA	14 (8.0)‡	157	NA	9 (5.7)‡	RR=1.39 (0.62 to 3.12)
	Multiple	High HD + PA	MSEP – Sleep (No. deteriorated)	IG1	40	176	NA	32 (18.2)‡	157	NA	32 (20.4)‡	RR=0.89 (0.57 to 1.39)
	Multiple	High HD + PA	MSEP – Sleep (No. deteriorated)	IG1	40	176	NA	39 (22.2)‡	157	NA	31 (19.7)‡	RR=1.12 (0.74 to 1.71)
	Multiple	High HD + PA	MSEP – Vitality	IG1	40	176	NA	22 (12.5)‡	157	NA	27 (17.2)‡	RR=0.73 (0.43 to 1.22)

Appendix H Table 3. Patient-Reported Measures of Subjective Well-Being (KQ1)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
			(No. deteriorated)									
	Multiple	High HD + PA	MSEP – Vitality (No. improved)	IG1	40	176	NA	25 (14.2)‡	157	NA	19 (12.1)‡	RR=1.17 (0.67 to 2.05)
Gill, 2019b[70] (HealtheSteps) Fair	Multiple	HD + PA	European Quality of Life	IG1	6	59	NR (NR)	5.92 (NR)	59	NR (NR)	4.37 (13.85)	1.55 (-3.25 to 6.35), 0.52
Greaves, 2015[71] (Waste the Waist) Fair	Multiple	High HD + PA	EQ-5D VAS	IG1	12	55	77 (14.9)	NR (NR)	53	76.4 (17)	NR (NR)	1.36 (-3.37 to 6.04), NSD
Haufe, 2019[75] Fair	Multiple	Medium HD + PA	SF-36 MCS	IG1	6	160	49.2 (9.4)	4.1 (8.55)	154	49.9 (9.7)	1.6 (9.2)	2.20 (0.70 to 3.70), 0.005
	Multiple	Medium HD + PA	SF-36 PCS	IG1	6	160	48.3 (1.8)	2.6 (6.98)	154	49.1 (7.6)	0.8 (7.65)	1.00 (-0.50 to 2.50), 0.201
Khanji, 2019[87] (HAPPY London) Good	Multiple	Low HD + PA	EQ-5D VAS	IG1	6	194	NR (NR)	NR (NR)	183	NR (NR)	0.01 (NR)	-0.01 (-0.02 to 0.05), 0.44
	Multiple	Low HD + PA	SF-36 (Overall)	IG1	6	194	NR (NR)	4.8 (NR)	183	NR (NR)	5.6 (NR)	-0.77 (-6.50 to 4.90), 0.79
Salisbury, 2016[108] Good	Multiple	Medium HD + PA	EQ-5D-3L	IG1	12	295	NR (NR)	NR (NR)	297	NR (NR)	NR (NR)	MD=0.01 (-0.01 to 0.03), 0.41
van Keulen, 2011[123] (Vitalum) Fair	HTN	Medium HD + PA	QALYs (quality-adjusted life years)	IG1	17	407	NR (NR)	NR (NR)	409	NR (NR)	NR (NR)	MD=0.02 (0.00 to 0.04), 0.07
	HTN	Medium HD + PA	QALYs (quality-adjusted life years)	IG2	17	408	NR (NR)	NR (NR)	409	NR (NR)	NR (NR)	MD=0.01 (-0.01 to 0.03), 0.32
	HTN	Low HD + PA	QALYs (quality-adjusted life years)	IG3	17	405	NR (NR)	NR (NR)	409	NR (NR)	NR (NR)	MD=0.02 (0.00 to 0.04), 0.09

Abbreviations: CG = control group; CI = confidence interval; Dys = dyslipidemia; EQ-5D-3L = EuroQol 5 Dimensions, 3 Levels; EQ-5D VAS = EuroQol 5 Dimensions Visual Analog Scale; F/U = followup timepoint; GHQ-30 = General Health Questionnaire – 30 items; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; MCS = Mental Component Summary; MSEP = Minor symptoms evaluation profile; NR = not reported; NSD =

no statistically significantly difference; PCS = Physical Component Summary; QALYs = quality-adjusted life years; RR = risk ratio; SD = standard deviation; SF-36 = Short Form Healthy Survey – 12 items; SF-36 = Short Form Healthy Survey – 36 items

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min
†Risk ratio unless otherwise specified
‡No. (%)

Appendix H Table 4. Meta-Analysis Summary of Pooled Intermediate Outcomes

Outcome (unit)	Population risk focus	Followup category	Effect size (95% CI)*	K	N	I^2
SBP (mm Hg)	Dyslipidemia	<12 months	--	--	--	--
		12-24 months	-0.57 (-3.90, 2.75)	3	498	0.0%
		>24 months	--	--	--	--
	Hypertension	<12 months	-2.84 (-4.38, -1.29)	16	5756	70.0%
		12-24 months	-1.97 (-2.59, -1.36)	16	5769	7.8%
		>24 months	-1.11 (-1.71, -0.51)	4	1749	0.0%
	Multiple risk factors	<12 months	-1.40 (-2.20, -0.60)	14	3837	0.0%
		12-24 months	-1.73 (-2.91, -0.55)	25	8313	51.0%
		>24 months	-4.37 (-36.77, 28.02)	2	797	75.8%
	All available studies	<12 months	-2.25 (-3.12, -1.37)	30	9523	57.9%
		12-24 months	-1.81 (-2.49, -1.13)	44	14580	37.3%
		>24 months	-1.84 (-412, 0.44)	6	2546	55.3%
DBP (mm Hg)	Dyslipidemia	<12 months	--	--	--	--
		12-24 months	-1.40 (-2.67, -0.13)	2	186	0.0%
		>24 months	--	--	--	--
	Hypertension	<12 months	-1.66 (-2.51, -0.80)	14	5139	67.8%
		12-24 months	-1.06 (-1.75, -0.38)	15	5461	43.4%
		>24 months	-0.03 (-2.50, 2.44)	4	1749	77.4%
	Multiple risk factors	<12 months	-0.85 (-1.40, -0.30)	12	3460	0.0%
		12-24 months	-1.22 (-1.82, -0.61)	23	7451	32.7%
		>24 months	-1.43 (-6.42, 3.57)	2	797	0.0%
	All available studies	<12 months	-1.35 (-1.88, -0.81)	26	8599	55.9%
		12-24 months	-1.16 (-1.57, -0.75)	40	13098	32.5%
		>24 months	-0.45 (-1.96, 1.06)	6	2546	68.7%
TC (mg/dL)	Dyslipidemia	<12 months	-3.84 (-9.44, 1.76)	6	1132	32.4%
		12-24 months	-3.80 (-7.22, -0.37)	9	2001	24.0%
		>24 months	--	--	--	--
	Hypertension	<12 months	-8.11 (-27.16, 10.93)	4	1356	88.3%
		12-24 months	-0.72 (-3.17, 1.73)	7	2349	18.3 %
		>24 months	-7.72 (-17.36, 1.92)	1	241	--
	Multiple risk factors	<12 months	-2.64 (-4.88, -0.39)	9	1932	0.0%
		12-24 months	-4.06 (-7.38, -0.74)	22	7064	73.9%
		>24 months	-6.07 (-121.37, 109.24)	2	748	90.6%
	All available studies	<12 months	-4.03 (-6.89, -1.18)	19	4420	52.0%
		12-24 months	-3.48 (-5.57, -1.38)	38	11414	65.9%
		>24 months	-6.64 (-29.64, 16.37)	3	989	81.2%
LDL-C (mg/dL)	Dyslipidemia	<12 months	-0.95 (-6.74, 4.85)	5	1128	44.9%
		12-24 months	-4.12 (-8.81, 0.57)	7	1271	36.3%
		>24 months	--	--	--	--
	Hypertension	<12 months	-2.66 (-13.68, 8.36)	3	1167	65.1%
		12-24 months	-1.57 (-4.78, 1.65)	5	2104	55.6%
		>24 months	--	--	--	--
	Multiple risk factors	<12 months	-1.73 (-4.34, 0.88)	8	1866	0.0%
		12-24 months	-1.71 (-4.64, 1.22)	20	5519	61.8%
		>24 months	-14.67 (-21.43, -7.91)	1	462	--
	All available studies	<12 months	-1.61 (-3.52, 0.30)	16	4161	17.0%
		12-24 months	-2.14 (-4.08, -0.21)	32	8894	55.9%
		>24 months	-14.67 (-21.43, -7.91)	1	462	--
HDL-C (mg/dL)	Dyslipidemia	<12 months	-1.16 (-1.19, -1.15)	3	373	0.0%
		12-24 months	-0.44 (-1.26, 0.37)	6	1033	0.0%
		>24 months	--	--	--	--
	Hypertension	<12 months	0.37 (-8.87, 9.61)	2	973	64.0

Appendix H Table 4. Meta-Analysis Summary of Pooled Intermediate Outcomes

Outcome (unit)	Population risk focus	Followup category	Effect size (95% CI)*	K	N	I^2
		12-24 months	0.69 (0.00, 1.38)	5	1979	0.0%
		>24 months	0.39 (-2.31, 3.09)	1	241	--
	Multiple risk factors	<12 months	0.48 (0.07, 0.89)	10	2696	0.0%
		12-24 months	0.81 (0.30, 1.32)	23	5962	39.4%
		>24 months	0.89 (-1.42, 3.21)	2	748	0.0%
	All available studies	<12 months	0.27 (-0.15, 0.69)	15	4042	0.0%
		12-24 months	0.58 (0.19, 0.98)	34	8974	33.7%
		>24 months	0.81 (0.05, 1.57)	3	989	0.0%
FBG (mg/dL)	All available studies	<12 months	-1.38 (-3.15, 0.39)	10	1973	62.9%
		12-24 months	-2.33 (-3.64, -1.02)	22	5950	82.5%
		>24 months	-2.27 (-8.39, 3.85)	4	3727	85.4%
DM Incidence	All available studies	All available (12-60 months)	RR=0.82 (0.66, 1.03)	5	7848	0.0%
Weight (kg)	Dyslipidemia	<12 months	-0.88 (-1.38, -0.38)	4	648	0.0%
		12-24 months	-1.40 (-3.17, 0.38)	6	887	86.0%
		>24 months	--	--	--	--
	Hypertension	<12 months	-2.64 (-3.79, -1.50)	10	3345	95.1%
		12-24 months	-1.82 (-2.64, -1.01)	9	3433	81.3%
		>24 months	-1.13 (-3.40, 1.13)	3	1698	84.7%
	Multiple risk factors	<12 months	-2.19 (-3.06, -1.33)	16	3967	85.8%
		12-24 months	-1.56 (-2.22, -0.90)	22	12025	86.7%
		>24 months	-0.84 (-1.50, 0.17)	5	5721	56.8%
	All available studies	<12 months	-2.18 (-2.76, -1.60)	30	7960	91.0%
		12-24 months	-1.59 (-2.06, -1.13)	37	16345	88.1%
		>24 months	0.98 (-1.54, -0.43)	8	7419	77.5%
BMI (kg/m^2)	Dyslipidemia	<12 months	-0.18 (-2.04, 1.67)	2	342	50.6%
		12-24 months	0.10 (-1.24, 1.43)	2	444	0.0%
		>24 months	--	--	--	--
	Hypertension	<12 months	-0.35 (-1.02, 0.33)	4	1252	67.2%
		12-24 months	-0.14 (-0.63, 0.36)	6	1509	66.2%
		>24 months	--	--	--	--
	Multiple risk factors	<12 months	-0.72 (-1.10, -0.33)	12	3512	88.2%
		12-24 months	-0.60 (-0.83, -0.37)	22	7956	81.9%
		>24 months	-0.58 (-3.12, 1.95)	2	748	71.4%
	All available studies	<12 months	-0.57 (-0.86, -0.29)	18	5106	86.7%
		12-24 months	-0.46 (-0.66, -0.26)	30	9909	83.3%
		>24 months	-0.58 (-3.12, 1.95)	2	748	71.4%
WC (cm)	Dyslipidemia	<12 months	0.10 (-1.59, 1.79)	1	137	--
		12-24 months	0.03 (-2.97, 3.03)	2	441	0.0%
		>24 months	--	--	--	--
	Hypertension	<12 months	-3.20 (-4.26, -2.14)	1	456	--
		12-24 months	-2.14 (-6.14, 1.85)	3	897	79.5%
		>24 months	-0.30 (-1.65, 1.05)	1	241	--
	Multiple risk factors	<12 months	-2.26 (-3.19, -1.33)	11	2435	77.0%
		12-24 months	-1.83 (-2.63, -1.03)	18	10370	85.3%
		>24 months	-0.54 (-1.07, -0.01)	1	3978	--
	All available studies	<12 months	-2.16 (-3.04, -1.29)	13	3028	78.0%
		12-24 months	-1.75 (-2.44, -1.06)	23	11708	87.3%
		>24 months	-0.51 (-1.54, 0.53)	2	4219	0.0%

Abbreviations: BMI = body mass index; cm = centimeters; CI = confidence interval; DBP = diastolic blood pressure; DM = diabetes mellitus; FBG = fasting blood glucose; HDL-C = high-density lipoprotein cholesterol; K = number of studies; kg = kilograms; kg/m^2 = kilograms per meter squared; LDL-C = low-density lipoprotein cholesterol; mg/dL = milligrams per deciliter;

Appendix H Table 4. Meta-Analysis Summary of Pooled Intermediate Outcomes

mm Hg = millimeters of mercury; N = number of participants analyzed; SBP = systolic blood pressure; TC = total cholesterol; WC = waist circumference

*Between-group mean difference in change unless otherwise specified

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Anderssen, 1995[40] (Oslo Diet and Exercise Study (ODES)) Fair	Multiple	Medium HD only	DBP	IG1	12	52	87.5 (8.65)	-3.4 (7.21)	43	87 (7.21)	-0.7 (8.52)	-2.70 (-5.91 to 0.51), NSD
	Multiple	Medium HD only	SBP	IG1	12	52	132.8 (15.14)	-6.4 (10.1)	43	128.7 (9.84)	-0.5 (11.15)	-5.90 (-10.22 to -1.58), <0.05
Appel, 2003[41] (PREMIER) Good	HTN	High HD + PA	DBP	IG1	6	269	84.6 (4)	-6.4 (6.8)	273	84.8 (4.3)	-3.8 (6.3)	-2.60 (-3.70 to -1.50), <0.001
	HTN	High HD + PA	DBP	IG2	6	268	85 (4.1)	-5.5 (6.7)	273	84.8 (4.3)	-3.8 (6.3)	-1.70 (-2.80 to -0.60), 0.002
	HTN	High HD + PA	DBP	IG2 (HTN subgroup)	6	97	NR (NR)	-7.4 (7.1)	97	NR (NR)	-3.8 (7.1)	-3.60 (-5.34 to -1.86), <0.05
	HTN	High HD + PA	DBP	IG1	18	269	84.6 (4)	-6.2 (7.8)	273	84.8 (4.3)	-5.2 (7.7)	-1.10 (-2.30 to 0.20), NSD
	HTN	High HD + PA	DBP	IG2	18	268	85 (4.1)	-6 (7.3)	273	84.8 (4.3)	-5.2 (7.7)	-0.60 (-1.90 to 0.60), NSD
	HTN	High HD + PA	DBP	IG2 (HTN subgroup)	18	96	87.2 (4)	-7.4 (8.8)	97	87.8 (4.5)	-6.5 (9.6)	-1.00 (-3.00 to 1.00),
	HTN	High HD + PA	SBP	IG1	6	269	134.9 (9.4)	-11.1 (9.9)	273	134.2 (10.1)	-6.6 (9.2)	-4.30 (-5.90 to -2.80), <0.001
	HTN	High HD + PA	SBP	IG2	6	268	135.5 (9.2)	-10.5 (10.1)	273	134.2 (10.1)	-6.6 (9.2)	-3.70 (-5.30 to -2.10), <0.001
	HTN	High HD + PA	SBP	IG2 (HTN subgroup)	6	97	NR (NR)	-14.2 (10.1)	97	NR (NR)	-7.8 (10.3)	-6.30 (-8.85 to -3.75), <0.05
	HTN	High HD + PA	SBP	IG1	18	269	134.9 (9.4)	-9.5 (10.8)	273	134.2 (10.1)	-7.4 (10.8)	-1.90 (-3.70 to -0.10), NSD
	HTN	High HD + PA	SBP	IG2	18	268	135.5 (9.2)	-8.6 (11.6)	273	134.2 (10.1)	-7.4 (10.8)	-0.90 (-2.70 to 0.90), NSD
	HTN	High HD + PA	SBP	IG2 (HTN subgroup)	18	96	144.1 (7.1)	-11 (13)	97	143.5 (8.2)	-9.9 (13.2)	-1.00 (-3.96 to 1.96), NR, NSD
Appel, 2011[42] (POWER Hopkins (Practice Based Opportunities for	Multiple	High HD + PA	DBP	IG1	6	123	71.7 (9.36)	0.6 (8.87)	110	73.3 (9.36)	1.4 (7.34)	-0.80 (-2.90 to 1.30), 0.44
	Multiple	High HD + PA	DBP	IG2	6	129	72.5 (9.43)	-0.6 (9.09)	110	73.3 (9.36)	1.4 (7.34)	-2.00 (-4.10 to 0.20), 0.069

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Weight Reduction)) Good	Multiple	High HD + PA	DBP	IG1	24	126	71.7 (9.36)	1.8 (8.98)	114	73.3 (9.36)	2.1 (9.61)	-0.40 (-2.60 to 1.90), 0.75
	Multiple	High HD + PA	DBP	IG2	24	122	72.5 (9.43)	1.6 (9.94)	114	73.3 (9.36)	2.1 (9.61)	-0.60 (-2.90 to 1.80), 0.65
	Multiple	High HD + PA	SBP	IG1	6	123	118.3 (12.88)	0.7 (13.31)	110	120.2 (11.7)	2.1 (11.54)	-1.40 (-4.60 to 1.80), 0.39
	Multiple	High HD + PA	SBP	IG2	6	129	119.2 (14.15)	-1.3 (14.77)	110	120.2 (11.7)	2.1 (11.54)	-3.40 (-6.80 to 0.00), 0.048
	Multiple	High HD + PA	SBP	IG1	24	126	118.3 (12.88)	2.6 (12.35)	114	120.2 (11.7)	3.6 (14.95)	-1.10 (-4.60 to 2.50), 0.55
	Multiple	High HD + PA	SBP	IG2	24	122	119.2 (14.15)	1.6 (13.25)	114	120.2 (11.7)	3.6 (14.95)	MD=-2.00 (-5.60 to 1.60), 0.28
Applegate, 1992[43] Fair	HTN	High HD + PA	DBP	IG1	6	21	86.5 (1.7)	-6.8 (NR)	26	88.4 (3.6)	-1.9 (NR)	NR, 0.1
	HTN	High HD + PA	SBP	IG1	6	21	142.6 (11.7)	-8.7 (NR)	26	144.5 (9.7)	-4.5 (NR)	NR, 0.22
Arroll, 1995[44] Fair	HTN	Low HD + PA	DBP	IG1	6	48	89.1 (NR)	-2.2 (NR)	43	94 (NR)	-4.8 (NR)	NR, NSD
	HTN	Low PA only	DBP	IG2	6	46	88.4 (NR)	-2.1 (NR)	43	94 (NR)	-4.8 (NR)	NR, NSD
	HTN	Low HD only	DBP	IG3	6	44	86.4 (NR)	-1.7 (NR)	43	94 (NR)	-4.8 (NR)	NR, NSD
	HTN	Low HD + PA	SBP	IG1	6	48	145 (NR)	-5.2 (NR)	43	145.3 (NR)	-6.2 (NR)	NR, NSD
	HTN	Low PA only	SBP	IG2	6	46	142.9 (NR)	-9 (NR)	43	145.3 (NR)	-6.2 (NR)	NR, NSD
	HTN	Low HD only	SBP	IG3	6	44	145.4 (NR)	-9.1 (NR)	43	145.3 (NR)	-6.2 (NR)	NR, NSD
Babazono, 2007[45] (PHPP) Fair	Multiple	Medium HD + PA	DBP	IG1	12	46	78.2 (9)	-3.7 (10.12)	41	79.3 (11.8)	-4.3 (11.62)	0.60 (-4.00 to 5.20), NSD
	Multiple	Medium HD + PA	SBP	IG1	12	46	127.6 (15.7)	-5.2 (16.79)	41	132 (17.8)	-8.7 (17.45)	3.50 (-3.72 to 10.72), NSD
Beckmann, 1995[46] Fair	HTN	Medium HD only	MAP (mean	IG1	12	32	102.9 (9.05)	-8.8 (7.84)	32	102.5 (8.49)	-0.4 (8.22)	-8.40 (-12.33 to -4.47), <0.001

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
			arterial pressure)									
Bennett, 2012[47] (Be Fit, Be Well [POWER]) Good	HTN	High HD + PA	DBP	IG1	6	180	79.34 (12.73)	0.3 (13.82)	185	77.45 (13.77)	1.28 (13.6)	-0.98 (-3.80 to 1.83), NSD
	HTN	High HD + PA	DBP	IG1	12	180	79.34 (12.73)	0.04 (14.49)	185	77.45 (13.77)	2.3 (13.6)	-2.26 (-5.15 to 0.64), NSD
	HTN	High HD + PA	DBP	IG1	18	180	79.34 (12.73)	0.49 (14.62)	185	77.45 (13.77)	2.73 (13.87)	-2.24 (-5.16 to 0.69), NSD
	HTN	High HD + PA	DBP	IG1	24	180	79.34 (12.73)	0.56 (13.28)	185	77.45 (13.77)	2 (12.79)	-1.44 (-4.13 to 1.24), NSD
	HTN	High HD + PA	SBP	IG1	6	180	130.22 (18.89)	0.49 (21.47)	185	128.55 (19.73)	1.78 (21.08)	-1.30 (-5.67 to 3.08), NSD
	HTN	High HD + PA	SBP	IG1	12	180	130.22 (18.89)	-1.38 (22.54)	185	128.55 (19.73)	3.35 (21.22)	-4.73 (-9.23 to -0.22), <0.05
	HTN	High HD + PA	SBP	IG1	18	180	130.22 (18.89)	-0.22 (22.67)	185	128.55 (19.73)	5.61 (21.49)	-5.83 (-10.38 to -1.28), <0.05
	HTN	High HD + PA	SBP	IG1	24	180	130.22 (18.89)	1.56 (20.66)	185	128.55 (19.73)	5.3 (19.99)	-3.73 (-7.91 to 0.45), NSD
Bennett, 2018[48] (Track) Good	Multiple	Medium HD + PA	DBP	IG1	6	170	82.1 (11.6)	-4.1 (11.64)	167	81.9 (11.8)	-2.5 (11.21)	-1.60 (-3.90 to 0.70), 0.16
	Multiple	Medium HD + PA	DBP	IG1	12	170	82.1 (11.6)	-5.2 (12.64)	167	81.9 (11.8)	-4.2 (12.2)	-1.00 (-3.50 to 1.50), 0.43
	Multiple	Medium HD + PA	SBP	IG1	6	170	130.1 (17.4)	-4.6 (19.29)	167	130 (17.6)	-3.4 (18.79)	-1.20 (-5.00 to 2.60), 0.54
	Multiple	Medium HD + PA	SBP	IG1	12	170	130.1 (17.4)	-8.4 (20.29)	167	130 (17.6)	-7.5 (19.45)	-0.90 (-4.90 to 3.10), 0.65
Beune, 2014[49] (Culturally Adapted Hypertension Education (CAHE)) Fair	HTN	Medium HD + PA	DBP	IG1	6	71	91.02 (9.61)	-5.73 (9.33)	68	89.6 (9.36)	-1.7 (8.77)	-3.01 (-5.73 to -0.30), 0.032
	HTN	Medium HD + PA	SBP	IG1	6	71	156.73 (12.26)	-9.95 (14.53)	68	155.19 (10.69)	-6.26 (13.61)	-1.69 (-6.01 to 2.62), 0.444
Blackford, 2016[50] (Albany Physical Activity and	Multiple	Medium HD + PA	DBP	IG1	6	130	87.21 (9.02)	-2.34 (9.55)	144	85.99 (8.75)	-1.03 (9.32)	-1.31 (-3.55 to 0.93), 0.18
	Multiple	Medium HD + PA	SBP	IG1	6	130	138.54 (14.05)	-5.24 (15.17)	144	138.56 (14.36)	-2.24 (16.04)	-3.00 (-6.70 to 0.70), 0.06

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Nutrition (APAN)) Fair												
Bo, 2007[52] Fair	Multiple	Medium HD + PA	DBP	IG1	12	169	88.2 (8.8)	-2.57 (9.32)	166	87.8 (9.5)	-0.28 (9.99)	-2.29 (-4.36 to -0.22), 0.03
	Multiple	Medium HD + PA	DBP	IG1	108	169	88.2 (8.8)	-4.2 (9.28)	166	87.8 (9.5)	-2.3 (9.96)	-1.90 (-3.96 to 0.16), 0.17
	Multiple	Medium HD + PA	SBP	IG1	12	169	142.6 (14.1)	-1.99 (18.77)	166	141.5 (15.2)	4.79 (16.99)	-6.78 (-10.61 to -2.95), <0.001
	Multiple	Medium HD + PA	SBP	IG1	108	169	142.6 (14.1)	-4.6 (15.22)	166	141.5 (15.2)	2.3 (16.66)	-6.90 (-10.32 to -3.48), 0.002
Bosworth, 2009[53] (Take Control of Your Blood pressure (TCYB)) Fair	HTN	Medium HD + PA	DBP	IG1	12	113	72 (12)	-3.1 (10.89)	132	70 (10)	1 (8.93)	-2.20 (-3.50 to -0.80), 0.001
	HTN	Medium HD + PA	DBP	IG2	12	127	71 (10)	-1.4 (9.33)	132	70 (10)	1 (8.93)	-1.40 (-2.60 to -0.10), 0.03
	HTN	Medium HD + PA	DBP	IG1	24	113	72 (12)	-3.2 (11.29)	132	70 (10)	1 (8.93)	-2.20 (-3.80 to -0.60), 0.009
	HTN	Medium HD + PA	DBP	IG2	24	127	71 (10)	0.4 (9.96)	132	70 (10)	1 (8.93)	0.40 (-1.10 to 1.90), 0.61
	HTN	Medium HD + PA	SBP	IG1	12	113	126 (20)	-5.2 (18.99)	132	124 (18)	0.7 (16.11)	-3.30 (-5.70 to -0.80), 0.009
	HTN	Medium HD + PA	SBP	IG2	12	127	124 (18)	-0.9 (16.71)	132	124 (18)	0.7 (16.11)	-1.60 (-3.90 to 0.70), 0.174
	HTN	Medium HD + PA	SBP	IG1	24	113	126 (20)	-4.5 (18.2)	132	124 (18)	0.7 (16.08)	-3.90 (-6.90 to -0.90), 0.01
	HTN	Medium HD + PA	SBP	IG2	24	127	124 (18)	1.2 (17.71)	132	124 (18)	0.7 (16.08)	0.60 (-2.20 to 3.40), 0.67
Broekhuizen, 2012[54] (PRO-FIT) Fair	Dys	Medium HD + PA	SBP	IG1	12	169	123 (14.4)	0 (14.95)	143	126.3 (15.7)	-1.1 (15.82)	1.10 (-2.34 to 4.54), NSD
Bruckert, 2008[55] (PEGASE (Effect of an Education Program)) Fair	Dys	Medium HD + PA	SBP	IG1	6	274	NR (NR)	-0.63 (NR)	199	NR (NR)	0.34 (NR)	NR, NSD

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Burke, 2006[56] (ADAPT) Fair	HTN	Medium HD + PA	DBP	IG1	16	106	77 (10.3)	0 (10.8)	98	76 (9.9)	2 (10.38)	-2.00 (-4.91 to 0.91), 0.62
	HTN	Medium HD + PA	DBP	IG1	40	123	77 (8.49)	0 (8.9)	118	76 (8.31)	1 (8.72)	-1.00 (-2.40 to 0.30), 0.146
	HTN	Medium HD + PA	SBP	IG1	16	106	128 (10.3)	2 (10.8)	98	126 (9.9)	4 (10.38)	-2.00 (-4.91 to 0.91), 0.729
	HTN	Medium HD + PA	SBP	IG1	40	123	128 (11.32)	-1 (11.87)	118	125 (11.08)	1 (11.62)	-1.40 (-3.50 to 0.70), 0.373
Chirinos, 2016[57] (Community Health and Risk-reduction for Metabolic Syndrome (CHARMS)) Fair	Multiple	High HD + PA	DBP	IG1	6	60	79.35 (9.49)	-3.02 (NR)	60	79.27 (9.57)	-2.54 (NR)	NR
	Multiple	High HD + PA	DBP	IG1	12	60	79.35 (9.49)	-0.93 (NR)	60	79.27 (9.57)	-3.8 (NR)	NR, NSD
	Multiple	High HD + PA	SBP	IG1	6	60	124.85 (16.46)	-1.83 (NR)	60	125.45 (17.31)	-4.8 (NR)	NR
	Multiple	High HD + PA	SBP	IG1	12	60	124.85 (16.46)	-0.64 (NR)	60	125.45 (17.31)	-6.32 (NR)	NR, NSD
Christian, 2011[58] Fair	Multiple	Medium HD + PA	DBP	IG1	12	133	83.2 (10.73)	-2.5 (12.26)	130	80.4 (10.23)	-0.9 (11.23)	-1.60 (-9.62 to 6.42), 0.13
	Multiple	Medium HD + PA	SBP	IG1	12	133	130.2 (14.3)	-2.2 (14.78)	130	129.9 (17.95)	-0.5 (18.43)	-1.70 (-13.14 to 9.74), 0.2
Cicolini, 2014[59] Fair	HTN	Medium HD + PA	DBP	IG1	6	100	87.5 (5.7)	-11 (5.7)	98	88.6 (2.3)	-7.6 (3.4)	-3.40 (-4.70 to -2.10), <0.001
	HTN	Medium HD + PA	SBP	IG1	6	100	150 (11)	-14.9 (8.1)	98	153 (12)	-10 (11.6)	-4.90 (-7.69 to -2.11), <0.001
Cochrane, 2012[60] Fair	Multiple	Medium HD + PA	DBP	IG1	12	236	85.3 (9.6)	-3.31 (8.35)	365	84.9 (9.5)	-3.56 (9.31)	0.25 (-1.18 to 1.68), NSD
	Multiple	Medium HD + PA	SBP	IG1	12	236	144.4 (16.2)	-5.64 (14.85)	365	146 (17)	-6.65 (16.67)	1.01 (-1.54 to 3.56), NSD
Cohen, 1991[61] Fair	HTN	Medium HD only	MAP (mean arterial pressure)	IG1	6	15	105.6 (NR)	1.2 (13.7)	15	105.9 (NR)	-2.3 (7.5)	3.50 (-4.40 to 11.40), >0.1
	HTN	Medium HD only	MAP (mean	IG1	12	15	105.6 (NR)	3 (14.2)	15	105.9 (NR)	-0.7 (11.3)	3.70 (-5.48 to 12.88), >0.1

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
			arterial pressure)									
Coleman, 2012[62] (Wisewoman California) Fair	Multiple	Medium HD + PA	DBP	IG1	12	433	76.6 (8.46)	-3.8 (NR)	436	77.2 (9.3)	-2.5 (NR)	NR, 0.103
	Multiple	Medium HD + PA	SBP	IG1	12	433	124.9 (13.39)	-5.9 (NR)	436	125.5 (13.96)	-3.7 (NR)	NR, 0.038
Ellsworth, 2016[66] Fair	Multiple	High HD + PA	DBP	IG1	12	89	80 (11.5)	-6.3 (14.2)	58	78.9 (11)	-1.6 (NR)	NR, 0.047
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	DBP	IG1	12	78	74.9 (6.98)	-1.63 (6.78)	75	73.6 (7.95)	0.73 (5.08)	-2.36 (-4.25 to -0.47), <0.05
	Multiple	High HD only	DBP	IG2	12	82	74.2 (7.85)	-1.51 (5.52)	75	73.6 (7.95)	0.73 (5.08)	-2.24 (-3.90 to -0.58), <0.05
	Multiple	High HD only	SBP	IG1	12	78	130.5 (14.42)	-2.94 (10.61)	75	126.4 (13.26)	2.36 (8.09)	-5.30 (-8.28 to -2.32), <0.05
	Multiple	High HD only	SBP	IG2	12	82	128.9 (13.63)	-3.12 (9.33)	75	126.4 (13.26)	2.36 (8.09)	-5.48 (-8.21 to -2.75), <0.05
Fagerberg, 1998[68] (Risk Factor Intervention Study (RIS)) Good (KQ1); Fair (KQ2)	Multiple	High HD + PA	DBP	IG1	12	239	91 (8)	-2.5 (8)	238	91 (9)	-0.8 (9.2)	-1.60 (-3.15 to -0.05), 0.039
	Multiple	High HD + PA	DBP	IG1	40	235	91 (8)	-4.9 (9.1)	227	91 (9)	-3.8 (9.6)	MD=-1.10 (-2.80 to 0.60), 0.2
	Multiple	High HD + PA	DBP	IG1	79	248	91 (8)	-4 (6.43)	252	91 (9)	-3 (7.69)	-1.00 (-2.29 to 0.29),
	Multiple	High HD + PA	SBP	IG1	12	239	155 (18)	-3 (16)	238	155 (20)	-2 (20)	-2.00 (-5.51 to 1.51), 0.34
	Multiple	High HD + PA	SBP	IG1	40	235	155 (18)	-2 (18.4)	227	155 (20)	-0.2 (20.5)	MD=-1.80 (-5.40 to 1.70), 0.31
	Multiple	High HD + PA	SBP	IG1	79	248	155 (18)	-1 (15.27)	252	155 (20)	1 (17.01)	-2.00 (-4.80 to 0.80),
Gill, 2019[69] (Heartmatters Challenge - First Responders) Fair	Multiple	High HD + PA	DBP	IG1	6	96	85.99 (10.23)	NR (NR)	79	84.32 (8.85)	NR (NR)	0.78 (-2.89 to 4.45), 0.69
	Multiple	High HD + PA	DBP	IG1	12	96	85.99 (10.23)	NR (NR)	79	84.32 (8.85)	NR (NR)	-1.55 (-5.16 to 2.06), 0.43
	Multiple	High HD + PA	SBP	IG1	6	96	128.03 (14.06)	NR (NR)	79	129.49 (15.28)	NR (NR)	-1.46 (-5.58 to 2.66), 0.51

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	SBP	IG1	12	96	128.03 (14.06)	NR (NR)	79	129.49 (15.28)	NR (NR)	0.05 (-3.99 to 4.09), 0.98
Gill, 2019[70] (HealtheSteps) Fair	Multiple	Medium HD + PA	DBP	IG1	6	59	NR (NR)	-1.57 (9.86)	59	NR (NR)	-1.84 (9.63)	0.27 (-3.26 to 3.81), 0.88
	Multiple	Medium HD + PA	SBP	IG1	6	59	NR (NR)	-6.38 (15.54)	59	NR (NR)	-6.61 (15)	0.23 (-5.02 to 5.48), 0.93
Greaves, 2015[71] (Waste the Waist) Fair	Multiple	High HD + PA	DBP	IG1	12	55	79.8 (13.7)	NR (NR)	53	84.3 (9.3)	NR (NR)	0.30 (-3.50 to 4.09), NSD
	Multiple	High HD + PA	SBP	IG1	12	55	137.7 (15.7)	NR (NR)	53	139.5 (16.4)	NR (NR)	1.09 (-3.67 to 5.85), NSD
Groeneveld, 2010[72] (Health Under Construction) Fair	Multiple	Medium HD + PA	DBP	IG1	6	259	89.1 (9.7)	-3.9 (10.73)	257	88.5 (9.4)	-2 (9.86)	-1.90 (-3.68 to -0.12), <0.05
	Multiple	Medium HD + PA	DBP	IG1	12	259	89.1 (9.7)	-3.7 (10.44)	257	88.5 (9.4)	-3.2 (10.07)	-0.50 (-2.27 to 1.27), NSD
	Multiple	Medium HD + PA	SBP	IG1	6	259	143 (15.8)	-5.2 (16.68)	257	141 (14.8)	-2.1 (16.07)	-3.10 (-5.93 to -0.27), NSD
	Multiple	Medium HD + PA	SBP	IG1	12	259	143 (15.8)	-4.9 (17)	257	141 (14.8)	-3.8 (16.3)	-1.10 (-3.97 to 1.77), NSD
Hardcastle, 2008[73] Fair	Multiple	Medium HD + PA	DBP	IG1	6	203	83.42 (9.63)	-1.9 (9.59)	131	81.92 (9.27)	0.78 (9.57)	-2.68 (-4.78 to -0.58), <0.05
	Multiple	Medium HD + PA	DBP	IG1	18	203	83.42 (9.63)	-1.02 (9.8)	131	81.92 (9.27)	0.89 (9.18)	-1.91 (-3.98 to 0.16), <0.01
	Multiple	Medium HD + PA	SBP	IG1	6	203	133.12 (16.53)	-2.87 (16.96)	131	132.41 (17.33)	-0.6 (18.24)	-2.27 (-6.17 to 1.63), NSD
	Multiple	Medium HD + PA	SBP	IG1	18	203	133.12 (16.53)	-4.14 (16.33)	131	132.41 (17.33)	-2.45 (18.4)	-1.69 (-5.56 to 2.18), NSD
Harris, 2012[74] (Health Improvement and Prevention Study (HIPS)) Fair	Multiple	High HD + PA	SBP	IG1	12	355	NR (NR)	NR (NR)	300	NR (NR)	NR (NR)	NR, 0.9
Haufe, 2019[75] Fair	Multiple	Medium HD + PA	SBP	IG1	6	160	138 (13)	-6 (12.7)	154	138 (14)	-3 (13.74)	-2.70 (-4.90 to -0.40), 0.020

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Hinderliter, 2014[76] (Exercise and Nutrition interventions for CardiOvasculaR hEalth (ENCORE)) Good	HTN	High HD only	DBP	IG1	12	46	86 (6)	-4.6 (6.81)	49	86 (6)	-6.4 (6.85)	1.80 (-0.95 to 4.55), NSD
	HTN	High HD only	SBP	IG1	12	46	138 (9)	-9.5 (9.09)	49	138 (9)	-3.9 (11.84)	-5.60 (-9.83 to -1.37), <0.05
HPT, 1990[77] (Hypertension Prevention Trial (HPT)) Good	HTN	High HD only	DBP	IG1	6	180	82.3 (NR)	-3.7 (6.71)	191	83 (NR)	-3 (6.91)	-0.70 (-2.09 to 0.69), <0.05
	HTN	High HD only	DBP	IG2	6	173	82.6 (NR)	-3.4 (6.58)	191	83 (NR)	-3 (6.91)	-0.40 (-1.77 to 0.97), 0.664
	HTN	High HD only	DBP	IG3	6	112	83 (NR)	-5.3 (7.41)	121	83.3 (NR)	-2.5 (7.7)	-2.80 (-4.76 to -0.84), 0.01
	HTN	High HD only	DBP	IG4	6	113	82.6 (NR)	-4 (7.44)	121	83.3 (NR)	-2.5 (7.7)	-1.50 (-3.44 to 0.44), <0.05
	HTN	High HD only	DBP	IG1	36	178	82.3 (NR)	-3.7 (6.67)	177	83 (NR)	-3 (6.65)	-0.70 (-2.09 to 0.69), <0.05
	HTN	High HD only	DBP	IG2	36	174	82.6 (NR)	-2.8 (6.6)	177	83 (NR)	-3 (6.65)	-0.90 (-2.27 to 0.47), 0.398
	HTN	High HD only	DBP	IG3	36	117	83 (NR)	-4.2 (8.65)	115	83.3 (NR)	-2.4 (8.58)	-1.80 (-3.96 to 0.36), 0.045
	HTN	High HD only	DBP	IG4	36	115	82.6 (NR)	-3.7 (8.58)	115	83.3 (NR)	-2.4 (8.58)	-1.30 (-3.52 to 0.92), <0.05
	HTN	High HD only	SBP	IG1	6	180	124.1 (NR)	-3.4 (8.05)	191	123.9 (NR)	-2.1 (8.29)	-1.30 (-2.96 to 0.36), <0.05
	HTN	High HD only	SBP	IG2	6	173	124 (NR)	-3.8 (7.89)	191	123.9 (NR)	-2.1 (8.29)	-1.70 (-3.46 to 0.06), 0.126
	HTN	High HD only	SBP	IG3	6	112	125.3 (NR)	-6.9 (7.41)	121	124.7 (NR)	-1.8 (7.7)	-5.10 (-7.06 to -3.14), <0.001
	HTN	High HD only	SBP	IG4	6	113	124.4 (NR)	-5.8 (7.44)	121	124.7 (NR)	-1.8 (7.7)	-4.00 (-5.94 to -2.06), <0.05
	HTN	High HD only	SBP	IG1	36	178	124.1 (NR)	-4.1 (9.34)	177	123.9 (NR)	-2.9 (9.31)	-1.20 (-3.14 to 0.74), <0.05
	HTN	High HD only	SBP	IG2	36	174	124 (NR)	-2.8 (9.23)	177	123.9 (NR)	-2.9 (9.31)	0.10 (-1.86 to 2.06), 0.885

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	High HD only	SBP	IG3	36	117	125.3 (NR)	-5 (9.73)	115	124.7 (NR)	-2.6 (9.65)	-2.40 (-4.95 to 0.15), 0.031
	HTN	High HD only	SBP	IG4	36	115	124.4 (NR)	-3.6 (9.65)	115	124.7 (NR)	-2.6 (9.65)	-1.00 (-3.49 to 1.49), NSD
Hyman, 2007[79] Fair	HTN	Medium HD + PA	DBP	IG1	6	92	83.7 (9.1)	-2.3 (9.34)	93	84.8 (8.9)	-3.1 (9.61)	0.80 (-1.93 to 3.53), NSD
	HTN	Medium HD + PA	DBP	IG2	6	96	87.4 (9.5)	-4.1 (11.82)	93	84.8 (8.9)	-3.1 (9.61)	-1.00 (-4.07 to 2.07), NSD
	HTN	Medium HD + PA	DBP	IG1	18	92	83.7 (9.1)	-1.6 (9.93)	93	84.8 (8.9)	-3.1 (9.72)	1.50 (-1.33 to 4.33), NSD
	HTN	Medium HD + PA	DBP	IG2	18	96	87.4 (9.5)	-3.9 (10.95)	93	84.8 (8.9)	-3.1 (9.72)	-0.80 (-3.75 to 2.15), NSD
	HTN	Medium HD + PA	SBP	IG1	6	92	137.4 (19.1)	-5.8 (19.38)	93	137.2 (17.2)	-3.3 (19.1)	-2.50 (-8.05 to 3.05), NSD
	HTN	Medium HD + PA	SBP	IG2	6	96	142 (18)	-7.6 (21.12)	93	137.2 (17.2)	-3.3 (19.1)	-4.30 (-10.04 to 1.44), NSD
	HTN	Medium HD + PA	SBP	IG1	18	92	137.4 (19.1)	-6.5 (19.62)	93	137.2 (17.2)	-2.9 (18.7)	-3.60 (-9.12 to 1.92), NSD
	HTN	Medium HD + PA	SBP	IG2	18	96	142 (18)	-7.9 (20.06)	93	137.2 (17.2)	-2.9 (18.7)	-5.00 (-10.53 to 0.53), <0.05
Jones, 1999[82] (Hypertension Optimal Treatment (HOT)) Fair	HTN	High HD only	DBP	IG1	6	51	105 (5)	-21.71 (4.49)	51	105 (4)	-22.59 (3.61)	0.88 (-0.70 to 2.46), NSD
	HTN	High HD only	DBP	IG1	12	51	105 (5)	-21.41 (4.48)	51	105 (4)	-22.68 (3.8)	1.27 (-0.34 to 2.88), NSD
	HTN	High HD only	DBP	IG1	18	51	105 (5)	-22.04 (4.47)	51	105 (4)	-21.71 (3.94)	-0.33 (-1.96 to 1.30), NSD
	HTN	High HD only	DBP	IG1	24	51	105 (5)	-21.94 (4.47)	51	105 (4)	-22.9 (3.68)	0.96 (-0.63 to 2.55), NSD
	HTN	High HD only	DBP	IG1	30	51	105 (5)	-20.47 (4.52)	51	105 (4)	-22.9 (3.61)	2.43 (0.84 to 4.02), NSD
	HTN	High HD only	SBP	IG1	6	51	165 (16)	-32 (15.02)	51	167 (12)	-32.88 (10.72)	0.88 (-4.18 to 5.94), NSD
	HTN	High HD only	SBP	IG1	12	51	165 (16)	-29.96 (14.72)	51	167 (12)	-32.96 (10.73)	3.00 (-2.00 to 8.00), NSD

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	High HD only	SBP	IG1	18	51	165 (16)	-32.43 (14.94)	51	167 (12)	-31.35 (10.75)	-1.08 (-6.13 to 3.97), NSD
	HTN	High HD only	SBP	IG1	24	51	165 (16)	-32.06 (14.6)	51	167 (12)	-34.17 (10.72)	2.11 (-2.86 to 7.08), NSD
	HTN	High HD only	SBP	IG1	30	51	165 (16)	-33.14 (14.71)	51	167 (12)	-33.94 (10.74)	0.80 (-4.20 to 5.80), NSD
Kandula, 2015[83] (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	Multiple	High HD + PA	SBP	IG1	6	31	127 (17)	-3.6 (11.52)	32	130 (17)	-3.4 (11.58)	-0.20 (-5.43 to 5.00), NSD
Kanke, 2015[84] Fair	Multiple	Medium HD + PA	DBP	IG1	6	25	NR (NR)	NR (NR)	19	NR (NR)	NR (NR)	NR, NSD
	Multiple	Medium HD + PA	DBP	IG1	12	22	NR (NR)	NR (NR)	18	NR (NR)	NR (NR)	NR, NSD
	Multiple	Medium HD + PA	SBP	IG1	6	25	NR (NR)	NR (NR)	19	NR (NR)	NR (NR)	NR, NSD
	Multiple	Medium HD + PA	SBP	IG1	12	22	NR (NR)	NR (NR)	18	NR (NR)	NR (NR)	NR, NSD
Kastarinen, 2002[85] (Lifestyle Intervention against Hypertension in Eastern Finland (LIHEF)) Fair	HTN	High HD + PA	DBP	IG1	12	360	91 (9)	-4 (NR)	355	91 (8)	-2.4 (NR)	MD=-1.60 (-2.70 to -0.60), <0.05
	HTN	High HD + PA	DBP	IG1	24	360	91 (9)	-4.3 (NR)	355	91 (8)	-3.2 (NR)	-1.10 (-2.40 to 0.20), <0.05
	HTN	High HD + PA	SBP	IG1	12	360	149 (16)	-4.7 (NR)	355	148 (16)	-3.4 (NR)	MD=-1.30 (-3.20 to 0.60), <0.05
	HTN	High HD + PA	SBP	IG1	24	360	149 (16)	-6.2 (NR)	355	148 (16)	-4.2 (NR)	-2.00 (-4.30 to 0.30), <0.05
Khanji, 2019[87] (HAPPY London) Good	Multiple	Low HD + PA	DBP	IG1	6	194	79.2 (9.2)	-2.37 (9.6)	183	80 (8.6)	-2.08 (9.07)	-0.29 (-1.60 to 1.10), 0.67
	Multiple	Low HD + PA	SBP	IG1	6	194	132.5 (13.3)	-3.18 (14.11)	183	132.3 (14.8)	-1.69 (15.47)	-1.50 (-4.20 to 1.20), 0.27
Koelewijn-van Loon, 2009 (Improving Patient	Multiple	Medium HD + PA	SBP	IG1	12	286	144 (19)	-6 (18.53)	261	150 (19)	-8 (18.53)	2.00 (-1.11 to 5.11), 0.004

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Adherence to Lifestyle Advice (IMPALA)) Fair												
Kramer, 2018[89] (Healthy Lifestyle Project) Fair	Multiple	High HD + PA	DBP	IG1	6	74	72.3 (8.8)	-1 (9.1)	41	73.2 (11.5)	-1.2 (9.6)	0.20 (-3.40 to 3.80), 0.88
	Multiple	High HD + PA	SBP	IG1	6	74	118.2 (11.7)	-3.4 (11.2)	41	119.1 (12.2)	-0.3 (10.3)	-3.10 (-7.16 to 0.96), 0.13
Langford, 1991[91] (Trial of Antihypertensive Interventions and Management (TAIM)) Fair	HTN	High HD + PA	DBP	IG1	6	265	93.8 (NR)	-12.84 (10.02)	264	93.6 (NR)	-10.36 (7.81)	-2.48 (-4.30 to -0.66), 0.001
	HTN	High HD only	DBP	IG2	6	258	94 (NR)	-11.07 (8.89)	264	93.6 (NR)	-10.36 (7.81)	-0.71 (-2.53 to 1.11), 0.347
	HTN	High HD + PA	SBP	IG1	6	265	142.3 (NR)	-17 (15.95)	264	143.1 (NR)	-14.2 (15.95)	-2.80 (-5.52 to -0.08), <0.05
	HTN	High HD only	SBP	IG2	6	258	144.8 (NR)	-15.8 (15.95)	264	143.1 (NR)	-14.2 (15.95)	-1.60 (-4.34 to 1.14), NSD
Lee, 2007[92] Fair	HTN	Medium PA only	DBP	IG1	6	91	83.5 (11.2)	-6.47 (9.5)	93	80.6 (8.8)	-4.71 (8.5)	-1.80 (-4.40 to 0.90), 0.19
	HTN	Medium PA only	SBP	IG1	6	91	152 (10.5)	-16.2 (14.8)	93	152.4 (11.1)	-8.1 (14.3)	-8.10 (-12.00 to -2.70), 0.002
Liira, 2014[93] Fair	Multiple	Medium HD + PA	DBP	IG1	12	46	82 (9.5)	1 (10.35)	42	84 (9.7)	-1 (10.17)	2.00 (-2.29 to 6.29), NSD
	Multiple	Medium HD + PA	SBP	IG1	12	46	132 (14.3)	3 (13.85)	42	136 (13.9)	-2 (13.76)	5.00 (-0.77 to 10.77), NSD
Migneault, 2012[94] Fair	HTN	High HD + PA	DBP	IG1	8	169	80.9 (12.5)	-1.28 (NR)	168	80.3 (11.8)	-0.1 (NR)	-1.18 (NR), NSD
	HTN	High HD + PA	DBP	IG1	12	169	80.9 (12.5)	-0.4 (NR)	168	80.3 (11.8)	-0.5 (NR)	NR, NSD
	HTN	High HD + PA	SBP	IG1	8	169	130.6 (19.8)	-2.06 (NR)	168	131.8 (18.6)	0.25 (NR)	-2.31 (NR), NSD
	HTN	High HD + PA	SBP	IG1	12	169	130.6 (19.8)	0.9 (NR)	168	131.8 (18.6)	-1.4 (NR)	NR, NSD
Moreau, 2001[95] Fair	HTN	Low PA only	DBP	IG1	6	15	84 (3.87)	-3 (3.07)	9	86 (6)	0.7 (2.28)	-3.70 (-5.85 to -1.55), NSD

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	Low PA only	SBP	IG1	6	15	142 (11.62)	-11 (4.94)	9	142 (9)	-0.8 (4.29)	-10.20 (-13.96 to -6.44), <0.05
Muhlhauser, 1993[97] (Hypertension Treatment and Teaching Program (HTTP)) Fair	HTN	Medium HD + PA	DBP	IG1	18	86	100 (7)	-6 (11)	74	98 (7)	-2 (10)	-4.00 (1.00 to 7.00), 0.018
	HTN	Medium HD + PA	SBP	IG1	18	86	162 (14)	-8 (17)	74	161 (13)	-3 (18)	-5.00 (0.00 to 10.00), 0.071
Niiranen, 2014[100] Fair	HTN	Medium HD + PA	DBP	IG1	12	112	87 (9)	-6 (8)	108	87 (8)	-7 (8)	1.00 (-4.46 to 6.46), 0.16
	HTN	Medium HD + PA	SBP	IG1	12	112	146 (19)	-8 (17)	108	148 (20)	-11 (17)	3.00 (-8.61 to 14.61), 0.25
Nolan, 2018[101] (Reducing Risk with E-based Support for Adherence to Lifestyle Change in Hypertension (REACH)) Fair	HTN	High HD + PA	DBP	IG1	12	100	87.3 (8.83)	-4.9 (7.4)	97	87.3 (8.76)	-3.5 (7.29)	-1.40 (-3.45 to 0.65), 0.17
	HTN	High HD + PA	SBP	IG1	12	100	141.5 (11.77)	-10.1 (12.5)	97	140.6 (11.68)	-6 (12.56)	-4.10 (-7.60 to -0.60), 0.02
Ogedegbe, 2014[102] (Counseling African Americans to Control Hypertension (CAATCH)) Fair	HTN	Medium HD + PA	DBP	IG1	6	529	91 (10)	-9 (NR)	510	91 (11)	-8.3 (NR)	NR, 0.6
	HTN	Medium HD + PA	DBP	IG1	9	529	91 (10)	-9.9 (NR)	510	91 (11)	-9.9 (NR)	NR, 0.86
	HTN	Medium HD + PA	DBP	IG1	12	529	91 (10)	-9.9 (NR)	510	91 (11)	-9.1 (NR)	NR, 0.46
	HTN	Medium HD + PA	SBP	IG1	6	529	150 (17)	-16 (NR)	510	153 (17)	-15.7 (NR)	NR, 0.82
	HTN	Medium HD + PA	SBP	IG1	9	529	150 (17)	-17.2 (NR)	510	153 (17)	-18 (NR)	NR, 0.62
	HTN	Medium HD + PA	SBP	IG1	12	529	150 (17)	-16.6 (NR)	510	153 (17)	-16.6 (NR)	NR, 0.96
Reid, 2014[103] Fair	Multiple	High HD + PA	DBP	IG1	12	211	76.8 (9)	-1.3 (9.71)	215	76.3 (9.9)	-1.5 (9.81)	0.20 (-1.65 to 2.05), 0.4

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	SBP	IG1	12	211	121.8 (15.3)	-3.3 (15.55)	215	120.4 (16.9)	-2.9 (16.68)	-0.40 (-3.46 to 2.66), 0.9
Rodriguez, 2012[104] Fair	HTN	Medium HD + PA	SBP	IG1	6	176	135.96 (13.78)	-4.7 (14.89)	177	137 (14.86)	-2.7 (3.39)	-2.00 (-4.26 to 0.26), 0.007
	HTN	Medium HD + PA	SBP	IG1	12	151	135.96 (13.78)	-5.38 (14.78)	157	137 (14.86)	-4.05 (15.03)	-1.33 (-4.66 to 2.00), NSD
Rodriguez-Cristobal, 2012[105] Fair	Multiple	High HD + PA	DBP	IG1	24	146	80.7 (9.8)	-5.2 (10.23)	154	81.7 (9.4)	-1.3 (9.51)	MD=-4.40 (-6.80 to -2.00), 0.0001
	Multiple	High HD + PA	SBP	IG1	24	146	133.8 (17.4)	-4.2 (17.16)	154	134.7 (18)	2.2 (17.41)	MD=-6.80 (-10.70 to -2.80), 0.0001
Rosas, 2015[106] (Vivamos Activos Fair Oaks (VAFO)) Good	Multiple	High HD + PA	DBP	IG1	6	82	74.1 (7.2)	-0.2 (6.47)	41	73.8 (8.6)	0.3 (7.13)	-0.50 (-3.09 to 2.09), 0.72
	Multiple	High HD + PA	DBP	IG2	6	84	73 (7.6)	-0.1 (6.55)	41	73.8 (8.6)	0.3 (7.13)	-0.40 (-2.99 to 2.19), 0.73
	Multiple	High HD + PA	DBP	IG1	12	82	74.1 (7.2)	0.3 (9.01)	41	73.8 (8.6)	-1.3 (8.87)	1.60 (-1.74 to 4.94), 0.4
	Multiple	High HD + PA	DBP	IG2	12	84	73 (7.6)	-0.6 (7.95)	41	73.8 (8.6)	-1.3 (8.87)	0.70 (-2.50 to 3.90), 0.62
	Multiple	High HD + PA	DBP	IG1	24	82	74.1 (7.2)	0.9 (8.32)	41	73.8 (8.6)	-0.2 (6.34)	1.10 (-1.55 to 3.75), 0.46
	Multiple	High HD + PA	DBP	IG2	24	84	73 (7.6)	1.2 (7.95)	41	73.8 (8.6)	-0.2 (6.34)	1.40 (-1.18 to 3.98), 0.33
	Multiple	High HD + PA	SBP	IG1	6	82	114.8 (12.7)	-1.8 (11.09)	41	117.2 (13.9)	-2.2 (13.31)	0.40 (-4.33 to 5.13), 0.87
	Multiple	High HD + PA	SBP	IG2	6	84	114.5 (13)	-0.1 (13.09)	41	117.2 (13.9)	-2.2 (13.31)	2.10 (-2.84 to 7.04), 0.41
	Multiple	High HD + PA	SBP	IG1	12	82	114.8 (12.7)	-1.3 (13.63)	41	117.2 (13.9)	-3 (15.05)	1.70 (-3.77 to 7.17), 0.57
	Multiple	High HD + PA	SBP	IG2	12	84	114.5 (13)	-2.2 (13.33)	41	117.2 (13.9)	-3 (15.05)	0.80 (-4.62 to 6.22), 0.77
	Multiple	High HD + PA	SBP	IG1	24	82	114.8 (12.7)	0.5 (15.48)	41	117.2 (13.9)	-0.2 (12.83)	0.70 (-4.46 to 5.86), 0.79
	Multiple	High HD + PA	SBP	IG2	24	84	114.5 (13)	0.6 (13.56)	41	117.2 (13.9)	-0.2 (12.83)	0.80 (-4.08 to 5.68), 0.74

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Rubinstein, 2016[107] Good	HTN	Medium HD + PA	DBP	IG1	12	94	77 (7.2)	-0.5 (8.24)	96	77.6 (6.4)	-0.1 (7.67)	-1.08 (-3.32 to 1.15), 0.32
	HTN	Medium HD + PA	SBP	IG1	12	94	128.9 (5.5)	-4 (9.41)	96	128 (6)	-2.2 (10.99)	-1.77 (-5.06 to 1.52), 0.29
Salisbury, 2016[108] Good	Multiple	Medium HD + PA	DBP	IG1	6	301	81.2 (9.6)	-3 (10.23)	296	80 (10.4)	-2 (10.56)	MD=-0.60 (-1.80 to 0.60), 0.34
	Multiple	Medium HD + PA	DBP	IG1	12	295	81.2 (9.6)	-4.6 (9.86)	291	80 (10.4)	-1.3 (10.65)	MD=-2.80 (-4.00 to -1.60), <0.001
	Multiple	Medium HD + PA	SBP	IG1	6	301	147.6 (16.2)	-6.6 (16.44)	296	148.1 (17.6)	-6.7 (17.41)	MD=0.00 (-1.90 to 1.90), 0.1
	Multiple	Medium HD + PA	SBP	IG1	12	295	147.6 (16.2)	-8 (15.95)	291	148.1 (17.6)	-5.9 (17.72)	MD=-2.70 (-4.70 to -0.60), 0.01
Schoenthaler, 2016[109] (Individual Motivational Interviewing - Therapeutic Lifestyle Changes (MINT-TLC)) Fair	HTN	High HD + PA	DBP	IG1	6	97	88.2 (10.83)	-7.2 (11.91)	97	90.1 (10.83)	-7.6 (11.91)	0.40 (-2.95 to 3.75), 0.7921
	HTN	High HD + PA	SBP	IG1	6	97	145.4 (13.79)	-9.5 (15.58)	97	147.2 (13.79)	-12.9 (15)	3.40 (-0.90 to 7.70), 0.1819
Stefanick, 1998[112] (Diet and Exercise for Elevated Risk (DEER)) Fair	Dys	High HD only	DBP	IG1 (Females)	12	46	NR (NR)	-1.9 (5)	45	NR (NR)	-0.6 (5.9)	-1.30 (-3.55 to 0.95), NSD
	Dys	High HD only	DBP	IG1 (Males)	12	49	NR (NR)	0.3 (5.2)	46	NR (NR)	1.8 (6.1)	-1.50 (-3.79 to 0.79), NSD
	Dys	High HD only	SBP	IG1 (Females)	12	46	NR (NR)	-3.5 (9.2)	45	NR (NR)	-2.4 (7.6)	-1.10 (-4.56 to 2.36), NSD
	Dys	High HD only	SBP	IG1 (Males)	12	49	NR (NR)	-1.7 (6.4)	46	NR (NR)	-0.3 (7.9)	-1.40 (-4.30 to 1.50), NSD
Svetkey, 2009[115] (Hypertension Improvement Project (HIP)) Fair	HTN	High HD + PA	DBP	IG1	6	132	75.3 (11.1)	-5.4 (NR)	132	73.3 (10.5)	-3.6 (NR)	NR, NSD
	HTN	High HD + PA	DBP	IG2	6	124	73.3 (12.6)	-3.4 (NR)	132	73.3 (10.5)	-3.6 (NR)	NR, NSD
	HTN	Medium HD + PA	DBP	IG3	6	137	74.3 (11)	-3.2 (NR)	132	73.3 (10.5)	-3.6 (NR)	NR, NSD

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	High HD + PA	DBP	IG1	18	128	75.3 (11.1)	-5.3 (NR)	122	73.3 (10.5)	-4.9 (NR)	NR, NSD
	HTN	High HD + PA	DBP	IG2	18	124	73.3 (12.6)	-3.4 (NR)	122	73.3 (10.5)	-4.9 (NR)	NR, NSD
	HTN	Medium HD + PA	DBP	IG3	18	134	74.3 (11)	-4.6 (NR)	122	73.3 (10.5)	-4.9 (NR)	NR, NSD
	HTN	High HD + PA	SBP	IG1	6	132	133.8 (16.3)	-9.7 (12.7)	132	131.6 (14.6)	-6.7 (12.8)	-3.00 (-6.08 to 0.08), NSD
	HTN	High HD + PA	SBP	IG2	6	124	132.1 (17.6)	-7.1 (12.1)	132	131.6 (14.6)	-6.7 (12.8)	-0.40 (-3.45 to 2.65), NSD
	HTN	Medium HD + PA	SBP	IG3	6	137	134.6 (15.7)	-5.3 (12.1)	132	131.6 (14.6)	-6.7 (12.8)	1.40 (-1.58 to 4.38), NSD
	HTN	High HD + PA	SBP	IG1	18	128	133.8 (16.3)	-8.6 (NR)	122	131.6 (14.6)	-7.5 (NR)	NR, NSD
	HTN	High HD + PA	SBP	IG2	18	124	132.1 (17.6)	-6.8 (NR)	122	131.6 (14.6)	-7.5 (NR)	NR, NSD
	HTN	Medium HD + PA	SBP	IG3	18	134	134.6 (15.7)	-7.5 (NR)	122	131.6 (14.6)	-7.5 (NR)	NR, NSD
Ter Bogt, 2009[116] (Groningen Overweight and Lifestyle (GOAL)) Good	Multiple	High HD + PA	DBP	IG1 (Females)	12	103	NR (NR)	-0.3 (9.6)	114	NR (NR)	0.2 (8.4)	-0.50 (-2.91 to 1.91), NSD
	Multiple	High HD + PA	DBP	IG1 (Males)	12	98	NR (NR)	-2.6 (11.2)	101	NR (NR)	-1.3 (7.8)	-1.30 (-3.99 to 1.39), NSD
	Multiple	High HD + PA	SBP	IG1 (Females)	12	103	NR (NR)	-5.3 (20.1)	114	NR (NR)	-2.2 (16.5)	-3.10 (-8.02 to 1.82), NSD
	Multiple	High HD + PA	SBP	IG1 (Males)	12	98	NR (NR)	-8.5 (16.8)	101	NR (NR)	-5.3 (12.7)	-3.20 (-7.35 to 0.95), NSD
Tiessen, 2012[117] (SPRING (Self-monitoring and Prevention of RIsk Factors by Nurse practitioners in the region of Groningen)) Fair	Multiple	Medium HD + PA	DBP	IG1	12	89	92 (9.5)	-4.4 (9.39)	90	91 (8.5)	-3.3 (7.26)	-1.10 (-3.50 to 1.40), NSD
	Multiple	Medium HD + PA	SBP	IG1	12	89	158 (17.1)	-6.8 (17.09)	90	158 (16.3)	-5.6 (14.28)	-1.20 (-5.80 to 3.40), NSD

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
TOHP I CRG, 1992[119] (Trials of Hypertension Prevention Phase I (TOHP I)) Good	HTN	High HD only	DBP	IG1	6	305	83.7 (2.7)	-3.88 (6.42)	397	83.9 (2.8)	-2.88 (6.32)	-1.00 (-1.95 to -0.04), <0.05
	HTN	High HD + PA	DBP	IG2	6	299	83.7 (2.6)	-6.3 (6.92)	239	84 (3)	-3.7 (6.18)	-2.50 (-3.68 to -1.32), <0.001
	HTN	High HD only	DBP	IG1	12	301	83.7 (2.7)	-4.44 (5.38)	392	83.9 (2.8)	-3.37 (5.74)	-1.06 (-1.90 to -0.22), <0.05
	HTN	High HD + PA	DBP	IG2	12	287	83.7 (2.6)	-5.8 (6.78)	237	84 (3)	-3.8 (6.16)	-2.00 (-2.98 to -1.02), <0.001
	HTN	High HD only	DBP	IG1	18	304	83.7 (2.7)	-4.35 (5.65)	395	83.9 (2.8)	-3.18 (5.8)	-1.17 (-2.03 to -0.31), <0.01
	HTN	High HD + PA	DBP	IG2	18	295	83.7 (2.6)	-6.2 (6.87)	236	84 (3)	-3.8 (6.14)	-2.40 (-3.38 to -1.42), <0.001
	HTN	High HD only	SBP	IG1	6	305	124.8 (8.5)	-5.86 (7.95)	397	125.1 (8.1)	-3.83 (8.46)	-2.03 (-3.26 to -0.80), <0.01
	HTN	High HD + PA	SBP	IG2	6	299	124.3 (8.4)	-6.5 (8.65)	239	124.6 (8.1)	-2.7 (7.73)	-3.80 (-5.17 to -2.43), 0.001
	HTN	High HD only	SBP	IG1	12	301	124.8 (8.5)	-5.83 (7.46)	392	125.1 (8.1)	-3.93 (7.43)	-1.90 (-3.02 to -0.78), <0.01
	HTN	High HD + PA	SBP	IG2	12	287	124.3 (8.4)	-5.4 (8.47)	237	124.6 (8.1)	-3.1 (7.7)	-2.30 (-3.67 to -0.93), 0.001
	HTN	High HD only	SBP	IG1	18	304	124.8 (8.5)	-5.08 (7.94)	395	125.1 (8.1)	-3.02 (8.31)	-2.06 (-3.28 to -0.84), <0.01
	HTN	High HD + PA	SBP	IG2	18	295	124.3 (8.4)	-5.3 (6.87)	236	124.6 (8.1)	-2.3 (7.68)	-2.90 (-4.27 to -1.53), <0.001
TOHP II CRG, 1997[120] (Trial of Hypertension Prevention II (TOHP II)) Good	HTN	High HD + PA	DBP	IG1	6	562	86 (1.9)	-5.6 (6.9)	538	85.8 (1.9)	-2.8 (6.1)	-2.80 (-3.58 to -2.02), <0.001
	HTN	High HD + PA	DBP	IG2	6	561	86 (1.9)	-5.5 (6.9)	538	85.8 (1.9)	-2.8 (6.1)	-2.70 (-3.48 to -1.92), <0.001
	HTN	High HD only	DBP	IG3	6	529	86.1 (1.9)	-4.4 (6.7)	538	85.8 (1.9)	-2.8 (6.1)	-1.60 (-2.38 to -0.82), <0.001
	HTN	High HD + PA	DBP	IG1	18	538	86 (1.9)	-4.5 (6.3)	525	85.8 (1.9)	-3.2 (5.8)	-1.30 (-2.08 to -0.52), <0.001
	HTN	High HD + PA	DBP	IG2	18	533	86 (1.9)	-4.5 (6.1)	525	85.8 (1.9)	-3.2 (5.8)	-1.30 (-2.08 to -0.52), <0.001

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	High HD only	DBP	IG3	18	513	86.1 (1.9)	-4.4 (6.5)	525	85.8 (1.9)	-3.2 (5.8)	-1.20 (-1.98 to -0.42), 0.002
	HTN	High HD + PA	DBP	IG1	36	537	86 (1.9)	-2.9 (6.7)	514	85.8 (1.9)	-2.4 (7)	-0.60 (-1.38 to 0.18), 0.19
	HTN	High HD + PA	DBP	IG2	36	527	86 (1.9)	-3.2 (6.5)	514	85.8 (1.9)	-2.4 (7)	-0.90 (-1.68 to -0.12), 0.04
	HTN	High HD only	DBP	IG3	36	515	86.1 (1.9)	-3 (6.5)	514	85.8 (1.9)	-2.4 (7)	-0.70 (-1.48 to 0.08), 0.1
	HTN	High HD + PA	SBP	IG1	6	562	127.4 (6.5)	-6.2 (8.6)	538	127.3 (6.4)	-2.2 (8.1)	-4.00 (-4.98 to -3.02), <0.001
	HTN	High HD + PA	SBP	IG2	6	561	127.6 (6.1)	-6 (8.1)	538	127.3 (6.4)	-2.2 (8.1)	-3.70 (-4.68 to -2.72), <0.001
	HTN	High HD only	SBP	IG3	6	529	127.7 (6.6)	-5.1 (8.6)	538	127.3 (6.4)	-2.2 (8.1)	-2.90 (-3.88 to -1.92), <0.001
	HTN	High HD + PA	SBP	IG1	18	538	127.4 (6.5)	-3.9 (8.3)	525	127.3 (6.4)	-1.8 (7)	-2.00 (-2.98 to -1.02), <0.001
	HTN	High HD + PA	SBP	IG2	18	533	127.6 (6.1)	-3.6 (7.9)	525	127.3 (6.4)	-1.8 (7)	-1.80 (-2.78 to -0.82), <0.001
	HTN	High HD only	SBP	IG3	18	513	127.7 (6.6)	-3.8 (8.2)	525	127.3 (6.4)	-1.8 (7)	-2.00 (-2.98 to -1.02), <0.001
	HTN	High HD + PA	SBP	IG1	36	537	127.4 (6.5)	-0.5 (9)	514	127.3 (6.4)	0.6 (8.5)	-1.10 (-2.08 to -0.12), 0.05
	HTN	High HD + PA	SBP	IG2	36	527	127.6 (6.1)	-0.8 (8.7)	514	127.3 (6.4)	0.6 (8.5)	-1.30 (-2.28 to -0.32), 0.01
	HTN	High HD only	SBP	IG3	36	515	127.7 (6.6)	-0.7 (9)	514	127.3 (6.4)	0.6 (8.5)	-1.20 (-2.18 to -0.22), 0.02
Wadden, 2011[127] (Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-UP)) Good	Multiple	High HD + PA	DBP	IG1	6	131	75.9 (11.3)	-0.2 (10.3)	130	76 (10.4)	-0.3 (10.26)	0.10 (-2.39 to 2.59), 0.941
	Multiple	High HD + PA	DBP	IG1	12	131	75.9 (11.3)	-0.8 (9.16)	130	76 (10.4)	-0.5 (9.12)	-0.30 (-2.52 to 1.92), 0.828
	Multiple	High HD + PA	DBP	IG1	24	131	75.9 (11.3)	-0.2 (10.3)	130	76 (10.4)	0.2 (10.26)	-0.40 (-2.89 to 2.09), 0.974
	Multiple	High HD + PA	SBP	IG1	6	131	122.8 (15.6)	0.3 (14.88)	130	120.9 (18.4)	-0.7 (14.82)	1.00 (-2.60 to 4.60), 0.567

Appendix H Table 5. Blood Pressure, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	SBP	IG1	12	131	122.8 (15.6)	0.8 (14.88)	130	120.9 (18.4)	1.2 (14.82)	-0.40 (-4.00 to 3.20), 0.849
	Multiple	High HD + PA	SBP	IG1	24	131	122.8 (15.6)	1.5 (18.31)	130	120.9 (18.4)	1.5 (18.24)	0.00 (-4.43 to 4.43), 0.998
Wister, 2007[129] Good	Multiple	Medium HD + PA	SBP	IG1	12	157	139 (15.2)	-7.49 (15.85)	158	136.1 (14.3)	-3.58 (16.03)	-3.91 (-7.43 to -0.39), <0.05
Wong, 2015[130] Good	HTN	Low HD only	DBP	IG1	6	254	90.5 (7.1)	-2.7 (15.04)	250	89.9 (6.6)	-1.4 (13.71)	-1.00 (-2.70 to 0.70), 0.24
	HTN	Low HD only	DBP	IG1	12	243	90.5 (7.1)	-2.9 (14.32)	242	89.9 (6.6)	-1.3 (14.29)	-1.10 (-2.90 to 0.60), 0.2
	HTN	Low HD only	SBP	IG1	6	254	145.2 (7.8)	-8.9 (18.3)	250	144.9 (7.3)	-8.3 (17.34)	-0.70 (-3.00 to 1.50), 0.54
	HTN	Low HD only	SBP	IG1	12	243	145.2 (7.8)	-9 (18.29)	242	144.9 (7.3)	-8.7 (17.06)	-0.10 (-2.40 to 2.20), 0.94
Wood, 2008[131] (EUROACTION) Fair	Multiple	High HD + PA	DBP	IG1	12	1019	NR (NR)	-4.1 (NR)	332	NR (NR)	-1.6 (NR)	-2.70 (-5.90 to 0.60), 0.09
	Multiple	High HD + PA	SBP	IG1	12	1019	NR (NR)	-7.6 (NR)	332	NR (NR)	-2.8 (NR)	-4.80 (-10.20 to 0.60), 0.07

Abbreviations: CG = control group; CI = confidence interval; DBP = diastolic blood pressure; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; KQ = key question; mm Hg = millimeters of mercury; MD = mean difference; NR = not reported; NSD = no statistically significantly difference; SBP = systolic blood pressure; SD = standard deviation

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min
†Between-group mean difference in change unless otherwise specified

Appendix H Table 6. Blood Pressure, Dichotomous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	BP outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Appel, 2003[41] (PREMIER) Good	HTN	High HD + PA	BP at goal (<120/80 mm Hg)	IG1	6	89/253 (35.2)	49/257 (19.1)	1.85 (1.36 to 2.50), <0.001
	HTN	High HD + PA	BP at goal (<120/80 mm Hg)	IG2	6	75/251 (29.9)	49/257 (19.1)	1.57 (1.14 to 2.15), <0.005
	HTN	High HD + PA	BP at goal (<120/80 mm Hg)	IG1	18	62/258 (24.0)	46/257 (17.9)	OR=1.17 (0.84 to 1.63), NSD
	HTN	High HD + PA	BP at goal (<120/80 mm Hg)	IG2	18	60/249 (24.1)	46/257 (17.9)	OR=1.25 (0.91 to 1.72), NSD
	HTN	High HD + PA	Hypertension incidence	IG1	6	9/156 (5.8)	18/160 (11.3)	0.51 (0.24 to 1.11), 0.12
	HTN	High HD + PA	Hypertension incidence	IG2	6	13/162 (8.0)	18/160 (11.3)	0.71 (0.36 to 1.41), 0.42
	HTN	High HD + PA	Percent with hypertension	IG1	6	30/253 (11.9)	67/257 (26.1)	0.45 (0.31 to 0.67), <0.001
	HTN	High HD + PA	Percent with hypertension	IG2	6	43/251 (17.1)	67/257 (26.1)	0.66 (0.47 to 0.92), 0.01
	HTN	High HD + PA	Percent with hypertension	IG1	18	57/258 (22.1)	82/257 (31.9)	OR=0.77 (0.62 to 0.97), <0.05
	HTN	High HD + PA	Percent with hypertension	IG2	18	60/249 (24.1)	82/257 (31.9)	OR=0.83 (0.67 to 1.04), NSD
Babazono, 2007[45] (PHPP) Fair	Multiple	Medium HD + PA	Hypertension incidence	IG1	12	10/46 (21.7)	6/41 (14.6)	1.49 (0.59 to 3.73), NSD
Bennett, 2012[47] (Be Fit, Be Well [POWER]) Good	HTN	High HD + PA	BP at goal (<140/90 mm Hg)	IG1	6	117/180 (65.0)	129/185 (69.7)	OR=1.02 (0.58 to 1.79), NSD
	HTN	High HD + PA	BP at goal (<140/90 mm Hg)	IG1	12	129/180 (71.7)	120/185 (64.9)	OR=1.39 (0.98 to 1.98), NSD
	HTN	High HD + PA	BP at goal (<140/90 mm Hg)	IG1	18	121/180 (67.2)	107/185 (57.8)	OR=1.28 (0.90 to 1.82), NSD
	HTN	High HD + PA	BP at goal (<140/90 mm Hg)	IG1	24	116/180 (64.4)	108/185 (58.4)	OR=1.52 (1.01 to 2.30), <0.05
Beune, 2014[49] (Culturally Adapted Hypertension Education (CAHE)) Fair	HTN	Medium HD + PA	BP at goal (SBP reduction ≥10 mm Hg)	IG1	6	34/71 (47.9)	29/68 (42.6)	OR=0.42 (0.11 to 1.54), 0.19
Bo, 2007[52] Fair	Multiple	Medium HD + PA	Percent with hypertension	IG1	12	143/169 (84.6)	148/166 (89.2)	OR=0.67 (0.35 to 1.29), 0.23

Appendix H Table 6. Blood Pressure, Dichotomous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	BP outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Bosworth, 2009[53] (Take Control of Your Blood pressure (TCYB)) Fair	HTN	Medium HD + PA	BP at goal (<140/90 mm Hg (<130/80 mm Hg if diabetic))	IG1	12	./159 (.)	./159 (.)	Risk difference in change=5.60 (0.90 to 10.20), NSD
	HTN	Medium HD + PA	BP at goal (<140/90 mm Hg (<130/80 mm Hg if diabetic))	IG2	12	./160 (.)	./159 (.)	Risk difference in change=2.10 (-2.20 to 6.20), NSD
	HTN	Medium HD + PA	BP at goal (<140/90 mm Hg (<130/80 mm Hg if diabetic))	IG1	24	./159 (.)	./159 (.)	Risk difference in change=11.00 (1.90 to 19.80), 0.012
	HTN	Medium HD + PA	BP at goal (<140/90 mm Hg (<130/80 mm Hg if diabetic))	IG2	24	./160 (.)	./159 (.)	Risk difference in change=4.30 (-4.50 to 12.90), 0.34
Edelman, 2006[65] Fair	Multiple	High HD + PA	BP at goal (<140/90 mm Hg (<130/80 mm Hg if diabetic))	IG1	10	63/77 (81.8)	53/77 (68.8)	1.19 (0.99 to 1.43), 0.34
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	Percent with hypertension	IG1	60	1938/2032 (95.4)	1899/1990 (95.4)	1.00 (0.99 to 1.01),
	Multiple	High HD only	Percent with hypertension	IG2	60	1833/1934 (94.8)	1899/1990 (95.4)	0.99 (0.98 to 1.01),
Fagerberg, 1998[68] (Risk Factor Intervention Study (RIS)) Good (KQ1); Fair (KQ2)	Multiple	High HD + PA	BP at goal (DBP <90 mm Hg)	IG1	12	188/239 (78.7)	175/238 (73.5)	1.07 (0.97 to 1.18), 0.23
	Multiple	High HD + PA	BP at goal (DBP <90 mm Hg)	IG1	40	151/235 (64.3)	140/227 (61.7)	1.04 (0.91 to 1.20), 0.63
HPT, 1990[77] (Hypertension Prevention Trial (HPT)) Good	HTN	High HD only	Hypertension incidence	IG1	36	41/189 (21.7)	65/194 (33.5)	0.65 (0.46 to 0.91),
	HTN	High HD only	Hypertension incidence	IG2	36	46/187 (24.6)	65/194 (33.5)	0.73 (0.53 to 1.01),
	HTN	High HD only	Hypertension incidence	IG3	36	35/124 (28.2)	65/194 (33.5)	0.84 (0.60 to 1.19),
	HTN	High HD only	Hypertension incidence	IG4	36	39/125 (31.2)	65/194 (33.5)	0.93 (0.67 to 1.29),

Appendix H Table 6. Blood Pressure, Dichotomous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	BP outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Jones, 1999[82] (Hypertension Optimal Treatment (HOT)) Fair	HTN	High HD only	BP at goal (DBP 80-90 mm Hg)	IG1	6	44/51 (86.3)	44/51 (86.3)	1.00 (0.86 to 1.17), NSD
	HTN	High HD only	BP at goal (DBP 80-90 mm Hg)	IG1	12	44/51 (86.3)	42/51 (82.4)	1.05 (0.89 to 1.24), NSD
	HTN	High HD only	BP at goal (DBP 80-90 mm Hg)	IG1	18	41/51 (80.4)	39/51 (76.5)	1.05 (0.86 to 1.29), NSD
	HTN	High HD only	BP at goal (DBP 80-90 mm Hg)	IG1	24	38/51 (74.5)	41/51 (80.4)	0.93 (0.75 to 1.14), NSD
	HTN	High HD only	BP at goal (DBP 80-90 mm Hg)	IG1	30	37/51 (72.5)	36/51 (70.6)	1.03 (0.80 to 1.31), NSD
Khanji, 2019[87] (HAPPY London) Good	Multiple	Low HD + PA	DBP at Goal (<90 mm Hg)	IG1	6	178/194 (91.8)	164/184 (89.1)	1.03 (0.96 to 1.10), 0.39
	Multiple	Low HD + PA	SBP at Goal (<140 mm Hg)	IG1	6	158/194 (81.4)	142/184 (77.2)	1.06 (0.95 to 1.17), 0.31
Langford, 1991[91] (Trial of Antihypertensive Interventions and Management (TAIM)) Fair	HTN	High HD + PA	BP at goal (DBP <90 mm Hg)	IG1	6	228/265 (86.0)	220/264 (83.3)	1.03 (0.96 to 1.11),
	HTN	High HD only	BP at goal (DBP <90 mm Hg)	IG2	6	207/258 (80.2)	220/264 (83.3)	0.96 (0.89 to 1.04),
Migneault, 2012[94] Fair	HTN	High HD + PA	BP at goal (<140/90 mm Hg (<130/80 mm Hg if diabetic))	IG1	8	./169 (.)	./168 (.)	Risk difference in change=0.80 (NR), NSD
	HTN	High HD + PA	BP at goal (DBP <90 mm Hg (<80 mm Hg if diabetic))	IG1	8	./169 (.)	./168 (.)	Risk difference in change=1.30 (NR), NSD
	HTN	High HD + PA	BP at goal (SBP <140 mm Hg (<130 mm Hg if diabetic))	IG1	8	./169 (.)	./168 (.)	Risk difference in change=-1.20 (NR), NSD
Muhlhauser, 1993[97] (Hypertension Treatment and Teaching Program (HTTP)) Fair	HTN	Medium HD + PA	Percent with hypertension	IG1	18	73/86 (84.9)	64/74 (86.5)	0.97 (0.81 to 1.16), NSD
Niiranen, 2014[100] Fair	HTN	Medium HD + PA	BP at goal (<140/85 mm Hg)	IG1	12	59/112 (52.7)	65/108 (60.2)	0.85 (0.47 to 1.52), 0.26

Appendix H Table 6. Blood Pressure, Dichotomous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	BP outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Ogedegbe, 2014[102] (Counseling African Americans to Control Hypertension (CAATCH)) Fair	HTN	Medium HD + PA	BP at goal (<140/90 mm Hg (<130/80 mm Hg for DM or CKD))	IG1	12	261/529 (49.3)	227/510 (44.5)	OR=1.21 (0.90 to 1.63), 0.21
Rodriguez, 2012[104] Fair	HTN	Medium HD + PA	BP at goal (<140/90 mm Hg (<130/80 mm Hg for DM or CKD))	IG1	6	114/176 (64.8)	81/177 (45.8)	1.42 (1.17 to 1.72), 0.001
Schoenthaler, 2016[109] (Individual Motivational Interviewing - Therapeutic Lifestyle Changes (MINT-TLC)) Fair	HTN	High HD + PA	BP at goal (<140/90 mm Hg (<130/80 mm Hg for DM or CKD))	IG1	6	36/97 (37.1)	42/97 (43.3)	0.86 (0.61 to 1.21), 0.437
TOHP I CRG, 1992[119] (Trials of Hypertension Prevention Phase I (TOHP I)) Good	HTN	High HD only	Hypertension incidence	IG1	18	28/327 (8.6)	47/417 (11.3)	0.84 (0.62 to 1.13), NSD
	HTN	High HD + PA	Hypertension incidence	IG2	18	20/308 (6.5)	34/256 (13.3)	0.66 (0.46 to 0.94), <0.05
TOHP II CRG, 1997[120] (Trial of Hypertension Prevention II (TOHP II)) Good	HTN	High HD + PA	Hypertension incidence	IG1	6	16/597 (2.7)	43/592 (7.3)	0.37 (NR), <0.001
	HTN	High HD + PA	Hypertension incidence	IG2	6	25/595 (4.2)	43/592 (7.3)	0.58 (0.36 to 0.94), 0.02
	HTN	High HD only	Hypertension incidence	IG3	6	26/576 (4.5)	43/592 (7.3)	0.61 (NR), 0.04
	HTN	High HD + PA	Hypertension incidence	IG1	18	88/589 (14.9)	124/588 (21.1)	0.71 (NR), 0.006
	HTN	High HD + PA	Hypertension incidence	IG2	18	97/584 (16.6)	124/588 (21.1)	0.78 (0.62 to 1.00), 0.05
	HTN	High HD only	Hypertension incidence	IG3	18	108/581 (18.6)	124/588 (21.1)	0.88 (NR), 0.28
	HTN	High HD + PA	Hypertension incidence	IG1	36	191/582 (32.8)	229/584 (39.2)	0.84 (NR), 0.02
	HTN	High HD + PA	Hypertension incidence	IG2	36	185/580 (31.9)	229/584 (39.2)	0.81 (0.70 to 0.95), 0.009
	HTN	High HD only	Hypertension incidence	IG3	36	198/575 (34.4)	229/584 (39.2)	0.88 (NR), 0.09

Appendix H Table 6. Blood Pressure, Dichotomous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	BP outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
	HTN	High HD + PA	Hypertension incidence	IG1	48	213/566 (37.6)	248/558 (44.4)	0.85 (NR), 0.02
	HTN	High HD + PA	Hypertension incidence	IG2	48	211/548 (38.5)	248/558 (44.4)	0.87 (NR), 0.06
	HTN	High HD only	Hypertension incidence	IG3	48	211/554 (38.1)	248/558 (44.4)	0.86 (NR), 0.04
Wood, 2008[131] (EUROACTION) Fair	Multiple	High HD + PA	BP at goal (<140/90 mm Hg (<135/85 mm Hg if diabetic))	IG1	12	586/1016 (57.7)	407/1004 (40.5)	Difference in probability=16.90 (2.00 to 31.80), 0.03

Abbreviations: BP = blood pressure; CG = control group; CI = confidence interval; Dys = dyslipidemia; DM = diabetes mellitus; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; KQ = key question; NR = not reported; NSD = no statistically significantly difference; OR = odds ratio; PREDIMED = Primary Prevention of Cardiovascular Disease with a Mediterranean Diet; RR = risk ratio; TONE = Trial of Nonpharmacologic Interventions in the Elderly

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

†Risk ratio unless otherwise specified

Appendix H Table 7. Lipids, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Ammerman, 2003[38] Fair	Dys	Medium HD only	HDL-C	IG1	6	154	45 (12.93)	-0.3 (NR)	189	43 (12.86)	1 (NR)	NR, NSD
	Dys	Medium HD only	HDL-C	IG1	12	153	45 (12.93)	1.8 (7.57)	196	43 (12.86)	1.6 (7.14)	0.20 (-1.36 to 1.76), NSD
	Dys	Medium HD only	LDL-C	IG1	6	154	181 (33.8)	-16 (33.35)	189	179 (33.34)	-16.6 (33.67)	0.50 (-7.60 to 8.70), NSD
	Dys	Medium HD only	LDL-C	IG1	12	153	181 (33.8)	-19.6 (38.45)	196	179 (33.34)	-16.7 (38.93)	-2.80 (-12.10 to 6.40), 0.5
	Dys	Medium HD only	TC	IG1	6	154	258 (45.56)	-15.4 (41.2)	189	256 (46.04)	-16.3 (42.34)	0.90 (-8.90 to 10.60), NSD
	Dys	Medium HD only	TC	IG1	12	153	258 (45.56)	-18.4 (43.91)	196	256 (46.04)	-15.6 (45.22)	-2.80 (-13.70 to 7.50), 0.6
Anderson, 1992[39] Fair	Dys	High HD only	HDL-C	IG1	12	48	49.03 (13.37)	-1.54 (5.35)	51	46.33 (11.03)	0.39 (5.51)	-1.93 (-4.07 to 0.21), NSD
	Dys	High HD only	HDL-C	IG2	12	47	50.97 (10.59)	0.39 (5.29)	51	46.33 (11.03)	0.39 (5.51)	0.00 (-2.14 to 2.14), NSD
	Dys	High HD only	LDL-C	IG1	12	48	161.78 (21.4)	-28.96 (21.4)	51	154.44 (19.3)	-15.44 (16.54)	-13.51 (-21.08 to -5.95), <0.002
	Dys	High HD only	LDL-C	IG2	12	47	159.46 (21.18)	-21.62 (21.18)	51	154.44 (19.3)	-15.44 (16.54)	-6.18 (-13.75 to 1.39), NSD
	Dys	High HD only	TC	IG1	12	48	235.13 (21.4)	-30.5 (24.07)	51	228.57 (19.3)	-16.22 (22.06)	-14.29 (-23.40 to -5.17), <0.01
	Dys	High HD only	TC	IG2	12	47	235.13 (18.53)	-22.78 (23.82)	51	228.57 (19.3)	-16.22 (22.06)	-6.56 (-15.68 to 2.55), NSD
Anderssen, 1995[40] (Oslo Diet and Exercise Study (ODES)) Fair	Multiple	Medium HD only	HDL-C	IG1	12	52	39 (8.49)	1.93 (4.44)	43	40.15 (7.72)	0.58 (3.78)	1.35 (-0.30 to 3.01), NSD
	Multiple	Medium HD only	LDL-C	IG1	12	52	164.86 (33.59)	-6.95 (27.8)	43	176.45 (32.82)	-8.49 (22.78)	1.54 (-8.63 to 11.72), NSD
	Multiple	Medium HD only	TC	IG1	12	52	245.95 (36.29)	-8.88 (25.1)	43	254.05 (32.82)	-6.18 (22.78)	-2.70 (-12.34 to 6.94), NSD
Appel, 2011[42] (POWER Hopkins (Practice Based Opportunities for	Multiple	High HD + PA	HDL-C	IG1	6	117	51.2 (14.05)	0.4 (6.49)	100	50.5 (11.66)	-0.3 (5)	0.70 (-0.80 to 2.20), 0.35
	Multiple	High HD + PA	HDL-C	IG2	6	121	53.5 (12.97)	1 (6.6)	100	50.5 (11.66)	-0.3 (5)	1.30 (-0.10 to 2.80), 0.07

Appendix H Table 7. Lipids, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Weight Reduction)) Good	Multiple	High HD + PA	HDL-C	IG1	24	105	51.2 (14.05)	3.5 (8.2)	93	50.5 (11.66)	1.8 (6.75)	1.70 (-0.40 to 3.70), 0.11
	Multiple	High HD + PA	HDL-C	IG2	24	110	53.5 (12.97)	2.2 (8.39)	93	50.5 (11.66)	1.8 (6.75)	0.30 (-1.70 to 2.30), 0.74
	Multiple	High HD + PA	LDL-C	IG1	6	117	106 (31.6)	-4.9 (18.39)	100	109.5 (32.65)	-4.7 (21)	-0.20 (-5.50 to 5.10), 0.93
	Multiple	High HD + PA	LDL-C	IG2	6	120	107.4 (30.65)	-3.2 (23)	100	109.5 (32.65)	-4.7 (21)	1.50 (-4.40 to 7.40), 0.62
	Multiple	High HD + PA	LDL-C	IG1	24	105	106 (31.6)	0.3 (25.62)	93	109.5 (32.65)	-5.4 (22.18)	5.70 (-1.00 to 12.40), 0.097
	Multiple	High HD + PA	LDL-C	IG2	24	110	107.4 (30.65)	-4.5 (31.46)	93	109.5 (32.65)	-5.4 (22.18)	0.90 (-6.60 to 8.30), 0.82
	Multiple	High HD + PA	TC	IG1	6	117	181.7 (35.11)	-6.4 (22.71)	100	187.3 (36.28)	-4.1 (24)	-2.30 (-8.50 to 3.80), 0.46
	Multiple	High HD + PA	TC	IG2	6	121	187.1 (36.55)	-6 (26.4)	100	187.3 (36.28)	-4.1 (24)	-1.90 (-8.50 to 4.80), 0.58
	Multiple	High HD + PA	TC	IG1	24	105	181.7 (35.11)	2.3 (28.69)	93	187.3 (36.15)	-5.4 (24.11)	7.80 (0.40 to 15.20), 0.039
	Multiple	High HD + PA	TC	IG2	24	110	187.1 (36.55)	-4.6 (35.66)	93	187.3 (36.15)	-5.4 (24.11)	0.80 (-7.50 to 9.10), 0.85
Babazono, 2007[45] (PHPP) Fair	Multiple	Medium HD + PA	HDL-C	IG1	12	46	54.5 (13.4)	2.2 (7.6)	41	55.7 (12.9)	0.8 (8.23)	1.40 (-1.94 to 4.74), NSD
	Multiple	Medium HD + PA	LDL-C	IG1	12	46	121 (29.2)	-1.4 (23.95)	41	123.8 (28.2)	0.1 (22.97)	-1.50 (-11.37 to 8.37), NSD
	Multiple	Medium HD + PA	TC	IG1	12	46	204.3 (31.8)	-2.4 (26.78)	41	207 (30.2)	2.6 (26.26)	-5.00 (-16.16 to 6.16), NSD
Beckmann, 1995[46] Fair	HTN	Medium HD only	HDL-C	IG1	12	32	49.81 (21.84)	-2.7 (11.96)	32	48.26 (21.84)	0.77 (11.96)	-3.47 (-9.34 to 2.39), NSD
	HTN	Medium HD only	TC	IG1	12	32	242.47 (43.68)	-14.67 (36.55)	32	236.29 (21.84)	-6.18 (18.27)	-8.49 (-22.65 to 5.66), NSD
Bennett, 2018 [48] (Track) Good	Multiple	Medium HD + PA	HDL-C	IG1	12	133	44.7 (14.1)	3.2 (12.65)	148	43.6 (13.8)	-0.3 (12.41)	3.50 (1.10 to 5.90), 0.005
	Multiple	Medium HD + PA	LDL-C	IG1	12	119	109.8 (31.7)	-5 (37.57)	133	111.7 (34.1)	-1.8 (37.95)	-3.20 (-10.50 to 4.10), 0.39

Appendix H Table 7. Lipids, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	Medium HD + PA	TC	IG1	12	136	185.9 (35)	-3.5 (41.65)	149	188.6 (40.9)	-6.6 (41.42)	3.10 (-4.70 to 10.90), 0.44
Blackford, 2016[50](Albany Physical Activity and Nutrition (APAN)) Fair	Multiple	Medium HD + PA	HDL-C	IG1	6	130	56.37 (16.22)	-0.39 (8.64)	144	56.37 (16.22)	-0.77 (8.59)	0.39 (-1.66 to 2.43), 0.93
	Multiple	Medium HD + PA	LDL-C	IG1	6	130	132.05 (31.27)	-3.09 (28.85)	144	128.19 (35.91)	0.77 (29.58)	-3.86 (-10.78 to 3.06), 0.13
	Multiple	Medium HD + PA	TC	IG1	6	130	214.67 (37.45)	-3.47 (32.19)	144	208.49 (42.47)	1.93 (34.49)	-5.41 (-13.30 to 2.49), 0.02
Bloemberg, 1991[51] Fair	Dys	Medium HD only	HDL-C	IG1	6	39	45.95 (9.27)	-0.77 (7.72)	41	42.86 (9.27)	0.39 (6.18)	-1.16 (-4.23 to 1.92), 0.27
	Dys	Medium HD only	TC	IG1	6	39	270.66 (39.77)	-12.36 (32.82)	41	269.88 (45.17)	-0.77 (30.5)	-11.58 (-25.48 to 2.32), <0.05
Bo, 2007[52] Fair	Multiple	Medium HD + PA	HDL-C	IG1	12	169	54.05 (11.58)	0.77 (5.41)	166	57.92 (11.58)	-2.7 (6.18)	3.47 (2.23 to 4.72), <0.001
	Multiple	Medium HD + PA	HDL-C	IG1	108	148	54.05 (11.58)	-3.86 (6.34)	138	54.05 (11.58)	-4.63 (6.25)	0.77 (-0.69 to 2.23), 0.56
	Multiple	Medium HD + PA	TC	IG1	12	169	223.94 (42.47)	-0.02 (33.2)	166	231.66 (42.47)	2.32 (34.36)	-2.34 (-9.58 to 4.90), 0.55
	Multiple	Medium HD + PA	TC	IG1	108	148	223.94 (42.47)	0 (35.86)	138	231.66 (42.47)	-3.09 (33.74)	3.09 (-4.98 to 11.16), 0.34
Broekhuizen, 2012[54] (PRO-FIT) Fair	Dys	Medium HD + PA	HDL-C	IG1	12	169	46.33 (15.44)	0 (8.46)	143	46.33 (15.44)	0 (8.46)	0.00 (-1.88 to 1.88), NSD
	Dys	Medium HD + PA	LDL-C	IG1	12	128	139 (50.19)	-3.86 (39.39)	105	142.86 (46.33)	-3.86 (38.76)	0.00 (-10.08 to 10.08), NSD
	Dys	Medium HD + PA	TC	IG1	12	169	204.63 (54.05)	-3.86 (42.58)	146	200.77 (46.33)	-3.86 (38.76)	0.00 (-8.99 to 8.99), NSD
Bruckert, 2008[55] (PEGASE (Effect of an Education Program)) Fair	Dys	Medium HD + PA	HDL-C	IG1	6	274	NR (NR)	0.87 (NR)	199	NR (NR)	0.38 (NR)	NR, NSD
	Dys	Medium HD + PA	LDL-C	IG1	6	274	NR (NR)	2 (NR)	199	NR (NR)	10 (NR)	-8.00 (NR), 0.032
	Dys	Medium HD + PA	TC	IG1	6	274	NR (NR)	-7.64 (NR)	199	NR (NR)	-3.4 (NR)	NR, NSD
	HTN	Medium HD + PA	HDL-C	IG1	16	123	52.12 (11.97)	1.93 (4.25)	118	51.35 (11.58)	0.77 (4.25)	1.16 (0.09 to 2.23), NSD

Appendix H Table 7. Lipids, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Burke, 2006[56] (ADAPT) Fair	HTN	Medium HD + PA	HDL-C	IG1	40	123	52.12 (11.97)	-1.16 (6.96)	118	51.35 (11.58)	-0.39 (6.75)	0.39 (-2.32 to 3.09), 0.803
	HTN	Medium HD + PA	LDL-C	IG1	16	123	NR (NR)	-4.63 (8.88)	118	NR (NR)	0.39 (12.74)	-5.02 (-7.80 to -2.24), <0.05
	HTN	Medium HD + PA	TC	IG1	16	123	196.91 (43.63)	-5.41 (13.13)	118	200.77 (32.05)	-2.7 (12.74)	-2.70 (-5.97 to 0.56), NSD
	HTN	Medium HD + PA	TC	IG1	40	123	196.91 (43.63)	0 (33.45)	118	200.77 (32.05)	3.86 (26.81)	-7.72 (-15.44 to 3.86), 0.04
Chirinos, 2016[57] (Community Health and Risk-reduction for Metabolic Syndrome (CHARMS)) Fair	Multiple	High HD + PA	HDL-C	IG1	6	60	37.77 (7.39)	1.53 (NR)	60	40.98 (10.19)	1.08 (NR)	NR, NSD
	Multiple	High HD + PA	HDL-C	IG1	12	60	37.77 (7.39)	2.04 (NR)	60	40.98 (10.19)	0.45 (NR)	NR, NSD
Christian, 2011[58] Fair	Multiple	Medium HD + PA	HDL-C	IG1	12	133	45.3 (13.85)	0.32 (9.54)	130	43.9 (12.93)	0.08 (12.35)	0.24 (-7.32 to 7.80), 0.43
	Multiple	Medium HD + PA	LDL-C	IG1	12	133	125.3 (40.75)	-8.8 (34.23)	130	129.2 (40.99)	-2.8 (36.07)	-6.00 (-30.02 to 18.02), 0.08
	Multiple	Medium HD + PA	TC	IG1	12	133	203.9 (45.67)	-8.9 (40.45)	130	207.9 (49.81)	-2.6 (41.17)	-6.30 (-34.17 to 21.57), 0.11
Cicolini, 2014[59] Fair	HTN	Medium HD + PA	LDL-C	IG1	6	100	144 (67)	-36.9 (44.2)	98	134 (60)	-26.8 (39.6)	-10.10 (-21.78 to 1.58), <0.001
	HTN	Medium HD + PA	TC	IG1	6	100	265 (64)	-60 (36.7)	98	251 (59)	-33.4 (38.1)	-26.60 (-37.02 to -16.18), <0.001
Cochrane, 2012[60] Fair	Multiple	Medium HD + PA	HDL-C	IG1	12	236	46.33 (11.58)	0.39 (6.18)	365	46.33 (11.58)	0.39 (5.79)	0.00 (-0.99 to 0.99), NSD
	Multiple	Medium HD + PA	TC	IG1	12	236	220.08 (34.75)	-21.62 (36.29)	365	220.08 (34.75)	-20.85 (35.91)	-0.77 (-6.69 to 5.14), NSD
Coleman, 2012[62] (Wisewoman California) Fair	Multiple	Medium HD + PA	HDL-C	IG1	12	433	45.1 (12.45)	2.6 (NR)	436	44.9 (13.72)	2 (NR)	NR, 0.285
	Multiple	Medium HD + PA	TC	IG1	12	433	198.2 (36.18)	1.9 (NR)	436	197.8 (37.68)	1.1 (NR)	NR, 0.906

Appendix H Table 7. Lipids, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Delahanty, 2001[63] Good	Dys	Medium HD + PA	HDL-C	IG1	6	44	47.1 (16.22)	-3 (8.55)	44	44.02 (11.97)	-1.82 (6.56)	-1.18 (-4.36 to 2.00), NSD
	Dys	Medium HD + PA	HDL-C	IG1	6	44	47.1 (16.22)	-3.09 (8.54)	44	44.02 (11.97)	-1.93 (6.56)	-1.16 (-4.34 to 2.02), NSD
	Dys	Medium HD + PA	HDL-C	IG1	12	43	47.1 (16.22)	3.09 (9.59)	44	44.02 (11.97)	3.08 (8.74)	0.01 (-3.85 to 3.87), NSD
	Dys	Medium HD + PA	HDL-C	IG1	12	43	47.1 (16.22)	3.09 (9.59)	44	44.02 (11.97)	3.09 (8.73)	0.00 (-3.86 to 3.86), NSD
	Dys	Medium HD + PA	LDL-C	IG1	6	44	165.64 (23.17)	-11.64 (18.68)	44	163.71 (26.25)	-3.91 (20.87)	-7.73 (-16.01 to 0.55), NSD
	Dys	Medium HD + PA	LDL-C	IG1	6	44	165.64 (23.17)	-11.97 (18.66)	44	163.71 (26.25)	-4.25 (20.86)	-7.72 (-15.99 to 0.55), NSD
	Dys	Medium HD + PA	LDL-C	IG1	12	43	165.64 (23.17)	-11.2 (18.93)	44	163.71 (26.25)	-13.13 (21.96)	1.93 (-6.68 to 10.54), NSD
	Dys	Medium HD + PA	LDL-C	IG1	12	43	165.64 (23.17)	-11.2 (18.93)	44	163.71 (26.25)	-13.13 (21.97)	1.93 (-6.68 to 10.54), NSD
	Dys	Medium HD + PA	TC	IG1	6	44	239 (28.19)	-16.22 (21.96)	44	237.84 (28.96)	-5.02 (22.88)	-11.20 (-20.57 to -1.83), <0.05
	Dys	Medium HD + PA	TC	IG1	6	44	239 (28.19)	-15.7 (21.97)	44	237.84 (28.96)	-4.44 (22.91)	-11.26 (-20.64 to -1.88), <0.05
	Dys	Medium HD + PA	TC	IG1	12	43	239 (28.19)	-8.11 (23.12)	44	237.84 (28.96)	-10.04 (23.91)	1.93 (-7.95 to 11.81), NSD
	Dys	Medium HD + PA	TC	IG1	12	43	239 (28.19)	-8.11 (23.12)	44	237.84 (28.96)	-10.04 (23.92)	1.93 (-7.96 to 11.82), NSD
Edelman, 2006[65] Fair	Multiple	High HD + PA	LDL-C	IG1	10	77	132.4 (35.1)	-11.3 (NR)	77	137.1 (35.6)	-4 (NR)	NR, 0.25
Ellsworth, 2016[66] Fair	Multiple	High HD + PA	HDL-C	IG1	12	89	47.8 (12.3)	0.2 (NR)	58	50.2 (14.5)	-2.3 (NR)	NR, 0.102
	Multiple	High HD + PA	LDL-C	IG1	12	89	111 (31)	-3.8 (NR)	58	116 (30)	-4.8 (NR)	NR, 0.761
	Multiple	High HD + PA	TC	IG1	12	89	185 (39)	-3.6 (NR)	58	192 (36)	-4.3 (NR)	NR, 0.921
Estruch, 2018[67] (Primary	Multiple	High HD only	HDL-C	IG1	12	78	52.2 (12.17)	0.48 (5.23)	75	53.4 (13.26)	0.4 (4.24)	0.08 (-1.43 to 1.59), NSD

Appendix H Table 7. Lipids, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	HDL-C	IG2	12	82	53.7 (12.47)	0.36 (4.11)	75	53.4 (13.26)	0.4 (4.24)	-0.04 (-1.35 to 1.27), NSD
	Multiple	High HD only	LDL-C	IG1	12	78	138.2 (35.82)	-6.5 (22.3)	75	129.9 (32.48)	-5.8 (20.55)	-0.70 (-7.49 to 6.09), NSD
	Multiple	High HD only	LDL-C	IG2	12	82	135.7 (33.26)	-11.3 (21.48)	75	129.9 (32.48)	-5.8 (20.55)	-5.50 (-12.08 to 1.08), NSD
	Multiple	High HD only	TC	IG1	12	78	223.4 (50.47)	-11.3 (25.01)	75	208.1 (37.56)	-4.6 (23.2)	-6.70 (-14.34 to 0.94), NSD
	Multiple	High HD only	TC	IG2	12	82	214.7 (38.35)	-13.6 (21.48)	75	208.1 (37.56)	-4.6 (23.2)	-9.00 (-16.01 to -1.99), <0.05
Fagerberg, 1998[68] (Risk Factor Intervention Study (RIS)) Good (KQ1); Fair (KQ2)	Multiple	High HD + PA	HDL-C	IG1	12	239	50.19 (15.44)	-2.32 (10.42)	238	46.33 (15.44)	-3.09 (11.58)	0.77 (-1.16 to 2.70), 0.43
	Multiple	High HD + PA	HDL-C	IG1	40	235	50.19 (15.44)	-1.93 (11.58)	227	46.33 (15.44)	-3.09 (11.2)	MD=1.16 (-1.16 to 3.09), 0.3
	Multiple	High HD + PA	HDL-C	IG1	79	248	50.19 (15.44)	-2.32 (9.27)	252	46.33 (15.44)	-3.09 (9.27)	0.77 (-0.74 to 2.29),
	Multiple	High HD + PA	LDL-C	IG1	12	239	177.61 (38.61)	-11.58 (30.89)	238	173.74 (42.47)	-3.86 (30.89)	-11.58 (-17.64 to -5.53), 0.000
	Multiple	High HD + PA	LDL-C	IG1	40	235	177.61 (38.61)	-27.8 (40.15)	227	173.74 (42.47)	-13.13 (31.27)	MD=-14.67 (-21.24 to -7.72), 0.0001
	Multiple	High HD + PA	LDL-C	IG1	79	248	177.61 (38.61)	-27.03 (30.89)	252	173.74 (42.47)	-7.72 (31.27)	-15.44 (-21.50 to -9.39),
	Multiple	High HD + PA	TC	IG1	12	239	258.69 (46.33)	-19.31 (38.61)	238	254.83 (46.33)	-3.86 (27.03)	-15.44 (-21.50 to -9.39), 0.000
	Multiple	High HD + PA	TC	IG1	40	235	258.69 (46.33)	-30.12 (43.24)	227	254.83 (46.33)	-15.06 (35.52)	MD=-15.06 (-22.39 to -7.72), 0.0001
	Multiple	High HD + PA	TC	IG1	79	248	258.69 (46.33)	-27.03 (30.89)	252	254.83 (46.33)	-7.72 (31.27)	-19.31 (-25.36 to -13.25),
Gill, 2019[69] (Heartmatters Challenge - First	Multiple	High HD + PA	HDL-C	IG1	6	96	45.58 (12.13)	NR (NR)	79	42.72 (10.37)	NR (NR)	2.40 (0.05 to 4.75), 0.08
	Multiple	High HD + PA	HDL-C	IG1	12	96	45.58 (12.13)	NR (NR)	79	42.72 (10.37)	NR (NR)	1.47 (-0.61 to 3.55), 0.20

Appendix H Table 7. Lipids, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Responders) Fair	Multiple	High HD + PA	LDL-C	IG1	6	96	130.64 (30.55)	NR (NR)	79	135.1 (31.87)	NR (NR)	-5.61 (-14.88 to 3.66), 0.28
	Multiple	High HD + PA	LDL-C	IG1	12	96	130.64 (30.55)	NR (NR)	79	135.1 (31.87)	NR (NR)	-3.39 (-10.90 to 4.12), 0.40
	Multiple	High HD + PA	TC	IG1	6	96	197.09 (36.23)	NR (NR)	79	202.17 (35.11)	NR (NR)	-6.85 (-14.91 to 1.21), 0.14
	Multiple	High HD + PA	TC	IG1	12	96	197.09 (36.23)	NR (NR)	79	202.17 (35.11)	NR (NR)	-4.16 (-11.75 to 3.43), 0.32
Greaves, 2015[71] (Waste the Waist) Fair	Multiple	High HD + PA	HDL-C	IG1	12	55	52.51 (13.13)	NR (NR)	52	53.67 (15.06)	NR (NR)	-0.39 (-3.09 to 2.32), NSD
	Multiple	High HD + PA	LDL-C	IG1	12	55	123.17 (36.68)	NR (NR)	51	123.55 (38.22)	NR (NR)	5.79 (-3.09 to 14.29), NSD
	Multiple	High HD + PA	TC	IG1	12	55	204.25 (40.54)	NR (NR)	52	210.04 (49.03)	NR (NR)	3.47 (-6.56 to 13.51), NSD
Groeneveld, 2010[72] (Health Under Construction) Fair	Multiple	Medium HD + PA	HDL-C	IG1	6	256	43.63 (7.72)	3.09 (4.88)	257	43.24 (8.11)	2.7 (5.09)	0.39 (-0.48 to 1.25), NSD
	Multiple	Medium HD + PA	HDL-C	IG1	12	256	43.63 (7.72)	2.7 (5.11)	257	43.24 (8.11)	1.93 (5.31)	0.77 (-0.13 to 1.67), NSD
Hardcastle, 2008[73] Fair	Multiple	Medium HD + PA	HDL-C	IG1	6	203	56.37 (14.67)	-1.93 (8.15)	131	58.69 (16.6)	-1.93 (9.09)	0.00 (-1.92 to 1.92), NSD
	Multiple	Medium HD + PA	HDL-C	IG1	18	203	56.37 (14.67)	-5.02 (7.8)	131	58.69 (16.6)	-5.02 (8.91)	0.00 (-1.87 to 1.87), NSD
	Multiple	Medium HD + PA	LDL-C	IG1	6	203	114.29 (44.02)	3.86 (34.8)	131	116.22 (41.7)	10.04 (33.33)	-6.18 (-13.63 to 1.27), NSD
	Multiple	Medium HD + PA	LDL-C	IG1	18	203	114.29 (44.02)	12.36 (35.51)	131	116.22 (41.7)	18.15 (32.99)	-5.79 (-13.26 to 1.68), NSD
	Multiple	Medium HD + PA	TC	IG1	6	203	212.74 (39)	-5.41 (33.3)	131	208.11 (35.91)	-0.77 (31.85)	-4.63 (-11.76 to 2.49), NSD
	Multiple	Medium HD + PA	TC	IG1	18	203	212.74 (39)	-5.79 (32.96)	131	208.11 (35.91)	5.02 (31.85)	-10.81 (-17.90 to -3.72), <0.01
Harris, 2012[74] (Health Improvement and Prevention Study	Multiple	High HD + PA	HDL-C	IG1	12	355	NR (NR)	NR (NR)	300	NR (NR)	NR (NR)	NR, 0.7
	Multiple	High HD + PA	LDL-C	IG1	12	355	NR (NR)	NR (NR)	300	NR (NR)	NR (NR)	NR, 0.6

Appendix H Table 7. Lipids, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
(HIPS)) Fair												
Haufe, 2019[75] Fair	Multiple	Medium HD + PA	HDL-C	IG1	6	160	45.1 (10)	0.2 (5.33)	154	44.1 (9.2)	-0.6 (5.04)	0.80 (-1.90 to 0.30), 0.13
Hyman, 1998[78] Fair	Dys	Medium HD only	TC	IG1	6	65	273.2 (40.3)	-8.2 (33)	58	272.4 (42.3)	-4.8 (36.5)	-3.40 (-15.75 to 8.95), 0.58
Hyman, 2007[79] Fair	HTN	Medium HD + PA	TC	IG1	6	92	194.9 (36.5)	-2.3 (34.24)	93	192.8 (46.7)	1.3 (37.32)	-3.60 (-13.92 to 6.72), NSD
	HTN	Medium HD + PA	TC	IG2	6	96	200.4 (34.5)	-7.3 (30.6)	93	192.8 (46.7)	1.3 (37.32)	-8.60 (-18.35 to 1.15), NSD
	HTN	Medium HD + PA	TC	IG1	18	92	194.9 (36.5)	0.6 (32.26)	93	192.8 (46.7)	-4.2 (37.48)	4.80 (-5.27 to 14.87), NSD
	HTN	Medium HD + PA	TC	IG2	18	96	200.4 (34.5)	-13.4 (30.24)	93	192.8 (46.7)	-4.2 (37.48)	-9.20 (-18.93 to 0.53), <0.05
Ives, 1993[80] (Rural Health Promotion Project (RHPP) Trial) Fair	Dys	Medium HD + PA	TC	IG1	30	332	267.8 (NR)	-17.3 (NR)	258	264.7 (NR)	-15.2 (NR)	NR,
	Dys	Medium HD + PA	TC	IG2	30	311	267.8 (NR)	-17.7 (NR)	258	264.7 (NR)	-15.2 (NR)	NR,
Kandula, 2015[83] (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	Multiple	High HD + PA	TC	IG1	6	31	185 (32)	-0.4 (20.13)	32	185 (32)	3.5 (20.18)	-3.90 (-13.88 to 6.12), NSD
Kastarinen, 2002[85] (Lifestyle Intervention against Hypertension in Eastern Finland (LIHEF)) Fair	HTN	High HD + PA	HDL-C	IG1	12	360	50.97 (12.74)	0.77 (NR)	355	52.51 (14.67)	0.39 (NR)	MD=0.39 (-0.39 to 1.54), NSD
	HTN	High HD + PA	HDL-C	IG1	24	360	50.97 (12.74)	3.86 (NR)	355	52.51 (14.67)	2.7 (NR)	1.16 (0.00 to 2.70), NSD
	HTN	High HD + PA	LDL-C	IG1	12	360	140.54 (31.27)	-2.32 (NR)	355	137.45 (30.5)	-0.39 (NR)	MD=-1.93 (-4.63 to 1.16), NSD
	HTN	High HD + PA	LDL-C	IG1	24	360	140.54 (31.27)	-4.25 (NR)	355	137.45 (30.5)	1.54 (NR)	-5.79 (-8.88 to -1.93), <0.05
	HTN	High HD + PA	TC	IG1	12	360	218.53 (35.14)	-1.93 (NR)	355	215.83 (35.91)	-1.16 (NR)	MD=-0.77 (-4.25 to 2.32), NSD

Appendix H Table 7. Lipids, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	High HD + PA	TC	IG1	24	360	218.53 (35.14)	-1.16 (NR)	355	215.83 (35.91)	2.7 (NR)	-4.25 (-7.72 to -0.39), <0.05
Keyserling, 1997[86] (Southeast Cholesterol Project) Fair	Dys	Medium HD only	LDL-C	IG1	7	135	182.3 (NR)	-12.4 (26.49)	145	178.6 (NR)	-7.4 (26.61)	-5.00 (-11.37 to 1.37), NSD
	Dys	Medium HD only	LDL-C	IG1	12	153	182.3 (NR)	-9.2 (26.97)	164	178.6 (NR)	-7.5 (27.15)	-1.70 (-7.84 to 4.44), NSD
	Dys	Medium HD only	TC	IG1	7	143	256.6 (NR)	-12.6 (26.55)	150	252.7 (NR)	-7.6 (26.45)	-5.00 (-11.26 to 1.26), NSD
	Dys	Medium HD only	TC	IG1	12	165	256.6 (NR)	-9.6 (26.85)	176	252.7 (NR)	-8 (26.93)	-1.60 (-7.50 to 4.30), NSD
Khanji, 2019[87] (HAPPY London) Good	Multiple	Low HD + PA	HDL-C	IG1	6	194	61.78 (19.30)	-1.16 (10.57)	183	61.78 (15.44)	-0.66 (8.46)	-0.39 (-3.86 to 0.00), 0.64
	Multiple	Low HD + PA	LDL-C	IG1	6	194	108.11 (38.61)	-3.86 (30.89)	183	111.97 (38.61)	-5.48 (30.89)	1.54 (-3.86 to 7.72), 0.56
	Multiple	Low HD + PA	TC	IG1	6	194	189.19 (42.47)	-6.18 (34.1)	183	196.91 (42.47)	-7.61 (34.1)	1.54 (-3.86 to 7.72), 0.60
Kramer, 2018[89] (Healthy Lifestyle Project) Fair	Multiple	High HD + PA	HDL-C	IG1	6	71	50.8 (14.4)	-1 (7)	37	49.2 (12.4)	-1.6 (7.1)	0.60 (-2.21 to 3.41), 0.19
	Multiple	High HD + PA	LDL-C	IG1	6	69	115.2 (33.3)	-0.2 (19.6)	36	113.6 (41.5)	-0.14 (21.4)	-0.06 (-8.44 to 8.32), 0.94
	Multiple	High HD + PA	TC	IG1	6	71	194.4 (37.8)	-2.5 (23)	37	192.7 (43.9)	-0.57 (23.6)	-1.93 (-11.23 to 7.37), 0.68
Langford, 1991[91] (Trial of Antihypertensive Interventions and Management (TAIM)) Fair	HTN	High HD + PA	TC	IG1	6	235	NR (NR)	4.25 (NR)	229	NR (NR)	8.11 (NR)	Regression parameter=-174.90 (-358.04 to 8.24), 0.0617
	HTN	High HD only	TC	IG2	6	228	NR (NR)	8.88 (NR)	229	NR (NR)	8.11 (NR)	Regression parameter=-32.82 (-218.98 to 153.34), 0.7296
Liira, 2014[93] Fair	Multiple	Medium HD + PA	HDL-C	IG1	12	46	50.19 (15.44)	3.86 (8.28)	42	54.05 (11.58)	3.86 (8.28)	0.00 (-3.46 to 3.46), NSD
	Multiple	Medium HD + PA	LDL-C	IG1	12	46	142.86 (27.03)	0 (22.61)	42	135.13 (27.03)	-3.86 (22.61)	3.86 (-5.60 to 13.32), NSD

Appendix H Table 7. Lipids, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Moy, 2001[96] Fair	Multiple	High HD only	HDL-C	IG1	24	117	NR (NR)	1.7 (11.58)	118	NR (NR)	0.31 (7.72)	1.39 (-1.13 to 3.91), 0.24
	Multiple	High HD only	LDL-C	IG1	24	117	181.47 (54.05)	-26.64 (42.47)	118	166.02 (46.33)	-15.44 (30.89)	-11.20 (-20.70 to -1.70), 0.0223
Neil, 1995[99] Fair	Dys	Medium HD only	HDL-C	IG1	6	103	45.56 (10.04)	-0.39 (5.5)	102	47.49 (10.81)	0.77 (6.18)	-1.16 (-2.76 to 0.44), NSD
	Dys	Medium HD only	HDL-C	IG2	6	104	47.49 (10.42)	1.93 (6.13)	102	47.49 (10.81)	0.77 (6.18)	1.16 (-0.52 to 2.84), NSD
	Dys	Medium HD only	LDL-C	IG1	6	103	197.3 (23.17)	-4.25 (21.29)	102	202.7 (25.1)	-7.34 (20.54)	3.09 (-2.64 to 8.82), NSD
	Dys	Medium HD only	LDL-C	IG2	6	104	199.61 (25.87)	-6.95 (21.98)	102	202.7 (25.1)	-7.34 (20.54)	0.39 (-5.42 to 6.19), NSD
	Dys	Medium HD only	TC	IG1	6	103	270.66 (23.55)	-3.86 (22.05)	102	279.15 (24.32)	-5.02 (20.35)	1.16 (-4.65 to 6.97), NSD
	Dys	Medium HD only	TC	IG2	6	104	276.06 (25.1)	-6.95 (22.67)	102	279.15 (24.32)	-5.02 (20.35)	-1.93 (-7.81 to 3.95), NSD
Nolan, 2018[101] (Reducing Risk with E-based Support for Adherence to Lifestyle Change in Hypertension (REACH)) Fair	HTN	High HD + PA	LDL-C	IG1	12	100	116.7 (38.25)	-0.6 (27.55)	97	118.6 (35.04)	0.8 (27.64)	-1.40 (-9.11 to 6.31), 0.68
	HTN	High HD + PA	TC	IG1	12	100	195.6 (44.13)	-2.3 (33.42)	97	195.8 (37.96)	4.5 (33.92)	-6.80 (-16.21 to 2.61), 0.11
Reid, 2014[103] Fair	Multiple	High HD + PA	HDL-C	IG1	12	211	51.35 (14.67)	0.39 (8.43)	215	50.19 (13.13)	-0.39 (6.93)	0.77 (-0.69 to 2.24), 0.7
	Multiple	High HD + PA	LDL-C	IG1	12	211	124.32 (33.2)	-4.25 (27.17)	215	126.64 (35.14)	-9.27 (29.56)	5.02 (-0.37 to 10.41), 0.6
	Multiple	High HD + PA	TC	IG1	12	211	198.07 (37.45)	-3.86 (31.5)	215	200 (39.38)	-9.65 (32.79)	5.79 (-0.31 to 11.90), 0.7
Rodriguez-Cristobal, 2012[105] Fair	Multiple	High HD + PA	HDL-C	IG1	24	146	54.2 (12)	7.5 (8)	154	55.2 (13.1)	5.1 (7.72)	MD=2.10 (-0.90 to 5.10), 0.171
	Multiple	High HD + PA	LDL-C	IG1	24	146	134.6 (26.9)	-3.5 (22.99)	154	134.3 (28.6)	-4.7 (25.23)	MD=1.90 (-6.00 to 9.90), 0.633

Appendix H Table 7. Lipids, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	TC	IG1	24	146	211.1 (26.7)	-6.7 (24.18)	154	210.2 (25.5)	14.2 (24.77)	MD=-19.20 (-25.60 to -12.70), 0.0001
Rosas, 2015[106] (Vivamos Activos Fair Oaks (VAFO)) Good	Multiple	High HD + PA	HDL-C	IG1	6	82	47.2 (9.4)	-0.4 (6.7)	41	44.9 (8.9)	0 (5.07)	-0.40 (-2.52 to 1.72), 0.76
	Multiple	High HD + PA	HDL-C	IG2	6	84	44.3 (12.7)	-1.4 (8.88)	41	44.9 (8.9)	0 (5.07)	-1.40 (-3.85 to 1.05), 0.29
	Multiple	High HD + PA	HDL-C	IG1	12	82	47.2 (9.4)	1.6 (11.09)	41	44.9 (8.9)	1.7 (9.03)	-0.10 (-3.76 to 3.56), 0.98
	Multiple	High HD + PA	HDL-C	IG2	12	84	44.3 (12.7)	0.6 (11.69)	41	44.9 (8.9)	1.7 (9.03)	-1.10 (-4.83 to 2.63), 0.59
	Multiple	High HD + PA	HDL-C	IG1	24	82	47.2 (9.4)	0.3 (16.17)	41	44.9 (8.9)	1.4 (9.03)	-1.10 (-5.56 to 3.36), 0.62
	Multiple	High HD + PA	HDL-C	IG2	24	84	44.3 (12.7)	-0.2 (16.37)	41	44.9 (8.9)	1.4 (9.03)	-1.60 (-6.06 to 2.86), 0.46
	Multiple	High HD + PA	LDL-C	IG1	6	82	107.8 (39.2)	5.5 (51.28)	41	107.8 (33.5)	12.9 (39.13)	-7.40 (-23.73 to 8.93), 0.39
	Multiple	High HD + PA	LDL-C	IG2	6	84	100.6 (30.8)	16.3 (106.15)	41	107.8 (33.5)	12.9 (39.13)	3.40 (-22.27 to 29.07), 0.79
	Multiple	High HD + PA	LDL-C	IG1	12	82	107.8 (39.2)	4 (30.72)	41	107.8 (33.5)	1.9 (29.15)	2.10 (-9.03 to 13.23), 0.72
	Multiple	High HD + PA	LDL-C	IG2	12	84	100.6 (30.8)	2.9 (27.12)	41	107.8 (33.5)	1.9 (29.15)	1.00 (-9.64 to 11.64), 0.86
	Multiple	High HD + PA	LDL-C	IG1	24	82	107.8 (39.2)	4.8 (39.73)	41	107.8 (33.5)	4 (33.11)	0.80 (-12.49 to 14.09), 0.91
	Multiple	High HD + PA	LDL-C	IG2	24	84	100.6 (30.8)	5.8 (32.97)	41	107.8 (33.5)	4 (33.11)	1.80 (-10.55 to 14.15), 0.77
	Multiple	High HD + PA	TC	IG1	6	82	181.6 (46)	-0.6 (44.58)	41	188 (40.4)	2.8 (32.95)	-3.40 (-17.36 to 10.56), 0.64
	Multiple	High HD + PA	TC	IG2	6	84	178.5 (38.7)	1.7 (29.23)	41	188 (40.4)	2.8 (32.95)	-1.10 (-12.97 to 10.77), 0.86
	Multiple	High HD + PA	TC	IG1	12	82	181.6 (46)	8.7 (34.65)	41	188 (40.4)	1.5 (34.22)	7.20 (-5.68 to 20.08), 0.3
	Multiple	High HD + PA	TC	IG2	12	84	178.5 (38.7)	1.8 (32.73)	41	188 (40.4)	1.5 (34.22)	0.30 (-12.30 to 12.90), 0.96

Appendix H Table 7. Lipids, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	TC	IG1	24	82	181.6 (46)	10.8 (46.43)	41	188 (40.4)	5.6 (31.84)	5.20 (-8.80 to 19.20), 0.48
	Multiple	High HD + PA	TC	IG2	24	84	178.5 (38.7)	7 (41.15)	41	188 (40.4)	5.6 (31.84)	1.40 (-11.73 to 14.53), 0.82
Salisbury, 2016[108] Good	Multiple	Medium HD + PA	TC	IG1	12	295	189.19 (46.33)	-11.58 (38.76)	288	189.19 (46.33)	-7.72 (37.31)	MD=-3.86 (-7.72 to 0.00), 0.17
Stefanick, 1998[112] (Diet and Exercise for Elevated Risk (DEER)) Fair	Dys	High HD only	HDL-C	IG1 (Females)	12	46	NR (NR)	0.3 (6)	45	NR (NR)	1 (6.1)	-0.70 (-3.19 to 1.79), NSD
	Dys	High HD only	HDL-C	IG1 (Males)	12	49	NR (NR)	-0.8 (4.4)	46	NR (NR)	-0.2 (4.3)	-0.60 (-2.35 to 1.15), NSD
	Dys	High HD only	LDL-C	IG1 (Females)	12	46	NR (NR)	-7.3 (18.9)	45	NR (NR)	-2.5 (16.6)	-4.80 (-12.10 to 2.50), NSD
	Dys	High HD only	LDL-C	IG1 (Males)	12	49	NR (NR)	-10.8 (18.8)	46	NR (NR)	-4.6 (21.1)	-6.20 (-14.26 to 1.86), NSD
	Dys	High HD only	TC	IG1 (Females)	12	46	NR (NR)	-7.9 (20.6)	45	NR (NR)	-1 (19.5)	-6.90 (-15.14 to 1.34), NSD
	Dys	High HD only	TC	IG1 (Males)	12	49	NR (NR)	-13.2 (19.3)	46	NR (NR)	-3.9 (21.6)	-9.30 (-17.56 to -1.04), NSD
Stevens, 2003[113] Fair	Dys	Medium HD only	TC	IG1	12	277	230.81 (23.17)	-7.39 (21.16)	271	232.08 (25.18)	-6.19 (23.06)	-2.47 (-4.91 to 2.51), 0.4
Ter Bogt, 2009[116] (Groningen Overweight and Lifestyle (GOAL)) Good	Multiple	High HD + PA	HDL-C	IG1 (Females)	12	103	NR (NR)	-4.25 (7.72)	114	NR (NR)	-4.63 (7.72)	0.39 (-1.67 to 2.44), NSD
	Multiple	High HD + PA	HDL-C	IG1 (Males)	12	98	NR (NR)	-2.32 (7.72)	101	NR (NR)	-1.93 (7.72)	-0.39 (-2.53 to 1.76), NSD
	Multiple	High HD + PA	LDL-C	IG1 (Females)	12	103	NR (NR)	5.79 (27.03)	114	NR (NR)	0.77 (27.03)	5.02 (-2.18 to 12.22), NSD
	Multiple	High HD + PA	LDL-C	IG1 (Males)	12	98	NR (NR)	-1.54 (23.17)	101	NR (NR)	4.63 (23.17)	-6.18 (-12.62 to 0.26), NSD
	Multiple	High HD + PA	TC	IG1 (Females)	12	103	NR (NR)	0.77 (30.89)	114	NR (NR)	-2.32 (30.89)	3.09 (-5.14 to 11.32), NSD
	Multiple	High HD + PA	TC	IG1 (Males)	12	98	NR (NR)	-6.95 (23.17)	101	NR (NR)	1.16 (27.03)	-8.11 (-15.10 to -1.12), NSD
Tiessen, 2012[117] (SPRING (Self-	Multiple	Medium HD + PA	HDL-C	IG1	12	89	50.19 (11.2)	2.7 (7.34)	90	50.19 (13.13)	3.86 (8.49)	-0.77 (-3.09 to 1.54), NSD

Appendix H Table 7. Lipids, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
monitoring and Prevention of RIsk Factors by Nurse practitioners in the region of Groningen)) Fair	Multiple	Medium HD + PA	LDL-C	IG1	12	89	139 (30.12)	-13.13 (33.59)	90	139 (31.27)	-6.95 (29.73)	-6.18 (-15.06 to 3.09), NSD
	Multiple	Medium HD + PA	TC	IG1	12	89	216.22 (32.82)	-12.36 (38.22)	90	216.22 (36.29)	-5.41 (31.66)	-6.56 (-16.99 to 3.47), NSD
Tomson, 1995[121] Fair	Dys	Medium HD only	HDL-C	IG1	12	41	NR (NR)	NR (NR)	35	NR (NR)	NR (NR)	NR, <0.05
	Dys	Medium HD only	TC	IG1	12	41	281.08 (9.27)	-10.42 (28.08)	35	281.85 (9.27)	-9.27 (27.71)	-1.16 (-13.73 to 11.42), NSD
van der Veen, 2002[122] (Nijmegen Family Practices Monitoring Project (NFPMP)) Fair	Dys	Medium HD only	HDL-C	IG1	12	67	NR (NR)	3.9 (NR)	63	NR (NR)	2.7 (NR)	NR, NSD
	Dys	Medium HD only	LDL-C	IG1	12	67	NR (NR)	-6.2 (NR)	63	NR (NR)	-7.7 (NR)	NR, NSD
	Dys	Medium HD only	TC	IG1	12	67	NR (NR)	-2.3 (NR)	63	NR (NR)	-6.2 (NR)	NR, NSD
Voils, 2013[126] (CouPLES) Fair	Dys	Medium HD + PA	LDL-C	IG1	6	103	126.2 (NR)	-2.1 (NR)	100	126.2 (NR)	-0.9 (NR)	NR,
	Dys	Medium HD + PA	LDL-C	IG1	11	106	126.2 (NR)	-4.9 (NR)	106	126.2 (NR)	-7.2 (NR)	2.30 (-3.60 to 8.30), 0.44
Wadden, 2011[127] (Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-UP)) Good	Multiple	High HD + PA	HDL-C	IG1	6	131	42.47 (11.58)	0 (0)	130	42.47 (11.58)	-0.39 (0)	NR, 0.643
	Multiple	High HD + PA	HDL-C	IG1	12	131	42.47 (11.58)	-0.77 (0)	130	42.47 (11.58)	0 (0)	NR, 0.502
	Multiple	High HD + PA	HDL-C	IG1	24	131	42.47 (11.58)	0.77 (0)	130	42.47 (11.58)	0.39 (0)	NR, 0.851
	Multiple	High HD + PA	LDL-C	IG1	6	131	111.97 (30.89)	-7.72 (44.19)	130	108.11 (38.61)	-7.72 (44.02)	0.00 (-10.70 to 10.70), 0.095
	Multiple	High HD + PA	LDL-C	IG1	12	131	111.97 (30.89)	-3.86 (44.19)	130	108.11 (38.61)	-7.72 (44.02)	3.86 (-6.84 to 14.56), 0.428
	Multiple	High HD + PA	LDL-C	IG1	24	131	111.97 (30.89)	-11.58 (44.19)	130	108.11 (38.61)	-11.58 (44.02)	0.00 (-10.70 to 10.70), 0.972
	Multiple	High HD + PA	TC	IG1	6	131	177.61 (34.75)	-11.58 (44.19)	130	181.47 (46.33)	-11.58 (44.02)	0.00 (-10.70 to 10.70), 0.971

Appendix H Table 7. Lipids, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	TC	IG1	12	131	177.61 (34.75)	-11.58 (44.19)	130	181.47 (46.33)	-11.58 (0)	NR, 0.801
	Multiple	High HD + PA	TC	IG1	24	131	177.61 (34.75)	-15.44 (44.19)	130	181.47 (46.33)	-15.44 (44.02)	0.00 (-10.70 to 10.70), 0.597
Wister, 2007[129] Good	Multiple	Medium HD + PA	HDL-C	IG1	12	157	50.19 (11.58)	1.54 (7.34)	158	50.19 (11.58)	1.16 (7.34)	0.39 (-1.23 to 2.01), NSD
	Multiple	Medium HD + PA	TC	IG1	12	157	223.94 (50.19)	-15.83 (44.4)	158	216.22 (46.33)	-5.41 (44.4)	-10.42 (-20.23 to -0.62), <0.05
Wong, 2015[130] Good	HTN	Low HD only	HDL-C	IG1	6	254	59.85 (16.6)	0.39 (31.4)	250	59.85 (16.6)	0.39 (31.15)	1.16 (-0.39 to 2.32), 0.1
	HTN	Low HD only	HDL-C	IG1	12	243	59.85 (16.6)	2.7 (30.71)	242	59.85 (16.6)	1.16 (30.64)	0.77 (-0.77 to 2.32), 0.34
	HTN	Low HD only	LDL-C	IG1	6	254	130.89 (31.27)	-5.79 (53.37)	250	125.48 (29.34)	-4.63 (52.95)	0.77 (-2.70 to 3.86), 0.7
	HTN	Low HD only	LDL-C	IG1	12	243	130.89 (31.27)	-5.79 (52.2)	242	125.48 (29.34)	-3.86 (52.1)	0.39 (-3.47 to 4.25), 0.88
	HTN	Low HD only	TC	IG1	6	254	215.06 (33.2)	-6.56 (56.51)	250	208.49 (32.43)	-5.41 (56.06)	1.16 (-2.70 to 5.02), 0.55
	HTN	Low HD only	TC	IG1	12	243	215.06 (33.2)	-5.79 (58.34)	242	208.49 (32.43)	-3.47 (55.16)	0.39 (-3.86 to 4.25), 0.91
Wood, 2008[131] (EUROACTION) Fair	Multiple	High HD + PA	LDL-C	IG1	12	1019	NR (NR)	-15.83 (NR)	332	NR (NR)	-1.16 (NR)	-13.13 (-20.08 to -6.18), 0.004
	Multiple	High HD + PA	TC	IG1	12	1019	NR (NR)	-14.67 (NR)	332	NR (NR)	0 (NR)	-13.13 (-20.85 to -5.79), 0.006

Abbreviations: CG = control group; CI = confidence interval; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HDL-C = high-density lipoprotein cholesterol; HTN = hypertension; IG = intervention group; Int arm = intervention arm; KQ = key question; LDL-C = low-density lipoprotein cholesterol; MD = mean difference; mg/dL = milligrams per deciliter; NR = not reported; NSD = no statistically significantly difference; SD = standard deviation; TC = total cholesterol

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min
†Between-group mean difference in change unless otherwise specified

Appendix H Table 8. Lipids, Dichotomous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	Percent with low HDL-C	IG1	60	694/1985 (35.0)	668/1946 (34.3)	1.02 (0.93 to 1.11),
	Multiple	High HD only	Percent with low HDL-C	IG2	60	656/1886 (34.8)	668/1946 (34.3)	1.01 (0.93 to 1.11),
Fagerberg, 1998[68] (Risk Factor Intervention Study (RIS)) Good (KQ1); Fair (KQ2)	Multiple	High HD + PA	TC at goal (<6.0 mmol/L)	IG1	40	120/235 (51.1)	88/227 (38.8)	1.32 (1.07 to 1.62), 0.01
	Multiple	High HD + PA	TC at goal (<6.0 mmol/L)	IG1	79	114/248 (46.0)	78/252 (31.0)	1.49 (1.18 to 1.87), 0.0007
	Multiple	High HD + PA	TC at goal (<6.0 mmol/L)	IG1	12	87/239 (36.4)	68/238 (28.6)	1.27 (0.98 to 1.66), 0.084
Khanji, 2019[87] (HAPPY London) Good	Multiple	Low HD + PA	LDL at goal (LDL <3 mmol/L)	IG1	6	121/194 (62.4)	108/184 (58.7)	1.06 (0.90 to 1.25), 0.51
	Multiple	Low HD + PA	TC at goal (TC <5 mmol/L)	IG1	6	116/194 (59.8)	101/184 (54.9)	1.09 (0.91 to 1.30), 0.37
Voils, 2013[126] (CouPLES) Fair	Dys	Medium HD + PA	LDL-C at goal (<100 mg/dL [high risk], <130 mg/dL [moderate risk], <160 [low-risk])	IG1	11	58/106 (54.7)	60/106 (56.6)	OR=0.95 (0.60 to 1.70), 0.87
	Dys	Medium HD + PA	LDL-C at goal (<100 mg/dL [high risk], <130 mg/dL [moderate risk], <160 [low-risk])	IG1	6	59/106 (55.7)	45/100 (45.0)	1.24 (0.94 to 1.63),
Wood, 2008[131] (EUROACTION) Fair	Multiple	High HD + PA	TC at goal (<5 mmol/L)	IG1	12	345/965 (35.8)	295/937 (31.5)	Difference in probability=2.40 (-9.90 to 14.80), 0.64
	Multiple	High HD + PA	LDL-C at goal (<3 mmol/L)	IG1	12	419/936 (44.8)	320/908 (35.2)	Difference in probability=8.70 (-5.20 to 22.70), 0.17

Abbreviations: CG = control group; CI = confidence interval; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HDL-C = high-density lipoprotein cholesterol; HTN = hypertension; IG = intervention group; Int arm = intervention arm; KQ = key question; LDL-C = low-density lipoprotein cholesterol; mmol/L = millimoles per liter; NR = not reported; NSD = no statistically significantly difference; OR = odds ratio; TC = total cholesterol

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

†Risk ratio unless otherwise specified

Appendix H Table 9. Glucose, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Anderssen, 1995[40] (Oslo Diet and Exercise Study (ODES)) Fair	Multiple	Medium HD only	FBG (mg/dL)	IG1	12	52	101.81 (14.6)	-3.6 (1.8)	43	97.49 (9.37)	0 (1.8)	-3.60 (-4.33 to -2.88), <0.05
Appel, 2011[42] (POWER Hopkins (Practice Based Opportunities for Weight Reduction)) Good	Multiple	High HD + PA	FBG (mg/dL)	IG1	6	117	103.9 (21.07)	-4.3 (15.14)	100	107.1 (30.32)	-3.4 (16)	-0.90 (-5.10 to 3.20), 0.66
	Multiple	High HD + PA	FBG (mg/dL)	IG2	6	121	104.8 (23.58)	-2.5 (20.9)	100	107.1 (30.32)	-3.4 (16)	0.90 (-3.90 to 5.70), 0.71
	Multiple	High HD + PA	FBG (mg/dL)	IG1	24	105	103.9 (21.07)	-2.6 (15.37)	93	107.1 (30.32)	-3.8 (22.18)	1.20 (-4.20 to 6.60), 0.66
	Multiple	High HD + PA	FBG (mg/dL)	IG2	24	110	104.8 (23.58)	-5.7 (17.83)	93	107.1 (30.32)	-3.8 (22.18)	-1.80 (-7.50 to 3.80), 0.52
Babazono, 2007[45] (PHPP) Fair	Multiple	Medium HD + PA	HbA1c (%)	IG1	12	46	5.5 (0.6)	0 (0.53)	41	5.4 (0.4)	0 (0.4)	0.00 (-0.20 to 0.20), NSD
Bennett, 2018 [48] (Track) Good	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	12	136	119.4 (52.1)	-4.9 (48.19)	151	115.7 (46)	3.2 (47.96)	-8.10 (-17.10 to 0.90), 0.08
	Multiple	Medium HD + PA	HbA1c (%)	IG1	12	129	6.6 (1.7)	-0.3 (0.87)	146	6.5 (1.6)	-0.2 (0.12)	-0.20 (-0.40 to 0.04), 0.11
Blackford, 2016[50] (Albany Physical Activity and Nutrition (APAN)) Fair	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	6	130	90.28 (8.29)	0.9 (7.55)	144	90.82 (8.83)	1.26 (8)	-0.36 (-2.20 to 1.48), 0.79
Bo, 2007[52] Fair	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	12	169	104.52 (14.42)	-4.69 (11.89)	166	104.52 (12.61)	1.26 (10.63)	-5.95 (-8.36 to -3.53), <0.001
	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	108	148	104.52 (14.42)	-5.59 (11.24)	138	104.52 (12.61)	-0.54 (13.72)	-5.05 (-7.97 to -2.13), 0.004
Broekhuizen, 2012[54] (PRO-FIT) Fair	Dys	Medium HD + PA	FBG (mg/dL)	IG1	12	169	88.3 (14.42)	-3.6 (11.43)	145	88.3 (18.02)	-1.8 (13.96)	-1.80 (-4.65 to 1.05), NSD
Burke, 2006[56] (ADAPT) Fair	HTN	Medium HD + PA	FBG (mg/dL)	IG1	16	123	90.1 (10.27)	-2.34 (4.14)	118	90.1 (14.96)	-2.16 (3.96)	-0.18 (-1.20 to 0.84), NSD
	HTN	Medium HD + PA	FBG (mg/dL)	IG1	40	123	90.1 (10.27)	0 (8.59)	118	90.1 (14.96)	0 (12.51)	0.00 (-1.80 to 1.80), 0.981
Chirinos, 2016[57] (Community Health and Risk-reduction for Metabolic Syndrome	Multiple	High HD + PA	FBG (mg/dL)	IG1	6	60	88.83 (10.9)	-2.38 (NR)	60	86.66 (9.47)	1.84 (NR)	NR, <0.05
	Multiple	High HD + PA	FBG (mg/dL)	IG1	12	60	88.83 (10.9)	-0.4 (NR)	60	86.66 (9.47)	4.02 (NR)	NR, <0.05

Appendix H Table 9. Glucose, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
(CHARMS)) Fair												
Christian, 2011[58] Fair	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	12	133	95.1 (11.6)	1.41 (12.65)	130	97.4 (10.76)	-0.12 (10.86)	1.53 (-6.50 to 9.56), 0.85
Cicolini, 2014[59] Fair	HTN	Medium HD + PA	FBG (mg/dL)	IG1	6	100	119 (29)	-13.6 (15.3)	98	127 (38)	-17.1 (25.2)	3.50 (-2.32 to 9.32), 0.9
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	FBG (mg/dL)	IG1	12	78	123.1 (38.3)	-6.13 (24.74)	75	113.8 (33.8)	3.51 (17.78)	-9.64 (-16.45 to -2.83), <0.05
	Multiple	High HD only	FBG (mg/dL)	IG2	12	82	119.6 (36.04)	-4.61 (24.07)	75	113.8 (33.8)	3.51 (17.78)	-8.12 (-14.70 to -1.54), NSD
Fagerberg, 1998[68] (Risk Factor Intervention Study (RIS)) Good (KQ1); Fair (KQ2)	Multiple	High HD + PA	FBG (mg/dL)	IG1	12	239	104.52 (43.25)	-7.21 (81.09)	238	104.52 (36.04)	3.6 (25.23)	-10.81 (-21.62 to 0.00), 0.051
	Multiple	High HD + PA	FBG (mg/dL)	IG1	40	235	104.52 (43.25)	-3.6 (34.24)	227	104.52 (36.04)	3.6 (25.23)	MD=-7.21 (-12.61 to -1.80), 0.011
	Multiple	High HD + PA	FBG (mg/dL)	IG1	79	248	104.52 (43.25)	-3.6 (26.13)	252	104.52 (36.04)	0 (21.08)	-3.60 (-8.47 to -0.18), NSD
Gill, 2019[69] (Heartmatters Challenge - First Responders) Fair	Multiple	High HD + PA	FBG (mg/dL)	IG1	12	66	100.66 (21.54)	NR (NR)	70	103.5 (9.19)	NR (NR)	3.20 (-17.79 to 24.19), 0.77
	Multiple	High HD + PA	HbA1c (%)	IG1	6	96	5.48 (0.39)	NR (NR)	79	5.64 (0.4)	NR (NR)	-0.12 (-0.20 to -0.04), 0.01
	Multiple	High HD + PA	HbA1c (%)	IG1	12	96	5.48 (0.39)	NR (NR)	79	5.64 (0.4)	NR (NR)	0.04 (-0.02 to 0.10), 0.17
Greaves, 2015[71] (Waste the Waist) Fair	Multiple	High HD + PA	FBG (mg/dL)	IG1	12	53	93.88 (9.01)	NR (NR)	53	96.59 (10.81)	NR (NR)	-2.34 (-5.23 to 0.72), NSD
	Multiple	High HD + PA	HbA1c (mmol/L)	IG1	12	54	38.1 (3.5)	NR (NR)	52	39.1 (5)	NR (NR)	-0.84 (-1.89 to 0.21), NSD
Groeneveld, 2010[72] (Health Under Construction) Fair	Multiple	Medium HD + PA	HbA1c (%)	IG1	6	250	5.66 (0.41)	0.04 (0.4)	255	5.66 (0.41)	0.04 (0.37)	0.00 (-0.07 to 0.07), NSD
	Multiple	Medium HD + PA	HbA1c (%)	IG1	12	2560	5.66 (0.41)	0.08 (0.37)	255	5.66 (0.41)	0.12 (0.4)	-0.04 (-0.09 to 0.01), NSD
Haufe, 2019[75] Fair	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	6	160	110.4 (22.1)	-6.4 (16.94)	154	109.4 (17.8)	-0.6 (14.36)	-5.40 (-7.60 to -3.20), <0.0001
Kandula, 2015[83] (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	Multiple	High HD + PA	FBG (mg/dL)	IG1	6	31	109 (21)	-1.8 (41.49)	32	114 (44)	12.4 (41.56)	-14.20 (-35.47 to 7.05), NSD

Appendix H Table 9. Glucose, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Khanji, 2019[87] (HAPPY London) Good	Multiple	Low HD + PA	FBG (mg/dL)	IG1	6	194	NR (NR)	-5.23 (NR)	183	NR (NR)	-4.79 (NR)	-0.54 (-3.60 to 3.60), 0.77
Kramer, 2018[89] (Healthy Lifestyle Project) Fair	Multiple	High HD + PA	FBG (mg/dL)	IG1	6	81	96 (10.3)	-3.4 (7.8)	41	95.9 (13.1)	-1.8 (6.3)	-1.60 (-4.17 to 0.97), 0.24
	Multiple	High HD + PA	HbA1c (%)	IG1	6	81	5.8 (0.32)	-0.15 (0.17)	41	5.76 (0.33)	-0.02 (0.17)	-0.13 (-0.19 to -0.07), 0.0002
Liira, 2014[93] Fair	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	12	46	104.52 (16.22)	-3.6 (12.33)	42	100.91 (7.21)	1.8 (8.22)	-5.41 (-9.75 to -1.06), NSD
Moreau, 2001[95] Fair	HTN	Low PA only	FBG (mg/dL)	IG1	6	15	100.91 (20.9)	-1.8 (15.89)	9	102.71 (21.62)	0 (16.57)	-1.80 (-15.29 to 11.69), NSD
Reid, 2014[103] Fair	Multiple	High HD + PA	FBG (mg/dL)	IG1	12	211	92.26 (9.37)	0.72 (8.54)	215	91.72 (10.63)	0.72 (8.75)	0.00 (-1.64 to 1.64), 0.3
Rosas, 2015[106] (Vivamos Activos Fair Oaks (VAFO)) Good	Multiple	High HD + PA	FBG (mg/dL)	IG1	6	82	111.9 (31.7)	0.4 (26.8)	41	110 (26.5)	4 (24.39)	-3.60 (-13.06 to 5.86), 0.47
	Multiple	High HD + PA	FBG (mg/dL)	IG2	6	84	116.6 (37.5)	0.7 (30.63)	41	110 (26.5)	4 (24.39)	-3.30 (-13.23 to 6.63), 0.52
	Multiple	High HD + PA	FBG (mg/dL)	IG1	12	82	111.9 (31.7)	-2.9 (27.26)	41	110 (26.5)	6.3 (24.71)	-9.20 (-18.79 to 0.39), 0.07
	Multiple	High HD + PA	FBG (mg/dL)	IG2	12	84	116.6 (37.5)	-1.6 (38.58)	41	110 (26.5)	6.3 (24.71)	-7.90 (-19.09 to 3.29), 0.18
	Multiple	High HD + PA	FBG (mg/dL)	IG1	24	82	111.9 (31.7)	-1.9 (46.43)	41	110 (26.5)	4.6 (34.53)	-6.50 (-21.09 to 8.09), 0.34
	Multiple	High HD + PA	FBG (mg/dL)	IG2	24	84	116.6 (37.5)	2.7 (52.37)	41	110 (26.5)	4.6 (34.53)	-1.90 (-17.30 to 13.50), 0.81
Stefanick, 1998[112] (Diet and Exercise for Elevated Risk (DEER)) Fair	Dys	High HD only	FBG (mg/dL)	IG1 (Females)	12	46	NR (NR)	-7.7 (6.6)	45	NR (NR)	-2.6 (15.2)	-5.10 (-9.93 to -0.27), NSD
	Dys	High HD only	FBG (mg/dL)	IG1 (Males)	12	49	NR (NR)	-7.6 (8.6)	46	NR (NR)	-3.8 (10.5)	-3.80 (-7.67 to 0.07), NSD
Ter Bogt, 2009[116] (Groningen Overweight and Lifestyle (GOAL)) Good	Multiple	High HD + PA	FBG (mg/dL)	IG1 (Females)	12	103	NR (NR)	-1.44 (10.81)	114	NR (NR)	-1.98 (9.01)	0.54 (-2.12 to 3.20), NSD
	Multiple	High HD + PA	FBG (mg/dL)	IG1 (Males)	12	98	NR (NR)	-0.54 (10.81)	101	NR (NR)	-0.9 (14.42)	0.36 (-3.17 to 3.89), NSD
Tiessen, 2012[117] (SPRING (Self-monitoring and Prevention of RIsk Factors by Nurse practitioners in the	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	12	89	97.31 (9.01)	3.06 (9.91)	90	97.31 (12.25)	5.05 (11.35)	-1.98 (-5.05 to 1.26), NSD

Appendix H Table 9. Glucose, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
region of Groningen)) Fair												
Toft, 2008[118] (Inter99) Fair	Multiple	High HD + PA	FBG (mg/dL)	IG1	60	2454	NR (NR)	NR (NR)	284	NR (NR)	NR (NR)	1.10 (-0.28 to 2.48), 0.116
Wadden, 2011[127] (Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-UP)) Good	Multiple	High HD + PA	FBG (mg/dL)	IG1	6	131	106.3 (32.4)	-0.4 (1.14)	130	111.7 (39.6)	0 (1.14)	-0.40 (-0.68 to -0.12), <0.05
	Multiple	High HD + PA	FBG (mg/dL)	IG1	12	131	106.3 (32.4)	-0.2 (1.14)	130	111.7 (39.6)	0.1 (1.14)	-0.30 (-0.58 to -0.02), NSD
	Multiple	High HD + PA	FBG (mg/dL)	IG1	24	131	106.3 (32.4)	0 (2.29)	130	111.7 (39.6)	0 (2.28)	0.00 (-0.55 to 0.55), NSD
Wister, 2007[129] Good	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	12	157	149.57 (46.85)	-6.67 (55.32)	158	145.96 (41.45)	0.18 (48.47)	-6.85 (-18.34 to 4.64), NSD
Wood, 2008[131] (EUROACTION) Fair	Multiple	High HD + PA	FBG (mg/dL)	IG1	12	1019	NR (NR)	-8.29 (NR)	332	NR (NR)	-5.05 (NR)	-1.98 (-13.52 to 9.55), 0.67

Abbreviations: BMI = body mass index; CG = control group; CI = confidence interval; cm = centimeters; Dys = dyslipidemia; FBG = fasting blood glucose; HbA1c = glycated hemoglobin; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; KQ = key question; mg/dL = milligrams per deciliter; MD = mean difference; NR = not reported; NSD = no statistically significantly difference; SD = standard deviation

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min
†Between-group mean difference in change unless otherwise specified

Appendix H Table 10. Glucose and Metabolic Syndrome, Dichotomous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Anderssen, 1995 (Oslo Diet and Exercise Study (ODES)) Fair	Multiple	Medium HD only	METS prevalence (Males with METS at baseline only)	IG1	12	22/34 (64.7)	23/26 (88.5)	0.73 (0.55 to 0.97), 0.023
Babazono, 2007[45] (PHPP) Fair	Multiple	Medium HD + PA	Diabetes incidence	IG1	12	11/46 (23.9)	10/41 (24.4)	0.98 (0.47 to 2.07), NSD
Bo, 2007[52] Fair	Multiple	Medium HD + PA	Diabetes incidence	IG1	12	3/169 (1.8)	12/166 (7.2)	OR=0.23 (0.06 to 0.85), 0.03
	Multiple	Medium HD + PA	Diabetes incidence	IG1	108	14/169 (8.3)	27/166 (16.3)	HR=0.47 (0.24 to 0.89), 0.021
	Multiple	Medium HD + PA	Percent with Hyperglycemia	IG1	12	27/169 (16.0)	81/166 (48.8)	OR=0.19 (0.11 to 0.32), <0.001
	Multiple	Medium HD + PA	IFG incidence	IG1	12	24/169 (14.2)	69/166 (41.6)	OR=0.22 (0.13 to 0.39), <0.001
	Multiple	Medium HD + PA	METS incidence	IG1	12	59/169 (34.9)	109/166 (65.7)	OR=0.28 (0.18 to 0.44), <0.001
Chirinos, 2016 (Community Health and Risk-reduction for Metabolic Syndrome (CHARMS)) Fair	Multiple	High HD + PA	METS prevalence	IG1	6	1320/1982 (66.6)	1326/1934 (68.6)	0.97 (0.93 to 1.01), NSD
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	Diabetes incidence	IG1	48	80/1154 (6.9)	101/1147 (8.8)	HR=0.60 (0.43 to 0.85), <0.05
	Multiple	High HD only	Diabetes incidence	IG2	48	92/1240 (7.4)	101/1147 (8.8)	HR=0.82 (0.61 to 1.10), NSD
	Multiple	High HD only	METS incidence	IG2	38	333/662 (50.3)	298/594 (50.2)	HR=1.08 (0.92 to 1.27), NSD
Greaves, 2015 (Waste the Waist) Fair	Multiple	High HD + PA	METS prevalence	IG1	12	21/54 (38.9)	32/53 (60.4)	0.64 (0.43 to 0.96), 0.034
Khanji, 2019[87] (HAPPY London) Good	Multiple	Low HD + PA	FBG at goal	IG1	6	162/194 (83.5)	149/184 (81.0)	1.03 (0.94 to 1.13), 0.60
Liira, 2014 Fair	Multiple	Medium HD + PA	METS prevalence	IG1	12	27/46 (58.7)	21/42 (50.0)	1.17 (0.80 to 1.73), 0.33

Appendix H Table 10. Glucose and Metabolic Syndrome, Dichotomous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Toft, 2008[118] (Inter99) Fair	Multiple	High HD + PA	Diabetes incidence	IG1	60	187/2454 (7.6)	21/284 (7.4)	1.03 (0.67 to 1.59), 0.892

Abbreviations: CG = control group; CI = confidence interval; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HR = hazard ratio; HTN = hypertension; IG = intervention group; IFG = impaired fasting glucose; Int arm = intervention arm; KQ = key question; NR = not reported; NSD = no statistically significantly difference; OR = odds ratio

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

†Risk ratio unless otherwise specified

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Ammerman, 2003[38] Fair	Dys	Medium HD only	Weight (kg)	IG1	6	154	79.5 (29.39)	-1.41 (6.37)	189	80 (30.16)	-0.45 (4.17)	-0.95 (-1.86 to -0.05), 0.04
	Dys	Medium HD only	Weight (kg)	IG1	12	189	79.5 (29.39)	-0.73 (4.91)	196	80 (30.16)	0 (NR)	-0.73 (-1.68 to 0.23), 0.13
Anderson, 1992[39] Fair	Dys	High HD only	Weight (kg)	IG1	12	48	71.08 (12.7)	-1.02 (3.54)	51	71.44 (9.91)	-0.44 (2.68)	-0.58 (-1.82 to 0.66), <0.05
	Dys	High HD only	Weight (kg)	IG2	12	47	72.04 (8.69)	-1.06 (2.49)	51	71.44 (9.91)	-0.44 (2.68)	-0.62 (-1.64 to 0.40), <0.05
Anderssen, 1995[40] (Oslo Diet and Exercise Study (ODES)) Fair	Multiple	Medium HD only	BMI (kg/m^2)	IG1	12	52	29.7 (4.2)	-1.3 (0.2)	43	28.3 (3.1)	0.4 (0.1)	-1.63 (-2.12 to -1.14), <0.05
	Multiple	Medium HD only	Waist circumference (cm)	IG1	12	52	105 (9.37)	-3.7 (4.33)	43	102.3 (9.18)	0.9 (2.62)	-4.60 (-6.01 to -3.19), <0.05
	Multiple	Medium HD only	Weight (kg)	IG1	12	52	93.4 (12.98)	-4 (5.05)	43	89.3 (13.77)	1.1 (2.62)	-5.10 (-6.68 to -3.52), <0.05
Appel, 2003[41] (PREMIER) Good	HTN	High HD + PA	Weight (kg)	IG1	6	233	98.8 (19.3)	-5.8 (5.8)	242	95.8 (17)	-1.1 (3.2)	-4.70 (-5.55 to -3.85), <0.001
	HTN	High HD + PA	Weight (kg)	IG2	6	238	96.2 (17.8)	-4.9 (5.5)	242	95.8 (17)	-1.1 (3.2)	-3.80 (-4.61 to -2.99), <0.001
	HTN	High HD + PA	Weight (kg)	IG2 (HTN subgroup)	6	97	98.1 (18.4)	-5.9 (5.9)	97	94.7 (16)	-1.3 (3.4)	-4.60 (-5.96 to -3.24), <0.05
	HTN	High HD + PA	Weight (kg)	IG1	18	241	98.6 (19.1)	-4.3 (7.4)	241	96 (17.2)	-1.5 (5)	-2.70 (-3.80 to -1.60), <0.001
	HTN	High HD + PA	Weight (kg)	IG2	18	235	95.7 (17.6)	-3.8 (6.1)	241	96 (17.2)	-1.5 (5)	-2.20 (-3.30 to -1.10), <0.001
Appel, 2011[42] (POWER Hopkins (Practice Based Opportunities for Weight Reduction)) Good	Multiple	High HD + PA	BMI (kg/m^2)	IG1	6	124	36.8 (16.45)	-2 (2.23)	113	36.8 (4.7)	-0.5 (1.06)	-1.40 (-2.00 to -0.90), <0.001
	Multiple	High HD + PA	BMI (kg/m^2)	IG2	6	129	36.1 (4.72)	-2.1 (2.27)	113	36.8 (4.7)	-0.5 (1.06)	-1.60 (-2.00 to -1.10), <0.001
	Multiple	High HD + PA	BMI (kg/m^2)	IG1	12	123	36.8 (16.45)	-1.8 (2.22)	108	36.8 (4.7)	-0.4 (2.08)	-1.40 (-1.90 to -0.80), <0.001
	Multiple	High HD + PA	BMI (kg/m^2)	IG2	12	124	36.1 (4.72)	-1.9 (2.23)	108	36.8 (4.7)	-0.4 (2.08)	-1.50 (-2.10 to -0.90), <0.001
	Multiple	High HD + PA	BMI (kg/m^2)	IG1	24	133	36.8 (16.45)	-1.7 (3.46)	129	36.8 (4.7)	-0.4 (2.27)	-1.30 (-2.10 to -0.60), <0.001

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	BMI (kg/m^2)	IG2	24	139	36.1 (4.72)	-1.7 (3.54)	129	36.8 (4.7)	-0.4 (2.27)	-1.30 (-2.00 to -0.60), <0.001
	Multiple	High HD + PA	Waist circumference (cm)	IG1	6	120	118.3 (14.1)	-5.4 (6.57)	110	118.5 (12.92)	-2.8 (4.2)	-2.60 (-4.00 to -1.20), <0.001
	Multiple	High HD + PA	Waist circumference (cm)	IG2	6	127	117.8 (12.97)	-6.4 (6.76)	110	118.5 (12.92)	-2.8 (4.2)	-3.50 (-5.00 to -2.00), <0.001
	Multiple	High HD + PA	Waist circumference (cm)	IG1	24	119	118.3 (14.1)	-6.3 (8.73)	107	118.5 (12.92)	-3.4 (7.24)	-2.80 (-4.80 to -0.90), 0.005
	Multiple	High HD + PA	Waist circumference (cm)	IG2	24	119	117.8 (12.97)	-6.7 (9.82)	107	118.5 (12.92)	-3.4 (7.24)	-3.30 (-5.40 to -1.20), 0.003
	Multiple	High HD + PA	Weight (kg)	IG1	6	124	104.9 (18.8)	-5.8 (6.68)	113	104.2 (15.27)	-1.5 (4.25)	-4.30 (-5.80 to -2.90), <0.001
	Multiple	High HD + PA	Weight (kg)	IG2	6	129	102.5 (14.15)	-6 (5.68)	113	104.2 (15.27)	-1.5 (4.25)	-4.50 (-5.80 to -3.20), <0.001
	Multiple	High HD + PA	Weight (kg)	IG1	12	123	104.9 (18.8)	-5.4 (7.76)	108	104.2 (15.27)	-1.1 (5.2)	-4.30 (-5.90 to -2.60), <0.001
	Multiple	High HD + PA	Weight (kg)	IG2	12	124	102.5 (14.15)	-5.7 (7.79)	108	104.2 (15.27)	-1.1 (5.2)	-4.50 (-6.10 to -2.90), <0.001
	Multiple	High HD + PA	Weight (kg)	IG1	24	133	104.9 (18.8)	-5.1 (9.23)	129	104.2 (15.27)	-0.8 (7.95)	-4.30 (-6.30 to -2.30), <0.001
	Multiple	High HD + PA	Weight (kg)	IG2	24	139	102.5 (14.15)	-4.5 (8.25)	129	104.2 (15.27)	-0.8 (7.95)	-3.80 (-5.60 to -1.90), <0.001
Applegate, 1992[43] Fair	HTN	High HD + PA	Weight (kg)	IG1	6	21	88.7 (NR)	-2.1 (NR)	26	79.7 (NR)	0.3 (NR)	NR, 0.0001
Arroll, 1995[44] Fair	HTN	Low HD + PA	Weight (kg)	IG1	6	48	NR (NR)	0.3 (NR)	43	NR (NR)	0.8 (NR)	NR
	HTN	Low PA only	Weight (kg)	IG2	6	46	NR (NR)	-0.7 (NR)	43	NR (NR)	0.8 (NR)	NR
	HTN	Low HD only	Weight (kg)	IG3	6	44	NR (NR)	-0.6 (NR)	43	NR (NR)	0.8 (NR)	NR

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Babazono, 2007[45] (PHPP) Fair	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	12	46	23.6 (3.2)	-0.5 (1.01)	41	24 (2.5)	-0.1 (0.78)	-0.40 (-0.78 to -0.02), NSD
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	46	58.5 (9.7)	-1.4 (3.04)	41	58.6 (9.1)	-0.5 (2.85)	-0.90 (-2.14 to 0.34), NSD
Beckmann, 1995[46] Fair	HTN	Medium HD only	BMI (kg/m^2)	IG1	12	32	27.9 (3.39)	-0.8 (1.07)	32	26.7 (3.39)	0 (1.07)	-0.80 (-1.33 to -0.27), <0.05
	HTN	Medium HD only	Weight (kg)	IG1	6	32	87.2 (12.45)	-2.4 (3.92)	32	83.6 (13.01)	0.8 (4.44)	-3.20 (-5.25 to -1.15), <0.05
	HTN	Medium HD only	Weight (kg)	IG1	12	32	87.2 (12.45)	-2.7 (2.83)	32	83.6 (13.01)	0.3 (4.24)	-3.00 (-4.77 to -1.23), <0.05
Bennett, 2012[47] (Be Fit, Be Well [POWER]) Good	HTN	High HD + PA	BMI (kg/m^2)	IG1	6	180	37.04 (4.96)	-0.48 (1.88)	185	36.99 (5.24)	-0.05 (1.77)	-0.43 (-0.80 to -0.05), <0.05
	HTN	High HD + PA	BMI (kg/m^2)	IG1	12	180	37.04 (4.96)	-0.54 (1.88)	185	36.99 (5.24)	-0.12 (1.77)	-0.42 (-0.80 to -0.03), <0.05
	HTN	High HD + PA	BMI (kg/m^2)	IG1	18	180	37.04 (4.96)	-0.5 (2.01)	185	36.99 (5.24)	-0.15 (1.9)	-0.35 (-0.75 to 0.06), <0.05
	HTN	High HD + PA	BMI (kg/m^2)	IG1	24	180	37.04 (4.96)	-0.58 (1.88)	185	36.99 (5.24)	-0.2 (1.77)	-0.38 (-0.75 to 0.00), <0.05
	HTN	High HD + PA	Weight (kg)	IG1	6	180	99.7 (16.29)	-1.25 (4.96)	185	100.61 (18.67)	-0.13 (4.76)	-1.11 (-2.12 to -0.10), <0.05
	HTN	High HD + PA	Weight (kg)	IG1	12	180	99.7 (16.29)	-1.37 (5.1)	185	100.61 (18.67)	-0.32 (4.9)	-1.05 (-2.09 to -0.01), <0.05
	HTN	High HD + PA	Weight (kg)	IG1	18	180	99.7 (16.29)	-1.28 (5.37)	185	100.61 (18.67)	-0.33 (5.17)	-0.95 (-2.03 to 0.14), <0.05
	HTN	High HD + PA	Weight (kg)	IG1	24	180	99.7 (16.29)	-1.53 (4.96)	185	100.61 (18.67)	-0.5 (4.76)	-1.03 (-2.03 to -0.03), <0.05
Bennett, 2018 [48] (Track) Good	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	6	170	35.9 (4.1)	-1.4 (2)	167	35.9 (3.7)	0.2 (1.88)	-1.60 (-2.00 to -1.20), <0.0001
	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	12	170	35.9 (4.1)	-1.4 (2.33)	167	35.9 (3.7)	-0.01 (1.98)	-1.40 (-1.80 to -0.90), <0.0001
	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	6	170	114.4 (10.2)	-3.4 (6.32)	167	115 (10.2)	0.1 (6.26)	-3.50 (-4.80 to -2.20), <0.0001

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	12	170	114.4 (10.2)	-2.9 (6.98)	167	115 (10.2)	0.6 (6.59)	-3.60 (-5.00 to -2.10), <0.0001
	Multiple	Medium HD + PA	Weight (kg)	IG1	6	170	98.9 (14.4)	-4.1 (4.99)	167	99.7 (13.8)	0.3 (4.94)	-4.40 (-5.50 to -3.30), <0.05
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	170	98.9 (14.4)	-4 (6.32)	167	99.7 (13.8)	-0.1 (5.93)	-3.80 (-5.10 to -2.50), <0.001
Blackford, 2016[50] (Albany Physical Activity and Nutrition (APAN)) Fair	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	6	151	29.55 (6.93)	-0.2 (2.2)	161	29.8 (7.05)	-0.1 (2.21)	-0.10 (-0.59 to 0.39), <0.001
	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	6	151	102.67 (13.58)	-2.11 (13.71)	161	101.41 (12.93)	-0.88 (12.81)	-1.23 (-4.18 to 1.72), 0.03
	Multiple	Medium HD + PA	Weight (kg)	IG1	6	151	85.2 (22.6)	-0.7 (7.4)	161	85.3 (21.9)	1.1 (6.94)	-1.80 (-3.39 to -0.21), 0.01
Bloemberg, 1991[51] Fair	Dys	Medium HD only	Weight (kg)	IG1	6	39	80.8 (9.9)	-0.94 (2.68)	41	83.3 (8.6)	0.06 (1.86)	-1.00 (-2.02 to 0.02), 0.03
Bo, 2007[52] Fair	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	12	169	29.7 (4.1)	-0.29 (1.79)	166	29.8 (4.6)	0.61 (1.97)	-0.90 (-1.30 to -0.50), <0.001
	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	108	148	29.7 (4.1)	-0.6 (1.34)	138	29.8 (4.6)	0.2 (1.5)	-0.80 (-1.13 to -0.47), 0.12
	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	12	169	99.6 (11.6)	-2.55 (5.21)	166	99.8 (10.6)	1.96 (6.67)	-4.51 (-5.79 to -3.23), <0.001
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	169	81.7 (14.9)	-0.75 (4.93)	166	81.3 (13.5)	1.63 (5.23)	-2.38 (-3.47 to -1.29), <0.001
	Multiple	Medium HD + PA	Weight (kg)	IG1	108	148	81.7 (14.9)	-1.7 (4.97)	138	81.3 (13.5)	-0.6 (4.22)	-1.10 (-2.17 to -0.03), 0.69
Broekhuizen, 2012[54] (PRO-FIT) Fair	Dys	Medium HD + PA	BMI (kg/m^2)	IG1	12	167	25.9 (4.5)	-0.01 (1.41)	147	27.1 (5.4)	0 (1.69)	-0.01 (-0.36 to 0.34), NSD
	Dys	Medium HD + PA	Waist circumference (cm)	IG1	12	165	86.4 (11.9)	-0.3 (11.71)	146	89.9 (14.5)	0 (14.4)	-0.30 (-3.24 to 2.64), NSD

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Burke, 2006[56] (ADAPT) Fair	HTN	Medium HD + PA	Waist circumference (cm)	IG1	16	123	96.6 (9.3)	-4.62 (2.21)	118	93.8 (8.4)	-1.22 (2.77)	-3.40 (-4.03 to -2.77), <0.001
	HTN	Medium HD + PA	Waist circumference (cm)	IG1	40	123	96.6 (9.3)	-2.5 (9.46)	118	93.8 (8.4)	-2 (9.64)	-0.30 (-1.70 to 1.00), 0.930
	HTN	Medium HD + PA	Weight (kg)	IG1	16	123	86.5 (12.73)	-3.52 (2.72)	118	84.4 (6.1)	-0.96 (1.88)	-2.56 (-3.15 to -1.97), <0.001
	HTN	Medium HD + PA	Weight (kg)	IG1	40	123	86.5 (12.73)	-1.5 (4.03)	118	84.4 (6.1)	-0.7 (6.41)	-0.70 (-1.80 to 0.40), 0.273
Chirinos, 2016[57] (Community Health and Risk-reduction for Metabolic Syndrome (CHARMS)) Fair	Multiple	High HD + PA	Waist circumference (cm)	IG1	6	60	104.58 (9.05)	-1.01 (NR)	60	105.21 (9.22)	0.1 (NR)	NR, NSD
	Multiple	High HD + PA	Waist circumference (cm)	IG1	12	60	104.58 (9.05)	-0.84 (NR)	60	105.21 (9.22)	-1.13 (NR)	NR
	Multiple	High HD + PA	Weight (kg)	IG1	6	60	87.75 (12.85)	-2.84 (NR)	60	88.03 (13.02)	-0.46 (NR)	NR, <0.05
	Multiple	High HD + PA	Weight (kg)	IG1	12	60	87.75 (12.85)	-2.36 (NR)	60	88.03 (13.02)	-0.54 (NR)	NR, <0.05
Christian, 2011[58] Fair	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	12	133	116.7 (14.91)	-2.2 (12.12)	130	113.8 (14.7)	1.5 (14.85)	-3.70 (-12.98 to 5.58), 0.01
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	133	93.92 (19.92)	-1.5 (5.27)	130	92.02 (22.6)	0.15 (4.02)	-1.65 (-4.83 to 1.54), 0.002
Cicolini, 2014[59] Fair	HTN	Medium HD + PA	BMI (kg/m^2)	IG1	6	100	29 (6.7)	-2.4 (3.5)	98	29 (5.1)	-1.3 (1.1)	-1.10 (-1.82 to -0.38), <0.001
Cochrane, 2012[60] Fair	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	12	236	28.7 (5)	-0.22 (1.96)	365	27.5 (4.1)	-0.02 (1.46)	-0.20 (-0.49 to 0.09), NSD
	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	12	231	101.3 (11.2)	-1.61 (5.51)	355	99.5 (11.8)	-1.19 (5.67)	-0.42 (-1.34 to 0.50), NSD
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	236	85 (14.5)	-0.51 (5.68)	365	82.6 (13.8)	-0.23 (4.58)	-0.28 (-1.14 to 0.58), NSD

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Cohen, 1991[61] Fair	HTN	Medium HD only	Weight (kg)	IG1	6	15	91.8 (NR)	-1.8 (3.4)	15	91.7 (NR)	0.56 (2.5)	-2.36 (-4.50 to -0.22), 0.04
	HTN	Medium HD only	Weight (kg)	IG1	12	15	91.8 (NR)	-0.88 (4)	15	91.7 (NR)	1.3 (3)	-2.18 (-4.71 to 0.35), <0.1
Coleman, 2012[62] (Wisewoman California) Fair	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	12	433	31.7 (5.87)	-0.2 (NR)	436	32.1 (6.28)	0 (NR)	NR, 0.321
Delahanty, 2001[63] Good	Dys	Medium HD + PA	Weight (kg)	IG1	6	44	79.6 (15.4)	-1.9 (4.87)	44	83.2 (15)	0 (4.74)	-1.90 (-3.91 to 0.11), <0.001
	Dys	Medium HD + PA	Weight (kg)	IG1	12	43	79.6 (15.4)	-1.4 (4.87)	44	83.2 (15)	0 (4.74)	-1.40 (-3.42 to 0.62), NSD
Edelman, 2006[65] Fair	Multiple	High HD + PA	BMI (kg/m^2)	IG1	10	77	33.3 (7.8)	-1.2 (NR)	77	34.1 (7.7)	-0.6 (NR)	NR, 0.11
Ellsworth, 2016[66] Fair	Multiple	High HD + PA	BMI (% change)	IG1	12	89	31.5 (6.5)	-2.8 (4.57)	58	31.1 (6.5)	0 (NR)	NR, <0.001
	Multiple	High HD + PA	Weight (% change)	IG1	12	89	89.1 (21)	-2.8 (4.57)	58	86.5 (20)	0 (NR)	NR, <0.001
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	Waist circumference (cm)	IG1	12	2524	100.2 (10.4)	-0.66 (6.14)	2420	100.9 (10.8)	-0.45 (7.07)	-0.35 (-0.70 to 0.00), 0.05
	Multiple	High HD only	Waist circumference (cm)	IG2	12	2433	100.2 (10.5)	-0.41 (6.27)	2420	100.9 (10.8)	-0.45 (7.07)	-0.08 (-0.45 to 0.29), 0.671
	Multiple	High HD only	Waist circumference (cm)	IG1	36	2127	100.2 (10.4)	0.14 (7.79)	1851	100.9 (10.8)	0.81 (8.79)	-0.71 (-1.16 to -0.25), 0.002
	Multiple	High HD only	Waist circumference (cm)	IG2	36	2114	100.2 (10.5)	0.44 (8.23)	1851	100.9 (10.8)	0.81 (8.79)	-0.37 (-0.86 to 0.11), 0.133
	Multiple	High HD only	Waist circumference (cm)	IG1	60	1501	100.2 (10.4)	0.85 (8.38)	1243	100.9 (10.8)	1.2 (9.37)	-0.55 (-1.16 to -0.06), 0.048
	Multiple	High HD only	Waist circumference (cm)	IG2	60	1241	100.2 (10.5)	0.37 (8.91)	1243	100.9 (10.8)	1.2 (9.37)	-0.94 (-1.60 to -0.27), 0.006

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD only	Weight (kg)	IG1	12	2524	76.7 (11.8)	-0.19 (3.63)	2420	77 (12.2)	-0.23 (4.19)	-0.02 (-0.23 to 0.20), 0.876
	Multiple	High HD only	Weight (kg)	IG2	12	2433	76.6 (11.9)	0.01 (3.9)	2420	77 (12.2)	-0.23 (4.19)	0.14 (-0.09 to 0.36), 0.231
	Multiple	High HD only	Weight (kg)	IG1	36	2127	76.7 (11.8)	-0.53 (4.71)	1851	77 (12.2)	-0.24 (5.62)	-0.36 (-0.68 to -0.04), 0.026
	Multiple	High HD only	Weight (kg)	IG2	36	2114	76.6 (11.9)	-0.16 (5.07)	1851	77 (12.2)	-0.24 (5.62)	-0.06 (-0.40 to 0.28), 0.712
	Multiple	High HD only	Weight (kg)	IG1	60	1501	76.7 (11.8)	-0.88 (5.31)	1243	77 (12.2)	-0.6 (5.4)	-0.43 (-0.86 to -0.01), 0.044
	Multiple	High HD only	Weight (kg)	IG2	60	1241	76.6 (11.9)	-0.4 (5.28)	1243	77 (12.2)	-0.6 (5.4)	-0.08 (-0.50 to 0.35), 0.73
Fagerberg, 1998[68] (Risk Factor Intervention Study (RIS)) Good (KQ1); Fair (KQ2)	Multiple	High HD + PA	BMI (kg/m^2)	IG1	12	239	27.3 (3.9)	-0.6 (1.2)	238	26.9 (3.5)	-0.1 (1)	MD=-0.40 (-0.70 to -0.20), 0.000
	Multiple	High HD + PA	BMI (kg/m^2)	IG1	40	235	27.3 (3.9)	-0.6 (1.6)	227	26.9 (3.5)	-0.2 (1.4)	MD=-0.40 (-0.60 to -0.10), 0.0007
	Multiple	High HD + PA	Weight (kg)	IG1	12	239	83.4 (14.1)	-1.9 (3.6)	238	82.1 (11.9)	-0.6 (3.1)	-1.30 (-1.95 to -0.65), 0.000
	Multiple	High HD + PA	Weight (kg)	IG1	40	227	83.4 (14.1)	-0.8 (4.2)	235	82.1 (11.9)	-2 (4.7)	MD=-1.20 (-2.00 to -0.30), 0.006
	Multiple	High HD + PA	Weight (kg)	IG1	79	248	83.4 (14.1)	-2.2 (4.42)	252	82.1 (11.9)	-0.6 (3.64)	-1.50 (-2.21 to -0.79),
Gill, 2019[69] (Heartmatters Challenge - First Responders) Fair	Multiple	High HD + PA	BMI (kg/m2)	IG1	6	96	31.8 (5.01)	NR (NR)	79	31.57 (4.48)	NR (NR)	-1.50 (-2.09 to -0.91), 0.001
	Multiple	High HD + PA	BMI (kg/m2)	IG1	12	96	31.8 (5.01)	NR (NR)	79	31.57 (4.48)	NR (NR)	-0.88 (-1.64 to -0.12), 0.06
	Multiple	High HD + PA	Waist circumference (cm)	IG1	6	96	104.59 (12.75)	NR (NR)	79	106.5 (12.87)	NR (NR)	-2.12 (-5.61 to 1.37), 0.27
	Multiple	High HD + PA	Waist circumference (cm)	IG1	12	96	104.59 (12.75)	NR (NR)	79	106.5 (12.87)	NR (NR)	-4.05 (-5.79 to -2.31), 0.003
	Multiple	High HD + PA	Weight (kg)	IG1	6	96	NR (NR)	NR (NR)	79	NR (NR)	NR (NR)	-5.09 (-7.03 to -3.15), 0.001

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	Weight (kg)	IG1	12	96	NR (NR)	NR (NR)	79	NR (NR)	NR (NR)	-3.88 (-5.78 to -1.98), 0.006
Gill, 2019[70] (HealtheSteps) Fair	Multiple	Medium HD + PA	BMI (kg/m2)	IG1	6	59	NR (NR)	-0.34 (1.84)	59	NR (NR)	-0.1 (1.75)	-0.23 (-0.89 to 0.42), <0.05
	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	6	59	103.4 (17.1)	-1.52 (6.14)	59	102.8 (15.7)	0.01 (6.04)	-1.53 (-3.74 to 0.69), 0.17
	Multiple	Medium HD + PA	Weight (kg)	IG1	6	59	84.2 (20.6)	-0.81 (5.26)	59	86.1 (23.6)	-0.35 (4.95)	-0.46 (-2.35 to 1.42), 0.63
Greaves, 2015[71] (Waste the Waist) Fair	Multiple	High HD + PA	BMI (kg/m^2)	IG1	12	55	33 (3.2)	NR (NR)	53	32.3 (3)	NR (NR)	-0.51 (-1.28 to 0.26), NSD
	Multiple	High HD + PA	Waist circumference (cm)	IG1	12	55	110 (10.7)	NR (NR)	53	110 (8.8)	NR (NR)	-2.18 (-4.43 to 0.06), 0.06
	Multiple	High HD + PA	Weight (kg)	IG1	12	55	96.6 (14)	-3.65 (5.22)	53	97.6 (12.8)	-1.9 (6.69)	-1.85 (-4.08 to 0.38), 0.103
Groeneveld, 2010[72] (Health Under Construction) Fair	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	6	261	28.8 (3.5)	-0.5 (1.11)	256	28.2 (3.6)	0.2 (1.19)	-0.70 (-0.90 to -0.50), <0.05
	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	12	261	28.8 (3.5)	-0.3 (1.16)	256	28.2 (3.6)	0.3 (1.22)	-0.60 (-0.81 to -0.39), <0.05
	Multiple	Medium HD + PA	Weight (kg)	IG1	6	261	93.1 (13.2)	-1.4 (4.16)	256	92 (12.8)	0.6 (4.18)	-2.00 (-2.72 to -1.28), <0.05
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	261	93.1 (13.2)	-0.9 (4.28)	256	92 (12.8)	0.9 (4.25)	-1.80 (-2.54 to -1.06), <0.05
Hardcastle, 2008[73] Fair	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	6	203	33.66 (5.12)	-0.13 (1.62)	131	33.37 (4.47)	0.06 (1.62)	-0.19 (-0.55 to 0.17), <0.05
	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	18	203	33.66 (5.12)	0.02 (1.6)	131	33.37 (4.47)	0.67 (1.53)	-0.65 (-0.99 to -0.31), <0.05
	Multiple	Medium HD + PA	Weight (kg)	IG1	6	203	93.64 (15.93)	-0.62 (4.99)	131	91.38 (16.88)	0.13 (5.45)	-0.75 (-1.91 to 0.41), <0.05
	Multiple	Medium HD + PA	Weight (kg)	IG1	18	203	93.64 (15.93)	0.48 (5)	131	91.38 (16.88)	1.37 (5.44)	-0.89 (-2.05 to 0.27), NSD
Harris, 2012[74] (Health	Multiple	High HD + PA	BMI (kg/m^2)	IG1	12	355	28.97 (5.58)	-0.91 (1.76)	300	29.68 (6.9)	-1.29 (2.24)	0.38 (0.07 to 0.69), 0.5

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Improvement and Prevention Study (HIPS)) Fair	Multiple	High HD + PA	Waist circumference (cm)	IG1 (Females)	12	232	NR (NR)	NR (NR)	169	NR (NR)	NR (NR)	NR, 0.4
	Multiple	High HD + PA	Waist circumference (cm)	IG1 (Males)	12	152	NR (NR)	NR (NR)	146	NR (NR)	NR (NR)	NR, 0.7
	Multiple	High HD + PA	Weight (kg)	IG1	12	355	NR (NR)	-0.07 (5.77)	300	NR (NR)	0.05 (6.3)	-0.12 (-1.05 to 0.81), 0.7
Haufe, 2019[75] Fair	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	6	160	115.6 (12.1)	-4.8 (12.46)	154	114.6 (12.6)	-0.8 (12.8)	-4.00 (-5.20 to -2.80), <0.0001
	Multiple	Medium HD + PA	Weight (kg)	IG1	6	160	107.4 (18.2)	-4.3 (4.9)	154	106.1 (20.3)	-0.8 (4.6)	-3.50 (-4.55 to -2.45), <0.0001
HPT, 1990[77] (Hypertension Prevention Trial (HPT)) Good	HTN	High HD only	Weight (kg)	IG1	6	178	78.5 (NR)	0.27 (2.4)	189	77.5 (NR)	0.27 (2.47)	0.00 (-0.50 to 0.50), <0.05
	HTN	High HD only	Weight (kg)	IG2	6	170	79.5 (NR)	0 (2.35)	189	77.5 (NR)	0.27 (2.47)	-0.27 (-0.72 to 0.18), 0.025
	HTN	High HD only	Weight (kg)	IG3	6	112	87.4 (NR)	-5.58 (2.86)	119	83.4 (NR)	0.18 (2.95)	-5.76 (-6.56 to -4.96), <0.001
	HTN	High HD only	Weight (kg)	IG4	6	111	84.1 (NR)	-3.9 (2.84)	119	83.4 (NR)	0.18 (2.95)	-4.08 (-4.83 to -3.33), <0.05
	HTN	High HD only	Weight (kg)	IG1	36	176	78.5 (NR)	1.13 (3.58)	175	77.5 (NR)	1.59 (3.57)	-0.46 (-1.21 to 0.29), <0.05
	HTN	High HD only	Weight (kg)	IG2	36	172	79.5 (NR)	0.95 (3.54)	175	77.5 (NR)	1.59 (3.57)	0.64 (-0.07 to 1.35), 0.179
	HTN	High HD only	Weight (kg)	IG3	36	117	87.4 (NR)	NR (NR)	113	83.4 (NR)	1.86 (4.36)	-3.49 (-4.65 to -2.33), <0.001
	HTN	High HD only	Weight (kg)	IG4	36	114	84.1 (NR)	-0.14 (4.38)	113	83.4 (NR)	1.86 (4.36)	-2.00 (-3.14 to -0.86), <0.05
Hyman, 1998[78] Fair	Dys	Medium HD only	Weight (kg)	IG1	6	65	86.64 (19.53)	-1.09 (NR)	58	87.37 (20.25)	-0.77 (NR)	-0.32 (NR), 0.53
Hyman, 2007[79] Fair	HTN	Medium HD + PA	BMI (kg/m^2)	IG1	6	92	31.8 (7.5)	-0.1 (2.35)	93	33.4 (8.2)	-0.1 (2.58)	0.00 (-0.71 to 0.71), <0.05
	HTN	Medium HD + PA	BMI (kg/m^2)	IG2	6	96	31.9 (7.8)	0 (2.51)	93	33.4 (8.2)	-0.1 (2.58)	0.10 (-0.63 to 0.83), <0.05

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	Medium HD + PA	BMI (kg/m^2)	IG1	18	92	31.8 (7.5)	0.1 (2.37)	93	33.4 (8.2)	-0.6 (2.57)	0.70 (-0.01 to 1.41), NSD
	HTN	Medium HD + PA	BMI (kg/m^2)	IG2	18	96	31.9 (7.8)	0.3 (2.8)	93	33.4 (8.2)	-0.6 (2.57)	0.90 (0.13 to 1.67), NSD
Johnston, 1995 Fair	Dys	Medium HD only	Weight (kg)	IG1	6	40	NR (NR)	NR (NR)	47	NR (NR)	NR (NR)	NR, NSD
	Dys	Medium HD only	Weight (kg)	IG2	6	43	NR (NR)	NR (NR)	47	NR (NR)	NR (NR)	NR, NSD
Jones, 1999[82] (Hypertension Optimal Treatment (HOT)) Fair	HTN	High HD only	Weight (kg)	IG1	6	51	97 (18)	-3.2 (4.3)	51	92 (18)	-1.8 (2.7)	-1.40 (-2.79 to -0.01), 0.05
	HTN	High HD only	Weight (kg)	IG1	12	51	97 (18)	-1.61 (NR)	51	92 (18)	-1.28 (NR)	NR, NSD
	HTN	High HD only	Weight (kg)	IG1	18	51	97 (18)	-1.82 (NR)	51	92 (18)	-1.44 (NR)	NR, NSD
	HTN	High HD only	Weight (kg)	IG1	24	51	97 (18)	-1.74 (NR)	51	92 (18)	-1.99 (NR)	NR, NSD
	HTN	High HD only	Weight (kg)	IG1	30	51	97 (18)	-1.26 (NR)	51	92 (18)	-2.22 (NR)	NR, NSD
Kandula, 2015[83] (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	Multiple	High HD + PA	Waist circumference (cm)	IG1	6	31	95 (13)	-0.7 (7.13)	32	98 (11)	1.6 (7.16)	-2.30 (-5.61 to 0.96), NSD
	Multiple	High HD + PA	Weight (kg)	IG1	6	31	72.6 (10.9)	-1.6 (2.78)	32	77.1 (14.5)	-0.2 (2.83)	-1.50 (-2.81 to -0.07), <0.05
Kanke, 2015[84] Fair	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	6	25	NR (NR)	NR (NR)	19	NR (NR)	NR (NR)	NR, NSD
	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	12	22	NR (NR)	NR (NR)	18	NR (NR)	NR (NR)	NR, NSD
	Multiple	Medium HD + PA	Weight (kg)	IG1	6	25	NR (NR)	NR (NR)	19	NR (NR)	NR (NR)	NR, NSD
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	22	NR (NR)	NR (NR)	18	NR (NR)	NR (NR)	NR, 0.68

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Kastarinen, 2002[85] (Lifestyle Intervention against Hypertension in Eastern Finland (LIHEF)) Fair	HTN	High HD + PA	Weight (kg)	IG1	12	360	81.1 (15.7)	-1.5 (NR)	355	80 (14.8)	-0.2 (NR)	MD=-1.30 (-1.70 to -0.90), <0.05
	HTN	High HD + PA	Weight (kg)	IG1	24	360	81.1 (15.7)	-1.5 (NR)	355	80 (14.8)	-0.3 (NR)	-1.20 (-1.70 to -0.70), <0.05
Khanji, 2019[87] (HAPPY London) Good	Multiple	Low HD + PA	BMI (kg/m2)	IG1	6	194	28.1 (5.6)	-0.42 (1.75)	183	27.4 (4.4)	-0.25 (1.39)	-0.17 (-0.40 to 0.00), 0.07
	Multiple	Low HD + PA	Waist circumference (cm)	IG1	6	194	95.8 (15.2)	-2.55 (14.96)	183	95.4 (12)	-2.05 (12)	-0.50 (-1.50 to 0.50), 0.31
	Multiple	Low HD + PA	Weight (kg)	IG1	6	194	80.7 (18.4)	-1.22 (5.78)	183	79.7 (16)	-0.76 (5.03)	-0.45 (-1.00 to 0.10), 0.10
Kramer, 2018[89] (Healthy Lifestyle Project) Fair	Multiple	High HD + PA	BMI (kg/m^2)	IG1	6	81	34.9 (6.7)	-1.9 (1.7)	43	33.4 (4.9)	-0.3 (1.3)	-1.60 (-2.14 to -1.06), <0.0001
	Multiple	High HD + PA	Waist circumference (in)	IG1	6	81	108.2 (14.73)	-4.32 (5.08)	43	105.66 (11.94)	-0.03 (5.08)	-4.29 (-6.17 to -2.41), <0.0001
	Multiple	High HD + PA	Weight (kg)	IG1	6	81	96.32 (21)	-5.35 (4.94)	43	91.38 (16.82)	-0.77 (3.27)	-4.58 (-6.03 to -3.13), <0.0001
Langford, 1991[91] (Trial of Antihypertensive Interventions and Management (TAIM)) Fair	HTN	High HD + PA	Weight (kg)	IG1	6	263	87.5 (NR)	-4.7 (4.67)	264	87.9 (NR)	-0.9 (4.67)	-3.80 (-4.60 to -3.00), <0.05
	HTN	High HD only	Weight (kg)	IG2	6	257	87.9 (NR)	-0.3 (4.67)	264	87.9 (NR)	-0.9 (4.67)	0.60 (-0.20 to 1.40), NSD
Lee, 2007[92] Fair	HTN	Medium PA only	BMI (kg/m^2)	IG1	6	91	25.4 (3.8)	-0.03 (NR)	93	25.31 (3.5)	-0.21 (NR)	NR, NSD
Liira, 2014[93] Fair	Multiple	Medium HD + PA	Weight (kg)	IG1	12	46	89.3 (12.9)	0.3 (4.14)	42	86.2 (11.4)	-0.7 (4.17)	1.00 (-0.74 to 2.74), NSD
Moreau, 2001[95] Fair	HTN	Low PA only	Weight (kg)	IG1	6	15	81.1 (22.85)	-1.3 (7.17)	9	79.1 (22.2)	0.6 (7.07)	-1.90 (-7.78 to 3.98), NSD

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Moy, 2001[96] Fair	Multiple	High HD only	BMI (kg/m^2)	IG1	24	117	28.5 (5)	-0.1 (1)	118	29.5 (7)	0.21 (2)	-0.31 (-0.71 to 0.09), 0.164
Neil, 1995[99] Fair	Dys	Medium HD only	BMI (kg/m^2)	IG1	6	103	26.64 (4.06)	-0.24 (1.28)	102	26.32 (4.32)	-0.24 (1.36)	0.00 (-0.36 to 0.36), NSD
	Dys	Medium HD only	BMI (kg/m^2)	IG2	6	104	26.31 (3.93)	-0.07 (1.32)	102	26.32 (4.32)	-0.24 (1.36)	0.17 (-0.20 to 0.54), NSD
Niiranen, 2014[100] Fair	HTN	Medium HD + PA	BMI (kg/m^2)	IG1	12	112	28.5 (4.5)	0 (1.08)	108	28.4 (4.1)	-0.1 (1.59)	0.10 (-0.83 to 1.03), 0.86
Reid, 2014[103] Fair	Multiple	High HD + PA	BMI (kg/m^2)	IG1	12	211	29.2 (5.4)	-1.3 (1.72)	215	29.6 (6)	-0.6 (1.92)	-0.70 (-1.05 to -0.35), 0.9
	Multiple	High HD + PA	Waist circumference (cm)	IG1	12	211	96.3 (13.5)	-3.8 (13.45)	215	97.4 (15.1)	-2.3 (14.49)	-1.50 (-4.15 to 1.15), 0.9
Rodriguez-Cristobal, 2012[105] Fair	Multiple	High HD + PA	BMI (kg/m^2)	IG1	24	146	30.3 (5.8)	-0.7 (1.95)	154	30.5 (5.1)	1.3 (1.59)	MD=-1.70 (-2.20 to -1.10), 0.0001
Rosas, 2015[106] (Vivamos Activos Fair Oaks (VAFO)) Good	Multiple	High HD + PA	BMI (kg/m^2)	IG1	6	82	35.5 (5.1)	-0.8 (1.39)	41	34.9 (4.4)	-0.4 (1.11)	-0.40 (-0.85 to 0.05), 0.07
	Multiple	High HD + PA	BMI (kg/m^2)	IG2	6	84	36 (5.7)	-0.6 (1.64)	41	34.9 (4.4)	-0.4 (1.11)	-0.20 (-0.69 to 0.29), 0.27
	Multiple	High HD + PA	BMI (kg/m^2)	IG1	12	82	35.5 (5.1)	-0.7 (1.85)	41	34.9 (4.4)	-0.3 (1.74)	-0.40 (-1.07 to 0.27), 0.2
	Multiple	High HD + PA	BMI (kg/m^2)	IG2	12	84	36 (5.7)	-0.6 (2.1)	41	34.9 (4.4)	-0.3 (1.74)	-0.30 (-1.00 to 0.40), 0.39
	Multiple	High HD + PA	BMI (kg/m^2)	IG1	24	82	35.5 (5.1)	-0.4 (2.54)	41	34.9 (4.4)	-0.2 (2.85)	-0.20 (-1.23 to 0.83), 0.72
	Multiple	High HD + PA	BMI (kg/m^2)	IG2	24	84	36 (5.7)	-0.4 (2.81)	41	34.9 (4.4)	-0.2 (2.85)	-0.20 (-1.26 to 0.86), 0.67
	Multiple	High HD + PA	Waist circumference (cm)	IG1	6	82	NR (NR)	-0.6 (1.85)	41	NR (NR)	0 (2.22)	-0.60 (-1.39 to 0.19), 0.14
	Multiple	High HD + PA	Waist circumference (cm)	IG2	6	84	NR (NR)	-0.7 (2.57)	41	NR (NR)	0 (2.22)	-0.70 (-1.57 to 0.17), 0.11

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	Waist circumference (cm)	IG1	12	82	NR (NR)	-0.6 (3.7)	41	NR (NR)	-1.3 (2.85)	0.70 (-0.48 to 1.88), 0.26
	Multiple	High HD + PA	Waist circumference (cm)	IG2	12	84	NR (NR)	-1.5 (3.27)	41	NR (NR)	-1.3 (2.85)	-0.20 (-1.32 to 0.92), 0.76
	Multiple	High HD + PA	Waist circumference (cm)	IG1	24	82	NR (NR)	-0.8 (3.23)	41	NR (NR)	-0.7 (3.01)	-0.10 (-1.26 to 1.06), 0.95
	Multiple	High HD + PA	Waist circumference (cm)	IG2	24	84	NR (NR)	-1.4 (3.27)	41	NR (NR)	-0.7 (3.01)	-0.70 (-1.86 to 0.46), 0.24
	Multiple	High HD + PA	Weight (% change)	IG1	6	82	NR (NR)	-0.02 (0.05)	41	NR (NR)	-0.01 (0.03)	-0.01 (-0.02 to 0.00), 0.24
	Multiple	High HD + PA	Weight (% change)	IG2	6	84	NR (NR)	-0.02 (0.05)	41	NR (NR)	-0.01 (0.03)	-0.01 (-0.02 to 0.00), 0.5
	Multiple	High HD + PA	Weight (% change)	IG1	12	82	NR (NR)	-0.02 (0.07)	41	NR (NR)	-0.01 (0.06)	-0.01 (-0.03 to 0.01), 0.92
	Multiple	High HD + PA	Weight (% change)	IG2	12	84	NR (NR)	-0.01 (0.07)	41	NR (NR)	-0.01 (0.06)	0.00 (-0.02 to 0.02), 0.96
	Multiple	High HD + PA	Weight (% change)	IG1	24	82	NR (NR)	-0.02 (0.07)	41	NR (NR)	0 (0.08)	-0.02 (-0.05 to 0.01), 0.72
	Multiple	High HD + PA	Weight (% change)	IG2	24	84	NR (NR)	-0.01 (0.49)	41	NR (NR)	0 (0.08)	-0.01 (-0.12 to 0.10), 0.92
	Multiple	High HD + PA	Weight (kg)	IG1	6	82	89.3 (15.9)	-2.1 (3.47)	41	88.6 (15.2)	-0.9 (3.17)	-1.20 (-2.43 to 0.03), 0.05
	Multiple	High HD + PA	Weight (kg)	IG2	6	84	89.3 (15.9)	-1.6 (3.97)	41	88.6 (15.2)	-0.9 (3.17)	-0.70 (-1.99 to 0.59), 0.28
	Multiple	High HD + PA	Weight (kg)	IG1	12	82	89.3 (15.9)	-1.9 (4.62)	41	88.6 (15.2)	-0.7 (4.75)	-1.20 (-2.97 to 0.57), 0.21
	Multiple	High HD + PA	Weight (kg)	IG2	12	84	89.3 (15.9)	-1.4 (4.91)	41	88.6 (15.2)	-0.7 (4.75)	-0.70 (-2.49 to 1.09), 0.49
	Multiple	High HD + PA	Weight (kg)	IG1	24	82	89.3 (15.9)	-1 (6.47)	41	88.6 (15.2)	-0.6 (6.81)	-0.40 (-2.91 to 2.11), 0.76

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	Weight (kg)	IG2	24	84	89.3 (15.9)	-1 (7.95)	41	88.6 (15.2)	-0.6 (6.81)	-0.40 (-3.09 to 2.29), 0.78
Rubinstein, 2016[107] Good	HTN	Medium HD + PA	BMI (kg/m^2)	IG1	12	94	28.7 (5.4)	0.2 (1.75)	96	30 (5.6)	0.2 (1.77)	-0.06 (-0.50 to 0.39), 0.81
	HTN	Medium HD + PA	Waist circumference (cm)	IG1	12	94	96.3 (13.8)	1.1 (14.06)	96	97.6 (12.5)	1.4 (11.99)	-0.06 (-2.29 to 2.16), 0.95
	HTN	Medium HD + PA	Weight (kg)	IG1	12	94	79.8 (17.3)	0.6 (5.71)	96	82.9 (16.3)	0.3 (5.09)	-0.03 (-1.28 to 1.23), 0.97
Salisbury, 2016[108] Good	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	6	301	31.2 (5.4)	-0.5 (1.73)	296	30.9 (5.7)	-0.3 (1.78)	MD=-0.30 (-0.50 to -0.10), 0.006
	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	12	293	31.2 (5.4)	-0.7 (1.71)	291	30.9 (5.7)	-0.1 (1.8)	MD=-0.40 (-0.60 to -0.10), 0.008
	Multiple	Medium HD + PA	Weight (kg)	IG1	6	301	93.2 (17.3)	-1.5 (5.55)	296	91.9 (18.9)	-0.8 (5.92)	MD=-0.90 (-1.50 to -0.20), 0.006
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	293	93.2 (17.3)	-1.9 (5.51)	291	91.9 (18.9)	-0.7 (6.01)	MD=-1.00 (-1.80 to -0.30), 0.008
Scott, 2018[110] Fair	Multiple	Medium PA only	BMI (kg/m^2)	IG1	6	17	NR (NR)	NR (NR)	18	NR (NR)	NR (NR)	Hedges g=0.02 (-0.64 to 0.69), 0.961
	Multiple	Medium PA only	Weight (kg)	IG1	6	17	89.59 (12.13)	0 (4.65)	18	89.21 (17.2)	0.18 (9.44)	-0.18 (-5.07 to 4.71), 0.925
Soto Rodriguez, 2016[111] Fair	Multiple	Medium HD only	BMI (kg/m^2)	IG1	12	117	27.57 (5.52)	0.12 (1.57)	113	27.34 (5.3)	0.47 (1.47)	-0.35 (-0.75 to 0.04), 0.018
	Multiple	Medium HD only	Waist circumference (cm)	IG1	12	117	105.3 (10.6)	0.03 (3.16)	113	106 (9.87)	0.79 (3.5)	-0.76 (-1.62 to 0.10), 0.034
Stefanick, 1998[112] (Diet and Exercise for Elevated Risk (DEER)) Fair	Dys	High HD only	Weight (kg)	IG1 (Females)	12	46	NR (NR)	-2.7 (3.5)	45	NR (NR)	0.8 (4.2)	-3.50 (-5.09 to -1.91), <0.001
	Dys	High HD only	Weight (kg)	IG1 (Males)	12	49	NR (NR)	-2.8 (3.5)	46	NR (NR)	0.5 (2.7)	-3.30 (-4.55 to -2.05), <0.001
Svetkey, 2008[114] (Weight Loss Maintenance	Multiple	High HD + PA	Percent weight change (% change)	IG1	30	341	NR (NR)	NR (NR)	341	NR (NR)	NR (NR)	LS Mean change=-1.80 (NR), <0.001

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
(WLM)) Good	Multiple	High HD + PA	Percent weight change (% change)	IG2	30	347	NR (NR)	NR (NR)	341	NR (NR)	NR (NR)	LS Mean change=-0.40 (NR), 0.5
	Multiple	High HD + PA	Weight (kg)	IG1	6	341	88.7 (16.9)	NR (NR)	341	87.4 (15.3)	NR (NR)	LS Mean change=-0.90 (NR), 0.001
	Multiple	High HD + PA	Weight (kg)	IG2	6	347	88.6 (15.4)	NR (NR)	341	87.4 (15.3)	NR (NR)	LS Mean change=-0.80 (NR), 0.003
	Multiple	High HD + PA	Weight (kg)	IG1	12	341	88.7 (16.9)	NR (NR)	341	87.4 (15.3)	NR (NR)	LS Mean change=-1.60 (NR), <0.001
	Multiple	High HD + PA	Weight (kg)	IG2	12	347	88.6 (15.4)	NR (NR)	341	87.4 (15.3)	NR (NR)	LS Mean change=-1.00 (NR), 0.005
	Multiple	High HD + PA	Weight (kg)	IG1	18	341	88.7 (16.9)	NR (NR)	341	87.4 (15.3)	NR (NR)	LS Mean change=-1.80 (NR), <0.001
	Multiple	High HD + PA	Weight (kg)	IG2	18	347	88.6 (15.4)	NR (NR)	341	87.4 (15.3)	NR (NR)	LS Mean change=-1.10 (NR), 0.003
	Multiple	High HD + PA	Weight (kg)	IG1	24	341	88.7 (16.9)	NR (NR)	341	87.4 (15.3)	NR (NR)	LS Mean change=-2.00 (NR), <0.001
	Multiple	High HD + PA	Weight (kg)	IG2	24	347	88.6 (15.4)	NR (NR)	341	87.4 (15.3)	NR (NR)	LS Mean change=-0.90 (NR), 0.045
	Multiple	High HD + PA	Weight (kg)	IG1	30	341	88.7 (16.9)	4 (5.54)	341	87.4 (15.3)	5.5 (5.54)	LS Mean change=-1.50 (-2.40 to -0.60), 0.001
	Multiple	High HD + PA	Weight (kg)	IG2	30	347	88.6 (15.4)	5.2 (5.59)	341	87.4 (15.3)	5.5 (5.54)	LS Mean change=-0.30 (-1.20 to 0.60), 0.51

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	Weight (kg)	IG1	60	243	88.3 (16.7)	NR (NR)	246	87.3 (15.4)	NR (NR)	-1.60 (-3.10 to -0.10), <0.05
Svetkey, 2009[115] (Hypertension Improvement Project (HIP)) Fair	HTN	High HD + PA	Weight (kg)	IG1	6	132	91.83 (17.01)	-3.17 (4.85)	132	91.65 (17.96)	-0.14 (2.86)	-3.04 (-4.00 to -2.08), <0.05
	HTN	High HD + PA	Weight (kg)	IG2	6	124	87.21 (17.23)	-2.36 (4.85)	132	91.65 (17.96)	-0.14 (2.86)	-2.22 (-3.21 to -1.24), <0.05
	HTN	Medium HD + PA	Weight (kg)	IG3	6	137	90.25 (17.41)	0.05 (5.08)	132	91.65 (17.96)	-0.14 (2.86)	0.18 (-0.80 to 1.16), NSD
	HTN	High HD + PA	Weight (kg)	IG1	18	128	91.83 (17.01)	-1.72 (4.44)	122	91.65 (17.96)	-0.95 (5.44)	-0.77 (-2.01 to 0.46), <0.05
	HTN	High HD + PA	Weight (kg)	IG2	18	124	87.21 (17.23)	-1.18 (5.53)	122	91.65 (17.96)	-0.95 (5.44)	-0.23 (-1.60 to 1.14), NSD
	HTN	Medium HD + PA	Weight (kg)	IG3	18	134	90.25 (17.41)	-0.18 (6.08)	122	91.65 (17.96)	-0.95 (5.44)	0.77 (-0.64 to 2.18), NSD
Ter Bogt, 2009[116] (Groningen Overweight and Lifestyle (GOAL)) Good	Multiple	High HD + PA	Waist circumference (cm)	IG1 (Females)	12	103	97 (9.8)	-2 (7.8)	114	97 (11.8)	-1.5 (6.8)	-0.50 (-2.46 to 1.46), NSD
	Multiple	High HD + PA	Waist circumference (cm)	IG1 (Males)	12	98	104 (7.8)	-2.8 (6.2)	101	105 (9.5)	-0.9 (4.5)	-1.90 (-3.41 to -0.39), <0.05
	Multiple	High HD + PA	Weight (kg)	IG1	12	169	88.3 (12.1)	-1.9 (4.9)‡	172	87.6 (13.7)	-0.9 (5)‡	-1.00 (-2.05 to 0.05), <0.05
	Multiple	High HD + PA	Weight (kg)	IG1 (Females)	12	103	NR (NR)	-1.5 (4.1)	114	NR (NR)	-1.4 (4.9)	-0.10 (-1.30 to 1.10), NSD
	Multiple	High HD + PA	Weight (kg)	IG1 (Males)	12	98	NR (NR)	-2.1 (4.8)	101	NR (NR)	0 (3.9)	-2.10 (-3.32 to -0.88), <0.05
	Multiple	High HD + PA	Weight (kg)	IG1	36	148	88.3 (12.1)	-1.4 (5.4)	165	87.6 (13.7)	-1 (5.2)	-0.40 (-1.58 to 0.78), 0.726
Tiessen, 2012[117] (SPRING (Self-monitoring and Prevention of RIsk Factors by Nurse practitioners in the region of	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	12	89	28 (3.3)	-0.1 (1.32)	90	29 (4)	-0.1 (1.67)	-0.04 (-0.50 to 0.40), NSD
	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	12	89	101 (8)	-3.7 (5.29)	90	102 (10.8)	-1.9 (5.88)	-1.80 (-3.40 to -0.20), <0.05

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Groningen)) Fair												
TOHP I CRG, 1992[119] (Trials of Hypertension Prevention Phase I (TOHP I)) Good	HTN	High HD only	Weight (kg)	IG1	6	327	82.7 (14.3)	NR (NR)	417	82.8 (14)	NR (NR)	-1.23 (NR), <0.0001
	HTN	High HD + PA	Weight (kg)	IG2	6	294	90.2 (13.3)	-5.68 (5.74)	237	89.3 (13)	-0.01 (3.24)	-5.67 (-6.45 to -4.90), <0.01
	HTN	High HD only	Weight (kg)	IG1	12	327	82.7 (14.3)	NR (NR)	417	82.8 (14)	NR (NR)	-0.82 (NR), 0.002
	HTN	High HD only	Weight (kg)	IG1	18	327	82.7 (14.3)	NR (NR)	417	82.8 (14)	NR (NR)	-0.39 (NR), 0.19
	HTN	High HD + PA	Weight (kg)	IG2	18	293	90.2 (13.3)	-3.83 (6.12)	235	89.3 (13)	0.07 (4.01)	-3.90 (-4.77 to -3.03), <0.01
TOHP II CRG, 1997[120] (Trial of Hypertension Prevention II (TOHP II)) Good	HTN	High HD + PA	Weight (kg)	IG1	6	566	93.6 (14.2)	-4.1 (5.1)	561	93.6 (13.5)	0.1 (3.2)	-4.30 (-4.89 to -3.71), <0.001
	HTN	High HD + PA	Weight (kg)	IG2	6	565	93.4 (14.1)	-4.4 (5.2)	561	93.6 (13.5)	0.1 (3.2)	-4.50 (-5.09 to -3.91), <0.001
	HTN	High HD only	Weight (kg)	IG3	6	539	94 (14.3)	-1.1 (3.7)	561	93.6 (13.5)	0.1 (3.2)	-1.20 (-1.59 to -0.81), <0.001
	HTN	High HD + PA	Weight (kg)	IG1	18	545	93.6 (14.2)	-2.2 (5.6)	551	93.6 (13.5)	0.7 (4.2)	-2.90 (-3.49 to -2.31), <0.001
	HTN	High HD + PA	Weight (kg)	IG2	18	545	93.4 (14.1)	-2 (5.8)	551	93.6 (13.5)	0.7 (4.2)	-2.70 (-3.30 to -2.10), <0.001
	HTN	High HD only	Weight (kg)	IG3	18	532	94 (14.3)	0.4 (4.3)	551	93.6 (13.5)	0.7 (4.2)	-0.30 (-0.89 to 0.29), 0.19
	HTN	High HD + PA	Weight (kg)	IG1	36	552	93.6 (14.2)	-0.3 (5.5)	554	93.6 (13.5)	1.8 (5.3)	-2.10 (-2.69 to -1.51), <0.001
	HTN	High HD + PA	Weight (kg)	IG2	36	547	93.4 (14.1)	-0.2 (5.9)	554	93.6 (13.5)	1.8 (5.3)	-1.90 (-2.60 to -1.30), <0.001
	HTN	High HD only	Weight (kg)	IG3	36	549	94 (14.3)	1.7 (5.2)	554	93.6 (13.5)	1.8 (5.3)	0.00 (-0.59 to 0.59), 0.92
van der Veen, 2002[122] (Nijmegen Family Practices	Dys	Medium HD only	BMI (kg/m^2)	IG1	6	70	28.1 (4.3)	-0.5 (0.6)	67	29.2 (4.8)	-0.2 (0.7)	-0.30 (-0.52 to -0.08), 0.01
	Dys	Medium HD only	BMI (kg/m^2)	IG1	12	67	28.1 (4.3)	0 (1.1)	63	29.2 (4.8)	-0.2 (1)	0.20 (-0.16 to 0.56), 0.03

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Monitoring Project (NFPMP)) Fair	Dys	Medium HD only	Waist circumference (cm)	IG1	6	70	94.3 (12.1)	-1.6 (4.9)	67	97.7 (10.3)	-1.7 (5.2)	0.10 (-1.59 to 1.79), 0.43
	Dys	Medium HD only	Waist circumference (cm)	IG1	12	67	94.3 (12.1)	-1.6 (6.6)	63	97.7 (10.3)	-1.8 (5.6)	0.20 (-1.90 to 2.30), 0.61
	Dys	Medium HD only	Weight (kg)	IG1	6	70	79.2 (14.9)	-1.3 (1.8)	67	80.3 (12)	-0.6 (1.9)	-0.70 (-1.32 to -0.08), 0.01
	Dys	Medium HD only	Weight (kg)	IG1	12	67	79.2 (14.9)	0.2 (3)	63	80.3 (12)	-0.6 (2.8)	0.80 (-0.20 to 1.80), 0.02
van Sluijs, 2005[124] (Physician-based Assessment and Counseling for Exercise (PACE)) Fair	Multiple	Medium PA only	BMI (kg/m^2)	IG1	12	171	29.3 (5.7)	NR (NR)	187	28.6 (4.2)	NR (NR)	Beta coefficient=0.21 (-0.14 to 0.55), 0.24
	Multiple	Medium PA only	Waist circumference (cm)	IG1	12	171	97.9 (14.1)	NR (NR)	187	98.3 (12.1)	NR (NR)	Beta coefficient=2.00 (0.92 to 3.07), <0.001
	Multiple	Medium PA only	Weight (kg)	IG1	12	171	85.8 (17.9)	NR (NR)	187	85.1 (15.2)	NR (NR)	Beta coefficient=0.27 (-0.45 to 1.00), 0.46
Viglione, 2019[125] (Goals for Eating and Moving (GEM)) Fair	Multiple	High HD + PA	Weight (kg)	IG1	6	21	NR (NR)	-1.52 (3.05)	22	NR (NR)	0.23 (3.64)	-1.75 (-3.75 to 0.25), 0.08
	Multiple	High HD + PA	Weight (kg)	IG1	12	21	NR (NR)	-1.02 (4.16)	22	NR (NR)	0.74 (4.9)	-1.76 (-4.47 to 0.95), 0.40
Wadden, 2011[127] (Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-UP)) Good	Multiple	High HD + PA	BMI (kg/m^2)	IG1	6	131	38.5 (4.6)	-1.3 (2.29)	130	39 (4.8)	-0.7 (2.28)	-0.60 (-1.15 to -0.05), 0.02
	Multiple	High HD + PA	BMI (kg/m^2)	IG1	12	131	38.5 (4.6)	-1.3 (2.29)	130	39 (4.8)	-0.8 (2.28)	-0.50 (-1.05 to 0.05), 0.18
	Multiple	High HD + PA	BMI (kg/m^2)	IG1	18	131	38.5 (4.6)	-1.1 (2.29)	130	39 (4.8)	-0.7 (2.28)	-0.40 (-0.95 to 0.15), 0.17
	Multiple	High HD + PA	BMI (kg/m^2)	IG1	24	131	38.5 (4.6)	-0.9 (2.29)	130	39 (4.8)	-0.6 (2.28)	-0.30 (-0.85 to 0.25), 0.27

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	Percent weight change (% change)	IG1	6	131	NR (NR)	-3.5 (5.72)	130	NR (NR)	-1.8 (5.7)	-1.70 (-3.09 to -0.31), 0.005
	Multiple	High HD + PA	Percent weight change (% change)	IG1	12	131	NR (NR)	-3.5 (6.87)	130	NR (NR)	-2.1 (6.84)	-1.40 (-3.06 to 0.26), 0.08
	Multiple	High HD + PA	Percent weight change (% change)	IG1	18	131	NR (NR)	-3.1 (8.01)	130	NR (NR)	-1.7 (7.98)	-1.40 (-3.34 to 0.54), 0.1
	Multiple	High HD + PA	Percent weight change (% change)	IG1	24	131	NR (NR)	-2.9 (8.01)	130	NR (NR)	-1.6 (6.84)	-1.30 (-3.11 to 0.51), 0.12
	Multiple	High HD + PA	Waist circumference (cm)	IG1	6	131	117.1 (11.9)	-4.9 (6.87)	131	119.8 (13.9)	-2.7 (6.87)	-2.20 (-3.86 to -0.54), 0.002
	Multiple	High HD + PA	Waist circumference (cm)	IG1	12	131	117.1 (11.9)	-4.6 (6.87)	130	119.8 (13.9)	-3.2 (6.84)	-1.40 (-3.06 to 0.26), 0.089
	Multiple	High HD + PA	Waist circumference (cm)	IG1	24	131	117.1 (11.9)	-4 (8.01)	130	119.8 (13.9)	-2.3 (7.98)	-1.70 (-3.64 to 0.24), 0.056
	Multiple	High HD + PA	Weight (kg)	IG1	6	131	106.3 (17.3)	-3.5 (5.72)	130	111.2 (20)	-2 (5.7)	-1.50 (-2.89 to -0.11), 0.03
	Multiple	High HD + PA	Weight (kg)	IG1	12	131	106.3 (17.3)	-3.4 (6.87)	130	111.2 (20)	-2.3 (6.84)	-1.10 (-2.76 to 0.56), 0.23
	Multiple	High HD + PA	Weight (kg)	IG1	18	131	106.3 (17.3)	-3 (8.01)	130	111.2 (20)	-1.9 (7.98)	-1.10 (-3.04 to 0.84), 0.22
	Multiple	High HD + PA	Weight (kg)	IG1	24	131	106.3 (17.3)	-2.9 (8.01)	130	111.2 (20)	-1.7 (7.98)	-1.20 (-3.14 to 0.74), 0.22
Wister, 2007[129] Good	Multiple	Medium HD + PA	BMI (kg/m^2)	IG1	12	157	31.8 (6.9)	-0.47 (1.95)	158	33.2 (7.6)	-0.33 (1.8)	-0.14 (-0.55 to 0.27), NSD
	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	12	157	105.7 (17.2)	-2.81 (7.03)	158	108.1 (17.7)	-2.31 (7.05)	-0.50 (-2.06 to 1.06), NSD
Wong, 2015[130] Good	HTN	Low HD only	BMI (kg/m^2)	IG1	6	254	24.17 (2.83)	-0.49 (4.8)	250	24.23 (3.06)	-0.33 (5.08)	-0.11 (-0.24 to 0.02), 0.08

Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	Low HD only	BMI (kg/m^2)	IG1	12	243	24.17 (2.83)	-0.52 (4.77)	242	24.23 (3.06)	-0.39 (5.08)	-0.05 (-0.20 to 0.10), 0.49
Wood, 2008[131] (EUROACTION) Fair	Multiple	High HD + PA	BMI (kg/m^2)	IG1	12	1019	NR (NR)	-0.47 (NR)	332	NR (NR)	0.13 (NR)	-0.56 (-0.86 to -0.25), 0.005
	Multiple	High HD + PA	Waist circumference (cm)	IG1	12	1019	NR (NR)	-1.66 (NR)	332	NR (NR)	-0.21 (NR)	-1.61 (-2.61 to -0.61), 0.009
	Multiple	High HD + PA	Weight (kg)	IG1	12	332	NR (NR)	NR (NR)	1019	NR (NR)	NR (NR)	-1.51 (-2.53 to -0.50), 0.01

Abbreviations: BMI = body mass index; CG = control group; CI = confidence interval; cm = centimeters; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; kg = kilograms; kg/m^2 = kilograms per meter squared; KQ = key question; MD = mean difference; NR = not reported; NSD = no statistically significantly difference; SD = standard deviation

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min
†Between-group mean difference in change unless otherwise specified
‡Mean percent change in weight (kg)

Appendix H Table 12. Adiposity, Dichotomous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Appel, 2011[42] (POWER Hopkins (Practice Based Opportunities for Weight Reduction)) Good	Multiple	High HD + PA	≥10% weight loss	IG1	6	31/124 (25.0)	4/113 (3.5)	7.06 (2.57 to 19.38), <0.001
	Multiple	High HD + PA	≥10% weight loss	IG2	6	30/129 (23.3)	4/113 (3.5)	6.57 (2.39 to 18.08), <0.001
	Multiple	High HD + PA	≥10% weight loss	IG1	24	26/133 (19.5)	11/128 (8.6)	2.27 (1.17 to 4.41), 0.01
	Multiple	High HD + PA	≥10% weight loss	IG2	24	24/131 (18.3)	11/128 (8.6)	2.13 (1.09 to 4.17), 0.02
	Multiple	High HD + PA	≥5% weight loss	IG1	6	57/124 (46.0)	16/113 (14.2)	3.25 (1.98 to 5.31), <0.001
	Multiple	High HD + PA	≥5% weight loss	IG2	6	68/129 (52.7)	16/113 (14.2)	3.72 (2.30 to 6.03), <0.001
	Multiple	High HD + PA	≥5% weight loss	IG1	24	55/133 (41.4)	24/128 (18.8)	2.21 (1.46 to 3.34), <0.001
	Multiple	High HD + PA	≥5% weight loss	IG2	24	50/131 (38.2)	24/128 (18.8)	2.04 (1.34 to 3.10), <0.001
Bennett, 2012[47] (Be Fit, Be Well [POWER]) Good	HTN	High HD + PA	≥5% weight loss	IG1	24	36/180 (20.0)	36/185 (19.5)	1.03 (0.68 to 1.55),
Bennett, 2018 [48] (Track) Good	Multiple	Medium HD + PA	≥5% weight loss	IG1	6	73/170 (42.9)	10/167 (6.0)	6.80 (3.60 to 12.70), <0.001
	Multiple	Medium HD + PA	≥5% weight loss	IG1	12	69/170 (40.6)	28/167 (16.8)	2.40 (1.60 to 3.50), <0.001
Bo, 2007[52] Fair	Multiple	Medium HD + PA	BMI ≥25 kg/m^2	IG1	12	141/169 (83.4)	149/166 (89.8)	OR=0.58 (0.30 to 1.10), 0.1
Christian, 2011[58] Fair	Multiple	Medium HD + PA	≥10% weight loss	IG1	12	10/133 (7.5)	3/130 (2.3)	OR=3.40 (NR), 0.024
	Multiple	Medium HD + PA	≥5% weight loss	IG1	12	35/133 (26.3)	11/130 (8.5)	OR=3.86 (NR), 0.001
Cicolini, 2014[59] Fair	HTN	Medium HD + PA	Percent obese	IG1	6	23/100 (23.0)	25/98 (25.5)	0.90 (0.55 to 1.48), 0.7
Kandula, 2015[83] (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	Multiple	High HD + PA	≥5% weight loss	IG1	6	6/31 (19.4)	3/32 (9.4)	2.06 (0.57 to 7.54), 0.26

Appendix H Table 12. Adiposity, Dichotomous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Kastarinen, 2002[85] (Lifestyle Intervention against Hypertension in Eastern Finland (LIHEF)) Fair	HTN	High HD + PA	BMI ≤25 kg/m^2	IG1	12	23/294 (7.8)	11/279 (3.9)	Difference in probability=3.90 (0.10 to 7.70), NSD
	HTN	High HD + PA	BMI ≤25 kg/m^2	IG1	24	24/294 (8.2)	10/279 (3.6)	Difference in probability=4.60 (1.00 to 8.40), <0.05
	HTN	High HD + PA	BMI loss ≥5%	IG1	12	55/294 (18.7)	26/279 (9.3)	Difference in probability=9.40 (3.80 to 15.00), <0.05
	HTN	High HD + PA	BMI loss ≥5%	IG1	24	65/294 (22.1)	29/279 (10.4)	Difference in probability=11.70 (5.80 to 17.70), <0.05
Khanji, 2019[87] (HAPPY London) Good	Multiple	Low HD + PA	BMI ≤25 kg/m^2	IG1	6	74/194 (38.1)	66/184 (35.9)	1.06 (0.82 to 1.38), 0.65
	Multiple	Low HD + PA	WC at goal (WC <102 cm for males; <88 cm for females)	IG1	6	127/194 (65.5)	119/184 (64.7)	1.01 (0.87 to 1.17), 0.87
Kramer, 2018[89] (Healthy Lifestyle Project) Fair	Multiple	High HD + PA	≥5% weight loss	IG1	6	45/81 (55.6)	4/43 (9.3)	5.97 (2.30 to 15.50), <0.001
	Multiple	High HD + PA	≥7% weight loss	IG1	6	32/81 (39.5)	2/43 (4.7)	8.49 (2.14 to 33.76), <0.001
Scott, 2018[110] Fair	Multiple	Medium PA only	≥5% weight loss	IG1	6	3/17 (17.6)	0/18 (0.0)	7.39 (0.41 to 133.24), NSD
Svetkey, 2008[114] (Weight Loss Maintenance (WLM)) Good	Multiple	High HD + PA	≥5% weight loss	IG1	30	144/341 (42.2)	116/341 (34.0)	1.24 (1.02 to 1.51), 0.02
	Multiple	High HD + PA	≥5% weight loss	IG2	30	122/347 (35.2)	116/341 (34.0)	1.03 (0.84 to 1.27), NSD
	Multiple	High HD + PA	≥5% weight loss	IG1	60	72/194 (37.1)	59/218 (27.1)	1.37 (1.03 to 1.82), 0.052
Wadden, 2011[127] (Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-UP)) Good	Multiple	High HD + PA	≥10% weight loss	IG1	12	14/131 (10.7)	5/130 (3.8)	2.78 (1.03 to 7.49), 0.04
	Multiple	High HD + PA	≥10% weight loss	IG1	24	13/131 (9.9)	8/130 (6.2)	1.61 (0.69 to 3.76), NSD
	Multiple	High HD + PA	≥5% weight loss	IG1	12	38/131 (29.0)	32/130 (24.6)	1.18 (0.79 to 1.76), NSD

Appendix H Table 12. Adiposity, Dichotomous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
	Multiple	High HD + PA	≥5% weight loss	IG1	24	34/131 (26.0)	28/130 (21.5)	1.21 (0.78 to 1.87), NSD
Wood, 2008[131] (EUROACTION) Fair	Multiple	High HD + PA	≥5% weight loss	IG1 (Overweight subgroup)	12	134/814 (16.5)	13/192 (6.8)	Difference in probability=10.40 (4.70 to 16.10), 0.005
	Multiple	High HD + PA	BMI ≤25 kg/m^2	IG1	12	230/1018 (22.6)	220/1002 (22.0)	Difference in probability=0.60 (-6.90 to 8.00), 0.85
	Multiple	High HD + PA	Percent obese	IG1	12	355/1018 (34.9)	291/1002 (29.0)	1.20 (1.06 to 1.36), <0.05
	Multiple	High HD + PA	Waist circumference	IG1	12	234/1009 (23.2)	152/1001 (15.2)	Difference in probability=7.90 (-2.30 to 18.10), 0.1

Abbreviations: CG = control group; CI = confidence interval; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; kg/m^2 = kilograms per meter squared; KQ = key question; NR = not reported; NSD = no statistically significantly difference; OR = odds ratio

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

†Risk ratio unless otherwise specified

Appendix H Table 13. CVD Risk Score Outcomes (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Instrument)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Bruckert, 2008[55] (PEGASE (Effect of an Education Program)) Fair	Dys	Medium HD + PA	10-year CVD risk (Modified Framingham Anderson model)	IG1	6	274	13.6 (8.48)	-0.66 (8.35)	199	12.4 (7.81)	0.06 (8.01)	-0.72 (-4.43 to 2.99), 0.08
Burke, 2006[56] (ADAPT) Fair	HTN	Medium HD + PA	10-year CHD risk (Wilson, 1998 model)	IG1 (Females)	40	67	2.8 (NR)	0.7 (NR)	67	2.5 (NR)	1.2 (NR)	NR, 0.560
	HTN	Medium HD + PA	10-year CHD risk (Wilson, 1998 model)	IG1 (Males)	40	56	10.2 (NR)	2 (NR)	51	8.9 (NR)	3.2 (NR)	NR, 0.748
Cochrane, 2012[60] Fair	Multiple	Medium HD + PA	10-year CVD risk (Framingham Anderson Model)	IG1	12	236	31.9 (10)	-2.8 (6.15)	365	32.9 (9.7)	-3.1 (6.48)	0.30 (-0.73 to 1.33), NSD
Coleman, 2012[62] (Wisewoman California) Fair	Multiple	Medium HD + PA	10-year CHD risk (Framinghan Anderson model)	IG1	12	433	0.07 (0.05)	-0.01 (NR)	436	0.07 (0.05)	0 (NR)	NR, 0.51
Edelman, 2006[65] Fair	Multiple	High HD + PA	10-year CHD risk (Framingham, Wilson 1998 model)	IG1	10	77	9.3 (NR)	16 (NR)	77	11.1 (NR)	12 (NR)	NR, 0.04
Greaves, 2015[71] (Waste the Waist) Fair	Multiple	High HD + PA	10-year CVD risk (QRISK2)	IG1	12	55	23.6 (9.8)	NR (NR)	51	22.5 (10.4)	NR (NR)	-0.76 (-2.19 to 0.66), NSD
Harris, 2012[74] (Health Improvement and Prevention Study (HIPS)) Fair	Multiple	High HD + PA	5-year CVD risk (Absolute 5-yr CVD risk)	IG1	12	355	NR (NR)	NR (NR)	300	NR (NR)	NR (NR)	NR, 0.1

Appendix H Table 13. CVD Risk Score Outcomes (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Instrument)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Khanji, 2019[87] (HAPPY London) Good	Multiple	Low HD + PA	10-year CVD risk (Framingham)	IG1	6	194	16 (9)	-1.23 (8.95)	183	17.8 (10)	-1.37 (9.76)	0.14 (-0.90 to 1.20), 0.79
	Multiple	Low HD + PA	10-year CVD risk (QRISK2)	IG1	6	194	NR (NR)	0.14 (NR)	183	NR (NR)	0.01 (NR)	0.24 (-0.40 to 0.60), 0.63
Koelewijn-van Loon, 2009 (Improving Patient Adherence to Lifestyle Advice (IMPALA)) Fair	Multiple	Medium HD + PA	10-year CVD mortality risk (SCORE w/o DM; UKPDS w/ DM)	IG1	12	286	4.3 (4.9)	-0.5 (4.55)	261	5.4 (6.3)	-0.7 (5.94)	0.20 (-0.69 to 1.09), 0.023
Lakerveld, 2013[90] (HOORN) Fair	Multiple	Medium HD + PA	10-year CVD mortality risk (SCORE)	IG1	6	314	4 (3)	0 (3)	308	3.8 (2.9)	-0.1 (2.95)	0.10 (-0.37 to 0.57), NSD
	Multiple	Medium HD + PA	10-year CVD mortality risk (SCORE)	IG1	12	314	4 (3)	0 (3)	308	3.8 (2.9)	-0.1 (4.03)	0.10 (-0.46 to 0.66), NSD
Langford, 1991[91] (Trial of Antihypertensive Interventions and Management (TAIM)) Fair	HTN	High HD + PA	8-year CVD risk (Framingham Risk Score)	IG1	6	235	NR (NR)	0.89 (0.33)	229	NR (NR)	0.98 (0.33)	-0.09 (-0.15 to -0.03), <0.05
	HTN	High HD only	8-year CVD risk (Framingham Risk Score)	IG2	6	228	NR (NR)	0.93 (0.3)	229	NR (NR)	0.98 (0.33)	-0.05 (-0.11 to 0.01), <0.05
Nolan, 2018[101] (Reducing Risk with E-based Support for Adherence to Lifestyle Change in Hypertension (REACH)) Fair	HTN	High HD + PA	10-year CVD risk (Framingham risk index for CVD)	IG1	12	100	16.5 (8.83)	-1.9 (7.14)	97	14.6 (8.76)	0.2 (7.29)	-2.10 (-4.12 to -0.08), 0.02

Appendix H Table 13. CVD Risk Score Outcomes (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Instrument)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Salisbury, 2016[108] Good	Multiple	Medium HD + PA	10-year CVD risk (QRISK2)	IG1	6	301	31.1 (10.2)	0.3 (10.25)	296	30.8 (9.5)	0.2 (9.5)	MD=0.10 (-0.20 to 0.40), 0.49
	Multiple	Medium HD + PA	10-year CVD risk (QRISK2)	IG1	12	295	31.1 (10.2)	0.2 (10.46)	291	30.8 (9.5)	0.4 (9.92)	MD=-0.40 (-1.20 to 0.30), 0.27
Ter Bogt, 2009[116] (Groningen Overweight and Lifestyle (GOAL)) Good	Multiple	High HD + PA	10-year CVD mortality risk (SCORE)	IG1 (Females)	12	103	NR (NR)	0.1 (1.7)	114	NR (NR)	0.46 (4.3)	-0.36 (-1.21 to 0.49), NSD
	Multiple	High HD + PA	10-year CVD mortality risk (SCORE)	IG1 (Males)	12	98	NR (NR)	-0.23 (2.8)	101	NR (NR)	-0.07 (1.3)	-0.16 (-0.77 to 0.45), NSD
Tiessen, 2012[117] (SPRING (Self-monitoring and Prevention of RIsk Factors by Nurse practitioners in the region of Groningen)) Fair	Multiple	Medium HD + PA	10-year CVD mortality risk (SCORE)	IG1	12	89	NR (NR)	-1.8 (2.89)	90	NR (NR)	-1.6 (2.9)	-0.20 (-1.10 to 0.60), NSD
Wister, 2007 Good	Multiple	Medium HD + PA	10-year CVD risk (Framingham global risk score)	IG1	12	157	12.5 (5.9)	-3.1 (5.63)	158	11 (6)	-1.3 (5.64)	-1.80 (-3.04 to -0.56), <0.01

Abbreviations: CG = control group; CHD = coronary heart disease; CI = confidence interval; CVD = cardiovascular disease; DM = diabetes mellitus; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; KQ = key question; MD = mean difference; NR = not reported; NSD = no statistically significantly difference; SD = standard deviation; UKPDS = UK Prospective Diabetes Study; w/o = without

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min
†Between-group mean difference in change unless otherwise specified

Appendix H Table 14. Other Intermediate Outcomes (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Anderssen, 1995[40] (Oslo Diet and Exercise Study (ODES)) Fair	Multiple	Medium HD only	METS prevalence	IG1 (Males w/METS at BL)	12	22/34 (64.7)	23/26 (88.5)	0.73 (0.55 to 0.97), 0.023
Bo, 2007[52] Fair	Multiple	Medium HD + PA	METS incidence	IG1	12	59/169 (34.9)	109/166 (65.7)	OR=0.28 (0.18 to 0.44), <0.001
Chirinos, 2016[57] (Community Health and Risk-reduction for Metabolic Syndrome (CHARMS)) Fair	Multiple	High HD + PA	METS prevalence	IG1	6	NR	NR	NR, NSD
	Multiple	High HD + PA	METS prevalence	IG1	12	NR	NR	NR, NSD
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	METS prevalence	IG1	60	1320/1982 (66.6)	1326/1934 (68.6)	0.97 (0.93 to 1.01),
	Multiple	High HD only	Incident PAD	IG2	60	26/2452 (1.1)	45/2444 (1.8)	HR=0.52 (0.32 to 0.86), <0.05
	Multiple	High HD only	METS prevalence	IG2	60	1223/1885 (64.9)	1326/1934 (68.6)	0.95 (0.90 to 0.99),
	Multiple	High HD only	Incident PAD	IG1	60	18/2539 (0.7)	45/2444 (1.8)	HR=0.36 (0.20 to 0.62), <0.05
	Multiple	High HD only	METS incidence	IG2	38	333/662 (50.3)	298/594 (50.2)	HR=1.08 (0.92 to 1.27), NSD
	Multiple	High HD only	METS incidence	IG1	38	329/663 (49.6)	298/594 (50.2)	HR=1.10 (0.94 to 1.30), NSD
Greaves, 2015[71] (Waste the Waist) Fair	Multiple	High HD + PA	METS prevalence	IG1	12	21/54 (38.9)	32/53 (60.4)	0.64 (0.43 to 0.96), 0.034
Liira, 2014[93] Fair	Multiple	Medium HD + PA	METS prevalence	IG1	12	27/46 (58.7)	21/42 (50.0)	1.17 (0.80 to 1.73), 0.33

Abbreviations: BL = baseline; CG = control group; CI = confidence interval; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HR = hazard ratio; HTN = hypertension; IG = intervention group; Int arm = intervention arm; KQ = key question; METS = metabolic syndrome; NR = not reported; NSD = no statistically significantly difference; OR = odds ratio; PAD = peripheral artery disease; RR = risk ratio

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

†Risk ratio unless otherwise specified

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Anderson, 1992[39] Fair	Dys	High HD only	Fiber (g/day)	IG1	12	48	19 (11.09)	5.6 (13.16)	51	17 (10)	0.1 (10)	5.50 (0.87 to 10.13), <0.05
	Dys	High HD only	Fiber (g/day)	IG2	12	47	17 (7.54)	3 (8.91)	51	17 (10)	0.1 (10)	2.90 (-0.84 to 6.64), NSD
	Dys	High HD only	MUFA (% energy)	IG1	12	48	12 (2.77)	-2 (3.46)	51	11 (2.86)	0 (3.57)	-2.00 (-3.39 to -0.61), <0.05
	Dys	High HD only	MUFA (% energy)	IG2	12	47	12 (3.43)	-2 (3.43)	51	11 (2.86)	0 (3.57)	-2.00 (-3.39 to -0.61), <0.05
	Dys	High HD only	PUFA (% energy)	IG1	12	48	8 (2.08)	-1 (2.77)	51	7 (2.86)	0 (2.86)	-1.00 (-2.11 to 0.11), NSD
	Dys	High HD only	PUFA (% energy)	IG2	12	47	8 (2.74)	0 (3.43)	51	7 (2.86)	0 (2.86)	0.00 (-1.25 to 1.25), NSD
	Dys	High HD only	Saturated fat (% energy)	IG1	12	48	11 (2.77)	-3 (3.46)	51	11 (3.57)	-1 (3.57)	-2.00 (-3.39 to -0.61), <0.05
	Dys	High HD only	Saturated fat (% energy)	IG2	12	47	11 (3.43)	-2 (2.74)	51	11 (3.57)	-1 (3.57)	-1.00 (-2.25 to 0.25), <0.05
Anderssen, 1995[40] (Oslo Diet and Exercise Study (ODES)) Fair	Multiple	Medium HD only	Dietary pattern score (score)	IG1 (Males)	12	45	30.7 (6.5)	1.2 (6.2)	36	29.6 (7.1)	-1.7 (5.1)	2.90 (0.44 to 5.36), <0.05
	Multiple	Medium HD only	MUFA (g/day)	IG1 (Males)	12	43	37.2 (13.6)	-12.3 (11.3)	36	33.1 (9.9)	-1.6 (11.2)	-10.70 (-15.68 to -5.72), <0.001
	Multiple	Medium HD only	PUFA (g/day)	IG1 (Males)	12	43	18.8 (8)	-4.9 (6.6)	36	16 (5.8)	-0.5 (5.7)	-4.40 (-7.11 to -1.69), ≤0.05
	Multiple	Medium HD only	Saturated fat (g/day)	IG1	12	52	NR (NR)	-14 (12.98)	43	NR (NR)	-1.9 (13.11)	-12.10 (-17.37 to -6.83), <0.05
Appel, 2003[41] (PREMIER) Good	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG1	6	243	4.7 (2.5)	3 (3.6)	248	4.4 (2.3)	0.5 (2.8)	2.50 (1.93 to 3.07), <0.001
	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG2	6	237	4.6 (2.3)	0.5 (2.6)	248	4.4 (2.3)	0.5 (2.8)	0.00 (-0.48 to 0.48), 0.79
	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG1	18	243	4.7 (2.5)	2.8 (3.4)	248	4.4 (2.3)	0.3 (2.7)	2.60 (2.20 to 3.10), <0.05

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG2	18	237	4.6 (2.3)	0.1 (2.7)	248	4.4 (2.3)	0.3 (2.7)	-0.10 (-0.50 to 0.40), NSD
	HTN	High HD + PA	MUFA (% energy)	IG1	6	236	12.8 (3.5)	-4.1 (3.55)	241	12.4 (3.2)	-0.3 (3.3)	-3.80 (-4.42 to -3.18), <0.0001
	HTN	High HD + PA	MUFA (% energy)	IG2	6	233	12.8 (3.6)	-1.8 (3.6)	241	12.4 (3.2)	-0.3 (3.3)	-1.50 (-2.12 to -0.88), <0.0001
	HTN	High HD + PA	MUFA (% energy)	IG1	18	247	12.8 (3.5)	-3 (3.66)	249	12.4 (3.2)	-0.4 (3.36)	-2.60 (-3.22 to -1.98), <0.0001
	HTN	High HD + PA	MUFA (% energy)	IG2	18	241	12.8 (3.6)	-1.2 (3.7)	249	12.4 (3.2)	-0.4 (3.36)	-0.80 (-1.43 to -0.17), NSD
	HTN	High HD + PA	Potassium (mmol/L)	IG1	6	214	68.1 (27)	19.3 (32.1)	233	66.9 (28.1)	-1.3 (28.7)	20.60 (14.94 to 26.26), <0.001
	HTN	High HD + PA	Potassium (mmol/L)	IG2	6	223	66.6 (23.9)	0.9 (22.3)	233	66.9 (28.1)	-1.3 (28.7)	2.20 (-2.51 to 6.91), 0.35
	HTN	High HD + PA	Potassium (mmol/L)	IG1	18	214	68.1 (27)	9.6 (30.4)	233	66.9 (28.1)	-2.5 (26.9)	12.70 (7.80 to 17.70), <0.05
	HTN	High HD + PA	Potassium (mmol/L)	IG2	18	233	66.6 (23.9)	0.2 (30.1)	233	66.9 (28.1)	-2.5 (26.9)	2.70 (-2.20 to 7.60), NSD
	HTN	High HD + PA	PUFA (% energy)	IG1	6	236	6.8 (2.6)	-1.7 (2.42)	241	6.7 (2.3)	-0.2 (2.21)	-1.50 (-1.92 to -1.08), <0.0001
	HTN	High HD + PA	PUFA (% energy)	IG2	6	233	7 (2.6)	-0.6 (2.51)	241	6.7 (2.3)	-0.2 (2.21)	-0.40 (-0.83 to 0.03), NSD
	HTN	High HD + PA	PUFA (% energy)	IG1	18	247	6.8 (2.6)	-1.2 (2.51)	249	6.7 (2.3)	0 (2.35)	-1.20 (-1.63 to -0.77), <0.01
	HTN	High HD + PA	PUFA (% energy)	IG2	18	241	7 (2.6)	-0.4 (2.65)	249	6.7 (2.3)	0 (2.35)	-0.40 (-0.84 to 0.04), NSD
	HTN	High HD + PA	Saturated fat (% energy)	IG1	6	243	10.9 (3)	-3.3 (3.9)	248	10.9 (3.3)	-0.4 (3.9)	-2.90 (-3.59 to -2.21), <0.001
	HTN	High HD + PA	Saturated fat (% energy)	IG2	6	237	10.9 (3.1)	-1.5 (4)	248	10.9 (3.3)	-0.4 (3.9)	-1.10 (-1.80 to -0.40), <0.001
	HTN	High HD + PA	Saturated fat (% energy)	IG1	18	243	10.9 (3)	-2.9 (3.4)	248	10.9 (3.3)	-0.6 (3.8)	-2.30 (-2.80 to -1.80), <0.05
	HTN	High HD + PA	Saturated fat (% energy)	IG2	18	237	10.9 (3.1)	-1.1 (3.7)	248	10.9 (3.3)	-0.6 (3.8)	-0.60 (-1.10 to 0.00), NSD

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG1	6	214	177.3 (80)	-32.6 (78.1)	233	173.2 (69.5)	-20.6 (71.6)	-12.00 (-25.93 to 1.93), 0.12
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG2	6	223	165.4 (70.1)	-31.6 (74.7)	233	173.2 (69.5)	-20.6 (71.6)	-11.00 (-24.44 to 2.44), 0.01
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG1	18	214	177.3 (80)	-24.5 (85.2)	233	173.2 (69.5)	-5.6 (89.8)	-15.40 (-29.10 to -1.70), <0.05
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG2	18	223	165.4 (70.1)	-18.4 (83.3)	233	173.2 (69.5)	-5.6 (89.8)	-16.70 (-30.30 to -3.20), <0.05
Arroll, 1995[44] Fair	HTN	Low HD + PA	Sodium (mmol/24-hr)	IG1	6	48	NR (NR)	NR (NR)	43	NR (NR)	NR (NR)	NR
	HTN	Low PA only	Sodium (mmol/24-hr)	IG2	6	46	NR (NR)	NR (NR)	43	NR (NR)	NR (NR)	NR
	HTN	Low HD only	Sodium (mmol/24-hr)	IG3	6	44	NR (NR)	NR (NR)	43	NR (NR)	NR (NR)	NR
	HTN	Low HD + PA	Sodium (score)	IG1	6	48	21.3 (9.01)	-7 (8.17)	43	21.2 (8.52)	-0.9 (7.95)	-6.10 (-9.41 to -2.79), <0.05
	HTN	Low PA only	Sodium (score)	IG2	6	46	22 (8.82)	-1.4 (8)	43	21.2 (8.52)	-0.9 (7.95)	-0.50 (-3.81 to 2.81), NSD
	HTN	Low HD only	Sodium (score)	IG3	6	44	22.3 (8.62)	-7.1 (8.04)	43	21.2 (8.52)	-0.9 (7.95)	-6.20 (-9.56 to -2.84), <0.05
Beckmann, 1995[46] Fair	HTN	Medium HD only	Sodium (mmol/24-hr)	IG1	6	32	195 (67.88)	-79 (65.24)	32	177 (56.57)	-2 (70.65)	-77.00 (-110.32 to -43.68), <0.05
	HTN	Medium HD only	Sodium (mmol/24-hr)	IG1	12	32	195 (67.88)	-72 (59.06)	32	177 (56.57)	-10 (53.96)	MD=-44.00 (-89.72 to -34.28),
Bennett, 2012[47] (Be Fit, Be Well [POWER]) Good	HTN	High HD + PA	Sodium (score, subscale of Hill-Bone Instrument)	IG1	6	180	5.52 (1.58)	-0.6 (1.21)	185	5.23 (1.5)	-0.15 (1.09)	-0.45 (-0.68 to -0.21), <0.001
	HTN	High HD + PA	Sodium (score, subscale of Hill-Bone Instrument)	IG1	12	180	5.52 (1.58)	-0.64 (1.21)	185	5.23 (1.5)	-0.13 (1.09)	-0.51 (-0.76 to -0.27), <0.001

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	High HD + PA	Sodium (score, subscale of Hill-Bone Instrument)	IG1	18	180	5.52 (1.58)	-0.57 (1.21)	185	5.23 (1.5)	-0.18 (1.22)	-0.39 (-0.63 to -0.14), 0.002
	HTN	High HD + PA	Sodium (score, subscale of Hill-Bone Instrument)	IG1	24	180	5.52 (1.58)	-0.61 (1.21)	185	5.23 (1.5)	-0.27 (1.09)	-0.33 (-0.56 to -0.11), 0.004
Bennett, 2018[48] (Track) Good	Multiple	Medium HD + PA	Dietary pattern score (DASH foods score)	IG1	12	113	2.35 (0.66)	-0.06 (0.71)	127	2.4 (0.75)	0.05 (0.72)	-0.11 (-0.29 to 0.07), 0.10
	Multiple	Medium HD + PA	Dietary pattern score (DASH nutrients score)	IG1	12	113	1.74 (1.38)	1.28 (1.51)	127	1.89 (1.46)	0.2 (1.32)	1.08 (0.72 to 1.44), <0.001
	Multiple	Medium HD + PA	Fiber (g/1000 kcal)	IG1	12	113	9.08 (3.25)	2.54 (3.38)	127	9.07 (3.22)	0.46 (2.95)	2.08 (1.27 to 2.89), <0.001
	Multiple	Medium HD + PA	Fruit (servings/d)	IG1	12	113	0.91 (0.74)	0.27 (0.09)	127	1.01 (0.82)	0.02 (0.78)	0.25 (0.11 to 0.39), 0.06
	Multiple	Medium HD + PA	Potassium (mg/1000 kcal)	IG1	12	113	1322.86 (312.92)	279.2 (350.02)	127	1355.5 (338.03)	48.38 (296.14)	230.82 (148.25 to 313.39), <0.001
	Multiple	Medium HD + PA	Saturated fat (% energy)	IG1	12	113	12.31 (2.4)	-0.99 (2.55)	127	12.05 (2.28)	0.26 (2.03)	-1.25 (-1.84 to -0.66), <0.001
	Multiple	Medium HD + PA	Sodium (mg/d)	IG1	12	113	3315.94 (1463.31)	-977.86 (1229.09)	127	3204.67 (1237.42)	-240.72 (1127.94)	-737.14 (-1036.87 to -437.41), <0.001
	Multiple	Medium HD + PA	Vegetables (servings/d)	IG1	12	113	3.12 (2.07)	0.17 (1.83)	127	2.87 (1.87)	0.1 (1.82)	0.07 (-0.39 to 0.53), 0.51
Beune, 2014[49] (Culturally Adapted	HTN	Medium HD + PA	Meeting diet and PA recs (score,	IG1	6	52	2.74 (0.73)	0.31 (0.68)	45	2.98 (0.7)	-0.13 (0.67)	0.34 (0.12 to 0.55), 0.003

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Hypertension Education (CAHE)) Fair			Morisky scale)									
Blackford, 2016[50] (Albany Physical Activity and Nutrition (APAN)) Fair	Multiple	Medium HD + PA	Fiber (score, Fat and Fiber Barometer)	IG1	6	151	23.3 (4.2)	1.6 (4.15)	159	23.4 (4)	0.2 (3.9)	1.40 (0.50 to 2.30), <0.001
	Multiple	Medium HD + PA	Fruit (servings/d)	IG1	6	151	1.5 (1.3)	0.5 (1.35)	159	1.5 (1.2)	-0.1 (1.15)	0.60 (0.32 to 0.88), 0.106
	Multiple	Medium HD + PA	Fruits and Vegetables (servings/d)	IG1	6	151	4.5 (3.16)	0.9 (3.03)	159	4 (2.99)	0.4 (3)	0.50 (-0.17 to 1.17), NSD
	Multiple	Medium HD + PA	Vegetables (servings/d)	IG1	6	151	3 (2.3)	0.4 (2.13)	159	2.5 (2.2)	0.5 (2.25)	-0.10 (-0.59 to 0.39), 0.002
Bloemberg, 1991[51] Fair	Dys	Medium HD only	Fiber (g/MJ)	IG1	6	39	2.4 (0.7)	0.6 (0.9)	40	2.5 (0.7)	0.1 (0.8)	0.50 (0.12 to 0.88), <0.01
	Dys	Medium HD only	MUFA (% energy)	IG1	6	39	14.2 (3.2)	-3 (3.4)	40	14 (3.2)	-0.6 (2.6)	-2.40 (-3.74 to -1.06), <0.01
	Dys	Medium HD only	PUFA (% energy)	IG1	6	39	6.8 (2.4)	2.8 (3.1)	40	6.6 (2.9)	0 (1.5)	2.80 (1.72 to 3.88), <0.01
	Dys	Medium HD only	Saturated fat (% energy)	IG1	6	39	16.5 (3.6)	-4.3 (3.9)	40	16.3 (4.7)	-0.7 (2.9)	-3.60 (-5.12 to -2.08), <0.01
Bo, 2007[52] Fair	Multiple	Medium HD + PA	Fiber (g/day)	IG1	12	169	19.2 (6.4)	1.7 (3.91)	166	19.4 (7.8)	0.17 (3.09)	1.53 (0.78 to 2.28), <0.001
	Multiple	Medium HD + PA	PUFA (% energy)	IG1	12	169	4.3 (1.3)	0.99 (1.72)	166	4.1 (1.2)	-0.04 (1.84)	1.03 (0.65 to 1.41), <0.001
	Multiple	Medium HD + PA	Saturated fat (% energy)	IG1	12	169	12.3 (2.6)	-1.97 (3.71)	166	12 (2.6)	-0.17 (3.62)	-1.80 (-2.58 to -1.02), <0.001
Broekhuizen, 2012[54] (PRO-FIT) Fair	Dys	Medium HD + PA	Fruit (servings/d)	IG1	12	169	1.5 (1.3)	0.1 (1.21)	145	1.4 (1.1)	0 (1.1)	0.10 (-0.16 to 0.36), NSD
	Dys	Medium HD + PA	Saturated fat (g/day)	IG1	12	171	30.8 (9.6)	-2.8 (9.81)	146	28.6 (9.8)	-1.2 (9.51)	-1.60 (-3.73 to 0.53), NSD
	Dys	Medium HD + PA	Vegetables (g/day)	IG1	12	169	162.1 (75.8)	9.4 (76.2)	146	151.2 (77.8)	12.2 (77.5)	-2.80 (-19.83 to 14.23), NSD

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Burke, 2006[56] (ADAPT) Fair	HTN	Medium HD + PA	Fiber (g/day)	IG1	16	123	24 (7.64)	2.3 (8.8)	118	24.1 (7.2)	0.1 (8.35)	2.20 (0.04 to 4.36), <0.05
	HTN	Medium HD + PA	Fiber (g/day)	IG1	40	123	24 (7.64)	0.2 (7.94)	118	24.1 (7.2)	0 (7.35)	0.20 (-1.73 to 2.13), NSD
	HTN	Medium HD + PA	Fruit (servings/d)	IG1	16	123	1.7 (1.13)	0.1 (1.13)	118	1.9 (1.11)	-0.1 (1.11)	0.20 (-0.08 to 0.48), NSD
	HTN	Medium HD + PA	Fruit (servings/d)	IG1	40	123	1.7 (1.13)	0.2 (0.57)	118	1.9 (1.11)	-0.3 (0.55)	0.50 (0.36 to 0.64), 0.147
	HTN	Medium HD + PA	Fruits and Vegetables (servings/d)	IG1	16	123	4.3 (1.96)	0.8 (2.1)	118	4.6 (1.91)	0 (1.91)	0.80 (0.29 to 1.31), NSD
	HTN	Medium HD + PA	Fruits and Vegetables (servings/d)	IG1	40	123	4.3 (1.96)	0.8 (1.01)	118	4.6 (1.91)	-0.4 (0.96)	1.20 (0.95 to 1.45), NSD
	HTN	Medium HD + PA	MUFA (% energy)	IG1	16	123	10.6 (5.38)	-1.9 (4.66)	118	10.7 (5.27)	0.1 (5.13)	-2.00 (-3.24 to -0.76), <0.001
	HTN	Medium HD + PA	MUFA (% energy)	IG1	40	123	10.6 (5.38)	-0.7 (4.71)	118	10.7 (5.27)	-0.2 (4.73)	-0.50 (-1.69 to 0.69), NSD
	HTN	Medium HD + PA	Potassium (g/day)	IG1	16	123	3.3 (1.13)	0 (1.13)	118	3.4 (0.83)	-0.2 (0.83)	0.20 (-0.05 to 0.45), NSD
	HTN	Medium HD + PA	Potassium (g/day)	IG1	40	123	3.3 (1.13)	0 (1.02)	118	3.4 (0.83)	-0.1 (1)	0.10 (-0.15 to 0.35), NSD
	HTN	Medium HD + PA	Potassium (mmol/24-hr)	IG1	16	106	79.3 (24.71)	3.8 (27.01)	98	85.4 (20.79)	-2.9 (21.85)	6.70 (-0.02 to 13.42), 0.826
	HTN	Medium HD + PA	PUFA (% energy)	IG1	16	123	4.6 (1.98)	-0.2 (1.98)	118	4.8 (2.22)	-0.2 (2.22)	0.00 (-0.53 to 0.53), NSD
	HTN	Medium HD + PA	PUFA (% energy)	IG1	40	123	4.6 (1.98)	0 (1.98)	118	4.8 (2.22)	-0.3 (2.09)	0.30 (-0.21 to 0.81), NSD
	HTN	Medium HD + PA	Saturated fat (% energy)	IG1	16	123	12.3 (5.66)	-2.9 (4.91)	118	12 (5.82)	-0.6 (5.69)	-2.30 (-3.64 to -0.96), <0.001
	HTN	Medium HD + PA	Saturated fat (% energy)	IG1	40	123	12.3 (5.66)	-1.5 (5.03)	118	12 (5.82)	-0.6 (5.19)	-0.90 (-2.19 to 0.39), 0.008
	HTN	Medium HD + PA	Sodium (g/day)	IG1	16	123	2.7 (0.85)	-0.4 (0.85)	118	2.8 (0.83)	-0.2 (1)	-0.20 (-0.43 to 0.03), <0.05

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	Medium HD + PA	Sodium (g/day)	IG1	40	123	2.7 (0.85)	-0.2 (0.85)	118	2.8 (0.83)	-0.1 (0.83)	-0.10 (-0.31 to 0.11), NSD
	HTN	Medium HD + PA	Sodium (mg/d)	IG1	16	123	NR (NR)	-156 (312)	118	NR (NR)	-78 (390)	-78.00 (-167.40 to 11.40), NSD
	HTN	Medium HD + PA	Sodium (mg/d)	IG1	40	123	NR (NR)	-78 (312)	118	NR (NR)	-39 (312)	-39.00 (-117.80 to 39.80), NSD
	HTN	Medium HD + PA	Sodium (mmol/24-hr)	IG1	16	106	151.8 (50.45)	11.7 (62.57)	98	160.8 (66.33)	4.3 (69.49)	7.40 (-10.80 to 25.60), 0.896
	HTN	Medium HD + PA	Vegetables (servings/d)	IG1	16	123	2.6 (1.13)	0.7 (1.3)	118	2.7 (1.11)	0.1 (1.11)	0.60 (0.30 to 0.90), <0.001
	HTN	Medium HD + PA	Vegetables (servings/d)	IG1	40	123	2.6 (1.13)	0.6 (0.61)	118	2.7 (1.11)	-0.1 (0.55)	0.70 (0.55 to 0.85), 0.147
Cicolini, 2014[59] Fair	HTN	Medium HD + PA	Fruit (servings/d)	IG1	6	100	2 (0.9)	0.7 (1.1)	98	1.9 (0.7)	0.2 (0.4)	0.50 (0.27 to 0.73), <0.001
Cochrane, 2012[60] Fair	Multiple	Medium HD + PA	Dietary pattern score (score)	IG1	12	236	2.2 (NR)	0.25 (NR)	365	2.1 (NR)	0.3 (NR)	NR
Delahanty, 2001[63] Good	Dys	Medium HD + PA	Fiber (g/day)	IG1	6	44	16 (9)	2 (8.54)	43	18 (10)	-2 (8.72)	4.00 (0.37 to 7.63), NSD
	Dys	Medium HD + PA	Fiber (g/day)	IG1	12	42	16 (9)	0 (8.19)	44	18 (10)	1 (9.54)	-1.00 (-4.75 to 2.75), NSD
	Dys	Medium HD + PA	MUFA (% energy)	IG1	6	44	12 (5)	-3 (4.58)	43	12 (5)	-1 (4.58)	-2.00 (-3.93 to -0.07), <0.01
	Dys	Medium HD + PA	MUFA (% energy)	IG1	12	42	12 (5)	-2 (4.58)	44	12 (5)	-2 (4.58)	0.00 (-1.94 to 1.94), NSD
	Dys	Medium HD + PA	PUFA (% energy)	IG1	6	44	6 (4)	1 (4)	43	6 (3)	-1 (2.65)	2.00 (0.58 to 3.42), NSD
	Dys	Medium HD + PA	PUFA (% energy)	IG1	12	42	6 (4)	-1 (3.61)	44	6 (3)	0 (2.65)	-1.00 (-2.34 to 0.34), NSD
	Dys	Medium HD + PA	Saturated fat (% energy)	IG1	6	44	11 (6)	-4 (5.29)	43	11 (4)	-1 (4)	-3.00 (-4.97 to -1.03), <0.001
	Dys	Medium HD + PA	Saturated fat (% energy)	IG1	12	44	11 (6)	-3 (5.29)	43	11 (4)	-1 (4)	-2.00 (-3.97 to -0.03), NSD
Eakin, 2009[64] (Logan Healthy	Multiple	Medium HD + PA	Fruit (servings/d)	IG1	12	225	1.6 (1)	0.5 (0.9)	204	1.5 (1.3)	0.2 (0.86)	0.30 (0.13 to 0.47), <0.001

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Living) Fair	Multiple	Medium HD + PA	Fruit (servings/d)	IG1	18	225	1.6 (1)	0.47 (0.9)	204	1.5 (1.3)	0.24 (0.86)	0.22 (0.05 to 0.40), 0.01
	Multiple	Medium HD + PA	Fruits and Vegetables (servings/d)	IG1	12	225	4.6 (2.36)	1.57 (3.68)	204	4.5 (2.61)	0.53 (3.51)	1.04 (0.36 to 1.72), NSD
	Multiple	Medium HD + PA	Fruits and Vegetables (servings/d)	IG1	18	225	4.6 (2.36)	1.24 (3.68)	204	4.5 (2.61)	0.42 (3.51)	0.82 (0.14 to 1.50), NSD
	Multiple	Medium HD + PA	Saturated fat (% energy)	IG1	12	225	14.5 (3.3)	-1.58 (3.3)	204	14.2 (3.4)	-0.57 (3.29)	-1.01 (-1.64 to -0.37), 0.002
	Multiple	Medium HD + PA	Saturated fat (% energy)	IG1	18	225	14.5 (3.3)	-1.58 (3.3)	204	14.2 (3.4)	-0.52 (3.29)	-1.06 (-1.70 to -0.43), 0.001
	Multiple	Medium HD + PA	Vegetables (servings/d)	IG1	12	225	3 (1.7)	1.07 (3.15)	204	3 (1.7)	0.33 (3)	0.73 (0.13 to 1.31), 0.015
	Multiple	Medium HD + PA	Vegetables (servings/d)	IG1	18	225	3 (1.7)	0.77 (3.15)	204	3 (1.7)	0.18 (3)	0.59 (-0.01 to 1.17), 0.051
Ellsworth, 2016[66] Fair	Multiple	High HD + PA	Saturated fat (% change)	IG1	12	89	19.7 (9.1)	-10.4 (NR)	58	22.3 (11)	-1.8 (NR)	NR, 0.02
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	Dietary pattern score (score, MEDAS-14)	IG1	12	941	8.77 (1.91)	1.81 (1.79)	754	8.4 (1.92)	0.44 (1.81)	1.37 (1.20 to 1.54), <0.01
	Multiple	High HD only	Dietary pattern score (score, MEDAS-14)	IG2	12	939	8.8 (1.88)	1.98 (1.81)	754	8.4 (1.92)	0.44 (1.81)	1.54 (1.37 to 1.71), <0.01
	Multiple	High HD only	Dietary pattern score (score, MEDAS-14)	IG1	24	935	8.77 (1.91)	1.97 (1.82)	630	8.4 (1.92)	0.53 (1.78)	1.44 (1.26 to 1.62), <0.01
	Multiple	High HD only	Dietary pattern score (score, MEDAS-14)	IG2	24	890	8.8 (1.88)	2.14 (1.76)	630	8.4 (1.92)	0.53 (1.78)	1.61 (1.43 to 1.79), <0.01
	Multiple	High HD only	Dietary pattern score	IG1	36	723	8.77 (1.91)	1.85 (1.82)	433	8.4 (1.92)	0.58 (1.84)	1.27 (1.05 to 1.49), <0.01

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
			(score, MEDAS-14)									
	Multiple	High HD only	Dietary pattern score (score, MEDAS-14)	IG2	36	624	8.8 (1.88)	2.12 (1.75)	433	8.4 (1.92)	0.58 (1.84)	1.54 (1.32 to 1.76), <0.01
	Multiple	High HD only	Dietary pattern score (score, MEDAS-14)	IG1	48	594	8.77 (1.91)	2.03 (1.83)	300	8.4 (1.92)	0.65 (1.83)	1.38 (1.13 to 1.63), <0.01
	Multiple	High HD only	Dietary pattern score (score, MEDAS-14)	IG2	48	489	8.8 (1.88)	2.23 (1.79)	300	8.4 (1.92)	0.65 (1.83)	1.58 (1.32 to 1.84), <0.01
	Multiple	High HD only	Dietary pattern score (score, MEDAS-14)	IG1	60	557	8.77 (1.91)	1.97 (1.83)	305	8.4 (1.92)	0.86 (1.8)	1.11 (0.86 to 1.36), <0.01
	Multiple	High HD only	Dietary pattern score (score, MEDAS-14)	IG2	60	438	8.8 (1.88)	2.24 (1.78)	305	8.4 (1.92)	0.86 (1.8)	1.38 (1.12 to 1.64), <0.01
	Multiple	High HD only	Dietary pattern score (score, MEDAS-14)	IG1	72	367	8.77 (1.91)	2.02 (1.86)	202	8.4 (1.92)	0.84 (1.82)	1.18 (0.86 to 1.50), <0.01
	Multiple	High HD only	Dietary pattern score (score, MEDAS-14)	IG2	72	281	8.8 (1.88)	2.32 (1.78)	202	8.4 (1.92)	0.84 (1.82)	1.48 (1.15 to 1.81), <0.01
	Multiple	High HD only	Fiber (g/day)	IG1	60	2364	25.7 (9.1)	-0.29 (10.29)	1941	24.7 (8.4)	-0.93 (9.44)	0.64 (-0.08 to 1.36), 0.1
	Multiple	High HD only	Fiber (g/day)	IG2	60	2108	25.7 (8.6)	1.36 (10.07)	1941	24.7 (8.4)	-0.93 (9.44)	2.29 (1.56 to 3.03), <0.001
	Multiple	High HD only	Fruit (servings/d)	IG1	60	2364	3 (1.7)	0.21 (1.86)	1941	2.8 (1.6)	0.15 (1.8)	0.05 (-0.09 to 0.19), 0.75

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD only	Fruit (servings/d)	IG2	60	2108	3 (1.6)	0.25 (1.87)	1941	2.8 (1.6)	0.15 (1.8)	0.10 (-0.04 to 0.24), 0.25
	Multiple	High HD only	Fruits and Vegetables (servings/d)	IG1	60	2364	5.8 (2.5)	0.13 (2.91)	1941	5.4 (2.4)	0.06 (3.21)	0.07 (-0.11 to 0.25), <0.05
	Multiple	High HD only	Fruits and Vegetables (servings/d)	IG2	60	2108	5.7 (2.4)	0.24 (2.75)	1941	5.4 (2.4)	0.06 (3.21)	0.18 (0.00 to 0.36), <0.05
	Multiple	High HD only	MUFA (% energy)	IG1	60	2364	19.6 (4.6)	2.52 (5.46)	1941	19.3 (4.7)	-0.53 (5.62)	3.05 (2.65 to 3.46), <0.001
	Multiple	High HD only	MUFA (% energy)	IG2	60	2108	19.6 (4.3)	1.32 (5.15)	1941	19.3 (4.7)	-0.53 (5.62)	1.89 (1.45 to 2.26), <0.001
	Multiple	High HD only	PUFA (% energy)	IG1	60	2364	6.1 (2.1)	-0.03 (2.36)	1941	6.2 (2.1)	-0.65 (2.25)	0.62 (0.45 to 0.79), <0.001
	Multiple	High HD only	PUFA (% energy)	IG2	60	2108	6.4 (2)	1.31 (2.46)	1941	6.2 (2.1)	-0.65 (2.25)	1.96 (1.77 to 2.14), <0.001
	Multiple	High HD only	Saturated fat (% energy)	IG1	60	2364	10 (2.2)	-0.56 (2.36)	1941	10 (2.3)	-0.79 (2.25)	0.24 (0.06 to 0.41), 0.004
	Multiple	High HD only	Saturated fat (% energy)	IG2	60	2108	10 (2.1)	-0.67 (2.34)	1941	10 (2.3)	-0.79 (2.25)	0.12 (-0.06 to 0.30), 0.3
	Multiple	High HD only	Vegetables (servings/d)	IG1	60	2364	2.8 (1.2)	-0.08 (1.49)	1941	2.6 (1.1)	-0.09 (1.91)	0.01 (-0.08 to 0.11), 0.98
	Multiple	High HD only	Vegetables (servings/d)	IG2	60	2108	2.7 (1.2)	-0.01 (1.29)	1941	2.6 (1.1)	-0.09 (1.91)	0.08 (-0.01 to 0.18), 0.12
Gill, 2019[70] (HealtheSteps) Fair	Multiple	Medium HD + PA	Dietary pattern score (score)	IG1	6	59	6.7 (2.6)	-1.84 (2.74)	59	6.4 (2.7)	-0.35 (2.63)	-1.50 (-2.42 to -0.58), 0.002
	Multiple	Medium HD + PA	Fats or sweets (score)	IG1	6	59	21.1 (6.2)	-1.38 (5.58)	59	19.7 (5.2)	-0.7 (5.39)	-0.68 (-2.55 to 1.19), 0.47
Greaves, 2015[71] (Waste the Waist) Fair	Multiple	High HD + PA	Dietary pattern score (Fat score of DINE questionnaire)	IG1	12	54	30 (9.1)	-5 (7.97)	52	32.2 (10.9)	-4 (10.34)	-2.22 (-5.12 to 0.68), 0.132

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	Dietary pattern score (Fruit and vegetable score of DINE questionnaire)	IG1	12	54	21.6 (7.3)	2.39 (7.08)	51	21.1 (6.6)	-0.35 (5.48)	2.91 (0.65 to 5.16), 0.012
	Multiple	High HD + PA	Fiber score (Fiber score of DINE questionnaire)	IG1	12	54	36.7 (11.6)	2.94 (10.87)	51	37 (10)	-2.51 (10.02)	5.33 (1.83 to 8.82), 0.003
Hardcastle, 2008[73] Fair	Multiple	Medium HD + PA	Fruits and Vegetables (servings/d)	IG1	6	203	6.31 (4.02)	1.02 (4.14)	131	6.94 (4.48)	0.64 (4.68)	0.38 (-0.60 to 1.36), NSD
	Multiple	Medium HD + PA	Fruits and Vegetables (servings/d)	IG1	18	203	6.31 (4.02)	-0.01 (3.9)	131	6.94 (4.48)	-0.71 (4.1)	0.70 (-0.18 to 1.58), NSD
Harris, 2012[74] (Health Improvement and Prevention Study (HIPS)) Fair	Multiple	High HD + PA	Fruits and Vegetables (servings/d)	IG1	6	250	4.73 (2.12)	0.85 (2.07)	216	4.59 (2.08)	0.4 (2.13)	0.45 (0.07 to 0.83), 0.002
	Multiple	High HD + PA	Fruits and Vegetables (servings/d)	IG1	12	355	4.73 (2.12)	0.12 (2.52)	300	4.59 (2.08)	-0.07 (2.36)	0.19 (-0.18 to 0.56), 0.47
Hinderliter, 2014[76] (Exercise and Nutrition interventions for CardiOvasculaR hEalth (ENCORE)) Good	HTN	High HD only	Potassium (mg/d)	IG1	12	36	NR (NR)	NR (NR)	37	NR (NR)	NR (NR)	NR
	HTN	High HD only	Sodium (mg/d)	IG1	12	36	NR (NR)	NR (NR)	37	NR (NR)	NR (NR)	NR
HPT, 1990[77] (Hypertension	HTN	High HD only	Potassium (mmol/24-hr)	IG1	6	170	64.68 (NR)	5.88 (25.56)	185	65.66 (NR)	-0.49 (26.66)	6.37 (0.94 to 11.80), NSD

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Prevention Trial (HPT)) Good	HTN	High HD only	Potassium (mmol/24-hr)	IG2	6	165	64.19 (NR)	0.98 (25.18)	185	65.66 (NR)	-0.49 (26.66)	1.47 (-4.29 to 7.23), 0.994
	HTN	High HD only	Potassium (mmol/24-hr)	IG3	6	102	67.13 (NR)	-5.39 (29.69)	116	67.62 (NR)	1.47 (26.39)	-6.86 (-14.54 to 0.82), 0.066
	HTN	High HD only	Potassium (mmol/24-hr)	IG4	6	104	69.09 (NR)	-0.49 (24.99)	116	67.62 (NR)	1.47 (26.39)	-1.96 (-8.75 to 4.83), NSD
	HTN	High HD only	Potassium (mmol/24-hr)	IG1	36	151	64.68 (NR)	4.41 (36.13)	155	65.66 (NR)	-1.96 (30.5)	6.37 (-1.13 to 13.87), NSD
	HTN	High HD only	Potassium (mmol/24-hr)	IG2	36	144	64.19 (NR)	4.41 (35.28)	155	65.66 (NR)	-1.96 (30.5)	6.37 (-1.31 to 14.05), 0.044
	HTN	High HD only	Potassium (mmol/24-hr)	IG3	36	101	67.13 (NR)	5.88 (34.47)	102	67.62 (NR)	0.49 (34.64)	5.39 (-4.21 to 14.99), 0.328
	HTN	High HD only	Potassium (mmol/24-hr)	IG4	36	96	69.09 (NR)	-3.92 (33.61)	102	67.62 (NR)	0.49 (34.64)	-4.41 (-13.92 to 5.10), NSD
	HTN	High HD only	Sodium (mmol/24-hr)	IG1	6	170	159.98 (NR)	-43.32 (64.41)	185	164.92 (NR)	-14.82 (67.19)	-28.50 (-42.19 to -14.81), <0.05
	HTN	High HD only	Sodium (mmol/24-hr)	IG2	6	165	162.64 (NR)	-35.72 (63.46)	185	164.92 (NR)	-14.82 (67.19)	-20.90 (-35.05 to -6.75), 0.002
	HTN	High HD only	Sodium (mmol/24-hr)	IG3	6	102	174.04 (NR)	-15.96 (72.92)	116	174.42 (NR)	-17.1 (73.67)	1.14 (-18.22 to 20.50), 0.922
	HTN	High HD only	Sodium (mmol/24-hr)	IG4	6	104	173.28 (NR)	-31.92 (69.75)	116	174.42 (NR)	-17.1 (73.67)	-14.82 (-33.78 to 4.14), NSD
	HTN	High HD only	Sodium (mmol/24-hr)	IG1	36	151	159.98 (NR)	-22.04 (70.04)	155	164.92 (NR)	0 (70.96)	-22.04 (-37.84 to -6.24), <0.05
	HTN	High HD only	Sodium (mmol/24-hr)	IG2	36	143	162.64 (NR)	-15.96 (68.16)	155	164.92 (NR)	0 (70.96)	-15.96 (-31.60 to -0.32), 0.053
	HTN	High HD only	Sodium (mmol/24-hr)	IG3	36	101	174.04 (NR)	-1.52 (72.56)	102	174.42 (NR)	8.36 (72.92)	-9.88 (-29.99 to 10.23), 0.114
	HTN	High HD only	Sodium (mmol/24-hr)	IG4	36	96	173.28 (NR)	-34.96 (70.74)	102	174.42 (NR)	8.36 (72.92)	-43.32 (-63.33 to -23.31), <0.05
Hyman, 2007[79] Fair	HTN	Medium HD + PA	Sodium (mmol/24-hr)	IG1	6	92	185.8 (77.9)	-16.6 (93.99)	93	189 (71)	0.3 (83.57)	-16.90 (-42.54 to 8.74), NSD
	HTN	Medium HD + PA	Sodium (mmol/24-hr)	IG2	6	96	200.7 (88.2)	-0.3 (91.68)	93	189 (71)	0.3 (83.57)	-0.60 (-25.60 to 24.40), NSD

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	Medium HD + PA	Sodium (mmol/24-hr)	IG1	18	92	185.8 (77.9)	9.5 (97.98)	93	189 (71)	0.8 (82.5)	8.70 (-17.41 to 34.81), NSD
	HTN	Medium HD + PA	Sodium (mmol/24-hr)	IG2	18	96	200.7 (88.2)	7.9 (95.37)	93	189 (71)	0.8 (82.5)	7.10 (-18.30 to 32.50), NSD
Kandula, 2015[83] (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	Multiple	High HD + PA	Fruits and Vegetables (servings/d)	IG1	6	31	3 (2)	0.04 (1.53)	32	2 (1)	0.5 (1.53)	-0.40 (-1.15 to 0.26), NSD
	Multiple	High HD + PA	Saturated fat (% energy)	IG1	6	31	7.7 (1.9)	0.37 (2.77)	32	7.9 (2.5)	0.58 (2.79)	-0.21 (-1.59 to 1.17), NSD
Kastarinen, 2002[85] (Lifestyle Intervention against Hypertension in Eastern Finland (LIHEF)) Fair	HTN	High HD + PA	Fiber (g/day)	IG1	12	317	22.8 (8.6)	-0.1 (7.7)	272	22.9 (8.4)	-0.7 (6.7)	0.60 (-0.60 to 1.80), 0.349
	HTN	High HD + PA	Fiber (g/day)	IG1	24	275	22.8 (8.6)	0.8 (7.3)	233	22.9 (8.4)	-1.4 (6.9)	2.20 (1.00 to 3.50), <0.001
	HTN	High HD + PA	MUFA (% energy)	IG1	12	317	11.8 (2.5)	-0.5 (2.7)	272	11.7 (2.8)	-0.1 (2.8)	-0.40 (-0.90 to 0.00), 0.054
	HTN	High HD + PA	MUFA (% energy)	IG1	24	275	11.8 (2.5)	-0.9 (2.7)	233	11.7 (2.8)	-0.2 (3.2)	-0.70 (-1.20 to -0.20), <0.008
	HTN	High HD + PA	Potassium (mmol/d)	IG1	12	360	83 (27)	1 (NR)	355	83 (28)	1 (NR)	0.00 (-4.00 to 4.00), NSD
	HTN	High HD + PA	Potassium (mmol/d)	IG1	24	360	83 (27)	3 (NR)	355	83 (28)	1 (NR)	2.00 (-2.00 to 5.00), NSD
	HTN	High HD + PA	PUFA (% energy)	IG1	12	317	5.5 (1.5)	-0.1 (1.6)	272	5.3 (1.5)	0 (1.7)	-0.10 (-0.40 to 0.20), 0.512
	HTN	High HD + PA	PUFA (% energy)	IG1	24	275	5.5 (1.5)	-0.1 (1.7)	233	5.3 (1.5)	0.1 (1.5)	-0.20 (-0.50 to 0.00), 0.105
	HTN	High HD + PA	Saturated fat (% energy)	IG1	12	317	13.6 (3.1)	-1.3 (3.3)	272	13.6 (3.2)	-0.1 (2.8)	-1.20 (-1.70 to -0.70), <0.0005
	HTN	High HD + PA	Saturated fat (% energy)	IG1	24	275	13.6 (3.1)	-1.8 (0.3)	233	13.6 (3.2)	-0.1 (3.3)	-1.70 (-2.30 to -1.10), <0.0005
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG1	12	360	146 (56)	-9 (NR)	355	142 (56)	-6 (NR)	-3.00 (-10.00 to 5.00), NSD
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG1	24	360	146 (56)	-7 (NR)	355	142 (56)	-2 (NR)	-5.00 (-14.00 to 3.00), NSD

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Koelewijn-van Loon, 2009 (Improving Patient Adherence to Lifestyle Advice (IMPALA)) Fair	Multiple	Medium HD + PA	Fruit (pieces/d)	IG1	12	252	1.73 (1.31)	0.23 (1.36)	236	1.87 (1.5)	0.14 (1.54)	0.09 (-0.17 to 0.34), 0.7
	Multiple	Medium HD + PA	Saturated fat (Dutch Fat Questionnaire)	IG1	12	252	16.6 (5.7)	-2.2 (5.56)	236	17.2 (5.3)	-1.8 (5.35)	-0.40 (-1.37 to 0.57), 0.034
	Multiple	Medium HD + PA	Vegetables (Tbsp/d)	IG1	12	252	3.39 (1.6)	0.26 (1.72)	236	3.24 (1.84)	0.1 (1.87)	0.16 (-0.16 to 0.48), 0.09
Lakerveld, 2013[90] (HOORN) Fair	Multiple	Medium HD + PA	Fruit (pieces/d)	IG1	6	314	1.1 (0.9)	0 (0.9)	308	1.1 (0.8)	0.2 (0.92)	-0.20 (-0.34 to -0.06), NSD
	Multiple	Medium HD + PA	Fruit (pieces/d)	IG1	12	314	1.1 (0.9)	0 (0.9)	308	1.1 (0.8)	0.1 (0.85)	-0.10 (-0.24 to 0.04), NSD
	Multiple	Medium HD + PA	Vegetables (g/day)	IG1	6	314	148 (69.5)	13 (109.81)	308	150 (70.4)	1 (69.47)	12.00 (-2.41 to 26.41), NSD
	Multiple	Medium HD + PA	Vegetables (g/day)	IG1	12	314	148 (69.5)	8 (72.19)	308	150 (70.4)	7 (81.91)	1.00 (-11.14 to 13.14), NSD
Langford, 1991[91] (Trial of Antihypertensive Interventions and Management (TAIM)) Fair	HTN	High HD + PA	Potassium (mmol/d)	IG1	6	237	57.4 (NR)	2.2 (30.36)	230	55.1 (NR)	3.8 (30.36)	-1.60 (-7.11 to 3.91), NSD
	HTN	High HD only	Potassium (mmol/d)	IG2	6	214	58.3 (NR)	10.9 (30.36)	230	55.1 (NR)	3.8 (30.36)	7.10 (1.45 to 12.75), <0.05
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG1	6	237	134.4 (NR)	1.3 (72.68)	230	129.6 (NR)	5.5 (72.68)	-4.20 (-17.39 to 8.99), NSD
	HTN	High HD only	Sodium (mmol/24-hr)	IG2	6	214	135.9 (NR)	-27.4 (72.68)	230	129.6 (NR)	5.5 (72.68)	-32.90 (-46.43 to -19.37), <0.05
Migneault, 2012[94] Fair	HTN	High HD + PA	Dietary quality score (Overall Diet Quality)	IG1	8	169	53.9 (17.6)	2.8 (NR)	168	55.8 (17)	-0.74 (NR)	3.54 (NR), <0.03
	HTN	High HD + PA	Dietary quality score (Overall Diet Quality)	IG1	12	169	53.9 (17.6)	2.2 (NR)	168	55.8 (17)	1.4 (NR)	NR, NSD
Moy, 2001[96] Fair	Multiple	High HD only	Saturated fat (% energy)	IG1	24	117	NR (NR)	-1.4 (3)	118	NR (NR)	-0.01 (3)	-1.39 (-2.16 to -0.63), 0.0005

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD only	Saturated fat (g/day)	IG1	24	117	30.2 (16)	-4.9 (12)	118	29.7 (15)	1.9 (16)	-6.80 (-10.41 to -3.19), 0.0002
Niiranen, 2014[100] Fair	HTN	Medium HD + PA	Potassium (mEq/8h)	IG1	12	107	17.9 (7.3)	1.2 (8.71)	95	19.1 (7.9)	0.3 (9.7)	0.90 (-5.73 to 7.53), 0.49
	HTN	Medium HD + PA	Saturated fat (% energy)	IG1	12	112	13 (2.8)	-0.7 (2.7)	108	12.5 (2.9)	-0.1 (2.92)	-0.60 (-2.52 to 1.32), 0.11
	HTN	Medium HD + PA	Sodium (mmol/24-hr)	IG1	12	112	176.7 (97.28)	-5.32 (97.46)	106	184.68 (93.1)	-3.42 (109.79)	-1.90 (-72.89 to 69.09), 0.91
Reid, 2014[103] Fair	Multiple	High HD + PA	Fruits and Vegetables (servings/d)	IG1	12	211	6.3 (3)	1.1 (3.22)	215	6.5 (3.1)	0.1 (3.05)	1.00 (0.40 to 1.60), 0.5
Rubinstein, 2016[107] Good	HTN	Medium HD + PA	Fruits and Vegetables (servings/d)	IG1	12	94	2.12 (1.8)	-0.28 (1.67)	96	1.79 (1.2)	-0.12 (1.25)	-0.28 (-0.78 to 0.21), 0.26
	HTN	Medium HD + PA	Sodium (servings/d)	IG1	12	94	1.16 (0.9)	-0.27 (1.01)	96	1.17 (0.7)	-0.27 (0.7)	-0.02 (-0.34 to 0.31), 0.92
Salisbury, 2016[108] Good	Multiple	Medium HD + PA	Dietary pattern score (Starting the Conversation questionnaire)	IG1	12	300	NR (NR)	NR (NR)	299	NR (NR)	NR (NR)	MD=0.60 (0.40 to 0.90), <0.001
Soto Rodriguez, 2016[111] Fair	Multiple	Medium HD only	Dietary pattern score (MEDAS-14)	IG1	12	117	7.06 (2.02)	2.31 (1.91)	113	6.96 (2.15)	0.23 (1.85)	2.08 (1.59 to 2.56), 0.000
Stefanick, 1998[112] (Diet and Exercise for Elevated Risk (DEER)) Fair	Dys	High HD only	MUFA (% energy)	IG1 (Females)	12	46	NR (NR)	-2.1 (3.5)	45	NR (NR)	0 (3.2)	-2.10 (-3.48 to -0.72), <0.05
	Dys	High HD only	MUFA (% energy)	IG1 (Males)	12	49	NR (NR)	-2.8 (3.4)	46	NR (NR)	0 (2.9)	-2.80 (-4.07 to -1.53), <0.001
	Dys	High HD only	PUFA (% energy)	IG1 (Females)	12	46	NR (NR)	-0.9 (2.3)	45	NR (NR)	-0.3 (2.4)	-0.60 (-1.57 to 0.37), NSD
	Dys	High HD only	PUFA (% energy)	IG1 (Males)	12	49	NR (NR)	-1.3 (2.2)	46	NR (NR)	-0.7 (1.7)	-0.60 (-1.39 to 0.19), NSD

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Dys	High HD only	Saturated fat (% energy)	IG1 (Females)	12	46	NR (NR)	-2.4 (2.8)	45	NR (NR)	0.2 (2.8)	-2.60 (-3.75 to -1.45), <0.001
	Dys	High HD only	Saturated fat (% energy)	IG1 (Males)	12	49	NR (NR)	-3.4 (3.2)	46	NR (NR)	0 (2.4)	-3.40 (-4.53 to -2.27), <0.001
Stevens, 2003[113]	Dys	Medium HD only	Fruits and Vegetables (servings/d)	IG1	12	277	3.09 (1.76)	1.24 (1.83)	271	3.21 (1.97)	0.19 (1.94)	0.93 (0.73 to 1.37), <0.001
	Dys	Medium HD only	MUFA (% energy)	IG1	12	277	15.2 (NR)	-2.1 (NR)	271	14.8 (NR)	-0.8 (NR)	NR, <0.001
	Dys	Medium HD only	PUFA (% energy)	IG1	12	277	8.3 (NR)	-1.6 (NR)	271	8.1 (NR)	-0.6 (NR)	NR, <0.001
	Dys	Medium HD only	Saturated fat (% energy)	IG1	12	277	14 (NR)	-1.6 (NR)	271	13.6 (NR)	-0.4 (NR)	NR, <0.001
Svetkey, 2009[115] (Hypertension Improvement Project (HIP)) Fair	HTN	High HD + PA	Dietary quality score (Healthy Eating Index)	IG1	6	132	3.41 (1.38)	0.68 (1.29)	132	3.37 (1.24)	-0.04 (1.09)	0.72 (0.43 to 1.01), NSD
	HTN	High HD + PA	Dietary quality score (Healthy Eating Index)	IG1	6	132	61.3 (12.8)	8.9 (11.5)	132	60.9 (11.7)	-0.2 (9.4)	9.10 (6.57 to 11.63), <0.05
	HTN	High HD + PA	Dietary quality score (Healthy Eating Index)	IG2	6	124	3.21 (1.36)	0.06 (1.2)	132	3.37 (1.24)	-0.04 (1.09)	0.10 (-0.18 to 0.38), <0.05
	HTN	High HD + PA	Dietary quality score (Healthy Eating Index)	IG2	6	124	60.8 (12.2)	0.9 (10.5)	132	60.9 (11.7)	-0.2 (9.4)	1.10 (-1.35 to 3.55), NSD
	HTN	Medium HD + PA	Dietary quality score (Healthy Eating Index)	IG3	6	137	3.34 (1.26)	0.41 (1.45)	132	3.37 (1.24)	-0.04 (1.09)	0.45 (0.14 to 0.76), <0.05
	HTN	Medium HD + PA	Dietary quality score	IG3	6	137	59.6 (12.1)	5 (12.2)	132	60.9 (11.7)	-0.2 (9.4)	5.20 (2.60 to 7.80), <0.05

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
			(Healthy Eating Index)									
	HTN	High HD + PA	Dietary quality score (Healthy Eating Index)	IG1	18	128	3.41 (1.38)	0.27 (1.4)	122	3.37 (1.24)	0.03 (1.37)	0.24 (-0.10 to 0.58), <0.05
	HTN	High HD + PA	Dietary quality score (Healthy Eating Index)	IG1	18	128	61.3 (12.8)	4.6 (11.6)	122	60.9 (11.7)	-1.6 (10.4)	6.20 (3.47 to 8.93), <0.05
	HTN	High HD + PA	Dietary quality score (Healthy Eating Index)	IG2	18	124	3.21 (1.36)	0.07 (1.21)	122	3.37 (1.24)	0.03 (1.37)	0.04 (-0.28 to 0.36), <0.05
	HTN	High HD + PA	Dietary quality score (Healthy Eating Index)	IG2	18	124	60.8 (12.2)	-0.03 (10.4)	122	60.9 (11.7)	-1.6 (10.4)	1.57 (-1.03 to 4.17), NSD
	HTN	Medium HD + PA	Dietary quality score (Healthy Eating Index)	IG3	18	134	59.6 (12.1)	3.7 (10.8)	122	60.9 (11.7)	-1.6 (10.4)	5.30 (2.70 to 7.90), <0.05
	HTN	Medium HD + PA	Dietary quality score (Healthy Eating Index)	IG3	18	134	3.34 (1.26)	0.16 (1.12)	122	3.37 (1.24)	0.03 (1.37)	0.13 (-0.18 to 0.44), <0.05
	HTN	High HD + PA	Fats or sweets (servings/d)	IG1	6	132	3 (1.7)	-0.9 (1.4)	132	2.9 (1.5)	-0.4 (1.2)	-0.50 (-0.81 to -0.19), <0.05
	HTN	High HD + PA	Fats or sweets (servings/d)	IG2	6	124	2.8 (1.4)	-0.2 (1.3)	132	2.9 (1.5)	-0.4 (1.2)	0.20 (-0.11 to 0.51), <0.05
	HTN	Medium HD + PA	Fats or sweets (servings/d)	IG3	6	137	2.8 (1.6)	-0.6 (1.4)	132	2.9 (1.5)	-0.4 (1.2)	-0.20 (-0.51 to 0.11), <0.05

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	High HD + PA	Fats or sweets (servings/d)	IG1	18	128	3 (1.7)	-0.6 (1.6)	122	2.9 (1.5)	-0.1 (1.5)	-0.50 (-0.88 to -0.12), <0.05
	HTN	High HD + PA	Fats or sweets (servings/d)	IG2	18	124	2.8 (1.4)	-0.1 (1.4)	122	2.9 (1.5)	-0.1 (1.5)	0.00 (-0.36 to 0.36), <0.05
	HTN	Medium HD + PA	Fats or sweets (servings/d)	IG3	18	134	2.8 (1.6)	-0.2 (1.4)	122	2.9 (1.5)	-0.1 (1.5)	-0.10 (-0.46 to 0.26), <0.05
	HTN	High HD + PA	Fruit (servings/d)	IG1	6	132	1.4 (1.1)	1 (1.3)	132	1.3 (0.9)	0.02 (0.9)	0.98 (0.71 to 1.25), NSD
	HTN	High HD + PA	Fruit (servings/d)	IG2	6	124	1.3 (0.9)	0.1 (0.7)	132	1.3 (0.9)	0.02 (0.9)	0.08 (-0.12 to 0.28), <0.05
	HTN	Medium HD + PA	Fruit (servings/d)	IG3	6	137	1.3 (1)	0.6 (1.3)	132	1.3 (0.9)	0.02 (0.9)	0.58 (0.31 to 0.85), <0.05
	HTN	High HD + PA	Fruit (servings/d)	IG1	18	128	1.4 (1.1)	0.5 (1.2)	122	1.3 (0.9)	-0.02 (0.9)	0.52 (0.26 to 0.78), <0.05
	HTN	High HD + PA	Fruit (servings/d)	IG2	18	124	1.3 (0.9)	0.01 (0.8)	122	1.3 (0.9)	-0.02 (0.9)	0.03 (-0.18 to 0.24), <0.05
	HTN	Medium HD + PA	Fruit (servings/d)	IG3	18	134	1.3 (1)	0.4 (1.1)	122	1.3 (0.9)	-0.02 (0.9)	0.42 (0.17 to 0.67), <0.05
	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG1	6	132	1.42 (1.13)	0.92 (1.34)	132	1.28 (0.9)	0.04 (0.81)	0.88 (0.61 to 1.15), NSD
	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG2	6	124	1.33 (0.99)	0.59 (1.27)	132	1.28 (0.9)	0.04 (0.81)	0.55 (0.29 to 0.81), <0.05
	HTN	Medium HD + PA	Fruits and Vegetables (servings/d)	IG3	6	137	1.23 (0.88)	0.09 (0.72)	132	1.28 (0.9)	0.04 (0.81)	0.05 (-0.13 to 0.23), <0.05
	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG1	18	128	1.42 (1.13)	0.55 (1.13)	122	1.28 (0.9)	0.01 (0.9)	0.54 (0.29 to 0.79), <0.05
	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG2	18	124	1.33 (0.99)	0.41 (1.13)	122	1.28 (0.9)	0.01 (0.9)	0.40 (0.14 to 0.66), <0.05

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	Medium HD + PA	Fruits and Vegetables (servings/d)	IG3	18	134	1.23 (0.88)	-0.03 (0.87)	122	1.28 (0.9)	0.01 (0.9)	-0.04 (-0.26 to 0.18), <0.05
	HTN	High HD + PA	Potassium (mg)	IG1	6	132	2621 (1079)	152 (942)	132	2662 (1127)	-253 (904)	405.00 (182.27 to 627.73), <0.05
	HTN	High HD + PA	Potassium (mg)	IG2	6	124	2470 (925)	-33.9 (657)	132	2662 (1127)	-253 (904)	219.10 (26.34 to 411.86), <0.05
	HTN	Medium HD + PA	Potassium (mg)	IG3	6	137	2475 (1212)	-19.5 (874)	132	2662 (1127)	-253 (904)	233.50 (20.89 to 446.11), <0.05
	HTN	High HD + PA	Potassium (mg)	IG1	18	128	2621 (1079)	-49.4 (1007)	122	2662 (1127)	-205 (1078)	155.60 (-103.29 to 414.49), NSD
	HTN	High HD + PA	Potassium (mg)	IG2	18	124	2470 (925)	-26.4 (781)	122	2662 (1127)	-205 (1078)	178.60 (-56.96 to 414.16), NSD
	HTN	Medium HD + PA	Potassium (mg)	IG3	18	134	2475 (1212)	-72 (801)	122	2662 (1127)	-205 (1078)	133.00 (-101.49 to 367.49), NSD
	HTN	High HD + PA	Potassium (mg/dL)	IG1	6	132	61.2 (27.9)	-0.2 (26.3)	132	61.6 (31.9)	-8.1 (27.5)	7.90 (1.41 to 14.39), <0.05
	HTN	High HD + PA	Potassium (mg/dL)	IG2	6	124	61.3 (22.8)	-3.1 (23.1)	132	61.6 (31.9)	-8.1 (27.5)	5.00 (-1.21 to 11.21), NSD
	HTN	Medium HD + PA	Potassium (mg/dL)	IG3	6	137	51.7 (23)	4.7 (19)	132	61.6 (31.9)	-8.1 (27.5)	12.80 (7.13 to 18.47), <0.05
	HTN	High HD + PA	Potassium (mg/dL)	IG1	18	128	61.2 (27.9)	-3.9 (23)	122	61.6 (31.9)	-5.7 (25.1)	1.80 (-4.18 to 7.78), NSD
	HTN	High HD + PA	Potassium (mg/dL)	IG2	18	124	61.3 (22.8)	3 (43.1)	122	61.6 (31.9)	-5.7 (25.1)	8.70 (-0.10 to 17.50), NSD
	HTN	Medium HD + PA	Potassium (mg/dL)	IG3	18	134	51.7 (23)	8.4 (22.4)	122	61.6 (31.9)	-5.7 (25.1)	14.10 (8.25 to 19.95), <0.05
	HTN	High HD + PA	Saturated fat (% energy)	IG1	6	132	10.5 (2.4)	-1.3 (2.1)	132	10.6 (2.5)	0.2 (2.3)	-1.50 (-2.03 to -0.97), <0.05
	HTN	High HD + PA	Saturated fat (% energy)	IG2	6	124	10.9 (2.7)	-1 (2.7)	132	10.6 (2.5)	0.2 (2.3)	-1.20 (-1.82 to -0.58), <0.05
	HTN	Medium HD + PA	Saturated fat (% energy)	IG3	6	137	11 (2.3)	-0.2 (2)	132	10.6 (2.5)	0.2 (2.3)	-0.40 (-0.92 to 0.12), <0.05
	HTN	High HD + PA	Saturated fat (% energy)	IG1	18	128	10.5 (2.4)	-1 (2.2)	122	10.6 (2.5)	0.1 (2.3)	-1.10 (-1.66 to -0.54), <0.05

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	High HD + PA	Saturated fat (% energy)	IG2	18	124	10.9 (2.7)	-0.9 (2.1)	122	10.6 (2.5)	0.1 (2.3)	-1.00 (-1.55 to -0.45), <0.05
	HTN	Medium HD + PA	Saturated fat (% energy)	IG3	18	134	11 (2.3)	-0.2 (2)	122	10.6 (2.5)	0.1 (2.3)	-0.30 (-0.83 to 0.23), <0.05
	HTN	High HD + PA	Saturated fat (g/day)	IG1	6	132	21.5 (12.6)	-5.9 (10.2)	132	20.9 (11.6)	-1.7 (6.9)	-4.20 (-6.30 to -2.10), <0.05
	HTN	High HD + PA	Saturated fat (g/day)	IG2	6	124	19.9 (10.6)	-1 (6.8)	132	20.9 (11.6)	-1.7 (6.9)	0.70 (-0.98 to 2.38), NSD
	HTN	Medium HD + PA	Saturated fat (g/day)	IG3	6	137	20.5 (12)	-4.7 (9.6)	132	20.9 (11.6)	-1.7 (6.9)	-3.00 (-4.99 to -1.01), <0.05
	HTN	High HD + PA	Saturated fat (g/day)	IG1	18	128	21.5 (12.6)	-4.7 (11.6)	122	20.9 (11.6)	-1.1 (9)	-3.60 (-6.17 to -1.03), <0.05
	HTN	High HD + PA	Saturated fat (g/day)	IG2	18	124	19.9 (10.6)	-1.2 (8)	122	20.9 (11.6)	-1.1 (9)	-0.10 (-2.23 to 2.03), NSD
	HTN	Medium HD + PA	Saturated fat (g/day)	IG3	18	134	20.5 (12)	-3.4 (8.3)	122	20.9 (11.6)	-1.1 (9)	-2.30 (-4.43 to -0.17), <0.05
	HTN	High HD + PA	Sodium (mg/d)	IG1	6	132	2346 (1170)	-338 (1051)	132	2345 (1114)	-217 (792)	-121.00 (-345.50 to 103.50), NSD
	HTN	High HD + PA	Sodium (mg/d)	IG2	6	124	2249 (968)	-114 (703)	132	2345 (1114)	-217 (792)	103.00 (-80.21 to 286.21), NSD
	HTN	Medium HD + PA	Sodium (mg/d)	IG3	6	137	2134 (1215)	-234 (902)	132	2345 (1114)	-217 (792)	-17.00 (-219.65 to 185.65), NSD
	HTN	High HD + PA	Sodium (mg/d)	IG1	18	128	2346 (1170)	-352 (1107)	122	2345 (1114)	-163 (968)	-189.00 (-446.45 to 68.45), NSD
	HTN	High HD + PA	Sodium (mg/d)	IG2	18	124	2249 (968)	-114 (858)	122	2345 (1114)	-163 (968)	49.00 (-179.71 to 277.71), NSD
	HTN	Medium HD + PA	Sodium (mg/d)	IG3	18	134	2134 (1215)	-145 (828)	122	2345 (1114)	-163 (968)	18.00 (-203.72 to 239.72), NSD
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG1	6	132	170.3 (76.2)	-31.4 (79.7)	132	174.7 (77)	-22.8 (71.2)	-8.60 (-26.83 to 9.63), NSD
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG2	6	124	150.9 (68)	-13.1 (62.2)	132	174.7 (77)	-22.8 (71.2)	9.70 (-6.65 to 26.05), NSD
	HTN	Medium HD + PA	Sodium (mmol/24-hr)	IG3	6	137	175.2 (82.9)	-23.6 (75.2)	132	174.7 (77)	-22.8 (71.2)	-0.80 (-18.30 to 16.70), NSD

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG1	18	128	170.3 (76.2)	-28 (76.6)	122	174.7 (77)	-8.3 (84.1)	-19.70 (-39.67 to 0.27), <0.05
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG2	18	124	150.9 (68)	-24 (85.2)	122	174.7 (77)	-8.3 (84.1)	-15.70 (-36.86 to 5.46), NSD
	HTN	Medium HD + PA	Sodium (mmol/24-hr)	IG3	18	134	175.2 (82.9)	-1.4 (69.9)	122	174.7 (77)	-8.3 (84.1)	6.90 (-12.15 to 25.95), NSD
	HTN	High HD + PA	Vegetables (servings/d)	IG1	6	132	3.1 (2.4)	1 (2.5)	132	2.9 (1.9)	0.1 (1.7)	0.90 (0.38 to 1.42), NSD
	HTN	High HD + PA	Vegetables (servings/d)	IG2	6	124	2.8 (1.6)	0.2 (1.6)	132	2.9 (1.9)	0.1 (1.7)	0.10 (-0.30 to 0.50), <0.05
	HTN	Medium HD + PA	Vegetables (servings/d)	IG3	6	137	3 (2.2)	0.5 (2.4)	132	2.9 (1.9)	0.1 (1.7)	0.40 (-0.10 to 0.90), <0.05
	HTN	High HD + PA	Vegetables (servings/d)	IG1	18	128	3.1 (2.4)	0.3 (2.5)	122	2.9 (1.9)	0.3 (2.5)	0.00 (-0.62 to 0.62), <0.05
	HTN	High HD + PA	Vegetables (servings/d)	IG2	18	124	2.8 (1.6)	0.04 (1.8)	122	2.9 (1.9)	0.3 (2.5)	-0.26 (-0.81 to 0.29), <0.05
	HTN	Medium HD + PA	Vegetables (servings/d)	IG3	18	134	3 (2.2)	0.03 (1.8)	122	2.9 (1.9)	0.3 (2.5)	-0.27 (-0.81 to 0.27), <0.05
Ter Bogt, 2009[116] (Groningen Overweight and Lifestyle (GOAL)) Good	Multiple	High HD + PA	Fruit (g/day)	IG1	12	169	130.5 (108.11)	85.1 (130)	172	137 (118.77)	64.1 (139.51)	21.00 (-7.62 to 49.62), 0.27
	Multiple	High HD + PA	Fruit (g/day)	IG1	36	158	130.5 (108.11)	84 (174.9)	172	137 (118.77)	63 (165.9)	21.00 (-15.86 to 57.86), 0.468
	Multiple	High HD + PA	Fruits and Vegetables (g/day)	IG1	12	169	275.7 (153.6)	101.2 (172)	172	295.6 (171.1)	77.7 (190.9)	23.50 (-15.05 to 62.05), NSD
	Multiple	High HD + PA	Fruits and Vegetables (g/day)	IG1	36	158	275.7 (153.6)	95.7 (221.5)	172	295.6 (171.1)	81.2 (222.3)	14.50 (-33.42 to 62.42), NSD
	Multiple	High HD + PA	Saturated fat (% energy)	IG1	12	169	12.9 (2.98)	-1.6 (2.65)	172	12.5 (3.01)	-1 (2.68)	-0.60 (-1.17 to -0.03), 0.16
	Multiple	High HD + PA	Saturated fat (% energy)	IG1	36	158	12.9 (2.98)	-0.9 (2.9)	172	12.5 (3.01)	-0.4 (2.7)	-0.50 (-1.11 to 0.11), 0.164
	Multiple	High HD + PA	Vegetables (g/day)	IG1	12	169	145.2 (67.65)	16.1 (65)	172	158.6 (77.28)	13.6 (77.95)	2.50 (-12.72 to 17.72), 0.87

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	Vegetables (g/day)	IG1	36	158	145.2 (67.65)	11.7 (74.1)	172	158.6 (77.28)	18.2 (86.7)	-6.50 (-23.86 to 10.86), 0.556
Toft, 2008[118] (Inter99) Fair	Multiple	High HD + PA	Fruit (g/day)	IG1 (Females)	60	1062	NR (NR)	NR (NR)	114	NR (NR)	NR (NR)	NR, NSD
	Multiple	High HD + PA	Fruit (g/day)	IG1 (Males)	60	1048	NR (NR)	NR (NR)	132	NR (NR)	NR (NR)	NR, NSD
	Multiple	High HD + PA	Saturated fat (% energy)	IG1 (Females)	12	1062	11.5 (6.65)	-1.6 (7.1)	114	11.5 (4.09)	-1.8 (4.23)	0.20 (-0.69 to 1.09), 0.65
	Multiple	High HD + PA	Saturated fat (% energy)	IG1 (Males)	12	1048	12.8 (8.26)	-1.4 (18)	132	12.8 (4.69)	-0.3 (5.01)	-1.10 (-2.48 to 0.28), 0.002
	Multiple	High HD + PA	Saturated fat (% energy)	IG1 (Females)	36	1062	11.5 (6.65)	-1.6 (7.62)	114	11.5 (4.09)	-1.2 (4.38)	-0.40 (-1.33 to 0.53), 0.26
	Multiple	High HD + PA	Saturated fat (% energy)	IG1 (Males)	36	1048	12.8 (8.26)	-1.3 (8.7)	132	12.8 (4.69)	-1.2 (5.19)	-0.10 (-1.13 to 0.93), 0.63
	Multiple	High HD + PA	Saturated fat (% energy)	IG1 (Females)	60	1062	11.5 (6.65)	-1.5 (7.1)	114	11.5 (4.09)	-1.3 (4.55)	-0.20 (-1.14 to 0.74), 0.59
	Multiple	High HD + PA	Saturated fat (% energy)	IG1 (Males)	60	1048	12.8 (8.26)	-1 (8.7)	132	12.8 (4.69)	-0.5 (5.19)	-0.50 (-1.53 to 0.53), 0.1
	Multiple	High HD + PA	Vegetables (g/day)	IG1 (Females)	60	1062	NR (NR)	NR (NR)	114	NR (NR)	NR (NR)	NR, NSD
	Multiple	High HD + PA	Vegetables (g/day)	IG1 (Males)	60	1048	NR (NR)	NR (NR)	132	NR (NR)	NR (NR)	NR, NSD
TOHP I CRG, 1992[119] (Trials of Hypertension Prevention Phase I (TOHP I)) Good	HTN	High HD only	Sodium (mmol/24-hr)	IG1	6	228	154.6 (59.9)	-55.68 (76.06)	323	156.4 (60.5)	2.77 (80.33)	-58.45 (-71.80 to -45.09), <0.01
	HTN	High HD only	Sodium (mmol/24-hr)	IG1	12	244	154.6 (59.9)	-54.4 (60.41)	342	156.4 (60.5)	-4.3 (68)	MD=-51.90 (-60.56 to -39.64), <0.001
	HTN	High HD only	Sodium (mmol/24-hr)	IG1	18	232	154.6 (59.9)	-55.19 (76.93)	330	156.4 (60.5)	-11.33 (77.68)	-43.86 (-56.88 to -30.84), <0.01

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
TOHP II CRG, 1997[120] (Trial of Hypertension Prevention II (TOHP II)) Good	HTN	High HD + PA	Sodium (mmol/24-hr)	IG1	18	447	179.3 (76.2)	-45.4 (88.8)	467	188 (80.9)	-16.8 (94.8)	-28.60 (-40.56 to -16.64), <0.001
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG2	18	460	180.9 (72.4)	-11.6 (86.2)	467	188 (80.9)	-16.8 (94.8)	5.20 (-6.56 to 16.96), 0.39
	HTN	High HD only	Sodium (mmol/24-hr)	IG3	18	450	186.1 (80.7)	-59.5 (91.7)	467	188 (80.9)	-16.8 (94.8)	-42.70 (-54.85 to -30.55), <0.001
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG1	36	471	179.3 (76.2)	-34.1 (90.9)	482	188 (80.9)	-10.5 (88.5)	-23.60 (-34.97 to -12.23), <0.001
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG2	36	475	180.9 (72.4)	-9 (87.1)	482	188 (80.9)	-10.5 (88.5)	1.50 (-9.67 to 12.67), 0.79
	HTN	High HD only	Sodium (mmol/24-hr)	IG3	36	470	186.1 (80.7)	-50.9 (86.3)	482	188 (80.9)	-10.5 (88.5)	-40.40 (-51.57 to -29.23), <0.001
van der Veen, 2002[122] (Nijmegen Family Practices Monitoring Project (NFPMP)) Fair	Dys	Medium HD only	MUFA (% energy)	IG1	6	70	14.6 (3.3)	-3.4 (3.3)	67	14.9 (2.6)	-0.7 (2.4)	-2.70 (-3.66 to -1.74), 0.000
	Dys	Medium HD only	MUFA (% energy)	IG1	12	67	14.6 (3.3)	-1.9 (4.1)	63	14.9 (2.6)	-0.3 (3.3)	-1.60 (-2.88 to -0.32), 0.01
	Dys	Medium HD only	Saturated fat (% energy)	IG1	6	70	15.2 (2.6)	-3.4 (2.7)	67	15.5 (2.3)	-0.8 (2.2)	-2.60 (-3.42 to -1.78), 0.000
	Dys	Medium HD only	Saturated fat (% energy)	IG1	12	67	15.2 (2.6)	-2.6 (2.7)	63	15.5 (2.3)	-0.9 (2.6)	-1.70 (-2.61 to -0.79), 0.000
van Keulen, 2011[123] (Vitalum) Fair	HTN	Medium HD + PA	Fruit (servings/d)	IG1	6	369	2.04 (1.55)	0.86 (1.6)	392	2.1 (1.69)	0.47 (1.67)	0.39 (0.16 to 0.62), <0.01
	HTN	Medium HD + PA	Fruit (servings/d)	IG2	6	369	2.04 (1.63)	0.55 (1.66)	392	2.1 (1.69)	0.47 (1.67)	0.08 (-0.16 to 0.32), <0.05
	HTN	Low HD + PA	Fruit (servings/d)	IG3	6	376	2.16 (1.69)	0.74 (1.73)	392	2.1 (1.69)	0.47 (1.67)	0.27 (0.03 to 0.51), <0.05
	HTN	Medium HD + PA	Fruit (servings/d)	IG1	11	307	2.04 (1.55)	0.74 (1.9)	326	2.1 (1.69)	0.26 (1.79)	0.48 (0.19 to 0.77), <0.01
	HTN	Medium HD + PA	Fruit (servings/d)	IG2	11	284	2.04 (1.63)	0.66 (1.9)	326	2.1 (1.69)	0.26 (1.79)	0.40 (0.11 to 0.69), <0.05
	HTN	Low HD + PA	Fruit (servings/d)	IG3	11	267	2.16 (1.69)	0.86 (2.01)	326	2.1 (1.69)	0.26 (1.79)	0.60 (0.29 to 0.91), <0.001
	HTN	Medium HD + PA	Fruit (servings/d)	IG1	17	302	2.04 (1.55)	0.26 (1.57)	327	2.1 (1.69)	-0.01 (1.64)	0.27 (0.02 to 0.52), <0.01

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	Medium HD + PA	Fruit (servings/d)	IG2	17	285	2.04 (1.63)	0.24 (1.61)	327	2.1 (1.69)	-0.01 (1.64)	0.25 (-0.01 to 0.51), <0.05
	HTN	Low HD + PA	Fruit (servings/d)	IG3	17	272	2.16 (1.69)	0.52 (1.75)	327	2.1 (1.69)	-0.01 (1.64)	0.53 (0.26 to 0.80), <0.001
	HTN	Medium HD + PA	Meeting diet and PA recs (score)	IG1	17	407	0.7 (0.7)	0.4 (1.01)	409	0.8 (0.7)	0.26 (1.01)	0.14 (0.02 to 0.26), 0.02
	HTN	Medium HD + PA	Meeting diet and PA recs (score)	IG2	17	408	0.7 (0.7)	0.5 (1.21)	409	0.8 (0.7)	0.26 (1.01)	0.24 (0.10 to 0.38), <0.001
	HTN	Low HD + PA	Meeting diet and PA recs (score)	IG3	17	405	0.8 (0.7)	0.62 (1.21)	409	0.8 (0.7)	0.26 (1.01)	0.36 (0.22 to 0.50), <0.001
	HTN	Medium HD + PA	Vegetables (g/day)	IG1	6	369	164 (81)	26 (78.17)	392	167 (80)	16 (80)	10.00 (-1.24 to 21.24), <0.05
	HTN	Medium HD + PA	Vegetables (g/day)	IG2	6	370	163 (81)	18 (80.02)	392	167 (80)	16 (80)	2.00 (-9.37 to 13.37), NSD
	HTN	Low HD + PA	Vegetables (g/day)	IG3	6	376	166 (88)	25 (84.72)	392	167 (80)	16 (80)	9.00 (-2.66 to 20.66), <0.05
	HTN	Medium HD + PA	Vegetables (g/day)	IG1	11	310	164 (81)	19 (83.61)	332	167 (80)	9 (81.54)	10.00 (-2.79 to 22.79), NSD
	HTN	Medium HD + PA	Vegetables (g/day)	IG2	11	290	163 (81)	25 (83.61)	332	167 (80)	9 (81.54)	16.00 (2.98 to 29.02), <0.05
	HTN	Low HD + PA	Vegetables (g/day)	IG3	11	267	166 (88)	39 (92.26)	332	167 (80)	9 (81.54)	30.00 (15.88 to 44.12), <0.001
	HTN	Medium HD + PA	Vegetables (g/day)	IG1	17	302	164 (81)	11 (84.72)	327	167 (80)	-3 (80.5)	14.00 (1.06 to 26.94), <0.05
	HTN	Medium HD + PA	Vegetables (g/day)	IG2	17	285	163 (81)	11 (83.07)	327	167 (80)	-3 (80.5)	14.00 (0.99 to 27.01), NSD
	HTN	Low HD + PA	Vegetables (g/day)	IG3	17	272	166 (88)	21 (90.07)	327	167 (80)	-3 (80.5)	24.00 (10.19 to 37.81), <0.01
Voils, 2013[126] (CouPLES) Fair	Dys	Medium HD + PA	Fiber (g/day)	IG1	6	81	14.8 (6.8)	-1.4 (6.75)	74	13.9 (6.7)	-1.4 (7.25)	0.00 (-2.21 to 2.21), NSD
	Dys	Medium HD + PA	Fiber (g/day)	IG1	11	88	14.8 (6.8)	-1.6 (6.56)	80	13.9 (6.7)	-2 (6.26)	0.40 (-1.54 to 2.34), 0.26

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Dys	Medium HD + PA	Saturated fat (% energy)	IG1	6	81	12.3 (2.9)	-1.2 (2.9)	74	12.6 (2.7)	-0.1 (3.04)	-1.10 (-2.04 to -0.16), <0.05
	Dys	Medium HD + PA	Saturated fat (% energy)	IG1	11	88	12.3 (2.9)	-0.9 (2.85)	80	12.6 (2.7)	-0.3 (2.81)	-0.60 (-1.46 to 0.26), 0.09
	Dys	Medium HD + PA	Saturated fat (g/day)	IG1	6	81	22.5 (14.8)	-6.7 (13.14)	74	21.3 (12.6)	-4.1 (11.4)	-2.60 (-6.46 to 1.26), NSD
	Dys	Medium HD + PA	Saturated fat (g/day)	IG1	11	88	22.5 (14.8)	-7.4 (12.9)	80	21.3 (12.6)	-3.9 (11.46)	-3.50 (-7.18 to 0.18), 0.02
Wadden, 2011[127] (Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-UP)) Good	Multiple	High HD + PA	Fruits and Vegetables (servings/d)	IG1	6	131	6.1 (3.9)	0.7 (5.72)	130	5.6 (4.1)	0.5 (5.7)	0.20 (-1.19 to 1.59), NSD
	Multiple	High HD + PA	Fruits and Vegetables (servings/d)	IG1	24	131	6.1 (3.9)	-0.6 (5.72)	130	5.6 (4.1)	0.3 (5.7)	-0.90 (-2.29 to 0.49), 0.195
Wister, 2007[129] Good	Multiple	Medium HD + PA	Dietary pattern score (score)	IG1	12	157	NR (NR)	0.3 (1.09)	158	NR (NR)	-0.05 (1.09)	0.35 (0.11 to 0.59), <0.01
Wong, 2015[130] Good	HTN	Low HD only	Dietary pattern score (score)	IG1	6	254	NR (NR)	NR (NR)	250	NR (NR)	NR (NR)	NR, 0.036
	HTN	Low HD only	Fruit (servings/d)	IG1	6	254	NR (NR)	NR (NR)	250	NR (NR)	NR (NR)	MD=0.12 (-0.14 to 0.38), 0.352
	HTN	Low HD only	Fruit (servings/d)	IG1	12	243	NR (NR)	NR (NR)	242	NR (NR)	NR (NR)	MD=0.05 (-0.16 to 0.26), 0.643
	HTN	Low HD only	Fruits and Vegetables (servings/d)	IG1	6	254	NR (NR)	NR (NR)	250	NR (NR)	NR (NR)	MD=0.27 (-0.30 to 0.84), <0.05
	HTN	Low HD only	Fruits and Vegetables (servings/d)	IG1	12	243	NR (NR)	NR (NR)	242	NR (NR)	NR (NR)	MD=0.51 (-0.05 to 1.07), NSD
	HTN	Low HD only	Vegetables (servings/d)	IG1	6	254	NR (NR)	NR (NR)	250	NR (NR)	NR (NR)	MD=0.15 (-0.24 to 0.54), 0.442
	HTN	Low HD only	Vegetables (servings/d)	IG1	12	243	NR (NR)	NR (NR)	242	NR (NR)	NR (NR)	MD=0.46 (0.04 to 0.88), 0.032

Appendix H Table 15. Dietary, Continuous Outcomes (KQ3)

Abbreviations: BMI = body mass index; CG = control group; CI = confidence interval; cm = centimeters; Dys = dyslipidemia; g/day = grams per day; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; KQ = key question; mg/d = milligrams per day; MD = mean difference; mmol/24-hr = millimoles per 24 hours; mmol/L = millimoles per liter; MUFA = monounsaturated fatty acids; NR = not reported; NSD = no statistically significantly difference; PUFA = polyunsaturated fatty acids; SD = standard deviation; servings/d = servings per day

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min
†Between-group mean difference in change unless otherwise specified

Appendix H Table 16. Dietary, Dichotomous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Appel, 2003[41] (PREMIER) Good	HTN	High HD + PA	Meeting diet recs (Met goal of ≤100 mmol/L sodium intake/d)	IG1	6	64/222 (28.8)	43/219 (19.6)	1.47 (1.05 to 2.06), <0.05
	HTN	High HD + PA	Meeting diet recs (Met goal of ≤100 mmol/L sodium intake/d)	IG2	6	81/220 (36.8)	43/219 (19.6)	1.88 (1.36 to 2.58), <0.05
	HTN	High HD + PA	Meeting diet recs (Met goal of ≤100 mmol/L sodium intake/d)	IG1	18	57/227 (25.1)	49/235 (20.9)	1.20 (0.86 to 1.68), NSD
	HTN	High HD + PA	Meeting diet recs (Met goal of ≤100 mmol/L sodium intake/d)	IG2	18	69/225 (30.7)	49/235 (20.9)	1.47 (1.07 to 2.02), <0.05
	HTN	High HD + PA	Meeting diet recs (Met goal of ≥9 F/V servings/d)	IG1	6	79/236 (33.5)	16/243 (6.6)	5.08 (3.06 to 8.44), <0.05
	HTN	High HD + PA	Meeting diet recs (Met goal of ≥9 F/V servings/d)	IG2	6	14/233 (6.0)	16/243 (6.6)	0.91 (0.46 to 1.83), NSD
	HTN	High HD + PA	Meeting diet recs (Met goal of ≥9 F/V servings/d)	IG1	18	74/247 (30.0)	13/252 (5.2)	5.81 (3.31 to 10.19), <0.05
	HTN	High HD + PA	Meeting diet recs (Met goal of ≥9 F/V servings/d)	IG2	18	13/241 (5.4)	13/252 (5.2)	1.05 (0.49 to 2.21), NSD
	HTN	High HD + PA	Meeting diet recs (Met goal of saturated fat ≤10% kcal/d)	IG1	6	182/230 (79.1)	103/232 (44.4)	1.78 (1.52 to 2.09), <0.001
	HTN	High HD + PA	Meeting diet recs (Met goal of saturated fat ≤10% kcal/d)	IG2	6	139/227 (61.2)	103/232 (44.4)	1.38 (1.16 to 1.65), <0.001
	HTN	High HD + PA	Meeting diet recs (Met goal of saturated fat ≤7% kcal/d)	IG1	6	107/230 (46.5)	36/232 (15.5)	3.00 (2.15 to 4.17), <0.001
	HTN	High HD + PA	Meeting diet recs (Met goal of saturated fat ≤7% kcal/d)	IG2	6	60/227 (26.4)	36/232 (15.5)	1.70 (1.18 to 2.47), 0.004
Babazono, 2007[45] (PHPP) Fair	Multiple	Medium HD + PA	Vegetables (≤1 meals/day w\vegetable servings)	IG1	12	6/46 (13.0)	11/41 (26.8)	0.49 (0.20 to 1.20), NSD
	Multiple	Medium HD + PA	Vegetables (≥2 meals/day w\vegetable servings)	IG1	12	40/46 (87.0)	30/41 (73.2)	OR=3.80 (1.00 to 14.00), <0.05
Eakin, 2009[64] (Logan Healthy Living) Fair	Multiple	Medium HD + PA	Meeting diet recs (% meeting guidelines for fruit intake (≥2 servings/d))	IG1	12	179/225 (79.6)	55/204 (27.0)	OR=1.99 (1.33 to 2.99), <0.05
	Multiple	Medium HD + PA	Meeting diet recs (% meeting guidelines for fruit intake (≥2 servings/d))	IG1	18	162/225 (72.0)	121/204 (59.3)	OR=1.65 (0.94 to 2.91), NSD

Appendix H Table 16. Dietary, Dichotomous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
	Multiple	Medium HD + PA	Meeting diet recs (% meeting guidelines for sat fat intake (≤10% of total calorie intake))	IG1	12	52/223 (23.3)	30/201 (14.9)	OR=1.79 (0.85 to 3.78), NSD
	Multiple	Medium HD + PA	Meeting diet recs (% meeting guidelines for sat fat intake (≤10% of total calorie intake))	IG1	18	41/223 (18.4)	21/201 (10.4)	OR=2.34 (0.86 to 6.35), NSD
	Multiple	Medium HD + PA	Meeting diet recs (% meeting guidelines for vegetable intake (≥5 servings/d))	IG1	12	95/225 (42.2)	41/204 (20.1)	OR=2.35 (1.43 to 3.88), <0.05
	Multiple	Medium HD + PA	Meeting diet recs (% meeting guidelines for vegetable intake (≥5 servings/d))	IG1	18	73/225 (32.4)	36/204 (17.6)	OR=2.37 (1.48 to 3.80), <0.05
Hyman, 2007[79] Fair	HTN	Medium HD + PA	Meeting diet recs (Prop. meeting goal of Na levels <100 mEq/L per day)	IG1	6	27/92 (29.3)	12/93 (12.9)	2.27 (1.23 to 4.21), 0.01
	HTN	Medium HD + PA	Meeting diet recs (Prop. meeting goal of Na levels <100 mEq/L per day)	IG2	6	16/96 (16.7)	12/93 (12.9)	1.29 (0.65 to 2.58), NSD
	HTN	Medium HD + PA	Meeting diet recs (Prop. meeting goal of Na levels <100 mEq/L per day)	IG1	18	9/92 (9.8)	16/93 (17.2)	0.57 (0.26 to 1.22), 0.06
	HTN	Medium HD + PA	Meeting diet recs (Prop. meeting goal of Na levels <100 mEq/L per day)	IG2	18	12/96 (12.5)	16/93 (17.2)	0.73 (0.36 to 1.45), NSD
Koelewijn-van Loon, 2009 (Improving Patient Adherence to Lifestyle Advice (IMPALA)) Fair	Multiple	Medium HD + PA	Fruit (Meeting national recommendation)	IG1	12	114/252 (45.2)	108/236 (45.8)	0.99 (0.81 to 1.20), 0.91
	Multiple	Medium HD + PA	Vegetables (Meeting national recommendation)	IG1	12	93/252 (36.9)	65/236 (27.5)	1.34 (1.03 to 1.74), 0.045
Lakerveld, 2013[90] (HOORN) Fair	Multiple	Medium HD + PA	Meeting diet recs (Meeting rec for fruit intake (≥2 pieces/day))	IG1	6	57/314 (18.2)	70/308 (22.7)	OR=1.60 (0.90 to 2.60), NSD
	Multiple	Medium HD + PA	Meeting diet recs (Meeting rec for fruit intake (≥2 pieces/day))	IG1	12	58/314 (18.5)	68/308 (22.1)	OR=1.40 (0.90 to 2.40), NSD
	Multiple	Medium HD + PA	Meeting diet recs (Meeting rec for vegetable intake (200 g/day))	IG1	6	55/314 (17.5)	57/308 (18.5)	OR=1.10 (0.70 to 1.70), NSD

Appendix H Table 16. Dietary, Dichotomous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
	Multiple	Medium HD + PA	Meeting diet recs (Meeting rec for vegetable intake (200 g/day))	IG1	12	62/314 (19.7)	56/308 (18.2)	OR=0.90 (0.60 to 1.50), NSD
Moy, 2001[96] Fair	Multiple	High HD only	Meeting diet recs (% meeting the National Cholesterol Education Program Adult Treatment Panel II (ATP II) guidelines (≤30%))	IG1	24	35/117 (29.9)	20/118 (16.9)	1.76 (1.09 to 2.87), 0.019
Svetkey, 2008[114] (Weight Loss Maintenance (WLM)) Good	Multiple	High HD + PA	Fruits and Vegetables (Number of participants who have increased their F&V intake)	IG1	30	257/292 (88.0)	230/287 (80.1)	1.10 (1.02 to 1.18), <0.1
	Multiple	High HD + PA	Fruits and Vegetables (Number of participants who have increased their F&V intake)	IG2	30	245/301 (81.4)	230/287 (80.1)	1.02 (0.94 to 1.10), NSD
Ter Bogt, 2009[116] (Groningen Overweight and Lifestyle (GOAL)) Good	Multiple	High HD + PA	Meeting diet recs (Percent meeting rec for fruit (200 g/d))	IG1	36	76/158 (48.1)	89/172 (51.7)	0.93 (0.75 to 1.15), 0.77
	Multiple	High HD + PA	Meeting diet recs (Percent meeting rec for saturated fat (10% of total energy intake/d))	IG1	36	34/158 (21.5)	32/172 (18.6)	1.16 (0.75 to 1.78), 0.35
	Multiple	High HD + PA	Meeting diet recs (Percent meeting rec for vegetables (200 g/d))	IG1	36	32/158 (20.3)	37/172 (21.5)	0.94 (0.62 to 1.43), 0.95
van Keulen, 2011[123] (Vitalum) Fair	HTN	Medium HD + PA	Meeting diet recs (Meeting guidelines for fruit (≥2 servings/day))	IG1	17	151/302 (50.0)	144/327 (44.0)	OR=1.44 (NR), NSD
	HTN	Medium HD + PA	Meeting diet recs (Meeting guidelines for fruit (≥2 servings/day))	IG2	17	137/285 (48.1)	144/327 (44.0)	OR=1.17 (NR), NSD
	HTN	Low HD + PA	Meeting diet recs (Meeting guidelines for fruit (≥2 servings/day))	IG3	17	166/272 (61.0)	144/327 (44.0)	OR=1.78 (NR), NSD
	HTN	Medium HD + PA	Meeting diet recs (Meeting guidelines for vegetables (≥200 g/day))	IG1	17	109/302 (36.1)	92/327 (28.1)	OR=1.32 (NR), NSD
	HTN	Medium HD + PA	Meeting diet recs (Meeting guidelines for vegetables (≥200 g/day))	IG2	17	97/285 (34.0)	92/327 (28.1)	OR=1.31 (NR), NSD

Appendix H Table 16. Dietary, Dichotomous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
	HTN	Low HD + PA	Meeting diet recs (Meeting guidelines for vegetables (≥200 g/day))	IG3	17	109/272 (40.1)	92/327 (28.1)	OR=1.73 (NR), NSD
Wood, 2008[131] (EUROACTION) Fair	Multiple	High HD + PA	Fruits and Vegetables (Goal ≥400 g/day)	IG1	12	799/1019 (78.4)	388/1001 (38.8)	Difference in probability=39.70 (18.10 to 61.30), 0.005

Abbreviations: BL = baseline; CG = control group; CI = confidence interval; F/V = fruit and vegetable; g/day = grams per day; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; mEq/L = milliequivalents per liter; min(s) = minutes; mmol/L = millimoles per liter; NR = not reported; NSD = no statistically significant difference; OR = odds ratio; prop = proportion; recs = recommendations; RR = risk ratio; servings/d = servings per day; wk = week

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

†Risk ratio unless otherwise specified

Appendix H Table 17. Physical Activity, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Time point (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Anderson, 1992[39] Fair	Dys	High HD only	Total energy expenditure (kJ/kg/d)	IG1	12	48	155 (27.2)	0.08 (16.9)	51	148.4 (11.5)	13.7 (28.2)	-13.62 (-22.72 to -4.52), NSD
	Dys	High HD only	Total energy expenditure (kJ/kg/d)	IG2	12	47	155.5 (22.5)	-5.73 (19)	51	148.4 (11.5)	13.7 (28.2)	-19.43 (-28.89 to -9.97), NSD
Anderssen, 1995[40] (Oslo Diet and Exercise Study (ODES)) Fair	Multiple	Medium HD only	Cardiorespiratory fitness (min)	IG1	12	52	NR (NR)	56.6 (121.87)	43	NR (NR)	8.2 (91.8)	48.40 (5.39 to 91.41), <0.05
	Multiple	Medium HD only	Cardiorespiratory fitness (mL/kg/min)	IG1	12	52	34.4 (5.05)	-0.3 (3.61)	43	34.3 (5.25)	-2 (3.28)	-1.70 (-1.90 to -1.50), <0.05
Appel, 2003[41] (PREMIER) Good	HTN	High HD + PA	Cardiorespiratory fitness (beats/min)	IG1	6	225	130 (14.6)	-9 (10.7)	233	129.8 (14.6)	-5.3 (9.7)	-3.70 (-5.57 to -1.83), <0.001
	HTN	High HD + PA	Cardiorespiratory fitness (beats/min)	IG2	6	225	130.5 (14.1)	-8 (11.1)	233	129.8 (14.6)	-5.3 (9.7)	-2.70 (-4.61 to -0.79), 0.005
	HTN	High HD + PA	Cardiorespiratory fitness (beats/min)	IG1	18	225	130 (14.6)	-9.5 (11)	233	129.8 (14.6)	-7.4 (10.4)	-2.10 (-4.00 to -0.10), 0.035
	HTN	High HD + PA	Cardiorespiratory fitness (beats/min)	IG2	18	225	130.5 (14.1)	-8.2 (11.2)	233	129.8 (14.6)	-7.4 (10.4)	-0.80 (-2.70 to 1.20), NSD
	HTN	High HD + PA	Total PA (kcal/kg)	IG1	6	240	33.6 (2.4)	0.6 (2.4)	242	33.7 (2.5)	0.3 (2.9)	0.30 (-0.18 to 0.78), 0.1
	HTN	High HD + PA	Total PA (kcal/kg)	IG2	6	232	33.8 (2.6)	0.4 (2.9)	242	33.7 (2.5)	0.3 (2.9)	0.10 (-0.42 to 0.62), 0.66
	HTN	High HD + PA	Total PA (kcal/kg)	IG1	18	240	33.6 (2.4)	0.8 (3.4)	242	33.7 (2.5)	0.6 (3.6)	0.10 (-0.30 to 0.60), NSD
	HTN	High HD + PA	Total PA (kcal/kg)	IG2	18	232	33.8 (2.6)	0.3 (2.6)	242	33.7 (2.5)	0.6 (3.6)	-0.20 (-0.70 to 0.30), NSD
Arroll, 1995[44] Fair	HTN	Low HD + PA	Moderate intensity energy expenditure (kJ/kg/d)	IG1	6	48	15.7 (27.02)	27.8 (42.09)	43	13.5 (26.23)	7.5 (40.97)	20.30 (3.22 to 37.38), <0.05

Appendix H Table 17. Physical Activity, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Time point (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	Low PA only	Moderate intensity energy expenditure (kJ/kg/d)	IG2	6	46	15.1 (4)	38.3 (46.28)	43	13.5 (26.23)	7.5 (40.97)	30.80 (12.67 to 48.93), <0.05
	HTN	Low HD only	Moderate intensity energy expenditure (kJ/kg/d)	IG3	6	44	10.6 (26.53)	27.4 (40.9)	43	13.5 (26.23)	7.5 (40.97)	19.90 (2.70 to 37.10), <0.05
	HTN	Low HD + PA	Total energy expenditure (kJ/kg/d)	IG1	6	48	145.2 (18.71)	16.2 (27.74)	43	145.5 (18.36)	7 (26.85)	9.20 (-2.02 to 20.42), NSD
	HTN	Low PA only	Total energy expenditure (kJ/kg/d)	IG2	6	46	145.2 (18.99)	24 (27.77)	43	145.5 (18.36)	7 (26.85)	17.00 (5.65 to 28.35), <0.05
	HTN	Low HD only	Total energy expenditure (kJ/kg/d)	IG3	6	44	143 (18.57)	14.9 (27.16)	43	145.5 (18.36)	7 (26.85)	7.90 (-3.45 to 19.25), NSD
Babazono, 2007[45] (PHPP) Fair	Multiple	Medium HD + PA	Total PA (steps/d)	IG1	12	46	7345 (3890)	3028 (3993.22)	41	7196 (3682)	-381 (3558.69)	3409.00 (1822.12 to 4995.88), ≤0.001
Blackford, 2016[50] (Albany Physical Activity and Nutrition (APAN)) Fair	Multiple	Medium HD + PA	Moderate intensity energy expenditure (MET-min/wk)	IG1	6	151	300 (585)	180 (753.31)	159	360 (640)	0 (638.01)	180.00 (24.21 to 335.79), 0.049
	Multiple	Medium HD + PA	Strength exercise (min/wk)	IG1	6	151	39.2 (168.9)	14.7 (151.58)	159	27.7 (66.8)	-2.7 (68.67)	17.40 (-9.03 to 43.83), 0.653
	Multiple	Medium HD + PA	Total PA (MET-min/wk)	IG1	6	151	807.5 (1486.9)	524.5 (1560.48)	159	990 (1357.5)	-17 (1582.44)	541.50 (191.57 to 891.43), 0.335
	Multiple	Medium HD + PA	Vigorous intensity PA (MET-min/wk)	IG1	6	151	181.5 (479.4)	36 (470.09)	159	203 (462.1)	-23.5 (446.21)	59.50 (-42.64 to 161.64), 0.537
	Multiple	Medium HD + PA	Walking (MET-min/wk)	IG1	6	151	396 (561)	181.5 (670.44)	159	330 (594)	66 (659.07)	115.50 (-32.59 to 263.59), 0.524
Bo, 2007[52] Fair	Multiple	Medium HD + PA	Total PA (MET-min/wk)	IG1	12	169	1134 (798)	283.8 (724.29)	166	1086 (960)	-15.6 (260.31)	299.40 (183.24 to 415.56), <0.001

Appendix H Table 17. Physical Activity, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Time point (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Broekhuizen, 2012[54] (PRO-FIT) Fair	Dys	Medium HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	12	171	422 (NR)	79 (NR)	146	363.1 (NR)	64.9 (NR)	Beta coefficient=1.11 (-0.12 to 0.33), NSD
Burke, 2006[56] (ADAPT) Fair	HTN	Medium HD + PA	Cardiorespiratory fitness (beats/min)	IG1	16	106	74 (10.3)	1 (10.3)	98	71 (9.9)	7 (17.15)	-6.00 (-9.92 to -2.08), 0.044
	HTN	Medium HD + PA	Cardiorespiratory fitness (beats/min)	IG1	40	123	73 (11.32)	-1 (10.2)	118	71 (8.31)	-1 (8.31)	-0.70 (-2.00 to 0.70), 0.675
	HTN	Medium HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	16	123	162 (169.75)	41 (124.49)	118	174 (116.39)	20 (119.16)	21.00 (-9.76 to 51.76), 0.185
	HTN	Medium HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	40	123	162 (169.75)	66 (169.75)	118	174 (116.39)	12 (136.1)	53.00 (15.00 to 91.00), 0.007
Christian, 2011[58] Fair	Multiple	Medium HD + PA	Total PA (MET-min/wk)	IG1	12	133	271.9 (424.8)	288.8 (659)	130	395.9 (552.31)	112.3 (1216.4)	176.50 (-496.83 to 849.83), 0.07
Cicolini, 2014[59] Fair	HTN	Medium HD + PA	Total PA (min/wk)	IG1	6	100	47.6 (56)	113.4 (63)	98	56.7 (65.8)	34.3 (61.6)	79.10 (61.74 to 96.46), <0.001
Cochrane, 2012[60] Fair	Multiple	Medium HD + PA	Total PA (NHS Primary Prevention Toolkit)	IG1	12	236	2.67 (NR)	0.14 (NR)	365	2.65 (NR)	0.15 (NR)	NR, NSD
Delahanty, 2001[63] Good	Dys	Medium HD + PA	Total energy expenditure (min/wk)	IG1	6	44	119 (126)	25 (128.05)	44	92 (97)	16 (103.52)	9.00 (-39.65 to 57.65), NSD
	Dys	Medium HD + PA	Total energy expenditure (min/wk)	IG1	12	43	119 (126)	29 (115.88)	44	92 (97)	43 (160.28)	-14.00 (-72.67 to 44.67), NSD
Eakin, 2009[64] (Logan Healthy	Multiple	Medium HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	12	225	142.5 (226.2)	71.19 (213)	204	142.4 (197.3)	82.23 (212.96)	-11.14 (-51.56 to 29.28), 0.589

Appendix H Table 17. Physical Activity, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Time point (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Living) Fair	Multiple	Medium HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	18	225	142.5 (226.2)	62.19 (213)	204	142.4 (197.3)	74.73 (212.96)	-12.54 (-52.95 to 27.88), 0.543
	Multiple	Medium HD + PA	Moderate to vigorous intensity PA (sessions/wk)	IG1	12	225	2.9 (3.8)	2.61 (4.95)	204	2.9 (3.5)	2.22 (5)	0.39 (-0.55 to 1.33), 0.491
	Multiple	Medium HD + PA	Moderate to vigorous intensity PA (sessions/wk)	IG1	18	225	2.9 (3.8)	2.24 (4.95)	204	2.9 (3.5)	2.13 (5)	0.11 (-0.83 to 1.05), 0.815
Edelman, 2006[65] Fair	Multiple	High HD + PA	Total PA (days/wk)	IG1	10	77	1.6 (NR)	2.1 (NR)	77	1.4 (NR)	1 (NR)	NR, 0.002
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	Leisure PA (MET-min/wk)	IG1 (Participants w/METs)	12	1236	1533 (1632.28)	133 (1946.18)	1094	1344 (1771.91)	77 (1890.04)	56.00 (-99.93 to 211.93), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG1 (Participants w/out METs)	12	663	1890 (1701.26)	126 (1977.14)	594	1750 (1784.39)	63 (1871.43)	63.00 (-149.84 to 275.84), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG2 (Participants w/METs)	12	1062	1561 (1571.22)	42 (1513.03)	1094	1344 (1771.91)	77 (1890.04)	-35.00 (-179.31 to 109.31), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG2 (Participants w/out METs)	12	662	2079 (1883.76)	-56 (2067.54)	594	1750 (1784.39)	63 (1871.43)	-119.00 (-336.84 to 98.84), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG1 (Participants w/METs)	36	1236	1533 (1632.28)	140 (1946.18)	1094	1344 (1771.91)	91 (2126.29)	49.00 (-117.27 to 215.27), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG1 (Participants w/out METs)	36	663	1890 (1701.26)	126 (2115.08)	594	1750 (1784.39)	126 (2872.43)	0.00 (-281.57 to 281.57), NSD

Appendix H Table 17. Physical Activity, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Time point (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG2 (Participants w/METs)	36	1062	1561 (1571.22)	112 (1955.3)	1094	1344 (1771.91)	91 (2126.29)	21.00 (-151.35 to 193.35), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG2 (Participants w/out METs)	36	662	2079 (1883.76)	-7 (2205.37)	594	1750 (1784.39)	126 (2872.43)	-133.00 (-418.63 to 152.63), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG1 (Participants w/METs)	60	1236	1533 (1632.28)	203 (2197.3)	1094	1344 (1771.91)	35 (2716.93)	168.00 (-34.30 to 370.30), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG1 (Participants w/out METs)	60	663	1890 (1701.26)	-49 (2666.84)	594	1750 (1784.39)	28 (2828.91)	-77.00 (-381.90 to 227.90), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG2 (Participants w/METs)	60	1062	1561 (1571.22)	49 (2502.32)	1094	1344 (1771.91)	35 (2716.93)	14.00 (-206.38 to 234.38), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG2 (Participants w/out METs)	60	662	2079 (1883.76)	-35 (2756.72)	594	1750 (1784.39)	28 (2828.91)	-63.00 (-372.60 to 246.60), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG1 (Participants w/METs)	84	1236	1533 (1632.28)	77 (4269.04)	1094	1344 (1771.91)	-14 (4547.9)	91.00 (-268.54 to 450.54), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG1 (Participants w/out METs)	84	663	1890 (1701.26)	-154 (5195.74)	594	1750 (1784.39)	-483 (6106.09)	329.00 (-301.50 to 959.50), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG2 (Participants w/METs)	84	1062	1561 (1571.22)	-77 (5121.02)	1094	1344 (1771.91)	-14 (4547.9)	-63.00 (-472.25 to 346.25), NSD

Appendix H Table 17. Physical Activity, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Time point (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG2 (Participants w/out METs)	84	662	2079 (1883.76)	-287 (5467.49)	594	1750 (1784.39)	-483 (6106.09)	196.00 (-447.88 to 839.88), NSD
Gill, 2019[70] (HealtheSteps) Fair	Multiple	Medium HD + PA	Total PA (MET-min/wk)	IG1	6	59	NR (NR)	2.13 (25.79)	59	NR (NR)	1.37 (25.67)	0.76 (-8.52 to 10.04), 0.87
	Multiple	Medium HD + PA	Walking (steps/d)	IG1	6	59	NR (NR)	1646 (3301.98)	59	NR (NR)	-1485 (3171.51)	3132.00 (1969.00 to 4294.00), <0.001
Greaves, 2015[71] (Waste the Waist) Fair	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	12	53	157.5 (156.1)	-3.57 (104.16)	53	151.2 (115.5)	22.89 (131.74)	-0.64 (-1.83 to 0.56), 0.291
	Multiple	High HD + PA	Sedentary time (min/wk)	IG1	12	53	4121.6 (520.8)	-31.64 (392.35)	53	3824.8 (619.5)	-81.2 (429.8)	113.40 (-44.10 to 270.20), 0.156
	Multiple	High HD + PA	Walking (steps/d)	IG1	12	53	6420 (3016)	-141 (1903)	53	6551 (2499)	166.1 (2291)	-345.00 (-1100.00 to 410.00), 0.367
Hardcastle, 2008[73] Fair	Multiple	Medium HD + PA	Moderate intensity PA (MET-min/wk)	IG1	6	203	440.69 (1091.22)	91.03 (1122.29)	131	576.15 (1159.23)	-62.13 (1076.72)	153.16 (-87.32 to 393.64), NSD
	Multiple	Medium HD + PA	Moderate intensity PA (MET-min/wk)	IG1	18	203	440.69 (1091.22)	420.92 (1361.82)	131	576.15 (1159.23)	510.09 (1482.49)	-89.17 (-404.67 to 226.33), NSD
	Multiple	Medium HD + PA	Total PA (MET-min/wk)	IG1	6	203	1854.08 (2174.67)	497.16 (2377.06)	131	2278.56 (2820.37)	-13.41 (2753.27)	510.57 (-63.20 to 1084.34), NSD
	Multiple	Medium HD + PA	Total PA (MET-min/wk)	IG1	18	203	1854.08 (2174.67)	1299.59 (2977.57)	131	2278.56 (2820.37)	993.54 (3470.03)	306.05 (-415.66 to 1027.76), NSD
	Multiple	Medium HD + PA	Vigorous intensity PA (MET-min/wk)	IG1	6	203	590.05 (1294.38)	146.67 (1356.16)	131	746.55 (1672.04)	-1.77 (1581.25)	148.44 (-180.38 to 477.26), NSD
	Multiple	Medium HD + PA	Vigorous intensity PA (MET-min/wk)	IG1	18	203	590.05 (1294.38)	470.69 (1850.51)	131	746.55 (1672.04)	225.49 (1872.6)	245.20 (-164.23 to 654.63), NSD
	Multiple	Medium HD + PA	Walking (MET-min/wk)	IG1	6	203	996.07 (1116.59)	199.47 (1205.19)	131	1242.45 (1432.69)	-191.96 (1390.63)	391.43 (101.27 to 681.59), <0.05
	Multiple	Medium HD + PA	Walking (MET-min/wk)	IG1	18	203	996.07 (1116.59)	269.07 (1251.18)	131	1242.45 (1432.69)	85.25 (1547.86)	183.82 (-132.22 to 499.86), <0.01

Appendix H Table 17. Physical Activity, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Time point (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Harris, 2012[74] (Health Improvement and Prevention Study (HIPS)) Fair	Multiple	High HD + PA	PA score (score)	IG1	6	250	3.71 (2.38)	0.88 (2.36)	216	3.38 (2.4)	0.51 (2.44)	0.37 (-0.07 to 0.81), 0.002
	Multiple	High HD + PA	PA score (score)	IG1	12	355	3.71 (2.38)	0.89 (2.49)	300	3.38 (2.4)	0.71 (2.49)	0.18 (-0.20 to 0.56), 0.005
Haufe, 2019[75] Fair	Multiple	Medium HD + PA	Cardiorespiratory fitness (W/kg)	IG1	6	160	0.83 (1.26)	1.06 (1.1)	154	0.93 (1.37)	0.84 (1.2)	0.22 (-0.03 to 0.47), <0.0001
	Multiple	Medium HD + PA	Total PA (MET min/wk)	IG1	6	160	384 (822)	180.0 (1187.9)	154	390 (540)	-144.0 (838.5)	324.00 (97.24 to 550.76), 0.010
Hyman, 2007[79] Fair	HTN	Medium HD + PA	Total PA (steps/d)	IG1	6	92	3624.4 (2917.5)	525 (3215)	93	3933 (3363.6)	-81 (3529.96)	606.00 (-366.77 to 1578.77), NSD
	HTN	Medium HD + PA	Total PA (steps/d)	IG2	6	96	3306 (2785.3)	409 (3570.83)	93	3933 (3363.6)	-81 (3529.96)	490.00 (-522.39 to 1502.39), NSD
	HTN	Medium HD + PA	Total PA (steps/d)	IG1	18	92	3624.4 (2917.5)	127 (2813.74)	93	3933 (3363.6)	-284.5 (3906.66)	411.50 (-568.80 to 1391.80), NSD
	HTN	Medium HD + PA	Total PA (steps/d)	IG2	18	96	3306 (2785.3)	438.9 (4776.82)	93	3933 (3363.6)	-284.5 (3906.66)	723.40 (-518.97 to 1965.77), NSD
Kandula, 2015[83] (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	6	31	56 (114)	9.5 (79.09)	32	44 (105)	4.4 (76.15)	5.10 (-32.98 to 43.26), NSD
Khanji, 2019[87] (HAPPY London) Good	Multiple	Low HD + PA	Total PA (min/wk)	IG1	6	194	495.6 (529.2)	175.7 (882.27)	183	454.3 (643.3)	59.14 (674.62)	116.55 (-72.10 to 305.20), 0.23
Koelewijn-van Loon, 2009 (Improving Patient Adherence to Lifestyle Advice	Multiple	Medium HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	12	252	405 (343)	55 (352.88)	236	447 (345)	2 (355.42)	53.00 (-9.88 to 115.88), 0.74

Appendix H Table 17. Physical Activity, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Time point (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
(IMPALA)) Fair												
Kramer, 2018[89] (Healthy Lifestyle Project) Fair	Multiple	High HD + PA	Leisure PA (MET-min/wk)	IG1	6	81	NR (NR)	996 (1224)	43	NR (NR)	432 (996)	564.00 (164.41 to 963.59), 0.007
	Multiple	High HD + PA	Total PA (min/wk)	IG1	6	81	NR (NR)	35.6 (224.7)	43	NR (NR)	29.7 (367)	5.90 (-114.21 to 126.01), 0.05
Lakerveld, 2013[90] (HOORN) Fair	Multiple	Medium HD + PA	Moderate intensity energy expenditure (MET-min/wk)	IG1	6	314	NR (NR)	NR (NR)	308	NR (NR)	NR (NR)	Beta coefficient=-66.50 (-156.10 to 22.40), NSD
	Multiple	Medium HD + PA	Moderate intensity energy expenditure (MET-min/wk)	IG1	12	314	NR (NR)	NR (NR)	308	NR (NR)	NR (NR)	Beta coefficient=-65.80 (-154.00 to 22.40), NSD
	Multiple	Medium HD + PA	Vigorous intensity PA (MET-min/wk)	IG1	6	314	NR (NR)	NR (NR)	308	NR (NR)	NR (NR)	Beta coefficient=-5.60 (-23.10 to 12.60), NSD
	Multiple	Medium HD + PA	Vigorous intensity PA (MET-min/wk)	IG1	12	314	NR (NR)	NR (NR)	308	NR (NR)	NR (NR)	Beta coefficient=-0.70 (-23.10 to 21.70), NSD
Migneault, 2012[94] Fair	HTN	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	8	169	162.4 (169)	-3.44 (NR)	168	126.3 (144.3)	2.77 (NR)	-6.21 (NR), NSD
	HTN	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	12	169	162.4 (169)	-21.3 (NR)	168	126.3 (144.3)	7.3 (NR)	NR, NSD
	HTN	High HD + PA	Total energy expenditure (kcal/day)	IG1	8	169	3234.7 (860.7)	43.8 (NR)	168	3188.5 (820.3)	-36.2 (NR)	80.00 (NR), 0.02
	HTN	High HD + PA	Total energy expenditure (kcal/day)	IG1	12	169	3234.7 (860.7)	-49.1 (NR)	168	3188.5 (820.3)	-5.2 (NR)	NR, NSD

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Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Time point (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
Niiranen, 2014[100] Fair	HTN	Medium HD + PA	Leisure PA (MJ/d)	IG1	12	112	0.49 (0.45)	0 (0.4)	108	0.51 (0.44)	0.07 (0.32)	-0.07 (-0.32 to 0.18), 0.15
Reid, 2014[103] Fair	Multiple	High HD + PA	Total PA (min/wk)	IG1	12	211	91.7 (102.5)	50.8 (113.51)	215	88.7 (99.7)	29.9 (104.72)	MD=23.90 (3.90 to 44.00), 0.03
Rodriguez, 2012[104] Fair	HTN	Medium HD + PA	Total PA (min/wk)	IG1	6	176	315.6 (453)	-17.4 (568.56)	177	297 (383.4)	-25.8 (407.27)	8.40 (-94.83 to 111.63), 0.88
	HTN	Medium HD + PA	Total PA (min/wk)	IG1	12	151	315.6 (453)	-60.6 (412.69)	155	297 (383.4)	31.2 (420.67)	-91.80 (-185.17 to 1.57), NSD
Rubinstein, 2016[107] Good	HTN	Medium HD + PA	Total PA (MET-min/wk)	IG1	12	94	971.5 (1544.1)	-348.9 (1345.49)	96	566.4 (779.9)	-188.5 (842.22)	-229.10 (-595.10 to 136.80), 0.22
Salisbury, 2016[108] Good	Multiple	Medium HD + PA	PA score (score, heiQ health directed behavior subscale)	IG1	12	297	NR (NR)	NR (NR)	294	NR (NR)	NR (NR)	MD=0.10 (0.00 to 0.20), 0.003
Scott, 2018[110] Fair	Multiple	Medium PA only	Moderate to vigorous intensity PA (kcal/wk)	IG1	6	17	4799.73 (3450.16)	86.18 (4126.59)	18	3287.62 (3379.06)	-1314.77 (4015.56)	1400.95 (-1298.90 to 4100.80), 0.027
	Multiple	Medium PA only	Total PA (steps/d)	IG1	6	17	5638.29 (3063.19)	-5.04 (2850.35)	18	5530.4 (3142.14)	-434.59 (2875.92)	429.55 (-1468.08 to 2327.18), 0.382
Svetkey, 2008[114] (Weight Loss Maintenance (WLM)) Good	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	30	342	172 (173.3)	NR (NR)	342	158.8 (141.8)	NR (NR)	-5.00 (-24.00 to 14.00), NSD
	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG2	30	348	159.1 (136.6)	NR (NR)	342	158.8 (141.8)	NR (NR)	-8.00 (-27.00 to 12.00), NSD
Svetkey, 2009[115] (Hypertension Improvement Project (HIP)) Fair	HTN	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	6	132	28.8 (106.7)	28.4 (134.9)	132	43.9 (122.5)	-15.7 (122)	44.10 (13.07 to 75.13), <0.05
	HTN	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG2	6	124	37.9 (89.1)	6.2 (103.2)	132	43.9 (122.5)	-15.7 (122)	21.90 (-5.72 to 49.52), NSD
	HTN	Medium HD + PA	Moderate to vigorous intensity PA (min/wk)	IG3	6	137	36.4 (127.1)	18.5 (297.8)	132	43.9 (122.5)	-15.7 (122)	34.20 (-19.84 to 88.24), NSD

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Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Time point (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	18	128	28.8 (106.7)	-0.7 (112.3)	122	43.9 (122.5)	-13 (145.7)	12.30 (-20.06 to 44.66), NSD
	HTN	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG2	18	124	37.9 (89.1)	-21.5 (138.8)	122	43.9 (122.5)	-13 (145.7)	-8.50 (-44.07 to 27.07), NSD
	HTN	Medium HD + PA	Moderate to vigorous intensity PA (min/wk)	IG3	18	134	36.4 (127.1)	5 (95.1)	122	43.9 (122.5)	-13 (145.7)	18.00 (-12.46 to 48.46), NSD
Ter Bogt, 2009[116] (Groningen Overweight and Lifestyle (GOAL)) Good	Multiple	High HD + PA	Moderate intensity energy expenditure (MET-min/wk)	IG1	36	111	424 (532)	16 (633)	137	467 (510)	73 (644)	-57.00 (-216.67 to 102.67), 0.166
	Multiple	High HD + PA	Moderate to vigorous intensity PA (MET-min/wk)	IG1	12	135	596 (589.84)	97 (572.06)	140	720 (624.81)	-22 (543.31)	119.00 (-12.95 to 250.95), 0.24
	Multiple	High HD + PA	Total PA (MET-min/wk)	IG1	12	120	2304 (1168.1)	-126 (997.64)	129	2026 (921.37)	-68 (909.78)	-58.00 (-295.72 to 179.72), 0.52
	Multiple	High HD + PA	Total PA (MET-min/wk)	IG1	36	111	2304 (1168.1)	-167 (1321)	97	2026 (921.37)	-92 (1218)	-75.00 (-420.17 to 270.17), 0.387
	Multiple	High HD + PA	Vigorous intensity PA (MET-min/wk)	IG1	36	111	217 (233)	59 (288)	137	237 (290)	45 (303)	14.00 (-59.79 to 87.79), 0.85
	Multiple	High HD + PA	Walking (MET-min/wk)	IG1	12	161	174 (213.63)	33 (194.21)	162	183 (191.57)	-5 (149.36)	38.00 (0.20 to 75.80), 0.05
	Multiple	High HD + PA	Walking (MET-min/wk)	IG1	36	139	174 (213.63)	25 (253)	153	183 (191.57)	23 (255)	2.00 (-56.32 to 60.32), 0.875
Toft, 2008[118] (Inter99) Fair	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1 (Females)	12	3126	291 (167.73)	-1.8 (380.19)	356	327 (175.47)	-38.8 (358.49)	37.00 (-2.55 to 76.55), NSD
	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1 (Males)	12	2965	286 (168.8)	-2.5 (359.38)	337	304 (167.05)	-18.9 (361.64)	16.40 (-24.32 to 57.12), NSD

Appendix H Table 17. Physical Activity, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Time point (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1 (Females)	36	3126	291 (167.73)	-7.7 (385.78)	356	327 (175.47)	-18.4 (371.7)	10.70 (-30.21 to 51.61), NSD
	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1 (Males)	36	2965	286 (168.8)	-5.3 (359.38)	337	304 (167.05)	-2.1 (357.97)	-3.20 (-43.55 to 37.15), NSD
	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1 (Females)	60	3126	291 (167.73)	-3.8 (363.42)	356	327 (175.47)	-21.9 (356.6)	18.10 (-21.07 to 57.27), NSD
	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1 (Males)	60	2965	286 (168.8)	1.4 (359.38)	337	304 (167.05)	-20.4 (350.63)	21.80 (-17.81 to 61.41), NSD
van Keulen, 2011[123] (Vitalum) Fair	HTN	Medium HD + PA	Moderate intensity PA (min/wk)	IG1	6	369	290.4 (237.6)	114.6 (281.02)	392	276.6 (217.8)	78.6 (256.01)	36.00 (-2.27 to 74.27), NSD
	HTN	Medium HD + PA	Moderate intensity PA (min/wk)	IG2	6	370	258.6 (223.8)	142.8 (278.15)	392	276.6 (217.8)	78.6 (256.01)	64.20 (26.18 to 102.22), <0.05
	HTN	Low HD + PA	Moderate intensity PA (min/wk)	IG3	6	376	291.6 (238.8)	123.6 (290.91)	392	276.6 (217.8)	78.6 (256.01)	45.00 (6.18 to 83.82), <0.01
	HTN	Medium HD + PA	Moderate intensity PA (min/wk)	IG1	11	307	290.4 (237.6)	49.8 (252.88)	331	276.6 (217.8)	42.6 (249.23)	7.20 (-31.80 to 46.20), NSD
	HTN	Medium HD + PA	Moderate intensity PA (min/wk)	IG2	11	285	258.6 (223.8)	109.2 (246.37)	331	276.6 (217.8)	42.6 (249.23)	66.60 (27.37 to 105.83), <0.01
	HTN	Low HD + PA	Moderate intensity PA (min/wk)	IG3	11	266	291.6 (238.8)	119.4 (283.42)	331	276.6 (217.8)	42.6 (249.23)	76.80 (33.43 to 120.17), <0.001
	HTN	Medium HD + PA	Moderate intensity PA (min/wk)	IG1	17	302	290.4 (237.6)	44.4 (254.99)	327	276.6 (217.8)	45.6 (249.23)	-1.20 (-40.66 to 38.26), NSD
	HTN	Medium HD + PA	Moderate intensity PA (min/wk)	IG2	17	285	258.6 (223.8)	96 (252.03)	327	276.6 (217.8)	45.6 (249.23)	50.40 (10.58 to 90.22), <0.01

Appendix H Table 17. Physical Activity, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Time point (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	Low HD + PA	Moderate intensity PA (min/wk)	IG3	17	272	291.6 (238.8)	52.2 (263.07)	327	276.6 (217.8)	45.6 (249.23)	6.60 (-34.72 to 47.92), NSD
van Sluijs, 2005[124] (Physician-based Assessment and Counseling for Exercise (PACE)) Fair	Multiple	Medium PA only	Moderate intensity energy expenditure (min/wk)	IG1	6	171	NR (NR)	NR (NR)	187	NR (NR)	NR (NR)	NR, NSD
	Multiple	Medium PA only	Moderate intensity energy expenditure (min/wk)	IG1	12	171	NR (NR)	NR (NR)	187	NR (NR)	NR (NR)	Beta coefficient=-34.17 (-110.91 to 42.56), 0.38
Voils, 2013[126] (CouPLES) Fair	Dys	Medium HD + PA	Moderate intensity PA (freq/wk)	IG1	6	96	8.3 (NR)	2.2 (NR)	94	8.3 (NR)	0.6 (NR)	NR, NSD
	Dys	Medium HD + PA	Moderate intensity PA (freq/wk)	IG1	11	100	8.3 (NR)	1.8 (NR)	98	8.3 (NR)	0.1 (NR)	IRR=1.20 (1.00 to 1.50), 0.06
	Dys	Medium HD + PA	Moderate intensity PA (min/wk)	IG1	6	96	414 (NR)	36 (NR)	94	414 (NR)	-12 (NR)	NR
	Dys	Medium HD + PA	Moderate intensity PA (min/wk)	IG1	11	100	414 (NR)	24 (NR)	98	414 (NR)	-18 (NR)	IRR=66.00 (54.00 to 84.00), 0.37
Wadden, 2011[127] (Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-	Multiple	High HD + PA	Total PA (kcal/wk)	IG1	6	131	1074.9 (1070.7)	113.7 (2140.31)	130	1153.4 (1536.4)	-49.6 (2109.32)	163.30 (-352.26 to 678.86), NSD
	Multiple	High HD + PA	Total PA (kcal/wk)	IG1	24	131	1074.9 (1070.7)	415.4 (2060.19)	130	1153.4 (1536.4)	-70.4 (2120.73)	485.80 (-21.51 to 993.11), 0.037

Appendix H Table 17. Physical Activity, Continuous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Time point (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
UP)) Good												
Wister, 2007[129] Good	Multiple	Medium HD + PA	PA score (score, 5-pt scale based on ACSM guidelines)	IG1	12	157	NR (NR)	0.17 (1.47)	158	NR (NR)	0.16 (1.54)	0.01 (-0.32 to 0.34), NSD

Abbreviations: ACSM = American College of Sports Medicine; BG = between-group; CG = control group; CI = confidence interval; Dys = dyslipidemia; FUP = followup timepoint; HD = healthy diet; HD + PA = healthy diet and physical activity; IG = intervention group; IRR = incident rate ratio; kcal/kg = kilocalories per kilogram; kcal/wk = kilocalories per week; kJ/kg/d = kilojoules per kilogram per day; MET-min/wk = metabolic equivalent of task minutes per week; METS = metabolic syndrome; min/wk = minutes per week; mL/kg/min = milliliters per kilogram per minute; NR = not reported; NSD = no statistically significant difference; PA = physical activity; pt = point; steps/d = steps per day

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min
†Between-group mean difference in change unless otherwise specified

Appendix H Table 18. Physical Activity, Dichotomous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Appel, 2003[41] (PREMIER) Good	HTN	High HD + PA	Meeting PA recs (Met goal of ≥180 min/wk of moderate-to-vigorous PA)	IG1	6	149/237 (62.9)	123/241 (51.0)	1.23 (1.05 to 1.44),
	HTN	High HD + PA	Meeting PA recs (Met goal of ≥180 min/wk of moderate-to-vigorous PA)	IG2	6	139/232 (59.9)	123/241 (51.0)	1.17 (1.00 to 1.38),
	HTN	High HD + PA	Meeting PA recs (Met goal of ≥180 min/wk of moderate-to-vigorous PA)	IG1	18	130/240 (54.2)	123/242 (50.8)	1.07 (0.90 to 1.26),
	HTN	High HD + PA	Meeting PA recs (Met goal of ≥180 min/wk of moderate-to-vigorous PA)	IG2	18	127/235 (54.0)	123/242 (50.8)	1.06 (0.90 to 1.26),
Burke, 2006[56] (ADAPT) Fair	HTN	Medium HD + PA	Meeting PA recs (At least 30 mins/day 5 days/wk)	IG1	16	76/123 (61.8)	68/118 (57.6)	1.07 (0.87 to 1.32),
Coleman, 2012[62] (Wisewoman California) Fair	Multiple	Medium HD + PA	Moderate intensity PA (yes/no)	IG1	12	365/433 (84.3)	335/435 (77.0)	1.09 (1.03 to 1.17),
Coleman, 2012[62] (Wisewoman California) Fair	Multiple	Medium HD + PA	Vigorous intensity PA (yes/no)	IG1	12	143/433 (33.0)	75/435 (17.2)	1.92 (1.50 to 2.45),
Eakin, 2009[64] (Logan Healthy Living) Fair	Multiple	Medium HD + PA	Meeting PA recs (% meeting PA guidelines (≥150 mins, ≥5 sessions/wk)	IG1	12	101/225 (44.9)	71/204 (34.8)	OR=1.34 (0.90 to 2.00), NSD
	Multiple	Medium HD + PA	Meeting PA recs (% meeting PA guidelines (≥150 mins, ≥5 sessions/wk)	IG1	18	84/225 (37.3)	79/204 (38.7)	OR=0.96 (0.64 to 1.45), NSD
Hardcastle, 2008[73] Fair	Multiple	Medium HD + PA	Meeting PA recs (≥600 MET min/wk)	IG1	6	152/203 (74.9)	96/131 (73.3)	1.02 (0.90 to 1.16),
	Multiple	Medium HD + PA	Not meeting PA recs, inactive	IG1	6	51/203 (25.1)	35/131 (26.7)	0.94 (0.65 to 1.36), 0.005
Hyman, 2007[79] Fair	HTN	Medium HD + PA	Meeting PA recs (Prop. mtg goal to increase PA by 1500 steps/d (or >10,000/wk))	IG1	6	33/92 (35.9)	25/93 (26.9)	1.33 (0.87 to 2.06), NSD
	HTN	Medium HD + PA	Meeting PA recs (Prop. mtg goal to increase PA by 1500 steps/d (or >10,000/wk))	IG2	6	27/96 (28.1)	25/93 (26.9)	1.05 (0.66 to 1.66), NSD

Appendix H Table 18. Physical Activity, Dichotomous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
	HTN	Medium HD + PA	Meeting PA recs (Prop. mtg goal to increase PA by 1500 steps/d (or >10,000/wk))	IG1	18	31/92 (33.7)	22/93 (23.7)	1.42 (0.90 to 2.27), NSD
	HTN	Medium HD + PA	Meeting PA recs (Prop. mtg goal to increase PA by 1500 steps/d (or >10,000/wk))	IG2	18	26/96 (27.1)	22/93 (23.7)	1.14 (0.70 to 1.87), NSD
Khanji, 2019[87] (HAPPY London) Good	Multiple	Low HD + PA	Meeting PA recs (PA >150 min/wk)	IG1	6	109/194 (56.2)	104/184 (56.5)	0.99 (0.83 to 1.19), 0.36
Kastarinen, 2002[85] (Lifestyle Intervention against Hypertension in Eastern Finland (LIHEF)) Fair	HTN	High HD + PA	Meeting PA recs (30 mins moderate intensity PA 3x week, among not meeting at BL)	IG1	12	60/173 (34.7)	41/171 (24.0)	Difference in probability=10.70 (1.20 to 20.30),
	HTN	High HD + PA	Meeting PA recs (30 mins moderate intensity PA 3x week, among not meeting at BL)	IG1	24	59/173 (34.1)	39/171 (22.8)	Difference in probability=11.30 (1.80 to 20.80),
Koelewijn-van Loon, 2009 (Improving Patient Adherence to Lifestyle Advice (IMPALA)) Fair	Multiple	Medium HD + PA	Meeting PA recs	IG1	12	163/252 (64.7)	153/236 (64.8)	1.00 (0.88 to 1.14), 0.97
Lakerveld, 2013[90] (HOORN) Fair	Multiple	Medium HD + PA	Meeting PA recs (Meeting rec for PA (≥30 min moderate-intensity PA ≥5 days/wk))	IG1	6	161/314 (51.3)	167/308 (54.2)	OR=0.70 (0.50 to 1.10), NSD
	Multiple	Medium HD + PA	Meeting PA recs (Meeting rec for PA (≥30 min moderate-intensity PA ≥5 days/wk))	IG1	12	162/314 (51.6)	160/308 (51.9)	OR=0.90 (0.60 to 1.40), NSD
Lee, 2007[92] Fair	HTN	Medium PA only	Walking (No change in walking frequency)	IG1	6	43/91 (47.3)	71/93 (76.3)	0.62 (0.48 to 0.79),
	HTN	Medium PA only	Walking (Walking less compared w/BL)	IG1	6	2/91 (2.2)	14/93 (15.1)	0.15 (0.03 to 0.62),
	HTN	Medium PA only	Walking (Walking more compared w/BL)	IG1	6	48/91 (52.7)	8/93 (8.6)	6.13 (3.07 to 12.23),

Appendix H Table 18. Physical Activity, Dichotomous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Liira, 2014[93] Fair	Multiple	Medium HD + PA	Meeting PA recs (PA ≥3 times per week)	IG1	12	7/46 (15.2)	7/42 (16.7)	0.91 (0.35 to 2.39), NSD
Migneault, 2012[94] Fair	HTN	High HD + PA	Leisure PA (>150 min/wk moderate-or-greater PA recs)	IG1	8	NR	NR	NR, NSD
Murphy, 2012 (National Exercise Referral Scheme (NERS)) Fair	Multiple	Medium PA only	Total PA (7D-PAR)	IG1	12	NR	NR	OR=1.29 (1.04 to 1.60), <0.05
Svetkey, 2008[114] (Weight Loss Maintenance (WLM)) Good	Multiple	High HD + PA	Total PA (Number of participants who have increased their PA)	IG1	30	228/292 (78.1)	207/287 (72.1)	1.08 (0.99 to 1.19), <0.1
	Multiple	High HD + PA	Total PA (Number of participants who have increased their PA)	IG2	30	201/301 (66.8)	207/287 (72.1)	0.93 (0.83 to 1.03), NSD
Ter Bogt, 2009[116] (Groningen Overweight and Lifestyle (GOAL)) Good	Multiple	High HD + PA	Meeting PA recs (Percent meeting rec for 150 mins/week PA (National Dutch recs)	IG1	36	82/111 (73.9)	101/137 (73.7)	1.00 (0.86 to 1.16), 0.28
	Multiple	High HD + PA	Meeting PA recs (Percent meeting rec for 60 min/week vigorous PA (ACSM fit guideline)	IG1	36	71/111 (64.0)	84/137 (61.3)	1.04 (0.86 to 1.27), 0.99
Tiessen, 2012[117] (SPRING (Self-monitoring and Prevention of RIsk Factors by Nurse practitioners in the region of Groningen)) Fair	Multiple	Medium HD + PA	Not meeting PA recs, inactive	IG1	12	NR	NR	Risk difference in change=-7.30 (-15.40 to 0.80), NSD
van Keulen, 2011[123] (Vitalum) Fair	HTN	Medium HD + PA	Meeting PA recs (Meeting guidelines for PA (≥5 days/wk for ≥30 min/day)	IG1	17	72/302 (23.8)	75/327 (22.9)	OR=1.57 (NR), <0.05
	HTN	Medium HD + PA	Meeting PA recs (Meeting guidelines for PA (≥5 days/wk for ≥30 min/day)	IG2	17	83/285 (29.1)	75/327 (22.9)	OR=2.08 (NR), <0.05
	HTN	Low HD + PA	Meeting PA recs (Meeting guidelines for PA (≥5 days/wk for ≥30 min/day)	IG3	17	73/272 (26.8)	75/327 (22.9)	OR=1.82 (NR), <0.05

Appendix H Table 18. Physical Activity, Dichotomous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
van Sluijs, 2005[124] (Physician-based Assessment and Counseling for Exercise (PACE)) Fair	Multiple	Medium PA only	Meeting PA recs (Meets ACSM/CDC guidelines)	IG1	12	NR	NR	OR=0.99 (0.62 to 1.57), 0.95
Wood, 2008[131] (EUROACTION) Fair	Multiple	High HD + PA	Meeting PA recs (≥30 mins, ≥4 times/week)	IG1	12	512/1018 (50.3)	222/1003 (22.1)	Difference in probability=29.40 (10.70 to 48.00), 0.01

Abbreviations: 7D-PAR = Standard 7-day Physical Activity Recall; ACSM = American College of Sports Medicine; BL = baseline; CG = control group; CI = confidence interval; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; MET = metabolic equivalent of task; min(s) = minutes; mtg = meeting; NR = not reported; NSD = no statistically significant difference; OR = odds ratio; PA = physical activity; prop = proportion; recs = recommendations; RR = risk ratio; wk = week

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

†Risk ratio unless otherwise specified

Appendix H Table 19. Harms Outcomes (KQ4)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Appel, 2003[41] (PREMIER) Good	HTN	High HD + PA	Serious musculoskeletal injuries	IG1	6	16/269 (5.9)	20/273 (7.3)	0.81 (0.43 to 1.53), NSD
	HTN	High HD + PA	Serious musculoskeletal injuries	IG2	6	17/268 (6.3)	20/273 (7.3)	0.87 (0.46 to 1.62), NSD
Appel, 2011[42] (POWER Hopkins (Practice Based Opportunities for Weight Reduction)) Good	Multiple	High HD + PA	Hospitalizations	IG1	24	18/138 (13.0)	15/138 (10.9)	1.20 (0.63 to 2.28), NSD
	Multiple	High HD + PA	Hospitalizations	IG2	24	15/139 (10.8)	15/138 (10.9)	0.99 (0.51 to 1.95), NSD
	Multiple	High HD + PA	Musculoskeletal injuries	IG1	24	1/138 (0.7)	0/138 (0.0)	3.00 (0.12 to 73.01), NSD
	Multiple	High HD + PA	Musculoskeletal injuries	IG2	24	0/139 (0.0)	0/138 (0.0)	NR, NSD
Bennett, 2012[47] (Be Fit, Be Well [POWER]) Good	HTN	High HD + PA	Gallbladder disease	IG1	24	0/180 (0.0)	2/185 (1.1)	0.21 (0.01 to 4.25), NSD
	HTN	High HD + PA	Hospitalizations	IG1	24	36/180 (20.0)	35/185 (18.9)	1.06 (0.70 to 1.61), NSD
	HTN	High HD + PA	Musculoskeletal injuries	IG1	24	1/180 (0.6)	0/185 (0.0)	3.08 (0.13 to 75.18), NSD
Bennett, 2018 [48] (Track) Good	Multiple	Medium HD + PA	Hospitalizations	IG1	12	11/176 (6.3)	1/175 (0.6)	10.94 (1.43 to 83.81), <0.05
	Multiple	Medium HD + PA	Musculoskeletal injuries	IG1	12	1/176 (0.6)	1/175 (0.6)	0.99 (0.06 to 15.77), NSD
Eakin, 2009[64] (Logan Healthy Living) Fair	Multiple	Medium HD + PA	SAEs	IG1	18	0/228 (0.0)	0/206 (0.0)	NR, NSD
Estruch, 2018[67] (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	Any adverse events	IG1	60	0/2543 (0.0)	0/2450 (0.0)	NR, NSD
	Multiple	High HD only	Any adverse events	IG2	60	0/2454 (0.0)	0/2450 (0.0)	NR, NSD
Gill, 2019[70] (HealtheSteps) Fair	Multiple	Medium HD + PA	Any adverse events	IG1	6	4/59 (6.8)	0/59 (0.0)	9.00 (0.50 to 163.53), NR
	Multiple	Medium HD + PA	SAEs	IG1	6	0/59 (0.0)	0/59 (0.0)	NR

Appendix H Table 19. Harms Outcomes (KQ4)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p-value
Groeneveld, 2010[72] (Health Under Construction) Fair	Multiple	Medium HD + PA	Any adverse events	IG1	12	0/408 (0.0)	0/408 (0.0)	NR, NSD
Haufe, 2019[75] Fair	Multiple	Medium HD + PA	Any adverse events	IG1	6	11/160 (6.9)	1/154 (0.6)	10.59 (1.38 to 81.03), 0.004
	Multiple	Medium HD + PA	Musculoskeletal injuries	IG1	6	1/160 (0.6)	0/154 (0.0)	2.89 (0.12 to 70.36), NR
Ogedegbe, 2014[102] (Counseling African Americans to Control Hypertension (CAATCH)) Fair	HTN	Medium HD + PA	Any adverse events	IG1	12	0.189‡	0.216‡	NR, 0.34
	HTN	Medium HD + PA	Hospitalizations	IG1	12	54/529 (10.2)	66/510 (12.9)	0.79 (0.56 to 1.11), 0.16
	HTN	Medium HD + PA	SAEs	IG1	12	0.115‡	0.139‡	NR, 0.28
Rodriguez, 2012[104] Fair	HTN	Medium HD + PA	Any adverse events	IG1	6	2/176 (1.1)	3/177 (1.7)	0.67 (0.11 to 3.96), NSD
Rosas, 2015[106] (Vivamos Activos Fair Oaks (VAFO)) Good	Multiple	High HD + PA	ED Visits	IG1	24	29/82 (35.4)	17/41 (41.5)	0.85 (0.53 to 1.36), NSD
	Multiple	High HD + PA	ED Visits	IG2	24	23/84 (27.4)	17/41 (41.5)	0.66 (0.40 to 1.09), NSD
	Multiple	High HD + PA	Hospitalizations	IG1	24	5/82 (6.1)	1/41 (2.4)	2.50 (0.30 to 20.70), NSD
	Multiple	High HD + PA	Hospitalizations	IG2	24	5/84 (6.0)	1/41 (2.4)	2.44 (0.29 to 20.22), NSD
Salisbury, 2016[108] Good	Multiple	Medium HD + PA	Any adverse events	IG1	12	38/325 (11.7)	38/316 (12.0)	0.97 (0.64 to 1.48), NSD
	Multiple	Medium HD + PA	SAEs	IG1	12	22/325 (6.8)	24/316 (7.6)	0.89 (0.51 to 1.56), NSD
Wadden, 2011[127] (Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-UP)) Good	Multiple	High HD + PA	SAEs	IG1	24	20/131 (15.3)	16/130 (12.3)	1.24 (0.67 to 2.29), NSD
Wood, 2008[131] (EUROACTION) Fair	Multiple	High HD + PA	Any adverse events	IG1	12	0/1019 (0.0)	0/1005 (0.0)	NR, NSD

Abbreviations: CG = control group; CI = confidence interval; ED = emergency department; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; NR = not reported; NSD = no statistically significant difference; RR = risk ratio; SAEs = serious adverse events

Appendix H Table 19. Harms Outcomes (KQ4)

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min
†Risk ratio unless otherwise specified
‡Mean number per 100 participants

Appendix I. Ongoing Studies

Trial Identifier	Principal Investigator	Study Name	Country	Estimated N	Purpose (as reported)	Estimated Completion Date
NCT02342808	James A. Blumenthal, PhD	Lifestyle Interventions in Treatment-Resistant Hypertension (TRIUMPH)	US	150	To examine the effects of a lifestyle intervention on fitness, dietary habits, and body weight in patients with resistant hypertension	December 2019
NCT01180673	Olugbenga Ogedegbe, MD	Counseling Older Adults to Control Hypertension (COACH)	US	251	To evaluate the effect of a senior center-based comprehensive therapeutic lifestyle intervention delivered through group-based counseling and motivational interviewing among hypertensive African American or Latino seniors aged ≥60 years	Completed as of March 2019. Awaiting publication of results.
ISRCTN18008011	Oliver Peacock, PhD	Multidimensional Individualized Physical Activity profiles for behavior Change using Technology (MiPACT)	UK	216	To examine whether personalized multidimensional physical activity feedback and self-monitoring using a web-based platform alongside in-person advice supports an increase in physical activity and weight loss in men and women at risk for future chronic disease	Completed as of November 2018. Awaiting publication of results.
ACTRN12613000715774	Julie Redfern, PhD	Consumer Navigation of electronic cardiovascular Tools (CONNECT)	AUS	934	To test whether a consumer-focused e-health strategy provided to Aboriginal and Torres Strait Islander and non-indigenous adults, recruited through primary care, at moderate-to-high risk of a cardiovascular disease event will improve risk factor control when compared with usual care	NR – Ongoing as of August, 2018
NCT02283697	Marcel Ruzicka, MD, PhD	Dietary Counseling to Reduce Salt Intake in Patients With High Blood Pressure	CAN	120	To test the efficacy of a structured counseling session by a registered dietitian in addition to usual care on sodium intake and blood pressure compared with usual care alone	December 2019
NCT02551640	Kamal Jethwani, MD	Improving Physical Activity Through a mHealth Intervention in Cardio-metabolic Risk Patients	US	300	To examine the effects of a smartphone-based physical activity-focused application in patients with cardiometabolic risk factors compared with usual care	December 2018. Awaiting publication of results.
NCT01838226	David Edelman, MD	Randomized Controlled Trial of Group Prevention Coaching	US	401	To test the effectiveness of a group prevention coaching (GPC) intervention in improving cardiovascular risk	Completed June, 2019. Awaiting publication of results

Appendix I. Ongoing Studies

Trial Identifier	Principal Investigator	Study Name	Country	Estimated N	Purpose (as reported)	Estimated Completion Date
NCT03052959	Lawrence Paszat, MD	BETTER HEALTH: Durham	US	120	To examine the effectiveness of supportive meetings between a specially trained prevention practitioner nurse and individuals aged 40-64 years to review recommended chronic disease prevention and screening activities (CDPS)	July 2019
NCT03164499	Sara Mora Simón, PhD	Intensive Intervention to Improve Lifestyles in Subjects With Intermediate Cardiovascular Risk	ESP	203	To evaluate the effectiveness of an intensive intervention to modify lifestyles of subjects with intermediate cardiovascular risk	Completed March 2019. Awaiting publication of results.
NCT03092960	Lisa Goldman Rosas, PhD	Comparing Two Innovative Approaches to Reduce Chronic Disease Risk Among Latino Men (HOMBRE)	US	424	To test a flexible lifestyle program designed to help Latino men make healthy lifestyle changes to lower their risk of developing diabetes and heart disease	July 2020
ISRCTN76069254	Aina Riera, PhD	Effectiveness of a brief multifactorial intervention in adherence to physical exercise prescription of moderate to high cardiovascular risk patients	ESP	616	To evaluate the effectiveness of a brief multifactorial intervention designed to improve the adherence to physical exercise prescription of moderate to high cardiovascular risk patients	Completed December 2017. Awaiting publication of results.
NCT02725203	Marieke J. Schuurmans, PhD	Unravelling Effectiveness of a Nurse-led Behavior Change Intervention to Enhance Physical Activity in Patients	NLD	195	To evaluate the effectiveness of the Active intervention, consisting of four nurse-led consultations over 3-months in patients at risk for cardiovascular disease	Completed October 2018. Awaiting publication of results.
ISRCTN54638034	Varun Anand, MBChB, BMedSc	Communicating cardiovascular disease risk in UK primary care	UK	60	To investigate the effects of GPs using heart age to communicate the risk of CVD to patients	Completed 2018. Awaiting publication of results.
ISRCTN89898870	Jordi Salas-Salvadó, MD, PhD	PREDIMED-Plus	ESP	6874	To evaluate whether intensive interventions involving an energy-restricted Mediterranean diet, promotion of physical activity, and behavioral support are likely to result in long-term weight loss, reduced	May 2020

Appendix I. Ongoing Studies

Trial Identifier	Principal Investigator	Study Name	Country	Estimated N	Purpose (as reported)	Estimated Completion Date
					CVD risk, and greater quality of life for older people with metabolic syndrome.	
NCT03577990	Willie M Abel, PhD	Interactive Technology-Enhanced Coaching (ITEC)	US	90	To evaluate the effectiveness of a technology coaching Intervention for black women with hypertension.	May 2022
NCT02499731	Rebecca A. Seguin-Fowler, PhD	Strong Hearts: Rural CVD Prevention	US	194	To evaluate the efficacy of the Strong Hearts Healthy Communities (SHHC) curriculum in a 24-week community based randomized controlled intervention trial in an underserved rural population.	February 2022

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