Behavioral Counseling Interventions in Primary Care To Reduce Risky/Harmful Alcohol Use by Adults: A Summary of the Evidence for the U.S. Preventive Services Task Force

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Background: **Primary health care visits offer opportunities to identify and intervene with risky or harmful drinkers to reduce alcohol consumption.**

Purpose: **To systematically review evidence for the efficacy of brief behavioral counseling interventions in primary care settings to reduce risky and harmful alcohol consumption.**

Data Sources: **Cochrane Database of Systematic Reviews, Database of Research Effectiveness (DARE), MEDLINE, Cochrane Controlled Clinical Trials, PsycINFO, HealthSTAR, CINAHL databases, bibliographies of reviews and included trials from 1994 through April 2002; update search through February 2003.**

Study Selection: **An inclusive search strategy (*alcohol** or *drink**) identified English-language systematic reviews or trials of primary care interventions to reduce risky/harmful alcohol use. Twelve controlled trials with general adult patients met our quality and relevance inclusion criteria.**

Data Extraction: **Investigators abstracted study design and setting, participant characteristics, screening and assessment procedures, intervention components, alcohol consumption and other outcomes, and quality-related study details.**

Data Synthesis: **Six to 12 months after good-quality, brief, multicontact behavioral counseling interventions (those with up to 15 minutes of initial contact and at least 1 follow-up), participants reduced the average number of drinks per week by 13% to 34% more than controls did, and the proportion of participants drinking at moderate or safe levels was 10% to 19% greater compared with controls. One study reported maintenance of improved drinking patterns for 48 months.**

Conclusions: **Behavioral counseling interventions for risky/harmful alcohol use among adult primary care patients could provide an effective component of a public health approach to reducing risky/harmful alcohol use. Future research should focus on implementation strategies to facilitate adoption of these practices into routine health care.**

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Alcohol misuse, including risky and harmful drinking, alcohol abuse, and dependence, is associated with numerous health and social problems and with more than 100 000 deaths per year (1). Risky drinkers consume alcohol above recommended daily, weekly, or per-occasion amounts. Harmful drinkers experience harm associated with their alcohol use but do not meet criteria for alcohol abuse or dependence (2). Persons who misuse alcohol have elevated risks for a host of health problems (3–6), including violence-related trauma and injury (4). Most individuals who consume alcohol do so in moderation and without adverse consequences, however, and observational research suggests light or moderate use may be beneficial for some people (7–20).

The assumption underlying brief behavioral counseling interventions in primary care is that, for identified risky or harmful drinkers, reducing overall alcohol consumption or adopting safer drinking patterns (that is, fewer drinks per occasion and not drinking before driving) will reduce the risk for medical, social, and psychological problems (21). Little experimental evidence supports this assumption, and most epidemiologic evidence relates health outcomes to existing drinking behaviors rather than to changes in drinking behaviors. Cross-sectional and cohort studies have consistently related high average alcohol consumption to short- or long-term health consequences (4, 22). A meta-analysis of studies examining the association between all-cause mortality and average alcohol consumption found that men averaging at least 4 drinks per day and women averaging 2 or more drinks per day experienced significantly increased mortality relative to nondrinkers (23). Studies also relate heavy per-occasion alcohol use ("binge drinking") to acute injury risks and alcohol-related life problems (4, 22). Injury rates are higher for binge drinkers who consume 5 or more drinks on one occasion as infrequently as 3 to 6 times per year, even when average intake is not excessive (24).

In the United States, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) has proposed epidemiologically based alcohol use guidelines to limit risks for short- and long-term drinking-related consequences by establishing age- and sex-specific recommended consumption thresholds (25). Maximum recommended consumption is 1 or less standard drink per day for adult women and for anyone older than 65 years of age and 2 or fewer standard drinks per day for adult men. These guidelines do not apply to persons (such as adolescents, pregnant women, and persons with alcohol dependence or medical conditions or medication use) for whom alcohol intake is contraindicated, or to circumstances (driving) in which no consumption is considered safe.

Primary care clinicians commonly see patients with a range of alcohol-related risks and problems. In Wisconsin, about 20% of primary care patients were found to exceed NIAAA guidelines and to qualify as risky drinkers (26). Across multiple primary care populations, 4% to 29% are

risky drinkers, 0.3% to 10% are harmful drinkers, and 2% to 9% exhibit alcohol dependence (27). Prevalence of these forms of alcohol misuse generally is higher in males and younger persons of all races and ethnicities (28).

The NIAAA and others encourage physicians to identify patients with alcohol-related risks or problems and to provide office-based brief interventions or referrals as needed (25, 29, 30). In everyday practice, screening and screening-related assessment procedures are necessary to identify the range of alcohol users in order to offer appropriate treatment (31, 32). Even so, few primary care clinicians use recommended screening protocols or offer treatment (33).

To assist the U.S. Preventive Services Task Force (USPSTF) in updating its 1996 recommendation (34), the Oregon Evidence-based Practice Center systematically reviewed the evidence on primary care–based behavioral counseling interventions for risky/harmful alcohol use; systematic evidence reviews and meta-analyses since the last USPSTF report (35–39) did not adequately address the key questions posed by the USPSTF. This review was exempted by the Institutional Review Board at Kaiser Permanente Northwest (FWA 00002344-IRB 00000405). Our review addressed the following questions:

1. Do behavioral counseling interventions in primary care reduce risky or harmful alcohol use? What are elements of effective interventions? Do such interventions improve health outcomes?

2. What methods were used to identify risky/harmful drinkers for behavioral counseling interventions in primary care?

3. What adverse effects are associated with interventions addressing risky/harmful drinkers in primary care?

4. What health care system influences are present in effective interventions for risky and harmful drinkers in primary care?

Table 1. **Criteria for Grading the Internal Validity of Individual Studies***

Randomized, controlled trials:
Adequate randomization, including concealment and equal distribution of potential confounders among groups
Maintenance of comparable groups (includes attribution, crossovers, adherence, contamination)
Important differential loss to follow-up or overall high loss to follow-up
Equal, reliable, and valid measurements (includes masking of outcome assessment)
Clear definition of interventions
Important outcomes considered
Intention-to-treat analysis

* The Methods Work Group of the U.S. Preventive Services Task Force developed a set of criteria to determine how well individual studies were conducted (internal validity) (40). The Task Force defined a 3-category rating of "good," "fair," and "poor" based on these criteria. In general, a good study meets all criteria well. A fair study does not meet, or it is not clear that it meets, at least one criterion but has no known important limitation that could invalidate its results. A poor study has important limitations. These specifications are not meant to be rigid rules but rather are intended to be general guidelines; individual exceptions, when explicitly explained and justified, can be made.

METHODS

We concentrated our review on the program elements of brief primary care interventions for risky and harmful drinkers and their effects on alcohol use, health outcomes, and intermediate alcohol-related outcomes. **Appendix Figure 1** shows the analytic framework and key questions guiding the entire systematic evidence review. Methods not described in this section appear in the Appendix, **Appendix Figures 2** and **3**, and **Table 1**. All Appendix material is available at www.annals.org.

Definitions

No consistent definitions for the drinking patterns that should be the focus of primary care interventions are available from existing guidelines or research; however, it is commonly held that less severe alcohol problems are appropriate for brief interventions in primary care, whereas more severe problems need specialty addiction treatment (41). We adapted the following definitions from a recent systematic review of primary care screening for alcohol problems (2). *Risky or hazardous drinkers* are at risk from consumption that exceeds daily, weekly, or per-occasion thresholds (other terms further distinguish risky/harmful users who exceed longer-term thresholds—"high-average" or "heavy users"—from "heavy occasional" or "binge" drinkers, who exceed per-occasion thresholds). *Harmful drinkers* experience physical, social, or psychological harm from their above-threshold alcohol use without meeting criteria for dependence. *Alcohol-abusing/-dependent drinkers* continue to use alcohol despite significant negative physical, psychological, and social consequences (42); generally meet criteria for abuse or dependence as outlined in the *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition (43); and are candidates for specialty addiction treatment. Our review focuses on studies oriented toward the risky/hazardous/harmful category, which we refer to as "risky/harmful" drinkers. Fiellin and colleagues (2) similarly divide the literature on screening instruments for alcohol problems into studies that focus primarily on risky, heavy, or harmful drinking and studies that focus on detecting alcohol abuse or dependence.

Among the brief intervention studies targeting risky/harmful drinkers selected for this review, we classified intervention groups into 1 of 3 levels of intensity: 1) "very brief interventions" had 1 session, up to 5 minutes long; 2) "brief interventions" had 1 session, up to 15 minutes long; and 3) "brief multicontact interventions" had an initial session up to 15 minutes long, plus follow-up contacts.

We used the definition of primary care recommended by the Institute of Medicine (44) (see Inclusion and Exclusion Criteria in the Appendix) to identify relevant medical settings for our review.

Inclusion and Exclusion Criteria

We included English-language reports of randomized or nonrandomized controlled clinical trials of nondependent drinkers 12 years of age or older who received a primary care behavioral counseling intervention primarily to reduce alcohol intake. We excluded studies based in hospitals or emergency departments, specialty addiction treatment settings, behavioral health departments, and schools or community agencies without health clinics. We also excluded studies among comorbid patient populations because of limited generalizability to primary care. We excluded studies rated as having poor quality, as described below.

Search Strategy

We identified 5 recent systematic reviews addressing primary care brief interventions to reduce risky/harmful alcohol use (35–39) and 3 addressing screening (2, 45, 46) from the Cochrane Database of Systematic Reviews and Database of Research Effectiveness (DARE). Relevant trials were identified from searches of MEDLINE, Cochrane Controlled Clinical Trials, PsycINFO, HealthSTAR, and CINAHL databases (1994 to April 2002), reference lists of systematic reviews, the USPSTF 1996 recommendation (34), and experts. We conducted separate searches in MEDLINE and PsycINFO from 1994 through April 2002 to identify any literature on harms related to alcohol screening, screening-related assessment, or intervention. None was found. The Appendix contains further search strategy details, along with information on our abstract and article review processes. We used USPSTF internal validity criteria (40) (**Table 1**), supplemented by specific quality criteria addressing study randomization, attrition, and intention-to-treat analyses from the Cochrane Drug and Alcohol Group (CDAG) (47) (**Appendix Figure 3**), to grade the quality of trials that met inclusion and exclusion criteria. We assigned each study's final quality rating according to investigator team consensus. Minimal to no attrition, nondifferential attrition, and replacement of missing values in the outcome analyses were key features of trials rated good quality. Studies receiving a consensus rating of poor quality ($n = 27$) were excluded from the review (**Appendix Table 2**). Major quality problems included nonrandom assignment, noncomparable baseline conditions, attrition rates greater than 30%, and inadequate or unavailable alcohol consumption outcomes. Seventeen studies met final setting and quality criteria (although 1 did not have study results available in time for our review) (48). Twelve of the 16 reviewed studies addressed nonpregnant adults and are the basis of this report. The others addressed pregnant women ($n = 3$) and adolescents ($n = 1$) and are reviewed elsewhere (41). A database search update through February 2003 revealed no new trials.

Data Abstraction

For all 12 included studies, 1 author abstracted relevant information using data abstraction forms. The Appendix describes the data abstraction. A second author checked all data in the final evidence tables.

We examined intervention groups ($n = 15$) from included studies ($n = 12$) by levels of intensity and use of 5 key intervention components (feedback, advice, goal-setting, further assistance, and follow-up) identified from previous research (25, 31, 34, 49). We recorded 3 commonly reported alcohol use outcomes that measured different but comparably important improvements in alcohol use at the end point nearest to 12 months' follow-up: 1) mean drinks per week or the reduction in mean drinks per week (follow-up minus baseline); 2) percentage of participants without binge drinking (usually defined as ≥ 5 drinks per occasion); and 3) percentage of participants achieving recommended drinking levels or patterns (as defined by the study). Where possible, we converted alcohol outcomes into consistent measures across studies and conveyed final results as "net" (that is, intervention minus control); the Appendix further describes our calculations. We did not undertake a quantitative synthesis of alcohol outcomes because of the lack of a clearly superior measure among the 3 alcohol use outcomes available and because of our judgment, supported by that of the USPSTF, that a qualitative synthesis that includes all outcomes would be most informative. Graphs displaying trial results by alcohol use outcome, with sex subgroups (where available), can be accessed elsewhere (41).

Role of the Funding Source

This research was funded by the Agency for Healthcare Research and Quality (AHRQ) under a contract to support the work of the USPSTF. The USPSTF members participated in the initial design and reviewed interim results and the final evidence review. The AHRQ had no role in study design, data collection, or synthesis, although AHRQ staff reviewed interim and final evidence reports and distributed the initial evidence report for external content review by 11 outside experts, including representatives of professional societies and federal agencies. The subsequently revised systematic evidence review on which this manuscript is based is available at www.ahrq.gov/clinic/serfiles.htm (41).

Data Synthesis

Characteristics of Behavioral Counseling Intervention Trials Reviewed

Table 2 and **Appendix Table 3** detail the 12 trials of primary care interventions for risky/harmful alcohol use. Seven trials (50–56) were judged good quality, and the rest were fair (57–61). All were randomized, controlled trials conducted in multiple primary care practices (ranging from 3 to 47 practices per study), except for 1 controlled clinical trial (57). All but 3 trials (51, 54, 59) involved more than 300 participants. The studies examined drinking outcomes after at least 12 months of follow-up, except for 1 with

Table 2. **Components of Interventions and Alcohol Outcomes among Adult Alcohol Intervention Trials, by Intervention Intensity***

Intervention Condition†	Population	Setting/Duration	Intervention	Outcomes	Study Quality
Very brief intervention conditions					
Richmond et al. (61)‡	378 adults age 18–70 y; baseline mean alcohol consumption: 38.5 drinks/wk	40 Australian primary care practices (119 physicians) Outcomes assessed at 12 mo	Group 1: alcohol assessment placed on chart before visit (n = 93) Group 2: Same as group 1 plus 5-min physician advice and self-help manual (n = 96)	Group 1 Mean drinks/wk§: 21.5 (women); 36.2 (men) Not bingeing: NR Moderate/safe drinking: 21.5% Group 2 Mean drinks/wk: 24.2 (women); 39.3 (men) Not bingeing: NR Moderate/safe drinking: 22.9% (P = NS)	Fair: nonrandom assignment, control follow-up not assessed, contamination between interventions, baseline differences not controlled for in all analyses
WHO Brief Intervention Study (58)‖¶ (group 1)	1559 adults age 18–70 y; baseline alcohol consumption: NR	Various outpatient medical settings in 8 countries, including United States Outcomes assessed at an average of 9 mo	Group 1: 5-min clinician advice	Group 1 Mean drinks/wk: NR Not bingeing: NR Moderate/safe drinking: 43% (women); 43% (men) Control group Mean drinks/wk: NR Not bingeing: NR Moderate/safe drinking: 35% (women) (P = NS); 35% (men) ($P < 0.05$)	Fair: possible noncomparable groups at baseline and follow-up, potential contamination across intervention conditions
Brief intervention conditions					
Anderson and Scott (54)	154 men age 17–69 y; baseline mean alcohol consumption: 52 drinks/wk	8 primary care group practices in United Kingdom Outcomes assessed at 12 mo	10-min clinician advice	Intervention group Change in mean drinks/wk: −15.7 Not bingeing: 77.50% Moderate/safe drinking: 17.50% Control group Change in mean drinks/wk: −9.2 (P = 0.06) Not bingeing: 60.81% ($P < 0.05$) Moderate/safe drinking: 5.41% ($P < 0.05$)	Good: relatively high attribution levels (31% and 39%), but baseline-forward-replacement of missing values analysis reported
Maisto et al. (60)¶ (group 1)	301 adults age ≥21 y; baseline alcohol consumption: 5.5 drinks/drinking day	12 primary care clinics in the United States Outcomes assessed at 12 mo	Group 1: 10- to 15-min advice from research staff	Group 1 Change in mean drinks/drinking day: −0.79 Change in mean drinks/wk: −8.3 Not bingeing: NR Moderate/safe drinking: NR Control group Change in mean drinks/drinking day: −0.85 (P = NS) Change in mean drinks/wk: −3.6 (P = NS) Not bingeing: NR Moderate/safe drinking: NR	Fair: high attribution (23%) without addressing loss to follow-up, unclear blinding, potential contamination between groups
Nilssen (57)‖¶ (group 1)	338 participants age 12–62 y (mean, 42 y); baseline alcohol consumption: NR	Residents of Tromso, Norway Outcomes assessed at 12 mo	Feedback given about biological assay results at study-initiated visit	Group 1 Mean alcohol consumption, g/d: 15.6 Not bingeing: NR Moderate/safe drinking: NR Control group Mean alcohol consumption, g/d: 39.2 ($P < 0.001$) Not bingeing: NR Moderate/safe drinking: NR	Fair: unclear allocation concealment, blinding of outcome assessment, possible noncomparable groups at baseline and follow-up
Scott and Anderson (59)	72 women age 17–69 y; baseline mean alcohol consumption: 35.3 drinks/wk	8 primary care group practices in United Kingdom Outcomes assessed at 12 mo	10-min clinician advice	Intervention group Change in mean drinks/wk: −11.6 Not bingeing: 87.9% Moderate/safe drinking: 27% Control group Change in mean drinks/wk: −10.0 (P = NS) Not bingeing: 84.6% (P = NS) Moderate/safe drinking: 26% (P = NS)	Fair: noncomparable groups at baseline, unclear allocation concealment, possible contamination of controls, inadequate power

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Table 2—**Continued**

Intervention Condition†	Population	Setting/Duration	Intervention	Outcomes	Study Quality
Senft et al. (56)	516 adults age ≥21 y; mean baseline alcohol consumption: 16.5 drinks/wk	3 primary care clinics in an HMO in the United States	30-s clinician advice plus 15-min motivational interview with study counselor	Intervention group Mean drinks/wk: 13.1 Not bingeing: 77% Moderate/safe drinking: 80% Control group Mean drinks/wk: 14.9 (P = NS) Not bingeing: 77% (P = NS) Moderate/safe drinking: 73.1% (P = 0.07)	Good: although high attribution (20%) (and differentially greater in intervention group), baseline-forward-replacement of missing values showed no effect on results
WHO Brief Intervention Study (58)‖¶ (group 2)	1559 adults age 18–70 y; baseline alcohol consumption: NR	Various outpatient medical settings in 8 countries, including United States Outcomes assessed at an average of 9 mo	Group 2: 15-min advice from health care provider	Group 2 Mean drinks/wk: NR Mean cL alcohol/d: males, 5.18; females, 3.39 Not bingeing: NR Moderate/safe drinking: males, 43%; females: 39% Control group: Mean drinks/wk: NR Mean cL alcohol/d: males, 6.29 (P < 0.001); females, 3.80 (P = NS) Not bingeing: NR Moderate/safe drinking: males, 35% (P < 0.05); females, 35% (P = NS)	Fair: possible noncomparable groups at baseline and follow-up, potential contamination across intervention conditions
Brief multicontact intervention conditions					
Curry et al. (50)	307 adults; mean age, 48.2 y; baseline alcohol consumption: 14.9 drinks/wk	Patients of 23 clinicians in an HMO in the United States Outcomes assessed at 12 mo, adjusted for missing data	≤5-min motivational clinician message, self-help manual, and up to 3 phone calls from research health educator	Intervention group Mean drinks/wk: 10.6 Not bingeing: 86% Moderate/safe drinking: 57% Control group Mean drinks/wk: 10.6 (P > 0.2) Not bingeing: 81% (P > 0.2) Moderate/safe drinking: 43 (P = 0.048)	Good: high, differential attribution (34% and 22%) addressed by multiple imputation procedure
Fleming et al. (53)	774 adults age 18–65 y; mean baseline alcohol consumption: 19.1 drinks/wk	17 primary care practices in the United States Outcomes assessed at 12 mo	2 brief clinician visits, each followed by phone call from nurse	Intervention group Mean drinks/wk: 11.5 Not bingeing: 52% Moderate/safe drinking: 84.7% Control group Mean drinks/wk: 15.5 (P < 0.001) Not bingeing: 31.7% (P < 0.001) Moderate/safe drinking: 68.9% (P < 0.001)	Good: low attribution (10%, slightly differential between groups), baseline-forward-replacement of missing values
Fleming et al. (51)	158 adults age ≥65 y; mean baseline alcohol consumption: 16 drinks/wk	24 primary care practices in the United States Outcomes assessed at 12 mo	Two 10- to 15-min clinician visits, each followed by phone call from nurse	Intervention group Mean drinks/wk: 9.9 Not bingeing: 69.2% Moderate/safe drinking: 84.6% Control group Mean drinks/wk: 16.3 (P < 0.001) Not bingeing: 50.8% (P < 0.025) Moderate/safe drinking: 65.7% (P < 0.005)	Good: all criteria met
Maisto et al. (60)¶ (group 2)	301 adults age ≥21 y; baseline alcohol consumption: 5.5 drinks/drinking day	12 primary care clinics in the United States Outcomes assessed at 12 mo	30- to 45-min motivational session with research interventionist plus two 15- to 20-min booster sessions	Group 2 Change in mean drinks/drinking day: −0.64 Change in mean drinks/wk: −5.5 Not bingeing: NR Moderate/safe drinking: NR Control group Change in mean drinks/drinking day: −0.85 (P = NS) Change in mean drinks/wk: −3.6 (P = NS) Not bingeing: NR Moderate/safe drinking: NR	Fair: high attribution (23%) without addressing loss to follow-up, unclear blinding, potential contamination between groups
Nilssen (57)‖¶ (group 2)	338 participants age 12–62 y (mean, 42 y); baseline alcohol consumption: NR	Residents of Tromso, Norway Outcomes assessed at 12 mo	Feedback given about biological assay results at study-initiated visit; participants invited to repeat visits with laboratory tests until γ-glutamyltransferase level normalized	Group 2 Mean alcohol consumption, g/d: 13.5 Not bingeing: NR Moderate/safe drinking: NR Control group Mean alcohol consumption, g/d: 39.2 (P < 0.001) Not bingeing: NR Moderate/safe drinking: NR	Fair: unclear allocation concealment, blinding of outcome assessment, possible noncomparable groups at baseline and follow-up

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Table 2—**Continued**

Intervention Condition†	Population	Setting/Duration	Intervention	Outcomes	Study Quality
Ockene et al. (52)	530 adults age 21–70 y; mean baseline alcohol consumption: 18.9 drinks/wk	4 primary care sites (93 clinicians) in the United States Outcomes assessed at 6 mo	5- to 10-min tailored consultation with clinician plus follow-up visit	Intervention group Change in mean drinks/wk: −6.0 Not bingeing: 31% Not bingeing and moderate/safe drinking: 38.7% Control group Change in mean drinks/wk: −3.1 (P = 0.003) Not bingeing: 26% (P = NS) Not bingeing and moderate/safe drinking: 28.3% ($P < 0.05$)	Good: met all criteria
Wallace et al. (55)‖	909 adults age 17–69 y; mean baseline alcohol consumption: 35.1 (females) and 62.2 (males) drinks/wk	47 group practices in England and Scotland	1 or 2 visits with clinician with up to 5 visits as needed	Intervention group Mean drinks/wk: females, 23.6; males, 44.0 Binge/heavy episodes: NR Moderate/safe drinking: females, 47.7%; males, 43.7% Control group Mean drinks/wk: females, 30.4 ($P < 0.05$); males: 55.6 ($P < 0.001$) Binge/heavy episodes: NR Moderate/safe drinking: females, 29.2% ($P < 0.05$); males, 25.5% ($P < 0.001$)	Good: met all criteria

* HMO = health maintenance organization; NR = outcome not reported; NS = reported as non–statistically significant in study; WHO = World Health Organization.
† Includes 15 intervention conditions from 12 studies. Multiple intervention groups from Maisto (60), Nilssen (57), and WHO (58) are further detailed in Appendix Table 3. Intervention definitions: "very brief" interventions include up to 5 minutes at initial contact with no follow-up contacts; "brief" interventions include up to 15 minutes at initial contact with no follow-up contact; "brief multicontact" interventions include up to 15 minutes at initial contact with multiple follow-up contacts.
‡ This study contributed 2 minimal intervention conditions, designated here as group 1 and group 2.
§ Mean drinks per week was reported as change scores from baseline for Ockene (52), Anderson and Scott (54), Maisto (60), and Scott and Anderson (59). Two studies—Nilssen (57) and WHO (58)—did not report mean drinks per week but did report average daily consumption measures, with some statistically significant between-group differences (Appendix Table 3).
‖ Trial results considered in 1996 U.S. Preventive Services Task Force recommendation for screening to detect problem drinking.
¶ This study reported 2 intervention conditions—designated here as group 1 and group 2—and 1 control.

6-month results (52) and 1 with at least 9 months of follow-up (58).

About one third of study participants were women; the exceptions were some older international studies that did not target women (54, 57, 58). Adults 65 years of age or older were included in 9 trials (50, 52, 54–56, 58–61) and were specifically targeted in another (51). Rates of participation of nonwhite persons were not reported in many older international studies and were low (4% to 27%) where reported in recent U.S. studies (50, 52, 53, 56).

The trials generally targeted risky or harmful drinkers or both and excluded known or suspected dependent drinkers, using variable criteria. However, more recent studies (those published after 1996) were more likely to include binge drinkers in addition to persons with high average consumption. These studies tended to define lower thresholds for risky weekly or average use and often excluded heavier drinkers who were at a lower threshold of average use or had any evidence of dependence or abuse. Generally, thresholds for risky alcohol consumption were lower for women than men. More details on inclusion and exclusion criteria applied within each trial are available in **Appendix Table 3** and in the full evidence report (41).

On the basis of our definitions, 2 studies evaluated very brief interventions (58, 61), 6 evaluated brief interventions (54, 56–60), and 7 evaluated brief multicontact interventions (50–53, 55, 57, 60). Twelve of the 15 interventions were delivered all or in part by the patient's usual primary care physician. Four of these used physicians to deliver initial and repeated intervention contacts (52, 55, 59, 61), whereas others used health educators and counselors (50, 56) or clinic nurses (51, 53) for some contacts.

Effectiveness of Behavioral Counseling Interventions on Risky/Harmful Alcohol Use

All 7 trials testing brief multicontact behavioral counseling interventions (50–53, 55, 57, 60) reported mean drinks per week or average daily consumption outcomes. Five studies (50–53, 55) reported the proportion of participants with safe or moderate alcohol use. Four studies reported the proportion of participants not bingeing (50–53). Six of these trials (50–53, 55, 57) reported a significant effect on at least 1 drinking outcome (**Table 2**). The seventh fair-quality study, delivered entirely by research personnel outside the clinical setting, found no significant effect on mean drinks per week, the only outcome measure it reported (60). Four good-quality trials (51–53, 55) reported that weekly drinking was reduced 13% to 34% more in intervention groups than in controls (that is, 13% to 34% net reduction), resulting in 2.9 to 8.7 fewer mean drinks per week at follow-up in intervention compared with control participants (data shown elsewhere) (40). One fair-quality brief multicontact intervention significantly reduced mean daily alcohol consumption (57), while 1 good-

quality trial did not significantly change average use (50). All 5 good-quality trials (50–53, 55) found significant effects on recommended or safe alcohol use, resulting in 10% to 19% more intervention participants than controls reporting recommended or safe drinking patterns (data shown elsewhere) (41). Two of 4 good-quality trials reported significantly reduced binge drinking (51, 53). In trials with at least 49% binge users in the study sample at baseline (51–53), binge drinking remained fairly common (31% to 69%) among intervention participants after intervention.

Of the 8 trials testing very brief interventions (58, 61) or brief interventions (54, 56–60), all reported mean drinks per week or average daily consumption outcomes. Six intervention groups from 5 studies (54, 56, 58, 59, 61) reported the proportion of participants with safe or moderate alcohol use; 3 reported the proportion not bingeing (54, 56, 59). Statistically significant results were limited to 3 studies (54, 57, 58), although results tended to favor intervention groups over control groups. One fair-quality very brief intervention (58) improved daily alcohol intake and the proportion of participants drinking moderately among males only. This result may have been due to limited power given the relatively small number of females in the study, or the very brief intervention could have been contaminated—interventionists also delivered a brief intervention protocol (which similarly improved outcomes in males) as part of the same study. A trial testing both brief and brief, multicontact interventions found an average intake effect for both, although potential for contamination was not clear (57). A good-quality brief intervention targeting males significantly improved the proportion with safe or moderate use and the proportion not bingeing (54).

All interventions that showed statistically significant improvements in alcohol outcomes of any intensity included at least 2 of 3 key elements—feedback, advice, and goal-setting. Since most effective interventions were multicontact ones, they also provided further assistance and follow-up. A few also reported tailoring intervention elements to each participant (50, 52).

We found no consistent differences between women and men in the effectiveness of interventions, particularly brief multicontact interventions (data displayed and discussed in detail elsewhere) (41). One intervention that targeted older adults (51) appeared as effective as or more effective than a similar intervention in younger adults (53).

Effectiveness of Behavioral Counseling Interventions on Health and Related Outcomes

About half of intervention studies reported morbidity-related outcomes, such as problem scores (54, 58, 59, 61), psychological scores (54, 59), and lifestyle improvements or reduced accidents and injuries (51, 53, 54). In 2 of the 4 studies examining problem scores, those in all groups generally improved, with no differences between intervention and control groups at follow-up (54, 61). The other 2 studies showed no changes from baseline to follow-up within or between groups (58, 59). With other outcomes, studies generally found no improvement or similar improvements in interventions and controls over the duration of the trials (51, 53, 54, 59). Of the 5 trials that examined health care utilization (53, 54, 56, 59), only 1 found reduced self-reported hospital days at 12 months (53). In a study evaluating brief interventions and brief, multicontact interventions (60), quality-of-life measures, including those related to alcohol-related problems, improved among the subset of intervention and control participants who reduced drinking by at least 20% (62).

We identified 4 reports of long-term health outcomes following 3 intervention trials (63–66). In 1 good-quality brief multicontact intervention trial (53), fewer hospital days were self-reported by the intervention group than controls after 48 months (429 vs. 664 days; $P < 0.05$), and there was a trend toward reduced all-cause mortality in intervention participants compared with controls (3 vs. 7 deaths; $P > 0.10$) (64). However, other morbidity-related outcomes did not significantly differ between groups. Significantly greater reductions in alcohol use among intervention participants compared with controls were maintained at 48 months.

In a second study, a brief single-contact intervention had no long-term effects on morbidity, mortality, or alcohol consumption at 10-year follow-up (66).

The third study (65), an intensive population-based intervention that alternately enrolled annual cohorts in screening and nonscreening study groups over many years, reported health outcomes but not alcohol consumption outcomes (the Malmö Screening and Intervention Study). Men age 32 to 37 years who were invited to participate had significantly lower total mortality rates (24/100 000 person-years) than noninvited controls (30/100 000 person-years) ($P < 0.02$) and had significantly reduced alcohol-related mortality after 3 to 21 years (65). In a nested, randomized, controlled trial within the Malmö Study, men age 45 to 49 years with elevated serum γ-glutamyltransferase levels who were randomly assigned to control groups had more alcohol-related deaths after a median of 13 years (relative risk, 2.0 [95% CI, 1.1 to 3.7]; $P = 0.026$) than those assigned to intensive intervention (63). Since this trial did not report alcohol use outcomes and it selected drinkers on the basis of confirmed elevations in serum γ-glutamyltransferase levels, participants may have been more severely affected than in other studies we reviewed.

Methods Used To Identify Risky and Harmful Alcohol Users

In the 12 trials reviewed, methods to identify alcohol users appropriate for brief interventions in primary care (**Table 2**, **Appendix Table 3**, and Table 11 from the systematic evidence review [41]) typically included screening (identifying patients with probable risky/harmful alcohol use) and screening-related assessment (confirming screening results and distinguishing patients suitable for brief

interventions from those needing specialty care referral). Screening typically involved self-administered questionnaires or brief interviews to assess average quantity or frequency and binge use. In recent U.S. studies (50–53, 56, 60), about 8% to 18% of patients screened "positive," and about half of these remained eligible for primary care intervention after assessment (data shown elsewhere [41]). Processes to identify patients were generally embedded, at least initially, within assessment of other behavioral health risks. Screening and assessment steps included an added respondent burden for research; however, this burden applied equally to intervention and control participants in all but 1 study (57). Many of the trials we reviewed used validated screening instruments (CAGE [4-item screening questionnaire to detect alcoholism], AUDIT [alcohol use disorders identification test—10-item instrument for risky/harmful use]) that have been shown to have reasonable-to-good test performance among primary care populations (2, 45, 46). Test performance is summarized elsewhere (41). Validated instruments were used alone (for example, AUDIT) or in combination (CAGE plus standardized questions on quantity and frequency) to detect patients with at-risk or harmful drinking, or alcohol abuse or dependence. Research personnel generally provided all or most of the screening and assessment for participants. Screening and assessment steps for each study, and their yields, are examined in greater detail elsewhere (41).

Adverse Effects of Screening and Intervention

We found no research that addressed adverse effects associated with alcohol use screening or assessment, or with behavioral counseling interventions for alcohol use. Three good-quality intervention trials reported greater dropout rates among participants receiving alcohol interventions than among controls (50, 55, 56), while 1 good-quality trial reported higher dropout among controls (54). Differential dropout rates did not affect outcomes since they were addressed analytically; however, dropout may indicate discomfort or dissatisfaction with the intervention, among other plausible explanations. These findings occurred in a minority of trials and cannot be explained with the available data.

Health Care System Supports and Influences

In all 12 trials, additional staff or systems support were required to provide screening and assessment services and, in some cases, intervention support. To identify potential study participants for screening and assessment, 2 studies used systems that highlight upcoming appointments (50, 52), while others used practice registries (54, 55, 59). In nearly every study, research staff conducted the screening and assessment outside the routine care encounter. Most of these processes took more than 30 minutes, although time estimates also include research-related procedures.

Provider training sessions, reported in many studies (50, 52–54, 58, 59, 61), ranged from 15 minutes to 2.5 hours. Several recent studies reported both initial and ongoing training (52, 53). Only 3 studies reported using incentives for participating providers or patients (51, 53, 60). Besides usual care physicians, studies also used research staff (50, 56, 58, 60) or nonphysician health care staff (51, 53) to deliver some or all of the intervention. Research staff often performed important support functions, such as prompting the provider and supplying intervention materials to the chart (50, 52, 56, 60). None reported using electronic medical record support.

Discussion

Summary of Research Findings

We found that good-quality brief multicontact behavioral counseling interventions reduced risky and harmful alcohol use by primary care patients for several alcohol outcomes. A recent meta-analysis that included 7 of the 12 trials we examined reported pooled estimates for the proportion drinking sensibly at follow-up, an absolute risk reduction of 10.5% (CI, 7.1% to 13.9%), with a number needed to treat for benefit of 10 (CI, 7 to 14) (67). We found similar results (ranging from 10% to 19% more intervention participants than controls achieving safe or recommended drinking levels) among studies providing brief multicontact interventions. We examined other equally relevant alcohol outcomes and found that good-quality brief multicontact intervention trials also reduced weekly drinking 2.9 to 8.7 mean drinks per week more than in controls (13% to 34% net reductions) but had inconsistent effects on binge drinking. Very brief or brief single-contact interventions were less effective or ineffective in reducing risky/harmful alcohol use. This finding contrasts with the significant results seen for very brief and brief tobacco interventions among adults in primary care and other medical settings (68). Effective interventions generally included advice, feedback, goal setting, and additional contacts for further assistance and support, although available evidence cannot clearly distinguish higher-intensity intervention effects from intervention components. The elements in effective interventions were generally consistent with the 5 A's (assess, advise, agree, assist, arrange) approach to behavioral counseling interventions adopted by the USPSTF (69).

Earlier intervention studies and reviews raised concerns that women either might not be as responsive to brief interventions as men or might be so responsive to screening alone that brief intervention would not confer much additional benefit. Our results are consistent with recent reviews that found no important sex differences in outcomes of brief interventions (31, 36, 38). Primary care interventions also appear effective in older as well as younger adults, according to the results from a trial targeting older adults (51) and inclusion of older adults in most trials reviewed.

Less is known about the direct effects of risky/harmful alcohol use interventions on morbidity and mortality than

on alcohol intake. Mortality benefits were seen primarily in 1 extended intensive intervention (with repeated contacts up to 5 years) among more severely affected drinkers (65). It is not clear whether mortality benefits will be seen with less severe drinkers undergoing the less intensive interventions typical of studies reviewed here. Since most favorable mortality outcomes were seen only in males or younger males, mortality benefits may accrue primarily to specific subgroups, and their demonstration may require 4 or more years of follow-up. Results were mixed for morbidity measures, and future research is clearly needed; primarily null findings may reflect lack of an effect, reduced power for secondary analyses, or insufficient measures.

Patients were identified for intervention by methods including standardized screening instruments such as AUDIT and CAGE (to detect alcoholism but not risky drinking) that have been shown to perform adequately in primary care populations (2, 45, 46). The 2-step strategy used in trials approximates the NIAAA-recommended approach, in which all patients identified as alcohol drinkers are asked about usual quantity and frequency of drinking, maximum drinks per occasion in the past month, and the 4 CAGE screening questions (wanting to Cut down on drinking, people Annoying you by criticizing your drinking, feeling Guilty about your drinking, and having an "Eye-opener" drink upon arising in the morning) (30). The second step is a confirmatory clinical assessment that also considers specific alcohol problems and dependence.

If primary care clinicians appropriately use these validated screening instruments in conjunction with clinical assessment and judgment, they are likely to identify patients in their practices who are similar to trial participants. Screening and assessment steps were not tested as part of the clinical protocol in these studies, however, and most interventions involved contact with research personnel to determine study eligibility. We found that at least 8% to 18% of general primary care patients would be candidates for brief interventions (screen positives), with at least half remaining eligible after completing the assessment step; according to available data, active refusal rates should be fairly small (41). In the recent meta-analysis of many of the same studies, a similar proportion (9% [range, 3% to 18%]) of patients screened positive, but estimates for the proportion remaining after the assessment step were much lower than ours (67). The authors used their lower estimate of the final screening yield to calculate a benefit for screening and intervention of 2 to 3 per 1000. They have been criticized, however, for such issues as equating the screening yields from recruitment for intervention efficacy trials with those that would result from usual care screening (70); other concerns about this meta-analysis have also been discussed (71–75).

Implications and Future Research Recommendations

Considerable work is needed to implement screening and brief intervention for risky/harmful alcohol use as part of routine practice, and more research is needed on effective strategies and supports for adoption of these services by physicians and health plans. While brief or very brief interventions may be more easily incorporated into routine primary care, effectiveness of risky/harmful alcohol use interventions probably depends on multiple contacts over time. Most primary care physicians report asking about alcohol use, but far fewer use recommended screening protocols (33) or prefer physician counseling as the means to address risky/harmful users (76). Current research points the way to persuading physicians to accept screening and intervention materials (77) and to providing training that increases screening and intervention activities (78). Prompting untrained physicians with alcohol screening results and simple treatment recommendations yields mixed results in terms of alcohol advice and discussions or patient drinking behaviors (48). Given the system supports provided for most trials, those seeking positive results from these interventions in real-world clinical practice will probably require similar support, such as 1) commitment to planning; 2) allocation of resources and staff to consistently identify risky/harmful alcohol-using patients; and 3) delivery resources (such as clinician training, prompts, materials, reminders, and referral resources).

Trials are needed to examine the direct effects on alcohol use, mortality, and morbidity (including quality of life, mental health, and social functioning) of screening followed by interventions for risky/harmful alcohol use and to report possible harms associated with screening, assessment, and brief intervention. Future intervention research should more directly target screening, interventions, and outcome measures to address binge use. Future research is also needed to establish possible cost savings (79) or cost-effectiveness (80) for these interventions.

Limitations of Our Review

We did not quantitatively summarize study trial results; however, our findings are generally consistent with findings from meta-analyses of brief interventions on alcohol consumption in primary care (36–38, 67).

Our review primarily addressed the effect of behavioral counseling interventions on patients identified as risky/harmful alcohol users and did not systematically address the performance of screening tests to identify these patients. We relied on the previous USPSTF recommendation and intervening systematic reviews by others for our conclusions about screening tests. We judged that methods to identify patients for the intervention trials and validated, feasible primary care screening tests (when coupled with clinical assessment) are sufficiently similar, after removing the burden imposed by research, although we did not test this assumption by this review.

The alcohol use outcomes relied on self-report, with occasional collateral verification, since there are no good objective measures of changes in alcohol use (81). Self-report of alcohol use has been found to be as accurate as or

more accurate than other measures if collected carefully, such as when elicited as part of a general health assessment by nonclinical personnel outside the clinical setting (82). Given that these conditions were often met in the trials reviewed and that we relied on finding net improvements in alcohol consumption patterns, we believe that self-reported alcohol consumption is a reasonable basis for the findings in this report.

We did not address health care interventions in settings other than primary care. Other settings, such as the emergency department or trauma units, may offer other important health care opportunities to address problematic alcohol use in patients.

Publication bias may also have affected our results. Although we located many unpublished or prepublished studies, we cannot be certain that we located all negative studies.

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Appendix

Methods

Analytic Framework and Key Questions

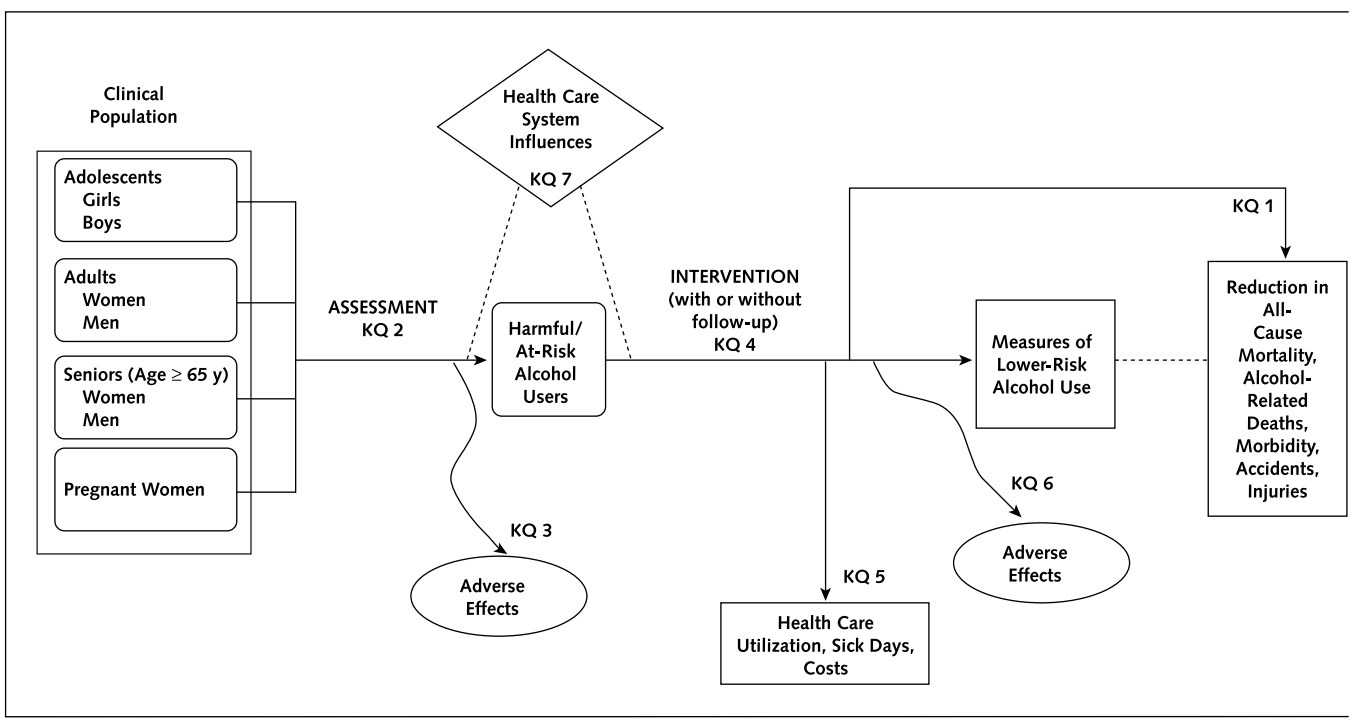
Using methods of the U.S. Preventive Services Task Force (USPSTF) (40), we developed an analytic framework and 7 key questions (KQs) to guide the review process (**Appendix Figure 1**). KQ 1 assessed direct evidence indicating that behavioral counseling interventions reduce morbidity or mortality. KQ 2 focused on methods used to identify appropriate target populations for alcohol-related behavioral counseling interventions in primary care. KQ 3 concentrated on adverse effects associated with alcohol use screening and screening-related assessment. KQ 4 addressed the effect of primary care identification and behavioral counseling interventions on risky/harmful alcohol use, and the essential elements of efficacious interventions. KQ 5 sought to identify other positive outcomes from behavioral counseling interventions to reduce risky/harmful alcohol use. KQ 6 addressed harms associated with behavioral counseling interventions. KQ 7 examined the context for interventions to reduce risky/harmful drinking by examining health care system influences present in effective screening, screening-related assessments, and behavioral interventions.

As a result of the emphasis of the last USPSTF recommendations on alcohol-related screening, and the availability of new research on brief counseling interventions, we concentrated our efforts on effects of brief primary care interventions to reduce alcohol use, on other intermediate outcomes of such interventions, and on associated health outcomes (KQs 1 and 4). We did not systematically review the evidence on the efficacy of screening tools, nor did we look for direct evidence that screening alone improves outcomes.

Search Strategy

Key Questions 1, 2, 4, 5, and 7. We searched the Cochrane Database of Systematic Reviews and Database of Research Effectiveness (DARE) (2001, issues 2 and 3; 2002, issue 1). We used an inclusive search strategy (*alcohol** or *drink**) to identify recent systematic reviews addressing brief interventions in primary care to reduce risky/harmful alcohol use. We found 5 recent systematic reviews of interventions (35–39). None of these adequately addressed our key questions: 1) They were conducted too long ago to include recent trials (37–39); 2) they mixed primary care and non–primary care settings (35, 37, 39); 3) they included dependent or comorbid drinkers or those not identified through the health care system, such as alcohol-drinking drivers (35, 37); or 4) they included poor-quality studies according to USPSTF criteria (36, 37, 39). More details on these reviews are available elsewhere (41). To identify relevant primary literature, we searched MEDLINE, Cochrane Controlled Clinical Trials, PsycINFO,

Appendix Figure 1. **Analytic framework and key questions (*KQs*).**



Appendix Table 1. **Literature Search Terms***

PsycINFO	
1	exp alcoholism/or exp Alcoholism/ or drinks$.mp. [mp = title, abstract, registry number word, MeSH term]
2	exp alcohol intoxication/ or exp alcohol drinking patterns/ or alcoholic intoxication.mp.
3	(binge drinking or heavy drinking or excessive alcohol or risky drinking or harmful drinking or hazardous drinking or excessive drinking or episodic drinking or heavier drinking).mp.
4	1 or 2 or 3
5	Limit 4 to treatment and prevention
6	(counsel$ or treatment or patient education or intervention$).mp.
7	exp rehabilitation education/ or exp drug education/ or exp drug abuse prevention/ or prevention.mp.
8	6 or 7
9	4 and 8
10	5 or 9
11	(randomized controlled trial$ or randomi$ or placebo$ or double blind or single blind or volunteer$ or control$ or prospective$).mp.
12	exp treatment effectiveness evaluation/
13	(clinical trial$ or research design$ or comparative stud$ or prospective stud$ or random allocation$).mp.
14	11 or 12 or 13
15	10 and 14
16	Limit 15 to (human and english language)
17	Limit 16 to yr = 1994–2002
MEDLINE	
1	(problem drink$ or alcohol$ or binge drinking or heavy drinking or excessive alcohol$ or risky drinking or harmful drinking or hazardous drinking).mp.
2	exp drinking behavior/ or exp alcohol-related disorders/
3	(heavy episodic$ or alcoholic intoxication).mp.
4	1 or 2 or 3
5	limit 4 to (clinical trial or clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial)
6	randomized controlled trials/ or randomized controlled trial$.mp. or randomi$.mp.
7	random allocation.mp. or exp clinical trials/ or double-blind method$.mp.
8	(single-blind method$ or clinical trial$ of placebo$).mp.
9	((single or double or treble or triple) adj (blind$ or mask$)).mp.
10	exp research design/ or research design$.mp. or comparative study/ or exp evaluation of studies/ or evaluation stud$.mp.
11	(follow-up studies or follow up stud$).mp. or prospective studies/or prospective stud.$.mp. or control$.mp. or prospective.mp. or volunteer$.mp.
12	6 or 7 or 8 or 9 or 10 or 11
13	4 and 12
14	5 or 13
15	limit 14 to (human and english language)
16	counseling/ or exp health education/ or (interview$ and motivat$).mp.
17	"Early Intervention (Education)"/
18	intervention studies/ or intervention.mp. or alcoholism/pc or exp drinking behavior/pc or prevent$.mp. or counsel$.mp.
19	17 or 18
20	15 and 19
21	limit 20 to yr = 1994–2001
HealthSTAR	
1	(problem drink$ or alcohol$ or binge drinking or heavy drinking or excessive alcohol$ or risky drinking or harmful drinking or hazardous drinking).mp.
2	exp drinking behavior/ or exp alcohol-related disorders/
3	(heavy episodic$ or alcoholic intoxication).mp.
4	1 or 2 or 3
5	limit 4 to (clinical trial or clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial)
6	randomized controlled trials/ or randomized controlled trial$.mp. or randomi$.mp.
7	random allocation.mp. or exp clinical trials/ or double-blind method$.mp.
8	(single-blind method$ or clinical trial$ or placebo$).mp.
9	((single or double or treble or triple) adj (blind$ or mask$)).mp.
10	exp research design/ or research design$.mp. or comparative study/ or exp evaluation studies/ or evaluation stud$.mp.
11	(follow-up studies or follow up stud$).mp. or prospective studies/ or prospective stud$.mp. or control$.mp. or prospective.mp. or volunteer$.mp.
12	6 or 7 or 8 or 9 or 10 or 11
13	4 and 12
14	5 or 13
15	limit 14 to (human and english language)
16	counseling/ or exp health education/ or (interview$ or motivat$).mp.
17	"Early Intervention (Education"/
18	intervention studies/ or intervention.mp. or alcoholism/pc or exp drinking behavior/pc or prevent$.mp. or counsel$.mp.
19	17 or 18
20	15 and 19
21	limit 20 to yr = 1994–2001
CINAHL	
1	exp alcoholism/ or exp Alcoholism/ or problem drink$.mp.
2	exp alcohol intoxication/ or exp alcohol drinking patterns/ or alcoholic intoxication.mp.
3	(binge drinking or heavy drinking or excessive alcohol or risky drinking or harmful drinking or hazardous drinking or excessive drinking or episodic drinking or heavier drinking).mp.
4	1 or 2 or 3
5	limit 4 to treatment and prevention
6	(counsel$ or treatment or patient education or intervention$).mp.
7	exp rehabilitation education/ or exp drug education/ or exp drug abuse prevention/ or prevention.mp.
8	6 or 7
9	4 and 8
10	5 or 9
11	(randomized controlled trial$ or randomi$ or placebo$ or double blind or single blind or volunteer$ or control$ or prospective$).mp.
12	exp treatment effectiveness evaluation/
13	(clinical trial$ or research design$ or comparative stud$ or prospective stud$ or random allocation$).mp.
14	11 or 12 or 13
15	10 and 14
16	limit 15 to (human and english language)
17	limit 16 to yr = 1994–2002
Cochrane Controlled Trials Registry	
1	Alcohol*
2	Drink*
3	1 or 2

*MeSH = Medical Subject Heading.

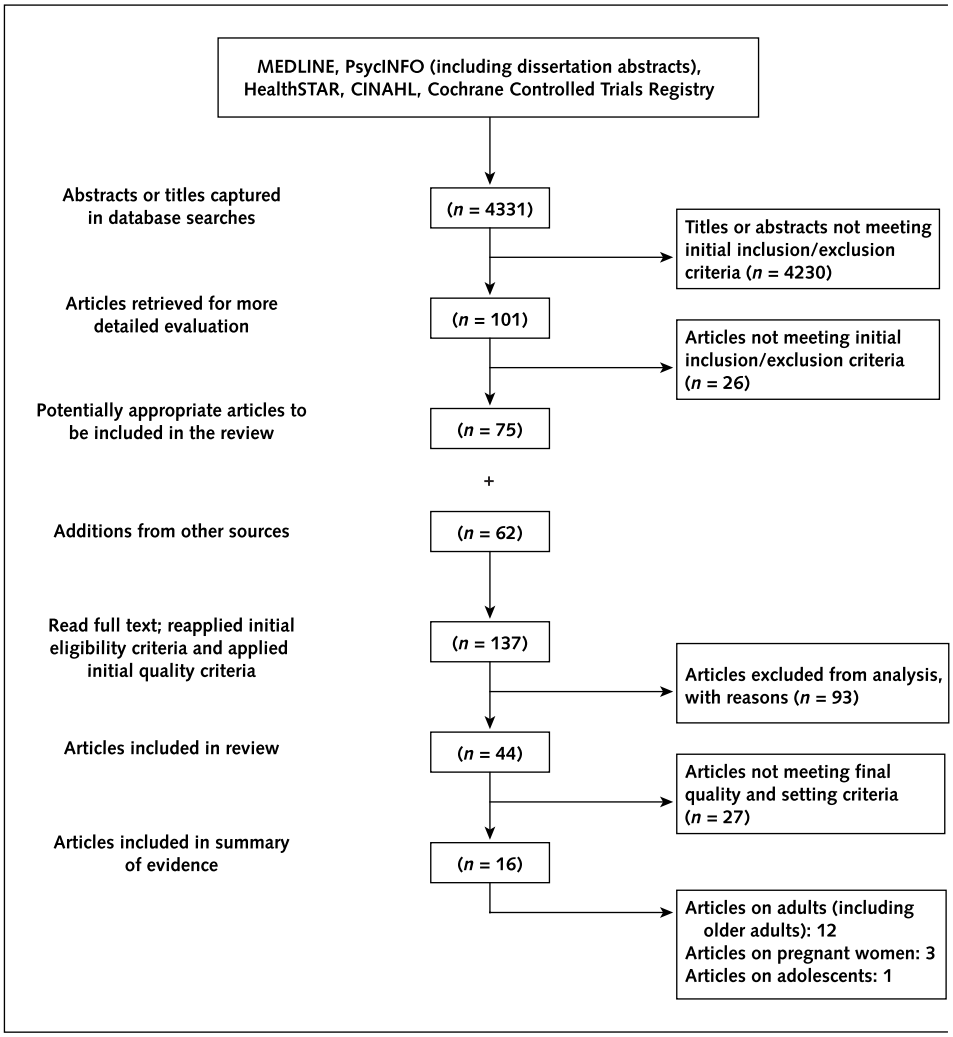
HealthSTAR, and CINAHL databases from 1994 through April 2002, using search strings detailed in **Appendix Table 1**. **Appendix Figure 2** shows results from this search (integrated with articles retrieved from outside sources).

Key Questions 3 and 6. We conducted searches in MEDLINE and PsycInfo from 1994 through April 2002, combining the terms described in **Appendix Table 1** with *adverse effects of screening* and *adverse effects of counseling* to identify any literature on the harms of alcohol screening, screening-related assessment, or intervention; none was found.

Inclusion and Exclusion Criteria

To be eligible for inclusion, a study had to be a randomized or controlled clinical trial of behavioral counseling interventions in risky/harmful drinkers conducted in a primary care setting, as defined in a recent Institute of Medicine report: "Primary care is the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community" (44). We excluded from this review other clinical settings, such as emergency departments and hospitals, specialty treatment, behavioral health, or community or school settings without clinics, to maximize the applicability of the review findings to primary care. Other exclusion criteria included non-En-

Appendix Figure 2. **Literature search and retrieval results.**



glish abstract, non–controlled trial study designs, population characteristics (age < 12 years, primarily dependent drinkers, comorbid populations such as patients with a dual diagnosis), or interventions without a behavioral intervention component.

Literature Review

Investigators reviewed 4331 nonduplicative titles and abstracts. A second investigator reviewed a random 35% of titles and abstracts for concordance. We found about 95% agreement in this dual review, and none of the 75 articles that met initial inclusion criteria were discrepantly coded. We also identified 62 outside source articles by contacting experts for unpublished studies, by reviewing bibliographies of all reviews and primary research articles located through database searching, and by retrieving all intervention trials cited in the alcohol screening chapter in the *1996 Guide to Clinical Preventive Services* (34). Titles and abstracts of all potentially included studies were re-reviewed for eligibility, and full-text articles retrieved from database searches and outside sources were assessed by using the same criteria. Quality of the articles was graded by using the USPSTF criteria (40), supplemented by guidelines on evaluating study randomization, attrition, and intention-to-treat analyses from the Cochrane Drug and Alcohol Group. A second investigator reviewed all included articles to confirm setting eligibility and quality ratings.

After we reapplied initial inclusion and quality criteria to the full text of 137 trials, 44 remained eligible. Of these, 27 were excluded; **Appendix Table 2** lists reasons for their exclusion (83–110). One trial that met final setting and quality criteria was not published in time for inclusion in this review (48). Twelve of the included studies addressed adults and are the basis for this paper; the 3 included studies that addressed pregnant women and 1 that addressed adolescents are reviewed elsewhere (41). An updated database search through February 2003 revealed no new trials.

Data Extraction, Reliability, and Validity Assessments

For included studies from any source, 1 of the authors abstracted relevant information using data abstraction forms. A sec-

Appendix Table 2. **Excluded Studies and Reasons for Exclusion***

Study, Year (Reference)	Population/Setting	Reason for Exclusion
Cordoba et al., 1998 (83)	Males age 14–50 y in Spain	Poor quality: 270/546 excluded from analysis (49%) because of loss to follow-up or nonadherence to protocol (60/270). Therefore, no intention-to-treat analysis. Unit of randomization was the primary care practice; unit of analysis was the patient. Other problems not listed because analytic approach represents a fatal flaw.
Dimeff, 1998 (PhD dissertation) (84); Dimeff and McNeely, 2000 (85)	College student health center patients in United States	Poor quality: Postrandomization attrition from both groups. Early dropouts from intervention group excluded from further analysis (did not use intention-to-treat design). Small sample (n = 36), short follow-up (30 days), very-low-intensity computer-based intervention.
Blair, 2000 (PhD dissertation) (86)	Undergraduate college students in United States	Poor quality: Nonrandomized allocation to treatment and control; participants were "assigned." Unequal assignment to treatment (n = 74) vs. control (n = 103) from using pilot study participants to increase sample size. Assembly of comparable groups at baseline was not reported. Loss to follow-up was significant at 4-wk follow-up (20/74 in treatment and 29/103 in controls). Outcomes in pre- and post-test design could not be matched between individuals at baseline and follow-up.
McIntosh et al., 1997 (87)	United States	Poor quality: Unclear allocation concealment with baseline noncomparability between comparison group numbers and probable differences in alcohol quantity and frequency measures, particularly among women. Inadequate power for analyses, including all participants at baseline; thus, results reported by sex subgroups must be underpowered.
Burton et al., 1995 (88)	United States	Poor quality: Single alcohol outcome measure not clearly defined; presumed measure (change in lifetime CAGE responses) is insensitive and lacks content, concurrent, and predictive validity for improvement among problem drinkers addressed as part of this population-based multifactorial risk factor intervention.
Aalto et al., 2000 (89)	Finland	Poor quality: Inadequate allocation concealment, with intervening physician "drawing a card" to assign randomization condition to patients during intervention. 34% overall loss to follow-up with large differences between groups that could affect results, even though not statistically significant, possibly because of small sample sizes. No replacement of missing values in analyses. Unclear blinding of participants or outcome assessors and unclear intervention delivery.
Aalto et al., 2001 (90)	Finland	Poor quality: Inadequate allocation concealment, with intervening physician "drawing a card" to assign randomization condition to patients during intervention. Unequal number of participants in comparison groups at baseline. 32% overall loss to follow-up with large differences between groups that could affect results, even though not statistically significant, possibly because of small sample sizes. No replacement of missing values in analyses. Unclear blinding of participants or outcome assessors and unclear intervention delivery.
Logsdon et al., 1989 (91)	United States	Poor quality: Use of single alcohol outcome measure without definition of how measured at baseline and how change was quantified. Otherwise well-conducted feasibility controlled clinical trial of multifactorial preventive intervention in primary care.
Persson and Magnusson, 1989 (92)	Sweden	Poor quality: Alcohol consumption measures reported for intervention groups but not controls. Unclear allocation concealment and 31% overall attrition rate. Unclear blinding of participants or outcome assessors.
Heather et al., 1987 (93)	Scotland	Poor quality: Less than half of intended intervention participants received the full intervention because of difficulties with implementation design. Postrandomization exclusions of participants with numbers not reported.
Israel et al., 1996 (94)	Canada	Poor quality: Loss to follow-up 30%, with no adjustment for missing data at follow-up. Baseline comparison of study group composition unclear.
Waterson and Murray-Lyon, 1990 (95)	England	Poor quality: Concealment of allocation a concern because clinics were assigned to conditions nonrandomly. High and differential attrition between groups (41% and 50% to first follow-up assessment, 26% and 66% at second follow-up assessment), which analyses do not address, reduce interpretability of findings.
Kristenson et al., 1983 (96)	Sweden	Poor quality: High attrition at first follow-up (2 y): 41% in intervention group, 27% in control group; unclear blinding at follow-up assessment.
Heather et al., 1987 (97)	Scotland	Excluded setting and poor quality: Media-recruited problem drinkers received 2 levels of self-help intervention. Attrition rate 55% with differences between groups and no replacement of missing values in analysis.
Antti-Poika et al., 1988 (98)	Finland	Excluded health care setting: Nurse and physician counseling of hospitalized injured male patients who screened as heavy drinkers or alcoholics was evaluated in randomly assigned intervention vs. controls.
Blondell et al., 2001 (99)	United States	Excluded health care setting: Brief physician intervention with and without peer intervention was compared to usual care among non–randomly assigned patients hospitalized for alcohol-related injuries.
Elvy et al., 1988 (100)	New Zealand	Excluded health care setting: Evaluation of inpatient referral of hospitalized problem drinkers.
Forsberg et al., 2000 (101)	Sweden	Excluded health care setting: Randomized comparison of brief vs. extensive alcohol intervention in an emergency surgical ward by surgical staff.
Gentilello, 1997 (102)	United States	Excluded health care setting: Randomized comparison of subsequent alcohol consumption and emergency department visits among alcohol-affected patients receiving an on-site intervention in a trauma center vs. controls.
Gentilello et al., 1999 (103)	United States	Excluded health care setting: Randomized comparison of reinjury rates among alcohol-affected patients in a level 1 trauma center receiving brief intervention vs. controls.
Heather et al., 1996 (104)	Australia	Excluded health care setting: Controlled trial of brief motivational interviewing, skills-based counseling, or usual care on alcohol consumption after discharge among hospitalized male heavy drinkers.
Monti et al., 1999 (105)	United States	Excluded health care setting: Randomized comparison of brief motivational interviewing or usual care on alcohol-related consequences among adolescents seen in the emergency department.
Watson, 1999 (106)	Scotland	Excluded health care setting: Comparison of 3 brief nursing interventions to reduce alcohol consumption on potential problem drinkers in general hospital wards.
Welte et al., 1998 (107)	United States	Excluded health care setting: Comparison of risk reduction intervention with treatment referral or usual care among general hospital patients at risk for (or with) alcohol dependence.
Romelsjo et al., 1989 (108)	Adults age 18–64 y in Sweden	Poor quality: Randomization process was not simple but rather a quota sample, stratified on general practitioner and then on practice. Masking of general practitioner not assured. Significant postrandomization exclusion (151/258 participants). Inclusion criteria not adequately applied, resulting in missing most eligible persons based on drinking (and not laboratory levels). Noncomparable groups assembled at baseline with respect to alcohol consumption and problems and no adjustment for differences. Attrition rate relatively low (11/83) and nondifferential. Does not appear to be intention-to-treat analysis because some cases followed up were not included in reported analyses. No statistical testing of results reported.

Continued on following page

Appendix Table 2—**Continued**

Study, Year (Reference)	Population/Setting	Reason for Exclusion
Oliansky et al., 1997 (109)	Adults age 18–55 y, adolescents age 12–18 y, women age 18–55 y in United States	Poor quality: Three different populations in 3 different clinics were "randomly" assigned to intervention vs. control conditions. In 2 clinics, random assignment was based on odd/even medical record numbers. In the third, the randomization method was not described. Comparability of intervention and control groups at baseline was not reported. The intervention was not clearly defined. The measures used to determine eligibility for the study and to measure outcomes (Substance Use Screening Instrument [SUSI]) is a novel instrument developed for this project. Study is reported as being based on AUDIT and CAGE but does not provide the actual items included in SUSI. Loss to follow-up was up to 39% in 1 clinic and was greater in intervention conditions if there were equal numbers in intervention and control groups initially (cannot be sure from report). Maintenance of comparable groups not reported. Outcomes were reported for all substances combined (alcohol, tobacco, and other drugs of abuse).
Tomson et al., 1998 (110)	Adults age 25–54 y in Sweden	Poor quality: Unequal randomization results (intervention $n = 100$, control $n = 122$) without rationale. Comparability of intervention and control groups at baseline not assured because control group not assessed for CAGE or alcohol consumption at baseline. Change in CAGE and alcohol consumption not measured in control group; therefore, measures not equal. Possible contamination of control condition by receipt of general practitioner intervention. High attrition rates (50%–62%), with loss to follow-up greater in the intervention condition. Analyses do not account for baseline differences and no test of between-group differences for primary outcomes (except γ-glutamyltransferase).

* AUDIT = alcohol use disorders identification test (10-item instrument for risky/harmful use); CAGE = 4-item screening questionnaire to detect alcoholism.

ond author checked all key data that appear in the evidence tables. All studies were abstracted onto standardized data abstraction forms developed for this review (available elsewhere [41]). Data abstraction forms addressed 3 main issues: 1) study recruitment, randomization, and attrition (adapted from CONSORT [Consolidated Standards of Reporting Trials]) (111); 2) study design, conduct, and results; and 3) study quality (40, 47). Selected abstraction details are described in the next section. One of 2 research assistants separately audited available study outcomes. At least 2 authors conducted a quality review audit of each study (**Appendix Figure 3**), emphasizing the key aspects of quality in this literature (allocation concealment, attrition and replacement of missing values, baseline and final comparability of groups, adequate intervention delivery, and masking of patients and outcome assessment). The final quality rating for each study (good, fair, poor) reported in the evidence tables was assigned by consensus of the investigator team.

Study Characteristics Extracted during Review

Study Identification. We abstracted author, year published, type of trial, setting, and definition of a standard drink used in each study.

Study Participants. We abstracted the total number randomly assigned to the study, the sex and racial distribution of participants, participants' baseline alcohol consumption, the proportion of participants who were alcohol-dependent, and the proportion who were motivated or help-seeking or thought they had a problem with alcohol. When sociodemographic or other baseline information on total study participants was unavailable, we reported intervention group characteristics in evidence tables.

Intervention and Control Conditions. Information abstracted included whether alcohol screening or screening-related assessment was masked within a more general lifestyle assessment; intervention and control protocols; whether the intervention involved personal contact; the intensity of personal contact (number of contacts and contact minutes); whether intervention delivery was measured and what percentage of participants received it; all provider types involved; the use of usual care or other clinical or research personnel; components of the intervention (detailed below); and reported adverse effects of screening or intervention. The intervention components we abstracted are considered important elements in brief interventions (25, 31, 34, 49):

1. Advice to reduce current drinking and/or about guidelines for low-risk use.

2. Feedback about current drinking patterns, problem indicators (such as laboratory results), or medical consequences of current use patterns.

3. Explicit goal-setting, usually for moderation and not abstinence.

4. Assistance in achieving the goal, including providing a menu of options for change, helping patients develop skills for managing high-risk drinking situations (for example, recognizing antecedents, planning ahead, pacing drinking), coping with problems without drinking, and providing self-help materials.

5. Providing follow-up in the form of telephone calls, repeat visits, or repeated monitoring of laboratory test results, physical examinations, and the like.

These components map to the 5 A's (assess, advise, agree, assist, arrange) adopted by the USPSTF for reporting the results of behavioral counseling interventions (69). We also evaluated the presence or absence of tailoring described as part of the intervention.

Outcomes. A large variety of alcohol use variables and measures reflecting different definitions of problematic use were reported in different studies (for more information, see **Table 1** in full systematic evidence review [41]). To facilitate comparison between studies, we chose 3 primary alcohol use outcome categories commonly reported in epidemiologic and intervention literature: average consumption, binge use, and safe/moderate/recommended use. We preferentially report the outcome measures as reported by the study authors, or, where necessary, we used established methods to recalculate reported study data into more comparable outcome measures (112). For average use outcomes, we abstracted the absolute follow-up levels (or change from base-

Appendix Table 3. **Evidence Table***

Study, Year (Reference)	Type of Trial, Setting, and Standard Drink	Participant Selection	Behavioral Intervention	Outcomes at 12 mo	Generalizability	Study Summary
Richmond et al., 1995 (61)	Controlled clinical trial in 40 primary care practices involving 119 general practitioners Australia Standard drink = 10 g ETOH	378 adults (age, 18–70 y) attending primary care visits who drank >35 drinks/wk (men) or >21 drinks/wk (women) Mean age: 39 y Women: 43% Nonwhite: NR Smokers: NR "Moderate alcohol dependence": 25%–42% Baseline alcohol consumption: mean, 38.5 drinks/wk Alcohol assessment: 2-step alcohol assessment in the waiting room before a routine visit. Patients self-administered 3-min Health and Fitness Questionnaire assessing alcohol, smoking, exercise, and weight; if results were "positive," 15-min interview assessment by research assistant including drinking diary for past week.	IG1 (n = 93) had alcohol assessment results placed on the chart for their visit with their usual PCP. IG2 (n = 96) received results of the assessment and brief (5 min) within-visit physician advice and a self-help manual. Intervention included advice and assistance. Delivery: Not assessed for IG1 or IG2. IG3 (n = 96) received the same brief advice intervention with 4 additional 15- to 20-min provider visits at 1 wk, 1 mo, 3 mo, and 5 mo. Delivery: 51% got only single visit (IG2 protocol). CG (n = 93) assessment results not put on chart. Not followed at 12 mo.	Note: For IG1 and IG2 only because intervention delivery inadequate for IG3. Mean drinks/wk† Women: IG1: 21.5 IG2: 24.2 Men: IG1: 36.2 IG2: 39.3 Binge/heavy drinking episodes: NR Not exceeding recommendations—≤28 units for men; ≤14 units for women (calculated from intention-to-treat analysis): IG1: 21.5% IG2: 22.9% (P = NS)	Broadly includes heavier drinkers (one third "moderately dependent") attending primary care. Excludes persons with severely dependent/severe alcohol-related problems, persons with previous or current alcohol treatment, or those for whom any alcohol consumption was contraindicated. Systems support: Usual care providers "trained." Receptionist or research assistant screened patients and prompted physician. No incentives.	Fair quality: Nonrandom assignment to study conditions could have allowed manipulation. True control condition follow-up not assessed. Possible contamination between IG1 and IG2. Delivery of IG3 inadequate to differentiate it from IG2. Baseline and follow-up noncomparability of groups on several measures, not controlled in all analyses. Very brief intervention (IG2) and assessment only (IG1) reduced consumption at 12 mo with no significant differences between conditions.
WHO Brief Intervention Study Group, 1996 (58)	RCT in various outpatient medical settings 8 countries including United States Standard drink = 1.5 cL ETOH (14 g or 0.5 oz)	1559 adults (age, 18–70 y) who drank >50 g ETOH/d (men) or 32 g ETOH/d (women) OR 6 or more drinks/occasion Mean age: NR Women: 19.2% Nonwhite: NR Smokers: NR Baseline alcohol consumption: NR Alcohol assessment: 2-step process: initial screening interview followed by 20-min face-to-face health interview addressing alcohol and other lifestyle issues.	IG1 (n = 503) received 5 min of health advice from a "health advisor" (46% RNs, 18% MD, 35% other) as part of a routine primary care visit. Intervention included feedback, advice, goal-setting. Delivery: NR. IG2 (n = 565) received 15 min of brief counseling from health advisor who also addressed behavioral techniques as part of the routine visit. Some sites offered 3 follow-up visits. Intervention included feedback, advice, goal-setting, assistance, follow-up (for some subsets). Delivery: NR. CG (n = 491) received assessment only.	Outcomes assessed at 6–19 mo (mean, 9 mo) Average cL of alcohol/d Men: IG1: 5.29 IG2: 5.18 CG: 6.29 (P < 0.001) Women: IG1: 2.99 IG2: 3.39 CG: 3.80 (P = NS) Average cL of alcohol per drinking occasion: Men: IG1: 10.16 IG2: 10.01 CG: 11.23 (P < 0.01) Women: IG1: 5.96 IG2: 6.27 CG: 6.83 (P = NS) Mean drinks/wk: NR Binge/heavy episodes: NR Reporting drinking within recommended weekly limits (no more than 24 cL of ETOH/wk for men or 13.3 cL of ETOH/wk for women): Men: IG1: 43% IG2: 43% CG: 35% (P < 0.05) Women: IG1: 43% IG2: 39% CG: 35% (P = NS)	Broadly includes multicultural, heavier-drinking primary care patients, many of whom may have been help-seeking. Excludes known or suspected alcoholics or very high daily consumers, those with prior liver damage or alcohol dependence treatment, and those warned by MD or other health professional to abstain. Systems support: Some provider training reported. No incentives reported.	Fair quality: Limited information with which to evaluate study quality regarding baseline comparability of groups and maintenance of comparable groups. Potential for contamination exists since different interventions were delivered by same interventionists. Very brief and brief interventions reduced daily alcohol consumption in men at an average of 9-mo follow-up compared with assessment only. Some interventions could have been brief multicontact. Among women, all groups significantly reduced consumption at follow-up without between-group differences.

Appendix Table 3—**Continued**

Anderson and Scott, 1992 (54)	RCT conducted in 8 community-based primary care group practices England Standard drink = 10 g ETOH	154 male patients (age, 17–69 y) registered with practices who exceeded 35 drinks/wk Mean age: 45.1 y Women: None Nonwhite: NR Smokers: NR Baseline alcohol consumption: 52 drinks/wk. Binge drinking: 43% Alcohol assessment: 2 steps: self-administered Health Survey Questionnaire by mail or in waiting room. If participants drank >35 drinks/wk, they were invited to structured assessment interview of alcohol use with research staff outside clinic.	IG (n = 80) received 10-min face-to-face visit with usual PCP at special visit scheduled after assessment. Intervention included advice and feedback. Delivery: NR. CG (n = 74) received no intervention after assessment unless requested.	Change in mean drinks/wk: IG: −15.7 CG: −9.2 (P = 0.06) Not bingeing: IG: 77.50% CG: 60.81% (P < 0.05) Attained low-risk drinking as measured by ≤22 drinks/wk: IG: 17.50% CG: 5.41% (P < 0.05)	Broadly includes heavier drinking (up to 105 drinks/wk) male primary care patients. 41% of patients had abnormal dependence scores. Excludes those drinking >105 drinks/wk and those who received advice to cut down in previous year. Systems support: Provider training (15–30 min). Research staff did alcohol assessment entirely outside clinic. No incentives.	Good quality: Relatively high attrition levels (IG, 31%; CG, 39%), but these were addressed by replacing missing values with baseline consumption levels. Otherwise overall good-quality criteria met. This brief intervention showed improved low-risk drinking, improved bingeing, and nearly significant changes in mean drinks/wk.
Maisto et al., 2001 (60)	RCT in 12 primary care clinics United States Standard drink = 0.6 oz ETOH	301 patients of primary care practices age ≥21 y with AUDIT score ≥8 OR ≥16 drinks/wk (men) or ≥12 drinks/wk (women) Mean age: 45.5 y Women: 32% Nonwhite: 23% Smokers: NR Baseline alcohol consumption: 5.5 drinks/drinking day Alcohol assessment: Self-adminstered AUDIT embedded in lifestyle questionnaire. If results were "positive," face-to-face structured 30-day TLFB alcohol assessment interview including AUDIT and Q/F questions, laboratory test, and blood pressure. Assessment results for all participants forwarded to PCP.	IG1 (n = 100) immediately after assessment received 10- to 15-min "brief advice" from research staff, which intentionally limited patient input. Intervention included feedback, advice, goal-setting. Delivery: 93% got brief advice session. IG2 (n = 101) received 30- to 45-min "motivational enhancement" session from research interventionist and two 15- to 20-min booster sessions. Intervention included feedback, advice, goal-setting, assistance, and follow-up. Delivery: 91% ≥1 session and 69% all 3 sessions. CG (n = 100) had assessment results forwarded to PCP.	Change in mean drinks/drinking day: IG1: −0.79 IG2: −0.64 CG: −0.85 (P = NS) Change in mean drinks/wk: IG1: −8.3 IG2: −5.5 CG: −3.6 (P = NS) Binge/heavy episodes: NR Reporting benefit: NR	Broadly includes primary care patients with risky/harmful drinking. Excludes those with acute alcoholic symptoms or recent substance abuse treatment. Not clearly applicable to primary care because there were no definite or clear provider/clinical staff roles. Systems support: Research staff provided all assessment and intervention. No provider training reported. Participants were paid for all assessments except the initial one.	Fair quality: Fairly high loss to follow-up (23%) with intention-to-treat analysis of complete cases only (no replacement of missing values). Unclear blinding of participants and outcomes. Potential contamination between levels of IG (since IG1 could have gotten more intensive intervention) and between IG and CG (since all participants' doctors received assessment results, but unclear how or if these were acted upon). Two intensities of motivational interviewing–based interventions by nonclinical staff showed null effects with similar reductions in alcohol consumption among interventions and control.
Nilssen, 1991 (57)	RCT conducted within The Tromso Study Norway Standard drink: NR	338 community-dwelling adults who met high-risk alcohol use criteria (drinking ≥1 bottle of wine or equivalent per occasion 1–2 times per mo OR drinking alcohol 2–3 times weekly) AND elevated GGT levels (45–200 U/L) Mean age: 42 y (approximately) Women: 14% Nonwhite: NR Smokers: 56% (approximately) Baseline alcohol consumption: NR Alcohol assessment: Population-based coronary heart disease risk factor screening of men age 12–62 y and women age 12–56 y included physical examination, laboratory tests, and questions about alcohol consumption along with other health behaviors. Risk group randomly assigned.	IG1 (n = 113) invited by letter to re-examination for "elevated blood test"; received information on causes of elevated GGT level (including alcohol) and had GGT redrawn. Mailed repeated GGT results and invited to re-screen at 1 y. Interventions included feedback assistance and letter follow-up. IG2 (n = 113) also invited by same letter to re-examination; intervention focused on further assessing and addressing alcohol consumption. GGT redrawn and repeated visits with laboratory tests offered until GGT level normalized. Interventions included feedback assistance and letter follow-up. Delivery: NR. CG (n = 112) had no alcohol-related contact.	Mean alcohol consumption, g/d: IG1: 15.6 IG2: 13.5 CG: 39.2 (P < 0.001) Bingeing: NR Reporting benefit: NR	Targeted "early-stage problem drinkers" (those with moderately increased GGT levels and self-reported increased alcohol intake) and did so among people already willing to participate in a heart disease risk assessment at outpatient clinic setting. Excluded known alcoholics. Systems support: Staff and training not clear. No incentives reported.	Fair quality: Report inadequately covers allocation concealment or blinding for participant or outcome assessment. Comparability of groups at baseline or follow-up not clear. Not clear who delivered the interventions or the potential for contamination. Brief intervention and brief, multicontact interventions among more severely affected problem drinkers reduced daily alcohol consumption compared with no intervention.
Scott and Anderson, 1990 (59)	RCT in 8 community-based primary care practices England Standard drink = 1 unit (10 g ETOH)	72 women (age, 17–69 y) registered with the practices who consumed 21–71 units of alcohol/wk Mean age: 44 y Women: 100% Nonwhite: 17% Smokers: NR	IG (n = 33) received 10-min face-to-face visit with usual PCP at special visit scheduled after assessment. Interventions included feedback and advice. Delivery: NR. CG (n = 39) received nothing after assessment unless requested.	Change in mean drinks/wk: IG: −11.6 CG: −10.0 (P = NS) Not bingeing at follow-up (≥14 units on ≥2 occasions in previous 3 mo):	Broadly includes heavier-drinking (up to 71 drinks/wk) female primary care patients. >50% of had abnormal dependence score. Excludes women consuming ≥71 units/wk or those who received advice to cut down alcohol use in previous year.	Fair quality: Noncomparable groups at baseline for percentage with abnormal dependence scores. Unclear allocation concealment. Intervention delivery uncertain and control possibly contaminated. Inadequate power.

Continued on following page

Appendix Table 3—**Continued**

Study, Year (Reference)	Type of Trial, Setting, and Standard Drink	Participant Selection	Behavioral Intervention	Outcomes at 12 mo	Generalizability	Study Summary
		Abnormal alcohol dependence scores; IG, 73%, CG, 41% Baseline alcohol consumption: 35.3 mean drinks/wk Alcohol assessment: 2-step alcohol and lifestyle assessment by research staff; if findings on self-administered survey were "positive," research staff conducted assessment interview, including 1-wk drinking diary.		IG: 87.9% CG: 84.6% (P = NS) Attained low-risk drinking (Health Survey Questionnaire ≤22 drinks/wk): IG: 27% CG: 26% (P = NS)	Systems support: Provider training (15–30 min). Research staff conducted all alcohol assessment outside clinic. No incentives.	Brief intervention in heavier-drinking women showed null effects on all alcohol consumption and other outcome measures. Both groups comparably reduced alcohol consumption.
Senft et al., 1997 (56)	RCT conducted in 3 large primary care HMO group practices (47 clinicians) Oregon and Washington Standard drink = 0.5 oz ETOH	516 adults age >21 y attending primary care visits with AUDIT score 8–21 OR 2 AUDIT Q/F item scores >5 OR ≥6 drinks/occasion at least weekly Mean age: 41.9 y Women: 28% Nonwhite: 17% Smokers: 50% Baseline alcohol consumption: 16.5 mean drinks/wk Binge drinking: 27% Alcohol assessment: Self-administered AUDIT-based alcohol use survey in waiting room.	IG (n = 260) received 30 s of advice from their usual PCP during the visit, immediately followed by a 15-min motivational interviewing–based session with a research health counselor. Intervention included advice, goal setting, and assistance. Delivery: 70% received advice and MI session. CG (n = 256) received usual care after assessment.	Mean drinks/wk (calculated from total drinks in prior 3 mo): All participants: IG: 13.1 CG: 14.9 (P = 0.13) Women: IG: 8.9 CG: 9.2 (P > 0.2) Men: IG: 14.7 CG: 17.5 (P = 0.08) Reporting no binge drinking: IG: 77% CG: 77% (P = NS) Reporting no more than 3 drinks/d for men and 2 drinks/d for women: IG: 80% CG: 73.1% (P = 0.07)	Broadly includes risky/harmful adult drinkers in primary care. Excludes dependent drinkers, those with AUDIT score >21. Systems support: Providers prompted with script to give advice only; research staff delivered assessment and most of intervention. No incentives.	Good quality: Although loss to follow-up of 20% overall (and differentially greater in IG), with dropouts less educated, missing values replaced in sensitivity analysis with no impact on reported results. Otherwise, overall good-quality criteria met. Brief intervention with no effects on average consumption or bingeing; modest intervention effects, primarily on total drinking days for women at 12 mo. Mean drinks were reduced at 6 mo (P = 0.04) but not at 12 mo (P = 0.13). IG tended toward more benefit (drinking within recommended limits) at 12 mo. Screening, recruitment, and intervention all occurred at a single primary care visit.
Curry et al., 2003 (50)	RCT conducted in HMO-based primary care practices with patients of 23 clinicians Washington Standard drink = 14 g ETOH	307 adults with AUDIT score ≤15 and risky use in past month: ≥2 mean drinks/d OR ≥2 occasions of ≥5 drinks OR driving after ≥3 drinks, who kept primary care appointments Mean age: 48.2 y Women: 36% Nonwhite: 20% Smokers: 27% Baseline alcohol consumption: 14.9 mean drinks/wk Binge drinking: 34% Alcohol assessment: Researchers assessed alcohol use in 10- to 15-min general health telephone interview (including AUDIT, alcohol use questions addressing Q/F, bingeing, driving after alcohol use) before scheduled routine visit.	IG (n = 151) received very brief (1–5 min) motivational message from their PCP and self-help manual at routine visit, plus up to 3 telephone counseling calls from research health educator. Intervention included feedback, advice, goal-setting, assistance, tailoring, and follow-up contact. Delivery: 99% got provider intervention and materials; 87% got at least 1 call. CG (n = 156) received usual care after assessment.	Mean drinks/wk: IG: 10.6 CG: 10.6 (P > 0.2) Reporting not bingeing: IG: 86% CG: 81% (P > 0.2) Reporting no at-risk drinking pattern (outcomes adjusted for missing data at follow-up): IG: 57% CG: 43% (P = 0.048)	Includes broadly defined risky/harmful adult drinkers with advance primary care appointments. Excludes persons with AUDIT score >15 and known alcoholics. Systems support: Provider training (15–60 min); research staff put intervention materials on chart and conducted assessment and follow-up calls. No incentives.	Good quality: Although high differential loss to follow-up (IG, 34%; CG, 22%), replacement of missing values using multiple imputation procedures in analysis. Otherwise, met overall good-quality criteria. Brief, multicontact intervention with minimal provider burden and multiple follow-up contacts was clearly delivered and reduced at-risk drinking patterns at 12 mo. No effects on average consumption.
Fleming et al., 1997 (53)	RCT conducted in 17 community-based primary care practices (64 physicians) in practice-based research network Wisconsin Standard drink = 12 g ETOH	774 adult patients (age, 18–65 y) with routine primary care visits who met "problem drinking" criteria: ≥2/4 CAGE questions OR men >14 drinks/wk OR ≥5 drinks/occasion; women>11 drinks/wk or ≥4 drinks/occasion Mean age: NR	IG (n = 392) had 2 brief visits scheduled 1 mo apart with usual PCP plus a call from clinic nurse 2 wk after each visit. Intervention included feedback, goal setting, assistance, and follow-up. Delivery: 76% completed the protocol and received both physician visits.	Mean drinks/wk: All participants: IG: 11.48 CG: 15.46 (P < 0.001) Women: IG: 8.03 CG: 13.20 (P <0.001)	Broadly includes lower-level risky/harmful drinkers visiting primary care. Excludes heavier users (>50 drinks/wk) and those with alcohol treatment or symptoms of withdrawal in previous year or who recently	Good quality: Low levels (≤10%) slightly differential loss to follow-up, but intention-to-treat with replacement of missing values. All other good-quality criteria met. Brief, multicontact intervention by the usual care PCP

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Appendix Table 3—**Continued**

		Women: 38% Nonwhite: 6% to 12% (approximately) Smokers: 55% (approximately) Baseline alcohol consumption: 19.1 mean drinks/wk Binge drinking: 85% Alcohol assessment: Self-administered Health Screening Survey (embedding CAGE and alcohol Q/F questions) in waiting room. If results were "positive," then 30-min face-to-face lifestyle interview (including 7-day TLFB alcohol review) by research personnel.	CG (n = 382) received usual care after assessment.	Men: IG: 13.62 CG: 16.86 ($P < 0.005$) No bingeing in past 30 days: All participants: IG: 52.04% CG: 31.68% ($P < 0.001$) Women: IG: 52.7% CG: 34.7% ($P < 0.025$) Men: IG: 51.6% CG: 29.8% ($P < 0.001$) Not drinking excessively: All participants: IG: 84.7% CG: 68.9% ($P < 0.001$) Women: IG: 85.1% CG: 66.0% ($P < 0.001$) Men: IG: 84.4% CG: 70.6% ($P < 0.005$)	received MD advice to change alcohol use. Systems support: Provider training (1 h followed by two 30-min booster sessions); research staff did all assessment; clinic nurses provided follow-up calls. Providers were paid $300 to participate and patients were paid $50 to complete study procedures.	reduced alcohol consumption in men and women and reduced proportions bingeing at 12 mo compared with no intervention. Women showed the greatest treatment effects.
Fleming et al., 1999 (51)	RCT conducted in 24 community-based primary care practices with 43 MDs in practice-based research network Wisconsin Standard drink: 12–14 g ETOH	158 adults age ≥65 y with scheduled visits who met hazardous drinking criteria: >2/4 CAGE questions OR men >11 drinks/wk or ≥4 drinks/occasion; women >8 drinks/wk or ≥3 drinks/occasion Age range: 65–75 y Women: 34% Nonwhite: NR Smokers: 10% Baseline alcohol consumption: 16 mean drinks/wk Binge drinking: 49% Alcohol assessment: 2-step alcohol and lifestyle assessment by research staff: if results on self-administered modified Health Screening Survey (including CAGE and alcohol Q/F questions) were "positive," then 30-min face-to-face lifestyle interview (including 7-d TLFB alcohol review).	IG (n = 71) had 2 brief 10- to 15-min visits scheduled 1 mo apart with usual PCP plus calls from clinic nurse 2 wk after each visit. Intervention included feedback, goal setting, assistance, and follow-up. Delivery: 94% received at least 1 physician visit. CG (n = 87) received a general health booklet after assessment.	Mean drinks/wk at 12 mo: IG: 9.9 CG: 16.3 ($P < 0.001$) Binge episodes in previous 30 d: IG: 1.8 CG: 5.4 ($P < 0.005$) Not bingeing: IG: 69.2% CG: 50.8% ($P < 0.025$) Not drinking excessively: IG: 84.6% CG: 65.7% ($P < 0.005$)	Broadly includes lower-level risky/harmful elderly persons (age ≥65 y) visiting primary care. Excludes heavier users (>50 drinks/wk) and those with alcohol treatment or symptoms of withdrawal in previous year or who recently received MD advice to change alcohol use. Systems support: Provider training provided; research staff did all assessment; clinic nurses provided follow-up calls. Providers were paid $250 to participate and patients were paid $70 to complete study procedures.	Good quality: Met overall good-quality criteria. Brief multicontact intervention among fairly stable (75% married) adults age ≥65 y reduced risky/harmful alcohol use at 12 mo for all alcohol consumption measures, including those relating to binge use. Effects were even greater than those seen with comparable-intensity interventions in younger adults and occurred by 3 mo. Self-reported alcohol use was corroborated by family members.
Ockene et al., 1999 (52)	RCT conducted in 4 primary care academic medical sites with 46 MDs and 47 NPs Massachusetts Standard drink = 12.8 g ETOH	530 adults seeking routine primary care who screened as "high-risk drinker" (≥2/4 CAGE questions OR men >12 drinks/wk OR ≥5 drinks/occasion in past mo; women >9 drinks/wk OR ≥4 drinks/occasion in past mo), and who made a primary care visit Age range: 21–70 y Women: 32% Nonwhite: 4.3% Smokers: 33.6% Baseline alcohol consumption: 18.9 mean drinks/wk Binge drinking: 70% Alcohol assessment: 2-step alcohol and lifestyle assessment by research staff:	IG (n = 274) received brief (5–10 min) face-to-face intervention tailored to patients' problem alcohol use from usual MD/NP at routine visit and were asked to make a follow-up appointment. Intervention included advice, goal setting, assistance, tailoring, and follow-up. Delivery: 99% reported provider discussion and 59% had follow-up visit within 6 mo. CG (n = 256) received general health pamphlet after assessment.	6-mo outcomes only: Change in mean drinks/wk: All participants: IG: −6.0 CG: −3.1 (P = 0.003) Women: IG: −6.8 CG: −3.5 (P = 0.003) Men: IG: −5.6 CG: −2.9 (P = 0.05) Not bingeing at 6 mo (calculated):	Includes broadly defined risky/harmful adult drinkers who have recently used primary care. Excludes those already in alcohol intervention program. Systems support: Provider training (2.5 h); research staff put intervention materials on chart and provided assessment. No incentives.	Good quality: Met overall good-quality criteria. Brief multicontact intervention with follow-up visit showed significant reductions in change in mean drinks/wk at 6 mo, even after adjustment for age, sex, and baseline drinking levels, and significantly improved proportion drinking safely. Binge use insignificantly improved.

Continued on following page

Appendix Table 3—**Continued**

Study, Year (Reference)	Type of Trial, Setting, and Standard Drink	Participant Selection	Behavioral Intervention	Outcomes at 12 mo	Generalizability	Study Summary
		if findings on self-administered or interview-based Health Habits Survey (including CAGE and alcohol Q/F questions) were "positive," then 20- to 35-min lifestyle interview (including 7-day TLFB alcohol review).		IG: 31% CG: 26% (P = NS) Reporting safe weekly and non-binge drinking at 6 mo: IG: 38.7% CG: 28.3% ($P < 0.05$)		
Wallace et al., 1988 (55)	RCT conducted in 47 group practices in research network England and Scotland Standard drink = 1 unit (not further defined)	909 adults (age, 17–69 y) who were registered primary care patients with self-assessed drinking problems OR ≥2/4 CAGE questions OR drank >35 units/wk (men) or >21 units/wk (women) Mean age: 42 y (approximately) Women: 29.1% Nonwhite: NR Smokers: NR Baseline mean alcohol consumption: Women: 35.1 drinks/wk Men: 62.2 drinks/wk Alcohol assessment: 2-step alcohol and lifestyle assessment by research staff: if findings on self-administered Health Survey Questionnaire at visit were "positive," then face-to-face structured interview of alcohol use.	IG (n = 450) contacted by PCP to schedule at least 1–2 visit(s), with up to 5 visits possible as needed. Intervention included feedback, advice, goal setting, assistance, and follow-up. Delivery: 83% of men and 92% of women completed ≥1 visit; 57% of men and 65% of women ≥2 visits. CG (n = 459) received general health booklet after assessment and no alcohol advice unless GGT level >150 IU/L or requested by patient.	Weekly consumption (units): Women: IG: 23.6 CG: 30.4 ($P < 0.05$) Men: IG: 44.0 CG: 55.6 ($P < 0.001$) Binge/heavy episodes: NR Not drinking excessively: Women: IG: 47.69% CG: 29.20% ($P < 0.05$) Men: IG: 43.71% CG: 25.47% ($P < 0.001$)	Broadly includes heavier-drinking adult primary care patients. Excludes those with recent medical advice about drinking or with GGT level >150 IU/L. Systems support: Provider training not reported. Research nurse did assessment. No incentives reported.	Good quality: At follow-up, IG lost 17% and CG lost 11%, so missing values were replaced with baseline values in analyses. Otherwise, overall good-quality criteria met. This brief, multicontact intervention by the PCP reduced alcohol consumption by men and women and the proportion drinking excessively at 12 mo compared with no intervention.

* AUDIT = alcohol use disorders identification test—10-item instrument for risky/harmful use; CAGE = 4-item screening questionnaire to detect alcoholism; CG = control group; ETOH = alcohol; GGT = serum γ-glutamyltransferase; HMO = health maintenance organization; IG = intervention group (numbered 1, 2 if >1 per study); MD = physician; MI = motivational interviewing; NP = nurse practitioner; NR = not reported; NS = not statistically significant ($P < 0.05$); PCP = primary care provider; Q/F = questions addressing quantity and frequency of alcohol use; RCT = randomized, controlled trial; RN = registered nurse; TLFB = timeline followback procedure; WHO = World Health Organization.

† No significant group by time interactions based on repeated-measures analysis.

Appendix Figure 3. **Risky/harmful alcohol use: quality recheck instrument.**

Study Authors: _____ Project Name: _____

Study Year: _____ *Journal:* _____ *Reviewer:* _____

Date: _____

1. Type of Randomization *Was there definite allocation concealment?* *(from CDAG Guidelines to Assess Study Quality)*	Mark best category: ☐ Adequate measures taken, such as central randomization, computerized systems, other strategies ☐ Unclear concealment measures, either not reported by authors or reported and not included in above ☐ Inadequate concealment measures, such as alternation, sequential assignment, dates of birth, day of week, or any other such approach
2. Attrition Bias *(from CDAG Guidelines to Assess Study Quality)*	What is overall loss to follow-up? Choose the category below that best describes the study: ☐ The trial presents an intention-to-treat analysis and very few losses to follow-up ☐ There is intention-to-treat analysis AND follow-up losses are equal to or less than 20% or there is replacement of missing values ☐ There is no reporting of dropouts, more than 20%–25% loss to follow-up, or wide differences in losses to follow-up between groups (Circle all that apply)
3. Were the patients and outcomes blinded? *(from CDAG Guidelines to Assess Study Quality)*	Choose the category below that best describes the study: ☐ Adequate blinding measures for participants (placebo) and in assessment of outcomes ☐ Unclear blinding for participants or in outcome assessment ☐ Inadequate blinding, especially in outcome assessment
4. Were there clear a priori outcomes, similar baseline characteristics between intervention group and control group, groups treated equally except for intended intervention?	Choose the category below that best describes the study: ☐ All criteria met (or at least the latter 2) ☐ Groups differ in some way but differences are handled in analysis/noncritical ☐ Groups differ and raise concerns about validity
5. Was the intervention clearly delivered? (How sure are we that the intervention patients received the intended protocol?)	☐ YES ☐ NO ☐ UNSURE
6. Overall Quality Impression	☐ GOOD—all criteria met and no significant concerns with 4 or 5 ☐ FAIR—criteria 1–3 at least partly met and no significant concerns with 4 or 5 ☐ POOR—at least one of first 3 criteria clearly not met Comments:

CDAG = Cochrane Drug and Alcohol Group.

line to 6 to 12 months' follow-up) in mean drinks per week for each group of the study. If these were not available, we abstracted any other recent average consumption measures and converted them to mean drinks per week where possible. For binge use, we abstracted the percentage or proportion of participants bingeing or not bingeing, or the reduction in either of these measures. We then calculated the converse (1 minus reported percentage), where necessary, to convert all measures to percentage not bingeing. Studies varied in their definition of safe, moderate, or recommended use of alcohol (based on attaining each study's recommended limits on average consumption or binge use). To consider what percentage of study participants attained these recommendations, we created or adapted the within-study definition that best fit each study's intervention rationale and focus. For each study, we then abstracted or calculated from reported data the percentage achieving "recommended" levels or patterns of alcohol use by group. For all the outcome categories, we recorded outcomes for all groups when studies had more than 1 intervention or control group. Similarly, we abstracted outcomes by sex where possible. We also examined health outcomes in the original intervention study (or subsequent reports) when available.

Generalizability. We recorded study recruitment (including

whether patients were primarily opportunistically recruited as part of routine care), provider support and training, use of research versus clinical personnel, and use of incentives for providers or patients to participate in the study.

Data Synthesis

To synthesize the results of the studies, we qualitatively compared results for the 3 selected alcohol use outcomes reported in the evidence tables and created 4 graphical outcome summaries (available elsewhere [41]). We examined the consistency and direction of the evidence for the effect of brief interventions on net (that is, intervention minus control) change in mean drinks per week ($n = 8$), on net percentage point decrease in average consumption from baseline ($n = 8$), on the proportion of participants not reporting binge drinking at follow-up ($n = 7$), and on the proportion of participants achieving recommended drinking levels or patterns after brief interventions ($n = 10$). To calculate the net reduction in mean drinks per week, we used reported mean differences in between-group changes from baseline to follow-up or calculated group means, changes in group means, and between-group net mean differences. For studies in which comparison of mean differences in drinks per week was a main outcome analysis and for which variance measures were also reported, we could calculate 95% CIs. To calculate the percentage point reduction in average consumption from baseline for each group, we divided the reduction in mean drinks per week by the baseline mean drinks per week and multiplied by 100. We then subtracted the percentage reduction in the control group from the percentage reduction in the intervention group to obtain the net percentage point reduction in mean drinks per week. For the remaining 2 outcomes, we used directly reported percentages or proportions of those in intervention and control groups 1) not bingeing and 2) achieving recommended drinking levels or patterns. Where necessary, we used the converse (1 minus the proportion) to convert data for comparability. If these latter 2 outcomes were not directly reported but other relevant data were available, we calculated the relevant percentages from the number reported as meeting the criterion at follow-up divided by the number randomly assigned to that group. Where available, outcomes were reported separately by sex. We examined results for all intervention groups ($n = 15$) for which these outcomes were reported or could be calculated.

Evidence Synthesis

We used the USPSTF approach to grade the overall quality of evidence for each key question (40); this summary information is reported elsewhere (41).