Behavioral Counseling to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults Without Known Cardiovascular Disease Risk Factors

Updated Evidence Report and Systematic Review for the US Preventive Services Task Force

Carrie D. Patnode, PhD; Corrine V. Evans, MPP; Caitlyn A. Senger, MPH; Nadia Redmond, MSPH; Jennifer S. Lin, MD

**IMPORTANCE**

Unhealthful dietary patterns, low levels of physical activity, and high sedentary time increase the risk of cardiovascular disease.

**OBJECTIVE**

To systematically review the evidence on the benefits and harms of behavioral counseling for the primary prevention of cardiovascular disease in adults without known cardiovascular risk factors to inform the US Preventive Services Task Force.

**DATA SOURCES**

MEDLINE, PubMed, Cochrane Central Register of Controlled Trials, and PsycINFO for studies published in the English language between January 1, 2013, and May 25, 2016, and ongoing surveillance in targeted publications through March 24, 2017. Studies included in the previous review were reevaluated for inclusion.

**STUDY SELECTION**

Randomized clinical trials of behavioral interventions targeting improved diet, increased physical activity, decreased sedentary time, or a combination of these among adults without known hypertension, dyslipidemia, diabetes, or impaired fasting glucose.

**DATA EXTRACTION AND SYNTHESIS**

Independent critical appraisal and data abstraction by 2 reviewers.

**MAIN OUTCOMES AND MEASURES**

Cardiometabolic health and intermediate outcomes, behavioral outcomes, and harms related to interventions.

**RESULTS**

Eighty-eight studies (N = 121,190) in 145 publications were included. There was no consistent benefit of the interventions on all-cause or cardiovascular mortality or morbidity (4 trials [n = 51,356]) or health-related quality of life (10 trials [n = 52,423]). There was evidence of small, statistically significant between-group mean differences for systolic blood pressure (−1.26 mm Hg [95% CI, −1.77 to −0.75]; 22 trials [n = 57,953]), diastolic blood pressure (−0.49 mm Hg [95% CI, −0.82 to −0.16]; 23 trials [n = 58,022]), low-density lipoprotein cholesterol level (−2.58 mg/dL [95% CI, −4.30 to −0.85]; 13 trials [n = 55,554]), total cholesterol level (−2.85 mg/dL [95% CI, −4.95 to −0.75]; 19 trials [n = 93,25]), and body mass index (−0.41 [95% CI, −0.62 to −0.19]; 20 trials [n = 55,059]) at 6 to 12 months as well as small-to-modest associations with dietary and physical activity behaviors. There was no evidence of greater incidence of serious adverse events, injuries, or falls in intervention vs control participants.

**CONCLUSIONS AND RELEVANCE**

Diet and physical activity behavioral interventions for adults not at high risk for cardiovascular disease result in consistent modest benefits across a variety of important intermediate health outcomes across 6 to 12 months, including blood pressure, low-density lipoprotein and total cholesterol levels, and adiposity, with evidence of a dose-response effect, with higher-intensity interventions conferring greater improvements. There is very limited evidence on longer-term intermediate and health outcomes or on harmful effects of these interventions.

Despite evidence that healthful dietary patterns, physical activity, and limited sedentary time are associated with reduced cardiovascular morbidity and mortality, most US adults are not meeting national recommendations for these behaviors. Counseling within primary care and interventions referred through primary care may be one strategy to improve these behaviors and subsequently prevent poor cardiovascular outcomes.

The US Preventive Services Task Force (USPSTF) has several recommendations related to cardiovascular disease (CVD) prevention, including guidance on healthy lifestyle counseling: screening and treatment for obesity, hypertension, and abnormal blood glucose levels; aspirin and statin use; and tobacco cessation interventions. The purpose of this review was to update the USPSTF review on the benefits and harms of behavioral counseling interventions for healthful diet, physical activity, and/or sedentary behavior for the primary prevention of cardiovascular disease among adults without known CVD or those with known hypertension, dyslipidemia, diabetes, or impaired fasting glucose. This review will help the USPSTF update their 2012 C grade recommendation that clinicians may choose to selectively counsel adults about healthful diet and physical activity.

Methods

Scope of Review

This review addressed 4 key questions (KQs) as shown in Figure 1. Methodological details (including study selection, a list of excluded studies, and description of data analyses), as well as more detailed results (including detailed descriptions of all of the interventions and data on effect modification and subpopulation results), are publicly available in the full evidence report at https://www.uspreventiveservicetaskforce.org/Page/Document/UpdateSummaryFinal/healthful-diet-and-physical-activity-for-cardiovascular-disease-prevention-in-adults-without-known-risk-factors-behavioral-counseling.

Data Sources and Searches

This review was designed as an extension of 2 prior systematic reviews conducted by the Kaiser Permanente Research Affiliates Evidence-based Practice Center for the USPSTF that focused on healthful diet and physical activity counseling for cardiovascular disease prevention among individuals with and without known CVD risk factors (ie, hypertension, dyslipidemia, diabetes, or impaired fasting glucose). As such, relevant studies from those reviews were reevaluated for potential inclusion. Then, the following databases were searched for new relevant English-language literature published between January 1, 2013, and May 25, 2016: MEDLINE, PubMed (publisher-supplied records only), PsycINFO, and the Cochrane Central Register of Controlled Trials (eMethods in the Supplement). Collectively, the literature searches encompassed literature published from 1966 through May 25, 2016. The database searches were supplemented by reviewing bibliographies from other relevant literature and from expert suggestions. ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry Platform were searched for ongoing trials. Since May 2016, ongoing surveillance was conducted using searches of a subset of core clinical journals identified by the USPSTF to identify major studies published in the interim that may affect the conclusions or understanding of the evidence and therefore the related USPSTF recommendation. The last surveillance was conducted on March 24, 2017, and identified no new studies.

Study Selection

Two reviewers independently reviewed all identified titles and abstracts and relevant full-text articles against prespecified inclusion and exclusion criteria (eTable 1 in the Supplement). Discrepancies were resolved through discussion and consensus. Eligible studies were fair- and good-quality randomized clinical trials that evaluated the effectiveness of primary care–relevant interventions focused on improving dietary habits, increasing physical activity, and/or reducing sedentary time with the primary aim of CVD primary prevention among adults 18 years or older. Studies were excluded from this review if they (1) targeted persons with known CVD, hypertension, dyslipidemia, diabetes, impaired fasting glucose or glucose tolerance, or a combination of these factors; (2) targeted persons categorized as high risk based on a cardiovascular risk-assessment tool; or (3) generically stated that participants must have 1 or more CVD risk factors to be included. In contrast, studies in adults who may be at elevated risk for CVD based on factors such as age, race/ethnicity, family history of CVD, overweight or obesity, high-normal blood pressure, or history of gestational diabetes, as well as those conducted among unselected samples or samples selected because of suboptimal behavior (eg, did not meet national physical activity guidelines) were included. Eligible interventions were those conducted in primary care or referred from primary care, or those deemed feasible for primary care or referral given the nature of the intervention delivery (eg, face-to-face counseling, telephone support), behavior change techniques (eg, goal setting, self-monitoring), or setting (eg, home, community). Studies had to report a behavioral outcome (ie, diet-, physical activity-, sedentary time–related measure), intermediate outcome (eg, blood pressure, lipid levels, weight, incidence of hypertension), or health outcome (ie, morbidity, mortality, health-related quality of life) or report adverse events related to the intervention.

Data Extraction and Quality Assessment

Two reviewers independently assessed the methodological quality of all eligible studies, using criteria outlined by the USPSTF (eTable 2 in the Supplement). Each study was assigned a final quality rating of good, fair, or poor: disagreements between the investigators were resolved through consensus after discussion and consultation with additional investigators. Studies were rated as poor quality and excluded if they had several important major risks of bias, including very high attrition at 6 to 12 months (eg, greater than 40%), differential attrition between intervention groups (eg, greater than 20%), lack of baseline comparability between groups without adjustment for those variables, or other issues in the conduct, analysis, or reporting of results of the trial that were judged to considerably bias the results (eg, possible selective reporting, inappropriate exclusion of participants from analyses, and questionable validity of randomization and allocation concealment procedures). One reviewer completed primary data abstraction, and a second reviewer checked all data for accuracy and completeness.
Data Synthesis and Analysis

Summary tables were created for study characteristics, population characteristics, intervention characteristics, and outcomes. The data on health outcomes (KQ1) and adverse events (KQ4) did not allow for pooled analyses and were summarized descriptively. For intermediate health outcomes (KQ2) and behavioral outcomes (KQ3), random-effects meta-analyses using the method of DerSimonian and Laird were run to calculate the pooled differences in mean changes (for continuous data) and pooled odds ratio (for binary data). The between-group difference for each outcome as reported by each respective study was pooled favoring adjusted over unadjusted reported effect estimates. If a between-group effect estimate and variance were not provided, a crude effect estimate was calculated. Within each study, 1-year outcome data were chosen for meta-analyses if available; otherwise, the point closest to 1 year was chosen. If a trial had more than 1 active intervention group, data for the most intensive group or the group that was the most similar with other interventions included in the analysis were plotted. Methods consistent with the previous review were used to estimate and categorize the intensity (total contact in minutes) of each intervention group as low (≤30 minutes), medium (31-360 minutes), or high (>360 minutes). Results at all other points and for all intervention groups within each trial were reported in tabular format.

Statistical heterogeneity among the pooled studies was examined using standard χ² tests, and the proportion of total variability in point estimates was approximated using the I² statistic. Visual displays were first used to investigate whether the heterogeneity among the results was associated with any prespecified population or intervention characteristics; meta-regression was then used when indicated. To evaluate small-study effects, funnel plots and the Egger test (for continuous outcomes) or Peters test (for dichotomous outcomes) were used. Stata version 13.1 (Stata Corp) was used for all quantitative analyses. All significance testing was 2-sided, and results were considered statistically significant at P < .05.

The strength of the overall body of evidence for each KQ was graded as high, moderate, low, or insufficient based on established methods and addressed the consistency, precision, reporting bias, study quality, and dose response related to each outcome.

Results

A total of 10 045 titles and abstracts and 351 articles were reviewed to determine if they met the prespecified inclusion criteria, and 88 trials (87 randomized clinical trials [n = 121 106] and 1 non-randomized clinical trial [n = 84]) reported in 145 publications were...
interventions, and specific outcome measures (included trials were highly variable in terms of their study populations, and were synthesized with 38 newly identified trials).21,24,26,31,33,34,38,42,47,49,50,52,56,57,61,63,64,66,69,72,76,79,82,85,86,88,90,95-98,102,104,109,112,114,118,119,121,126-128,130,132,136,143,146,147,149,151,159 and were included in the analysis.21-165 Fifty trials were carried forward from the previous review22,26,31,33,34,38,42,47,49,50,52,56,57,61,63,64,66,69,72,76,79,82,85,86,88,90,95-98,102,104,109,112,114,118,119,121,126-128,130,132,136,143,146,147,149,151,159 and were synthesized with 38 newly identified trials.21,24,26,31,33,34,38,42,47,49,50,52,56,57,61,63,64,66,69,72,76,79,82,85,86,88,90,95-98,102,104,109,112,114,118,119,121,126-128,130,132,136,143,146,147,149,151,159 The included trials were highly variable in terms of their study populations, interventions, and specific outcome measures (Table 1). The majority of the trials took place in the United States and were conducted within or recruited from a primary care setting. There was great diversity in the interventions tested: 23 trials focused on healthful diet and physical activity, another 24 on healthful diet only, and 44 on physical activity only. Intervention intensity (total minutes of contact) ranged from 3 minutes to 2340 minutes (39 hours), with a mean of 6 hours and 11 minutes. Low-intensity interventions were mostly mailed, print-based interventions, whereas medium- and high-intensity interventions involved one-on-one individual and telephone counseling and group sessions.

Effects of Interventions on Health Outcomes

Key Question 1. Do primary care behavioral counseling interventions to improve diet, increase physical activity, and/or reduce sedentary behavior improve health outcomes in adults?

Twelve of the 88 included trials reported health outcomes.52,63,66,69,76,82,86,97,121,146,147,154 Only 2 of these trials62,75,4 were identified as part of the update, and both reported quality-of-life outcomes. Four trials (n = 51,356) reported all-cause or CVD-related mortality.82,246,147,151 of which 3 also reported cardiovascular events.146,147,151 All 4 of these trials focused on high-intensity diet interventions. Overall, few deaths were reported, and no differences were observed between treatment and control groups over 3 to 15 years of follow-up. The 3 trials that reported cardiovascular events or composite CVD outcomes showed some beneficial results, although results were mixed. The Women’s Health Initiative dietary modification trial (n = 48,835) showed no difference in major coronary heart disease events (ie, nonfatal myocardial infarction [MI] or coronary heart disease death) (adjusted hazard ratio [HR], 0.93 [95% CI, 0.83 to 1.05]) or fatal and nonfatal stroke (HR, 0.94 [95% CI, 0.86 to 1.02]).81 In contrast, long-term observational follow-up from the Trial of Hypertension Prevention (TOHP) phase I and II (n = 2415) showed a significant difference in CVD (defined as MI, stroke, revascularization, or CVD death) between treatment groups over 10 to 15 years of follow-up (HR, 0.70 [95% CI, 0.53 to 0.94]).48 When revascularization was excluded from the definition, however, significance was lost (adjusted HR, 0.72 [95% CI, 0.50 to 1.03]).
<table>
<thead>
<tr>
<th>Source</th>
<th>Study Quality</th>
<th>Country</th>
<th>Sample Size, Population Description (% Women)</th>
<th>Age, Mean, y</th>
<th>Intervention</th>
<th>Intervention Focus</th>
<th>Duration, wk</th>
<th>Intervention Intensity</th>
<th>Setting</th>
<th>PCC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aadahl et al, 2014</td>
<td>Good</td>
<td>Denmark</td>
<td>166 adults (57.2)</td>
<td>52.0</td>
<td>Counseling</td>
<td>PA</td>
<td>26</td>
<td>Medium</td>
<td>Research clinic</td>
<td></td>
</tr>
<tr>
<td>Aittasalo et al, 2006</td>
<td>Fair</td>
<td>Finland</td>
<td>265 adults (75.8)</td>
<td>47.0</td>
<td>Brief counseling</td>
<td>PA</td>
<td>0.14</td>
<td>Low</td>
<td>Primary care</td>
<td></td>
</tr>
<tr>
<td>Albright et al, 2014</td>
<td>Fair</td>
<td>United States</td>
<td>311 postpartum women (100)</td>
<td>31.8</td>
<td>Tailored telephone counseling plus website</td>
<td>PA</td>
<td>52</td>
<td>Medium</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Aldana et al, 2006</td>
<td>Fair</td>
<td>United States</td>
<td>348 adults (71.8)</td>
<td>50.5</td>
<td>Group counseling</td>
<td>HD + PA</td>
<td>4</td>
<td>High</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Alexander et al, 2010</td>
<td>Fair</td>
<td>United States</td>
<td>2540 adults (68.8)</td>
<td>46.3</td>
<td>Tailored web-based + email counseling</td>
<td>HD</td>
<td>52</td>
<td>Medium</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Baron et al, 1990</td>
<td>Fair</td>
<td>United Kingdom</td>
<td>368 adults (48.6)</td>
<td>41.7</td>
<td>Counseling</td>
<td>HD</td>
<td>12</td>
<td>Medium</td>
<td>Primary care</td>
<td></td>
</tr>
<tr>
<td>Bennett et al, 2013</td>
<td>Good</td>
<td>United States</td>
<td>194 overweight or obese black women (100)</td>
<td>35.4</td>
<td>Counseling, tailored print materials, and self-monitoring</td>
<td>HD + PA</td>
<td>52</td>
<td>High</td>
<td>Primary care</td>
<td></td>
</tr>
<tr>
<td>Beresford et al, 1997</td>
<td>Fair</td>
<td>United States</td>
<td>4778 adults (68.0)</td>
<td>NR</td>
<td>Brief counseling and self-help material</td>
<td>HD</td>
<td>2</td>
<td>Low</td>
<td>Primary care</td>
<td></td>
</tr>
<tr>
<td>Bernstein et al, 2002</td>
<td>Fair</td>
<td>United States</td>
<td>70 older adults (80.0)</td>
<td>77.9</td>
<td>Home-based education</td>
<td>HD</td>
<td>26</td>
<td>High</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Bickmore et al, 2013</td>
<td>Fair</td>
<td>United States</td>
<td>263 older adults (61.2)</td>
<td>71.3</td>
<td>Computer-based counseling</td>
<td>PA</td>
<td>52</td>
<td>Medium</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Brekke et al, 2005</td>
<td>Fair</td>
<td>Sweden</td>
<td>77 adults with family history of type 2 diabetes (36.8)</td>
<td>42.6</td>
<td>Group counseling (diet)</td>
<td>HD</td>
<td>104</td>
<td>High</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Bryan et al, 2013</td>
<td>Fair</td>
<td>United States</td>
<td>238 adults (80.4)</td>
<td>28.2</td>
<td>Tailored print mailings</td>
<td>PA</td>
<td>52</td>
<td>Low</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Burke et al, 2013</td>
<td>Fair</td>
<td>Australia</td>
<td>478 older adults (48.3)</td>
<td>65.8</td>
<td>Self-help booklet and phone and email counseling</td>
<td>HD + PA</td>
<td>26</td>
<td>Medium</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Carpenter et al, 2004</td>
<td>Fair</td>
<td>United States</td>
<td>98 adults (64.3)</td>
<td>49.6</td>
<td>Group counseling</td>
<td>HD</td>
<td>24</td>
<td>High</td>
<td>Research clinic</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mailed materials and website</td>
<td>HD</td>
<td>24</td>
<td>Low</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carroll et al, 2010</td>
<td>Fair</td>
<td>United States</td>
<td>394 adults (69.0)</td>
<td>46.4</td>
<td>Tailored print mailings</td>
<td>PA</td>
<td>26</td>
<td>Low</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Castro et al, 2011</td>
<td>Fair</td>
<td>United States</td>
<td>181 adults (65.8)</td>
<td>59.1</td>
<td>Counseling</td>
<td>PA</td>
<td>52</td>
<td>Medium</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Peer counseling</td>
<td>PA</td>
<td>52</td>
<td>Medium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coates et al, 1999</td>
<td>Fair</td>
<td>United States</td>
<td>2208 postmenopausal women (100)</td>
<td>60.0</td>
<td>Group counseling</td>
<td>HD</td>
<td>52</td>
<td>High</td>
<td>Research clinic</td>
<td></td>
</tr>
<tr>
<td>De Vet et al, 2009</td>
<td>Fair</td>
<td>Netherlands</td>
<td>709 adults (67.3)</td>
<td>45.9</td>
<td>Self-directed and self-selected activity plan (with repeat planning)</td>
<td>PA</td>
<td>26</td>
<td>Low</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Delichatsios et al, 2001</td>
<td>Fair</td>
<td>United States</td>
<td>298 adults (72.1)</td>
<td>45.9</td>
<td>Automated telephone counseling</td>
<td>HD</td>
<td>26</td>
<td>Medium</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Elley et al, 2003</td>
<td>Good</td>
<td>New Zealand</td>
<td>878 adults (66.3)</td>
<td>57.9</td>
<td>Counseling with tailored prescription</td>
<td>PA</td>
<td>52</td>
<td>Medium</td>
<td>Primary care</td>
<td></td>
</tr>
<tr>
<td>Estabrooks et al, 2011</td>
<td>Fair</td>
<td>United States</td>
<td>115 adults (61.0)</td>
<td>48.8</td>
<td>Group counseling</td>
<td>PA</td>
<td>12</td>
<td>Medium</td>
<td>Research clinic</td>
<td></td>
</tr>
<tr>
<td>Fjeldsøe et al, 2015</td>
<td>Fair</td>
<td>Australia</td>
<td>263 women with young children (100)</td>
<td>31.9</td>
<td>Counseling and regular text messages</td>
<td>PA</td>
<td>12</td>
<td>Medium</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Franko et al, 2008</td>
<td>Fair</td>
<td>United States</td>
<td>476 college students (56.3)</td>
<td>20.1</td>
<td>Web-based intervention + booster session</td>
<td>5</td>
<td>Medium</td>
<td>University computer laboratory and home</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(continued)
<table>
<thead>
<tr>
<th>Source</th>
<th>Study Quality*</th>
<th>Country</th>
<th>Sample Size, Population Description (% Women)</th>
<th>Age, Mean, y</th>
<th>Intervention Focus</th>
<th>Duration, wk</th>
<th>Intervention Intensityb</th>
<th>Setting</th>
<th>PCCc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fries et al,57 2005</td>
<td>Fair</td>
<td>United States</td>
<td>754 adults (64.1)</td>
<td>47.3</td>
<td>Tailored print mailing and brief counseling call</td>
<td>HD</td>
<td>6</td>
<td>Low</td>
<td>Home</td>
</tr>
<tr>
<td>Gao et al,58 2015</td>
<td>Fair</td>
<td>United States</td>
<td>261 older adults (17.2)</td>
<td>63.2</td>
<td>Individual counseling and tailored print materials</td>
<td>PA</td>
<td>52</td>
<td>Medium</td>
<td>Home</td>
</tr>
<tr>
<td>Gell and Wadsworth,60 2015</td>
<td>Fair</td>
<td>United States</td>
<td>87 women (100)</td>
<td>47.2</td>
<td>Targeted text messages</td>
<td>PA</td>
<td>24</td>
<td>Low</td>
<td>Other</td>
</tr>
<tr>
<td>Goldstein et al,61 1999</td>
<td>Good</td>
<td>United States</td>
<td>355 adults (64.5)</td>
<td>65.6</td>
<td>Brief counseling with tailored prescription</td>
<td>PA</td>
<td>26</td>
<td>Low</td>
<td>Primary care</td>
</tr>
<tr>
<td>Grandes et al,63 2009</td>
<td>Good</td>
<td>Spain</td>
<td>4317 adults (65.6)</td>
<td>50.0</td>
<td>Brief counseling</td>
<td>PA</td>
<td>NR</td>
<td>Low</td>
<td>Primary care</td>
</tr>
<tr>
<td>Green et al,64 2002</td>
<td>Fair</td>
<td>United States</td>
<td>316 adults (52.5)</td>
<td>44.0</td>
<td>Telephone counseling</td>
<td>PA</td>
<td>12</td>
<td>Medium</td>
<td>Home</td>
</tr>
<tr>
<td>Greene et al,66 2008</td>
<td>Fair</td>
<td>United States</td>
<td>1280 older adults (69.6)</td>
<td>75.0</td>
<td>Tailored print mailings and counseling telephone calls</td>
<td>HD</td>
<td>52</td>
<td>Medium</td>
<td>Home</td>
</tr>
<tr>
<td>Greenlee et al,67 2015</td>
<td>Fair</td>
<td>United States</td>
<td>70 Hispanic breast cancer survivors (100)</td>
<td>56.6</td>
<td>Group counseling</td>
<td>HD</td>
<td>12</td>
<td>High</td>
<td>Research clinic</td>
</tr>
<tr>
<td>Halbert et al,69 2000</td>
<td>Fair</td>
<td>Australia</td>
<td>299 older adults (54.5)</td>
<td>67.6</td>
<td>Counseling</td>
<td>PA</td>
<td>26</td>
<td>Medium</td>
<td>Primary care</td>
</tr>
<tr>
<td>Hargreaves et al,71 2016</td>
<td>Fair</td>
<td>New Zealand</td>
<td>97 adults (84.5)</td>
<td>46.2</td>
<td>Tailored walking program</td>
<td>PA</td>
<td>12</td>
<td>Medium</td>
<td>Home</td>
</tr>
<tr>
<td>Harland et al,72 1999</td>
<td>Fair</td>
<td>United Kingdom</td>
<td>523 adults (58.3)</td>
<td>NR</td>
<td>Counseling and PA vouchers</td>
<td>PA</td>
<td>12</td>
<td>Medium</td>
<td>Primary care</td>
</tr>
<tr>
<td>Hinderliter et al,73 2014</td>
<td>Good</td>
<td>United Kingdom</td>
<td>298 older adults (53.7)</td>
<td>NR</td>
<td>Counseling and self-monitoring</td>
<td>PA</td>
<td>52</td>
<td>Medium</td>
<td>Primary care</td>
</tr>
<tr>
<td>Hellénius et al,74 1993</td>
<td>Fair</td>
<td>Sweden</td>
<td>158 men with moderately elevated CVD risk factors (0)i</td>
<td>46.0</td>
<td>Counseling (diet)</td>
<td>HD</td>
<td>2</td>
<td>Medium</td>
<td>Primary care</td>
</tr>
<tr>
<td>Hivert et al,75 2007</td>
<td>Fair</td>
<td>Canada</td>
<td>115 college students (81.7)</td>
<td>19.7</td>
<td>Group counseling</td>
<td>HD + PA</td>
<td>104</td>
<td>High</td>
<td>Other</td>
</tr>
<tr>
<td>HPT Research Group,76 1990</td>
<td>Good</td>
<td>United States</td>
<td>587 adults with high-normal DBP (36.8)</td>
<td>38.6</td>
<td>Group counseling (potassium and sodium focus)</td>
<td>HD</td>
<td>156</td>
<td>High</td>
<td>Research clinic</td>
</tr>
<tr>
<td>Jacobs et al,77 2011</td>
<td>Fair</td>
<td>Belgium</td>
<td>314 adults (66.6)</td>
<td>40.5</td>
<td>Counseling</td>
<td>HD + PA</td>
<td>52</td>
<td>High</td>
<td>Research clinic</td>
</tr>
<tr>
<td>Jeffery and French,78 1999</td>
<td>Fair</td>
<td>United States</td>
<td>1226 adults (80.2)</td>
<td>38.3</td>
<td>Nontailored print mailings</td>
<td>HD + PA</td>
<td>156</td>
<td>Low</td>
<td>Home</td>
</tr>
<tr>
<td>John et al,79 2002</td>
<td>Fair</td>
<td>United States</td>
<td>729 adults (51.0)</td>
<td>45.9</td>
<td>Counseling</td>
<td>HD</td>
<td>12</td>
<td>Medium</td>
<td>Research clinic</td>
</tr>
<tr>
<td>Kallings et al,80 2009</td>
<td>Good</td>
<td>Sweden</td>
<td>101 overweight or obese older adults (57.4)</td>
<td>NR</td>
<td>Counseling with tailored prescription</td>
<td>PA</td>
<td>NR</td>
<td>Medium</td>
<td>Primary care</td>
</tr>
<tr>
<td>Kattelmann et al,81 2014</td>
<td>Fair</td>
<td>United States</td>
<td>1639 young adults (67.2)</td>
<td>19.3</td>
<td>Web-based intervention</td>
<td>HD + PA</td>
<td>64</td>
<td>Medium</td>
<td>Home</td>
</tr>
<tr>
<td>Katz et al,82 2008</td>
<td>Fair</td>
<td>United States</td>
<td>316 adults (67.1)</td>
<td>NR</td>
<td>Provider training</td>
<td>PA</td>
<td>26</td>
<td>High</td>
<td>Primary care</td>
</tr>
</tbody>
</table>

(continued)
<table>
<thead>
<tr>
<th>Source</th>
<th>Study Qualitya</th>
<th>Country</th>
<th>Sample Size, Population Description (% Women)</th>
<th>Age, Mean, y</th>
<th>Intervention</th>
<th>Intervention Focus</th>
<th>Duration, wk</th>
<th>Intervention Intensityb</th>
<th>Setting</th>
<th>PCCc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kerr et al,91 2016</td>
<td>Fair</td>
<td>Australia</td>
<td>247 young adults (65.6)</td>
<td>24.3</td>
<td>Tailored text messages (with booster messages)</td>
<td>HD</td>
<td>24</td>
<td>Low</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>King et al,95 2007</td>
<td>Fair</td>
<td>United States</td>
<td>218 adults (69.8)</td>
<td>60.8</td>
<td>Automated telephone counseling</td>
<td>PA</td>
<td>52</td>
<td>Medium</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>King et al,94 2013</td>
<td>Good</td>
<td>United States</td>
<td>200 adults (51.3)</td>
<td>55.2</td>
<td>Telephone counseling with self-monitoring (PA and diet simultaneous)</td>
<td>HD + PA</td>
<td>52</td>
<td>Medium</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Kinmonth et al,96 2008</td>
<td>Fair</td>
<td>United Kingdom</td>
<td>365 adults with family history of type 2 diabetes (62.0)</td>
<td>40.6</td>
<td>Telephone counseling</td>
<td>PA</td>
<td>52</td>
<td>Medium</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Kolt et al,97 2007</td>
<td>Good</td>
<td>New Zealand</td>
<td>186 older adults (66.1)</td>
<td>74.2</td>
<td>Telephone counseling</td>
<td>PA</td>
<td>12</td>
<td>Medium</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Kristal et al,98 2000</td>
<td>Fair</td>
<td>United States</td>
<td>1459 adults (49.1)</td>
<td>44.9</td>
<td>Tailored print mailings and counseling call</td>
<td>HD</td>
<td>52</td>
<td>Low</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Lawton et al,102 2008</td>
<td>Good</td>
<td>New Zealand</td>
<td>1089 women (100)</td>
<td>58.9</td>
<td>Counseling with tailored prescription</td>
<td>PA</td>
<td>38</td>
<td>Medium</td>
<td>Primary care</td>
<td></td>
</tr>
<tr>
<td>Lewis et al,103 2013</td>
<td>Good</td>
<td>United States</td>
<td>448 adults (87.1)</td>
<td>42.6</td>
<td>Tailored print mailings</td>
<td>PA</td>
<td>26</td>
<td>Low</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Lutz et al,104 1999</td>
<td>Fair</td>
<td>United States</td>
<td>710 adults (64.4)</td>
<td>39.3</td>
<td>Tailored print mailings with tailored prescription</td>
<td>HD</td>
<td>16</td>
<td>Low</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Mailey and McAuley,106</td>
<td>Fair</td>
<td>United States</td>
<td>141 women (100)</td>
<td>37.3</td>
<td>Group counseling</td>
<td>PA</td>
<td>26</td>
<td>Medium</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Marcus et al,109 2007</td>
<td>Fair</td>
<td>United States</td>
<td>239 adults (82.0)</td>
<td>44.5</td>
<td>Telephone counseling</td>
<td>PA</td>
<td>52</td>
<td>Medium</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Marcus et al,110 2013</td>
<td>Good</td>
<td>United States</td>
<td>292 Hispanic/Latina women (100)</td>
<td>40.7</td>
<td>Tailored print mailings and self-monitoring</td>
<td>PA</td>
<td>52</td>
<td>Medium</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Marsaux et al,111 2015</td>
<td>Fair</td>
<td>Europe1</td>
<td>1067 adults (58.4)</td>
<td>39.9</td>
<td>Tailored web-based advice (diet, physical activity, and phenotype)</td>
<td>HD + PA</td>
<td>26</td>
<td>Low</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Marshall et al,112 2003</td>
<td>Fair</td>
<td>Australia</td>
<td>462 adults (57.6)</td>
<td>49.0</td>
<td>Tailored print mailing</td>
<td>PA</td>
<td>0.14</td>
<td>Low</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Martinson et al,113 2008</td>
<td>Good</td>
<td>United States</td>
<td>1049 adults (72.4)</td>
<td>57.1</td>
<td>Counseling</td>
<td>PA</td>
<td>104</td>
<td>High</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Mosca et al,114 2008</td>
<td>Good</td>
<td>United States</td>
<td>501 adults with family history of CVD (66.3)</td>
<td>48.0</td>
<td>Counseling</td>
<td>HD + PA</td>
<td>38</td>
<td>Medium</td>
<td>Research clinic</td>
<td></td>
</tr>
<tr>
<td>Napolitano et al,115 2006</td>
<td>Fair</td>
<td>United States</td>
<td>280 women (100)</td>
<td>47.2</td>
<td>Tailored print mailings</td>
<td>PA</td>
<td>26</td>
<td>Low</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Norris et al,116 2000</td>
<td>Fair</td>
<td>United States</td>
<td>847 adults (52.1)</td>
<td>54.9</td>
<td>Counseling</td>
<td>PA</td>
<td>20</td>
<td>Medium</td>
<td>Primary care</td>
<td></td>
</tr>
</tbody>
</table>

(continued)
Table 1. Characteristics of All Included Trials (continued)

<table>
<thead>
<tr>
<th>Source</th>
<th>Study Quality</th>
<th>Country</th>
<th>Sample Size, Population Description (% Women)</th>
<th>Age, Mean, y</th>
<th>Intervention</th>
<th>Intervention Focus</th>
<th>Duration, wk</th>
<th>Intervention Intensity</th>
<th>Setting</th>
<th>PCC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parekh et al, 2014</td>
<td>Fair</td>
<td>Australia</td>
<td>4676 adults (69.2)</td>
<td>46.9</td>
<td>Computer-tailored print mailings (2 contacts)</td>
<td>HD + PA</td>
<td>12</td>
<td>Low</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Pelmezi et al, 2009</td>
<td>Fair</td>
<td>United States</td>
<td>93 Hispanic/Latina women (100)</td>
<td>41.4</td>
<td>Tailored print mailings and self-monitoring</td>
<td>PA</td>
<td>26</td>
<td>Low</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Pinto et al, 2002</td>
<td>Fair</td>
<td>United States</td>
<td>298 adults (72.1)</td>
<td>45.9</td>
<td>Automated telephone counseling</td>
<td>PA</td>
<td>26</td>
<td>Medium</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Pinto et al, 2005</td>
<td>Fair</td>
<td>United States</td>
<td>100 older adults (65.0)</td>
<td>68.5</td>
<td>Counseling with tailored prescription</td>
<td>PA</td>
<td>26</td>
<td>Medium</td>
<td>Primary care</td>
<td></td>
</tr>
<tr>
<td>Roderick et al, 1997</td>
<td>Fair</td>
<td>United Kingdom</td>
<td>956 adults (50.0)</td>
<td>47.3</td>
<td>Counseling</td>
<td>HD</td>
<td>5</td>
<td>Medium</td>
<td>Primary care</td>
<td></td>
</tr>
<tr>
<td>Ruffin et al, 2011</td>
<td>Fair</td>
<td>United States</td>
<td>4248 adults (69.7)</td>
<td>50.6</td>
<td>Computer-tailored web-based intervention</td>
<td>HD + PA</td>
<td>26</td>
<td>Low</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Sacerdote et al, 2006</td>
<td>Fair</td>
<td>Italy</td>
<td>3179 adults (50.0)</td>
<td>44.4</td>
<td>Brief counseling</td>
<td>HD</td>
<td>1</td>
<td>Low</td>
<td>Primary care</td>
<td></td>
</tr>
<tr>
<td>Simkin-Silverman et al, 1995</td>
<td>Good</td>
<td>United States</td>
<td>535 premenopausal women (100)</td>
<td>47.1</td>
<td>Group counseling</td>
<td>HD + PA</td>
<td>234</td>
<td>High</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Smith et al, 2014</td>
<td>Fair</td>
<td>Australia</td>
<td>59 overweight or obese women with history of gestational diabetes (100)</td>
<td>35.4</td>
<td>Counseling</td>
<td>HD + PA</td>
<td>26</td>
<td>Medium</td>
<td>Research clinic</td>
<td></td>
</tr>
<tr>
<td>Spruytvoet et al, 2015</td>
<td>Fair</td>
<td>Netherlands</td>
<td>1349 adults (64.6)</td>
<td>49.4</td>
<td>Web-based tailored education-plus feedback</td>
<td>HD</td>
<td>6</td>
<td>Medium</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Stewart et al, 2001</td>
<td>Fair</td>
<td>United States</td>
<td>173 older adults (65.9)</td>
<td>74.4</td>
<td>Group counseling</td>
<td>PA</td>
<td>52</td>
<td>High</td>
<td>Research clinic</td>
<td></td>
</tr>
<tr>
<td>Taveras et al, 2011</td>
<td>Fair</td>
<td>United States</td>
<td>84 postpartum women (100)</td>
<td>32.9</td>
<td>Postpartum counseling</td>
<td>HD + PA</td>
<td>26</td>
<td>High</td>
<td>Primary care</td>
<td></td>
</tr>
<tr>
<td>Thompson et al, 2008</td>
<td>Fair</td>
<td>United States</td>
<td>200 American Indian women (100)</td>
<td>29.2</td>
<td>Group counseling</td>
<td>HD + PA</td>
<td>20</td>
<td>High</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Thompson et al, 2014</td>
<td>Good</td>
<td>United States</td>
<td>49 older adults (81.2)</td>
<td>79.5</td>
<td>Counseling and self-monitoring</td>
<td>PA</td>
<td>24</td>
<td>High</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Tinker et al, 2008</td>
<td>Good</td>
<td>United States</td>
<td>48835 postmenopausal women (100)</td>
<td>62.2</td>
<td>Group counseling</td>
<td>HD</td>
<td>312</td>
<td>High</td>
<td>Research clinic</td>
<td></td>
</tr>
<tr>
<td>TOHP Collaborative Research Group (Phase I), 1992</td>
<td>Fair</td>
<td>United States</td>
<td>744 adults with high-normal DBP (26.6)</td>
<td>43.0</td>
<td>Group counseling</td>
<td>HD</td>
<td>78</td>
<td>High</td>
<td>Research clinic</td>
<td></td>
</tr>
<tr>
<td>TOHP Collaborative Research Group (Phase II), 1997</td>
<td>Good</td>
<td>United States</td>
<td>1190 moderately overweight adults with high-normal DBP (33.4)</td>
<td>43.7</td>
<td>Group counseling</td>
<td>HD</td>
<td>156</td>
<td>High</td>
<td>Research clinic</td>
<td></td>
</tr>
<tr>
<td>Tokunaga-Nakawatase et al, 2014</td>
<td>Fair</td>
<td>Japan</td>
<td>216 adults with family history of type 2 diabetes (34.8)</td>
<td>45.2</td>
<td>Computer-tailored print mailings</td>
<td>HD + PA</td>
<td>26</td>
<td>Low</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>Vallee et al, 2013</td>
<td>Fair</td>
<td>Finland</td>
<td>3059 college-aged women (100)</td>
<td>19.0</td>
<td>Counseling</td>
<td>HD + PA</td>
<td>104</td>
<td>Medium</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Van Hoecle et al, 2014</td>
<td>Fair</td>
<td>Belgium</td>
<td>442 older adults (66.7)</td>
<td>69.</td>
<td>Counseling</td>
<td>PA</td>
<td>10</td>
<td>Medium</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>van Stralen et al, 2010</td>
<td>Fair</td>
<td>Netherlands</td>
<td>8500 adults (57.0)</td>
<td>64.0</td>
<td>Tailored print mailings with environmental focus</td>
<td>PA</td>
<td>14</td>
<td>Low</td>
<td>Home</td>
<td></td>
</tr>
<tr>
<td>(continued)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

© 2017 American Medical Association. All rights reserved.
Ten trials reported quality-of-life outcomes and reported modest improvements at 6 and 12 months among intervention participants but no consistent benefit of the intervention compared with control conditions.36,37,38,39

Effects of Interventions on Intermediate Health Outcomes

Key Question 2. Do primary care behavioral counseling interventions to improve diet, increase physical activity, and/or reduce sedentary behavior improve intermediate outcomes associated with cardiovascular disease (CVD) in adults?

Thirty-four of the included trials (n = 75,793) reported the effects of behavioral interventions on at least 1 intermediate outcome (ie, blood pressure, lipid levels, glucose levels, or adiposity measures); nearly half of the trials were of good quality.21,26,31,32,38,39,47,52,63,67,71,76,78,79,82,85,86,88,89,91,96,98,102,118,130,132,136,146,147,149,151,153,160 When trials were pooled, healthful diet, physical activity interventions, or both were associated with small but statistically significant improvements in systolic blood pressure (22 trials), diastolic blood pressure (23 trials), low-density lipoprotein cholesterol (LDL-C) level (13 trials), total cholesterol level (19 trials), and adiposity measures (20 trials), compared with controls at 6 months or more (Table 1). Pooled between-group mean differences were −1.26 mm Hg (95% CI, −1.77 to −0.75) for systolic blood pressure, −0.49 mm Hg (95% CI, −0.82 to −0.16) for diastolic blood pressure, −2.58 mg/dL (95% CI, −4.30 to −0.85) for LDL-C level, and −2.85 mg/dL (95% CI, −4.95 to −0.75) for total cholesterol level—all in favor of intervention vs control groups with follow-up times of 6 months or more. For adiposity outcomes, interventions were associated with improvements in body mass index (mean difference, −0.41 [95% CI, −0.62 to −0.20]; calculated as weight in kilograms divided by height in meters squared), waist circumference (mean difference, −1.04 kg [95% CI, −1.56 to −0.51]), and waist circumference (mean difference, −1.19 cm [95% CI, −1.79 to −0.59]), with considerable statistical heterogeneity (I² > 90%) in all analyses. There was no evidence of an association between healthful diet, physical activity counseling, or both and levels of high-density lipoprotein cholesterol, triglycerides, or fasting glucose in pooled analyses (Table 2).

Among the intermediate outcomes showing a positive association, dose-response effects were evident, with increasing intervention intensity associated with larger improvements in intermediate outcomes (Table 2). High-intensity interventions were consistently associated with statistically significant benefit on intermediate outcomes, and the effect sizes were slightly higher in analyses limited to the subset of high-intensity interventions (6-12 trials per outcome), compared with the results of combining trials of all intensities. The associations between medium-intensity interventions (5-9 trials per outcome) and intermediate outcomes were less
consistent and generally showed no benefit, with the exception of the outcome of weight. There was insufficient evidence (only 1-4 trials per outcome) to assess the association between low-intensity interventions and intermediate outcomes.

Meta-analyses stratified by diet-only messages, physical activity-only messages, or combined diet and physical activity messages were consistent with those seen in analyses stratified by intensity (results available in the full evidence report). Healthful diet interventions (with or without physical activity messages) (7-16 trials per outcome), which were mostly high-intensity interventions, consistently showed statistically significant favorable associations with intermediate outcomes. No such benefit was seen when limiting the analyses to physical activity-only trials, which were largely of low intensity, although there were far fewer trials included in these analyses (4-8 trials per outcome). There was no evidence of effect modification based on whether the intervention was linked to primary care (independent of intervention intensity), the number of intervention sessions, the duration of the intervention, whether the intervention included group sessions, the focus of the intervention message (eg, specific dietary message), the population risk for CVD, or study quality. Very few trials reported longer-term effects (ie, greater than 12 months of follow-up) on intermediate outcomes, and there was no consistent pattern in the effects over time among those that did. In addition, there was no evidence of small-study effects for any of the intermediate outcomes.

Table 2. Pooled Results of Intermediate Outcomes for All Interventions and by Intervention Intensity

<table>
<thead>
<tr>
<th>Outcome</th>
<th>All Interventions</th>
<th>Intervention Intensity</th>
<th>Medium (31-360 min)*</th>
<th>Low (≤30 min)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of Trials</td>
<td>Mean Difference in Change (95% CI)</td>
<td>No. of Trials</td>
<td>Mean Difference in Change (95% CI)</td>
</tr>
<tr>
<td>Blood pressure, mm Hg</td>
<td>22</td>
<td>−1.26 (−1.77 to −0.75)</td>
<td>12</td>
<td>−1.55 (−2.21 to −0.89)</td>
</tr>
<tr>
<td>Diastolic</td>
<td>23</td>
<td>−0.49 (−0.82 to −0.16)</td>
<td>12</td>
<td>−0.67 (−0.98 to −0.37)</td>
</tr>
<tr>
<td>Lipids, mg/dL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LDL-C</td>
<td>13</td>
<td>−2.58 (−4.30 to −0.83)</td>
<td>19.6</td>
<td>−4.51 (−6.85 to −2.16)</td>
</tr>
<tr>
<td>Total cholesterol</td>
<td>19</td>
<td>−2.85 (−4.95 to −0.75)</td>
<td>50.8</td>
<td>−5.32 (−8.84 to −1.81)</td>
</tr>
<tr>
<td>HDL-C</td>
<td>15</td>
<td>−0.17 (−1.05 to 0.71)</td>
<td>55.2</td>
<td>−0.54 (−2.08 to 1.00)</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>13</td>
<td>−1.82 (−5.05 to 1.42)</td>
<td>4.7</td>
<td>−3.43 (−8.16 to 1.31)</td>
</tr>
<tr>
<td>Fasting glucose, mg/dL</td>
<td>13</td>
<td>−0.36 (−1.22 to 0.5)</td>
<td>42.4</td>
<td>−1.35 (−2.24 to −0.45)</td>
</tr>
</tbody>
</table>
| BMI*                           | 20              | −0.41 (−0.62 to −0.19) | 95.8             | −0.81 (−0.99 to −0.63) | 73.8           | −0.19 (−0.42 to 0.04) | 76.4           | −0.05 (−0.39 to 0.28) | 85.6
| Weight, kg                     | 20              | −1.04 (−1.56 to −0.51) | 92.4             | −1.62 (−2.31 to −0.93) | 92.5           | −0.44 (−0.82 to −0.06) | 40.5           | −0.23 (−1.56 to 0.40) |
| Waist circumference, cm        | 17              | −1.19 (−1.79 to −0.59) | 91.8             | −1.92 (−2.66 to −1.17) | 82.1           | −0.77 (−1.63 to 0.09)  | 79.0           | −0.04 (−0.27 to 0.35)  |

Abbreviations: BMI, body mass index; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; NA, not applicable.

SI conversion factors: To convert LDL-C, total cholesterol, and HDL-C values from mmol/L to mg/dL, multiply by 38.67; for fasting glucose, multiply by 0.0555.

Effects of Interventions on Behavioral Outcomes

Key Question 3. Do primary care behavioral counseling interventions to improve diet, increase physical activity, and/or reduce sedentary behavior improve associated health behaviors in adults?

All but 273 of the 88 included studies (n = 117,589) reported the effects of a behavioral intervention on dietary, physical activity, and/or sedentary behavior outcomes. More than one-third of the studies that reported behavioral outcomes (36/86 studies) were newly identified as part of this update. Almost all of the behavioral outcomes were based on self-report; 3 trials measured urinary sodium excretion, and 11 trials used accelerometers or pedometers to capture objective measures of physical activity. The instruments, modes of administration, and summary measures were highly variable across trials that measured behavioral outcomes through self-report.

Overall, there was evidence that behavioral interventions generally improved participants’ dietary intake and physical activity levels. Mean between-group differences for dietary outcomes showed consistent benefit for healthful diet interventions (with or without physical activity messages) vs control groups at 6 months’ or greater follow-up, but the precision in the magnitude of effects was highly

© 2017 American Medical Association. All rights reserved.
variable across trials; thus, pooled results are not presented. Be-
tween-group differences for dietary outcomes were in the magni-
tude of 65 kcal/d (favoring the control group) to ~500 kcal/d
(favoring the intervention group) in total energy intake (11 trials), 0.8
to ~11 percentage points in the percentage of calories from fat
(15 trials), and ~0.3 to ~4.1 percentage points in the percentage of
calories from saturated fat (9 trials). Effects on fruit and vegetable
intake ranged from between-group differences of ~0.2 serving/d
(favoring the control group) to 2.2 servings/d (favoring the inter-
vention group) (16 trials); between-group differences in grams of fi-
ber per day ranged from 1 g to 2.5 g in favor of the intervention group
(6 trials). Reductions in sodium (urinary sodium excretion or self-
reported dietary intake) ranged from ~380 mg/d to ~1380 mg/d
(6 trials). Only 9 trials reported the effects of the interventions on
dietary outcomes at greater than 12 months of follow-up (ie, 1.5 to
6 years of follow-up), with a lack of effect or slightly attenuated ef-
fect being seen over time.

Physical activity interventions (with or without dietary mes-
sages) were associated with a 35-minute (95% CI, 22.0 to 47.0) in-
crease in physical activity per week compared with controls in pooled
analyses at 6 to 12 months of follow-up (27 trials). The standard-
ized effect size when pooling 46 trials that reported any continu-
ous measure of physical activity (eg, minutes per day, minutes per
week, metabolic-equivalent minutes per week, score) was a mean
difference of 0.20 (95% CI, 0.14 to 0.26) in favor of the interven-
tion group. Additionally, meta-analysis indicated that intervention
group participants had an odds ratio of 1.32 (95% CI, 1.12 to 1.56) for
meeting physical activity recommendations, compared with those
in the control group (16 trials). Data on physical activity outcomes
beyond 12 months were sparsely reported. Studies that limited their
inclusion to participants with suboptimal levels of physical activity
at baseline (eg, below the recommended level of 150 minutes per
week) resulted in greater increases in physical activity compared with
those that did not limit inclusion based on baseline physical activity
levels. In contrast to findings for intermediate outcomes, there
was no evidence of effect modification based on intervention in-
tensity. Likewise, there was no evidence of a difference in effects
for interventions focused only on physical activity messages vs those
focused on both physical activity and healthful diet messages.

Only 4 trials reported measures of sedentary behavior inde-
pendent of physical activity behavior. Of these 4 trials, 2 found sta-
tistically significant group × time effects on self-reported minutes
of sitting, including 1 trial that specifically targeted reductions in daily
television viewing and total sitting time.

Harms of Interventions
Key Question 4. What adverse events are associated with primary
care behavioral counseling interventions to improve diet, increase
physical activity, and/or reduce sedentary behavior in adults?

Harms of included interventions were sparsely reported and
were inconsistently defined. Fourteen of the included trials
(n = 8220) specifically mentioned the occurrence of harms or lack of
harms. Across these studies, there were no serious adverse events related to the interventions
reported, although none were hypothesized. Seven physical activity-
focused trials (n = 3565) reported the incidence of injuries, frac-
tures, or falls; only 1 trial among women aged 40 to 74 years re-
ported significantly more injuries (19% vs 14%, P = .03) and falls (37% vs 29%, P < .001) among participants in the intervention group than
in the control group, respectively, over 24 months of follow-up. 102

Discussion
This systematic review was conducted to assist the USPSTF in up-
dating its 2012 recommendation on healthful diet and physical ac-

tivity counseling for the primary prevention of CVD in persons with-
out traditional CVD risk factors. 22,32,35,41,44,52,73,78,95,97,102,121,132,150 This updated systematic review was generally consistent in magnitude with the
2010 review on this topic 15 and slightly lower in magnitude com-
pared with the associations seen in the 2014 review among per-
sons at high risk for CVD 14 (eTable 3 in the Supplement).

Table 3 summarizes the findings for this evidence review. Health-
ful diet and physical activity behavioral interventions in persons with-
out traditional CVD risk factors were associated with modest reduc-
tions in blood pressure, levels of total cholesterol and LDL-C, and
adiposity measures at approximately 6 to 12 months of follow-up,
compared with control conditions. The interventions varied con-
siderably across the studies, such as in their behavioral focus (diet
only, physical activity only, or diet plus physical activity messages),
their delivery mode (group and individual in-person counseling, tele-
phone counseling, print-based, or technology-based), and their in-
tensity (number of sessions, length of sessions, and duration of the
intervention). There was evidence of a dose-response relationship,
with increasing intervention intensity being associated with larger
improvements in intermediate outcomes, but there was insuffi-
cient evidence to assess the effects of low-intensity interventions
alone on intermediate outcomes. There was considerably more evi-
dence for behavioral outcomes, with 86 trials reporting the effects of
counseling interventions on dietary intake, physical activity, and/or
sedentary behaviors. The direction of effects for all behavioral out-
comes was reasonably consistent and suggested generally a small
benefit for dietary outcomes and a moderate benefit for physical ac-
tivity. However, there was substantial variation in outcome mea-
sures and insufficient evidence on the effects of interventions on
sedentary behaviors.

The evidence for the effects of interventions on longer-term
health outcomes, including all-cause and CVD-specific mortality, CVD
events, and health-related quality of life, as well as intermediate car-
diometabolic outcomes past 1 year, was sparse and inconsistent, pre-
cluding a robust conclusion. Likewise, a limited number of trials re-
ported on harms of the interventions, and none of these studies
found any serious adverse events related to the interventions.

In the context of sparse randomized clinical trial evidence for
the effect of healthful diet and physical activity interventions on
health outcomes, observational evidence from very large, indi-
vidual participant–data meta-analyses of prospective cohort stud-
ies can be used to estimate and bound the potential benefit of pro-
portional differences in intermediate outcomes on the risk of
morbidity and mortality. Such evidence suggests that small differ-
ences in blood pressure, blood cholesterol levels, and body mass in-
dex can translate into small differences in important health out-
comes (see full evidence report). 166-168
### Table 3. Summary of Evidence, by Key Question

<table>
<thead>
<tr>
<th>No. of RCTs, No. of Observations</th>
<th>Study Quality</th>
<th>Body of Evidence Limitations</th>
<th>Consistency/Precision</th>
<th>Applicability</th>
<th>Summary of Findings by Outcome</th>
<th>Reporting Bias</th>
<th>EPC Assessment of Strength of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>KQ1: Do Primary Care Behavioral Counseling Interventions to Improve Diet, Increase Physical Activity, and/or Reduce Sedentary Behavior Improve Health Outcomes in Adults?</strong></td>
<td>12 RCTs n = 58,848 (2/12 trials identified in update; both new studies reported QOL outcomes)</td>
<td>Good: 5 Fair: 7</td>
<td>Data from 2 trials based on observational follow-up after trials were completed. Few studies reported QOL measures; most reported domain-specific QOL instead of summary scores.</td>
<td>Reasonably consistent(^b) Imprecise</td>
<td>Mortality and CVD event data limited to high-intensity diet-only interventions, and most studies were among individuals with high-normal BP. Largest trial in postmenopausal women. QOL data limited to mostly physical activity trials.</td>
<td>No difference in all-cause or CVD-related mortality in high-intensity diet-only interventions at 3 to 15 y of follow-up (4 studies, n = 51,356). Mixed findings for effects on CVD events in 3 high-intensity diet-only interventions at 8 to 15 y follow-up. Largest trial in postmenopausal women (n = 48,835) found no difference in major CVD events or stroke among women without a history of CVD over 8.1 y of follow-up. No consistent benefit of interventions on QOL at 6-12 mo (10 studies, n = 52,423).</td>
<td>Undetected for mortality and CVD events Suspected for QOL(^b)</td>
</tr>
<tr>
<td><strong>KQ2: Do Primary Care Behavioral Counseling Interventions to Improve Diet, Increase Physical Activity, and/or Reduce Sedentary Behavior Improve Intermediate Outcomes Associated With CVD in Adults?</strong></td>
<td>34 RCTs n = 71,793 (10/34 trials identified in update)</td>
<td>Good: 13 Fair: 21</td>
<td>Considerable statistical heterogeneity ((I^2 &gt; 90%)) for meta-analyses of adiposity outcomes. Limited evidence beyond 12 mo or for incidence of hypertension, dyslipidemia, or diabetes.</td>
<td>Consistency and precision varied across intermediate outcomes; more consistent and precise for blood pressure and LDL-C(^c)</td>
<td>Generally applicable to adults not at risk for CVD. Intensity of intervention confounded with setting; high-intensity interventions were more likely to take place outside of primary care and show effectiveness. Few physical activity–focused trials reported intermediate outcomes.</td>
<td>Small, statistically significant improvements in SBP (−1.26 mm Hg [95% CI, −1.77 to −0.76], 22 studies) and DBP (−0.49 mm Hg [95% CI, −0.82 to −0.16], 23 studies), LDL-C (−2.58 mg/dL [95% CI, −4.30 to −0.85], 13 studies), total cholesterol (−2.85 mg/dL [95% CI, −4.95 to −0.75], 19 studies), and adiposity outcomes (BMI, −0.41 [95% CI, −0.62 to −0.20], 20 studies) at 6–12 mo associated with healthful diet, physical activity interventions, or both. Evidence of dose-response effect with increasing intervention intensity associated with larger improvements in intermediate outcomes. Insufficient evidence to assess the effects of low-intensity interventions alone. No evidence of an association with levels of HDL-C, triglycerides, or FBG.</td>
<td>Undetected</td>
</tr>
</tbody>
</table>

(continued)
Table 3. Summary of Evidence, by Key Question (continued)

<table>
<thead>
<tr>
<th>No. of RCTs, No. of Observations</th>
<th>Study Quality</th>
<th>Body of Evidence Limitations</th>
<th>Consistency/Precision</th>
<th>Applicability</th>
<th>Summary of Findings by Outcome</th>
<th>Reporting Bias</th>
<th>EPC Assessment of Strength of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>KQ3: Do Primary Care Behavioral Counseling Interventions to Improve Diet, Increase Physical Activity, and/or Reduce Sedentary Behavior Improve Associated Health Behaviors in Adults?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>86 studies, n = 117,589 (36/86 trials identified in update)</td>
<td>Good: 18, Fair: 68</td>
<td>Almost all outcomes based on self-report instruments, recall periods, and summary measures were extremely heterogeneous, with varying evidence of validity and reliability. Few interventions incorporated messages to decrease sedentary behavior.</td>
<td>Reasonably consistent Imprecise</td>
<td>Generally applicable to adults not at risk for CVD. Larger effect sizes for physical activity outcomes were seen for persons with lower levels of physical activity at baseline. Most trials that reported a physical activity outcome were of low or medium intensity.</td>
<td>Magnitude and precision in differences for dietary outcomes were quite variable across studies and resulted in considerable heterogeneity in meta-analysis. Between-group differences for dietary outcomes were in magnitude of 65 (favoring the control group) to −500 kcal/d (favoring the intervention group) in total energy intake (11 studies), 0.8 to −11 points in percentage of calories from fat (15 studies), and −0.3 to −4.1 points in percentage of calories from saturated fat (9 studies), and approximately −380 to nearly −1400 mg/d of sodium (6 studies). Effects on fruit and vegetable intake ranged from between-group differences of −0.2 servings/d (favoring control group) to 2.2 servings/d (favoring intervention group) (16 studies); between-group differences in grams of fiber per day ranged from 1 to 2.5 g in favor of intervention group (6 studies). Small, statistically significant association with behavioral interventions and physical activity in favor of interventions over controls (SMD, 0.20 [95% CI, 0.14 to 0.26]; 46 studies). An analysis of physical activity found difference of approximately 35 min of physical activity per wk between groups (mean difference, 34.5 min/wk [95% CI, 22.0 to 47.0]; 27 studies). Significantly higher odds of meeting PA recommendations (150 min/wk of PA) among intervention vs control group participants (OR, 1.32 [95% CI, 1.12 to 1.64]; 16 studies). Effects on cardiorespiratory fitness were generally consistent with results for self-reported physical activity. Insufficient evidence for sedentary behaviors.</td>
<td>Undetected</td>
<td>Low</td>
</tr>
</tbody>
</table>
Table 3. Summary of Evidence, by Key Question (continued)

<table>
<thead>
<tr>
<th>No. of RCTs, No. of Observations</th>
<th>Study Quality</th>
<th>Body of Evidence Limitations</th>
<th>Consistency/Precision</th>
<th>Applicability</th>
<th>Summary of Findings by Outcome</th>
<th>Reporting Bias</th>
<th>EPC Assessment of Strength of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>KQ: What Adverse Events Are Associated With Primary Care Behavioral Counseling Interventions to Improve Diet, Increase Physical Activity, and/or Reduce Sedentary Behavior in Adults?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14 RCTs (n = 8220)</td>
<td>Good: 7</td>
<td>Harms sparsely reported for included trials. Few details provided about how harms were recorded and specific events that occurred.</td>
<td>Reasonably consistent and precise</td>
<td>Applicable to physical activity interventions. Did not include observational evidence on harms related to changes in diet or physical activity.</td>
<td>No serious adverse events related to behavioral interventions (8 studies). Seven PA trials generally found no differences in rates of injuries, fractures, falls, or CV events. Only 1 trial among women aged 40–74 y found significantly more injuries and falls among intervention vs control group participants.</td>
<td>Undetected</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index; BP, blood pressure; CV, cardiovascular; CVD, cardiovascular disease; DBP, diastolic blood pressure; EPC, evidence-based practice center; FPG, fasting blood glucose; HDL-C, high-density lipoprotein cholesterol; HR, hazard ratio; KQ, key question; LDL-C, low-density lipoprotein cholesterol; OR, odds ratio; PA, physical activity; QOL, quality of life; RCT, randomized clinical trial; SBP, systolic blood pressure; SMD, standardized mean difference.

SI conversion factors: To convert LDL-C and total cholesterol values to mmol/L, multiply by 0.0259.

* Reasonably consistent and reasonably precise for DBP and LDL-C; inconsistent and imprecise for total cholesterol, HDL-C, and triglycerides; and inconsistent and reasonably precise for adiposity outcomes.

* All but 1 study was a randomized clinical trial; the 1 remaining study was a nonrandomized clinical trial.

* Despite the relatively limited number of studies that reported harms related to interventions, there is moderate confidence that there are no serious harms related to behavioral counseling interventions for healthful diet and physical activity.
these methods can be prone to bias. While researchers must fit the specific measurement instruments and summary variables to the needs of their particular study aims, research protocols, and sample characteristics, the field of research could benefit from more standardization of behavioral outcome measurement.

Studies that were heterogeneous with respect to clinical and demographic characteristics, interventions, and settings were intentionally pooled. For most outcomes, the statistical heterogeneity of pooled analyses was unimportant ($I^2 < 40\%$) or moderate ($I^2 = 30\%-60\%$) and therefore still reasonable to allow for interpreting of pooled estimates. However, given the clinical heterogeneity, interpreting the 95\% confidence intervals instead of the summary estimate helps inform the true magnitude of effects on the individual outcomes.

**Conclusions**

Diet and physical activity behavioral interventions for adults not at high risk for cardiovascular disease result in consistent modest benefits across a variety of important intermediate health outcomes across 6 to 12 months, including blood pressure, low-density lipoprotein and total cholesterol levels, and adiposity, with evidence of a dose-response effect, with higher-intensity interventions conferring greater improvements. There is very limited evidence on longer-term intermediate and health outcomes or on harmful effects of these interventions.


