CLINICAL GUIDELINE | Annals of Internal Medicine

Behavioral Counseling to Promote Physical Activity and a Healthful Diet to Prevent Cardiovascular Disease in Adults: A Systematic Review for the U.S. Preventive Services Task Force

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Background: Poor diet and lack of physical activity can worsen cardiovascular health, yet most Americans do not meet diet and physical activity recommendations.

Purpose: To assist the U.S. Preventive Services Task Force in updating its previous recommendations by systematically reviewing trials of physical activity or dietary counseling to prevent cardiovascular disease.

Data Sources: MEDLINE, PsycINFO, Cochrane Central Register of Controlled Trials (2001 to January 2010), experts, and existing systematic reviews.

Study Selection: Two investigators independently reviewed 13 562 abstracts and 481 articles against a set of a priori inclusion criteria and critically appraised each study by using design-specific quality criteria.

Data Extraction and Analysis: Data from 73 studies (109 articles) were abstracted by one reviewer and checked by a second reviewer. Random-effects meta-analyses were conducted for multiple intermediate health and behavioral outcomes.

Data Synthesis: Long-term observational follow-up of intensive sodium reduction counseling showed a decrease in the incidence of cardiovascular disease; however, other direct evidence for reduction in disease morbidity is lacking. High-intensity dietary counseling, with or without physical activity counseling, resulted in changes of −0.3 to −0.7 kg/m^2 in body mass index (adiposity), −1.5 mm Hg (95% CI, −0.9 to −2.1 mm Hg) in systolic blood pressure, −0.7 mm Hg (CI, −0.6 to −0.9 mm Hg) in diastolic pressure, −0.17 mmol/L (CI, −0.09 to −0.25 mmol/L) (−6.56 mg/dL [CI, −3.47 to −9.65 mg/dL]) in total cholesterol level, and −0.13 mmol/L (CI, −0.06 to −0.21 mmol/L) (−5.02 mg/dL [CI, −2.32 to −8.11 mg/dL]) in low-density lipoprotein cholesterol level. Medium- and high-intensity counseling resulted in moderate to large changes in self-reported dietary and physical activity behaviors.

Limitations: Meta-analyses for some outcomes had large statistical heterogeneity or evidence for publication bias. Only 11 trials followed outcomes beyond 12 months.

Conclusion: Counseling to improve diet or increase physical activity changed health behaviors and was associated with small improvements in adiposity, blood pressure, and lipid levels.

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Editor's Note: As part of the U.S. Preventive Services Task Force's (USPSTF) ongoing commitment to clarity about its work and methods, the USPSTF is inviting public comment on all draft recommendation statements. The USPSTF's draft recommendation statement on behavioral counseling to promote physical activity and a healthful diet to prevent cardiovascular disease will soon be available for public comment at www.uspreventiveservicestaskforce.org/. *As a result, the recommendation on behavioral counseling to promote physical activity and a healthful diet to prevent cardiovascular disease does not appear with this accompanying background review. Once finalized, the recommendation statement will reflect any changes made based on the public comments received. A summary of these changes will be included in a new section of the final recommendation statement.*

See also:

Web-Only
Appendix Figure
Conversion of graphics into slides

Diseases associated with physical inactivity and poor diet rank among the leading causes of illness and death in the United States (1, 2) and are well-established determinants in many chronic diseases, including cardiovascular and cerebrovascular disease, hypertension, dyslipidemia, and type 2 diabetes (1, 3–5). Although persons of all ages benefit from regular exercise (5), Americans generally do not meet recommended levels of physical activity (6, 7). Americans' diets are also drastically out of line with the generally accepted dietary recommendations published by many organizations, such as the U.S. Department of Health and Human Services (8, 9).

In 2002 and 2003, the USPSTF concluded that evidence was insufficient to recommend for or against behavioral counseling in primary care settings to promote physical activity (I recommendation) or behavioral counseling to promote a healthful diet in unselected patients in primary care (I recommendation). We therefore performed this review to assist in the updating of these recommendations. This review combines counseling for both physical activity and dietary change with a focus on the prevention of cardiovascular disease in adults without known diabetes, hypertension, dyslipidemia, or coronary heart disease. To conduct this review, we developed an analytic framework

with 4 key questions (**Appendix Figure**, available at www.annals.org) that included the effect of dietary or physical activity counseling on health outcomes (key question 1), intermediate cardiovascular disease–related outcomes (key question 2), behavioral outcomes (key question 3), and harms of the counseling interventions (key question 4).

Methods

The full report (10) provides a detailed description of our methods, including search strategies and excluded studies.

Data Sources and Searches

To identify literature published for each key question since the previous recommendations, we searched MEDLINE, PsycINFO, and the Cochrane Central Register of Controlled Trials from January 2001 to January 2010. We supplemented our searches with suggestions from experts and reference lists from other relevant publications, including the 2 previous USPSTF systematic reviews and 9 related existing reviews (11–21).

Study Selection

Two investigators independently reviewed 13 562 abstracts and 481 articles against the specified inclusion criteria (**Figure**). We included trials with primary care–relevant counseling on physical activity (for example, aerobic activities, such as walking, cycling, or swimming, or resistance training) or healthful diet interventions (for example, appropriate calorie intake; increased intake of fruits and vegetables, whole grains, and fiber; balanced intake of fats; or decreased sodium). We excluded interventions primarily aimed at weight loss or those that provided controlled diets or supervised physical activity. Primary care–relevant counseling included interventions that were conducted in, judged feasible to be conducted in (such as phone or electronic interventions), or potentially referable from a primary care setting. Interventions had to be compared with usual care, a minimal intervention, or an attention-control group. We excluded interventions that targeted persons with known hypertension, hyperlipidemia, diabetes, or cardiovascular disease and trials in which more than 50% of the population had known heart disease or any one or a combination of these risk factors. We required a minimum follow-up of 6 months after randomization. A priori outcomes included true health outcomes (morbidity or mortality related to cardiovascular disease); intermediate outcomes and physiologic changes associated with health outcomes (blood pressure, lipid profile, fasting glucose level and glucose tolerance, and adiposity); and behavioral outcomes (any self-reported change in physical activity or dietary intake). We did not include cost-effectiveness or cost-related outcomes. For harms, we included any observational studies that reported serious cardiovascular harms, such as acute cardiac events during or immediately after physical activity.

Data Extraction and Quality Assessment

Articles that met our inclusion criteria were critically appraised by 2 reviewers using the USPSTF and National Institute for Health and Clinical Excellence design-specific quality criteria (22). The reviewers were each blinded to the other's initial ratings, and discrepancies were resolved by consensus. Articles were rated as good, fair, or poor quality. Good-quality studies met all of the specified quality criteria, whereas fair-quality studies did not but had no fatal flaws in the design, execution, or reporting of the study. Poor-quality studies were excluded from this review.

For included studies, 1 investigator extracted data on study setting, populations, interventions, and prespecified outcomes into standardized evidence tables and a second investigator verified all extracted data.

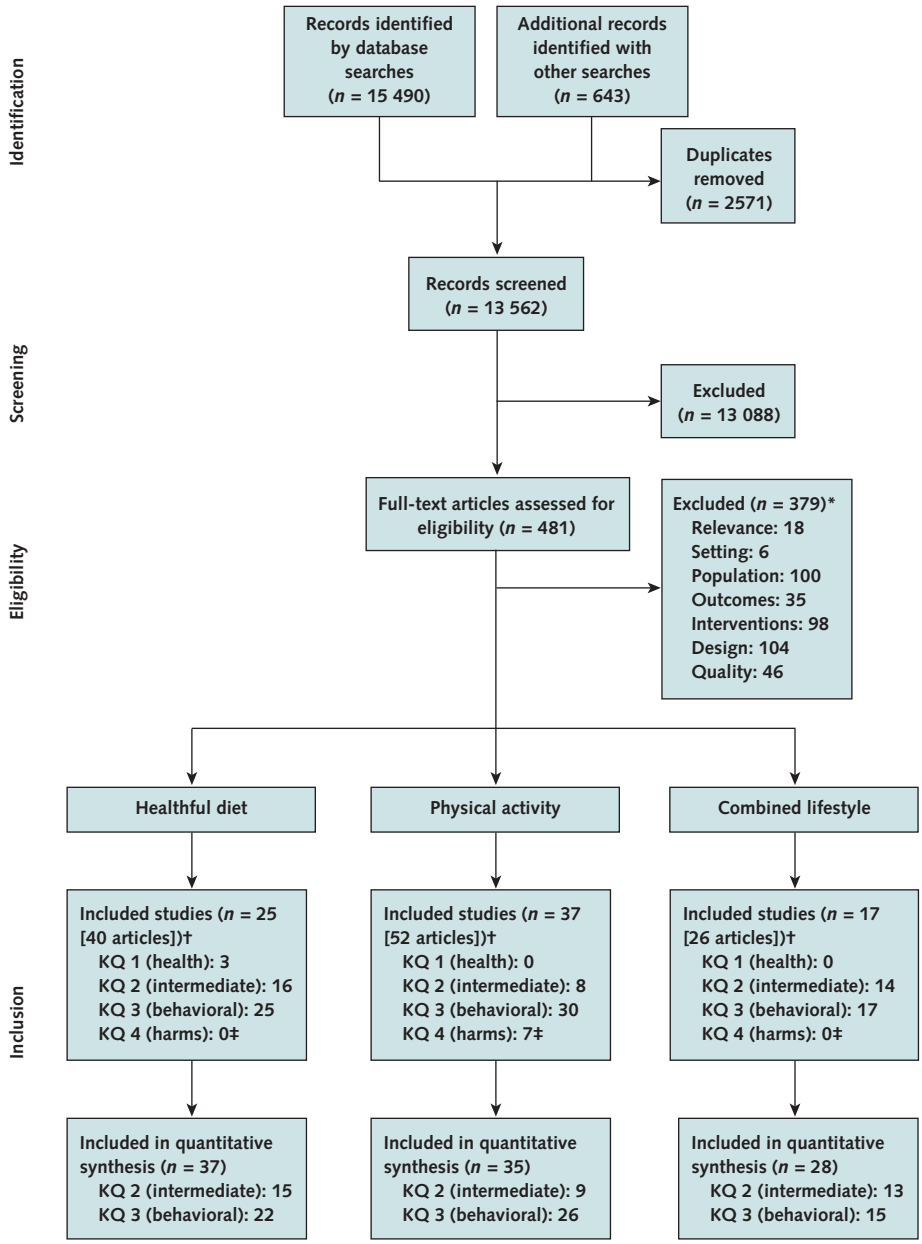
Data Synthesis and Analysis

We conducted random-effects meta-analyses to estimate the effect size of counseling on all intermediate health outcomes and behavioral outcomes. We combined all trials with a given outcome and conducted separate analyses for each of the 3 intervention targets (physical activity, healthful diet, and combined) and, if applicable, for the specific dietary message (sodium reduction, focus on fruits and vegetables only, or general low-fat or heart-healthy dietary counseling). Analyses were stratified by estimated intervention intensity (low [≤30 minutes], medium [between 31 minutes and 6 hours of contact], or high [>6 hours of contact]). Trials were also categorized by population risk as being unselected or selected only on the basis of age; selected for suboptimal behavior (such as sedentary behavior or poor dietary intake); or selected for individual or population risk factors for increased incidence of cardiovascular disease (such as mildly elevated diastolic blood pressure or fasting glucose or serum lipid levels, obesity, or poverty or poor access to health care).

We assessed the presence of statistical heterogeneity among the studies by using standard chi-square tests and estimated the magnitude of heterogeneity by using the I^2 statistic (23). Tests of publication bias to determine whether the distribution of the effect sizes was symmetric with respect to the precision measure were performed by using funnel plots and the Egger linear regression method (24, 25). Meta-regressions were performed on the basis of the random-effects models to examine the effect of 4 a priori variables of heterogeneity (intervention intensity, intervention target, study population risk, and recruitment method [volunteer vs. study-identified]) on effect size. To interpret effect sizes of standardized mean differences, we used the Cohen d statistic, in which an effect size of 0.2 to 0.3 generally represents a small effect; 0.5, a moderate effect; and 0.8, a large effect (26).

All analyses were performed by using Stata, version 10.0 (StataCorp, College Station, Texas).

Figure. **Summary of evidence search and selection.**



KQ = key question.
* We excluded 28 articles for different reasons in different areas; 7 were excluded for 1 area and included for another.
† We included 8 studies in more than 1 area.
‡ Additional studies identified for harms (not including trials included for KQs 1 to 3).

Role of the Funding Source

We worked with 4 USPSTF liaisons at key points throughout the review process to develop and refine the scope and resolve other issues. The Agency for Healthcare Research and Quality funded this research under a contract to support the USPSTF. The funding source had no role in study selection, quality assessment, or synthesis, although they provided project oversight, reviewed the draft evidence synthesis, and assisted in external review of the draft evidence synthesis.

RESULTS

We identified 66 trials that reported the effects of counseling for physical activity, healthful diet, or both. Thirty trials (27–71), comprising 15 265 patients, tested

the effect of counseling persons to increase physical activity, and 26 of these (14 172 patients) were included in our meta-analyses (27–29, 31, 33, 35–37, 42, 45, 47, 48, 50, 51, 53–57, 59, 61, 63–65, 67, 69, 70). Twenty-five trials (29, 30, 37, 38, 42, 43, 48, 72–103), comprising 71 267 patients, tested the effect of counseling persons to eat a healthful diet; 24 of these studies (70 969 patients) were included in our meta-analyses (37, 42, 48, 72–78, 81, 82, 85–93, 96, 99, 103). Seventeen trials (42–44, 76, 104–125), comprising 5105 patients, examined the effects of counseling persons for both physical activity and healthful diet; we included 15 of these (4475 patients) in our meta-analyses (42, 76, 104, 106, 108, 111, 113–118, 121, 124, 125). Some trials were not included in our meta-analyses because they did not provide necessary data; for example, some reported results only in figures without providing group means and others did not provide SEs or SDs. In addition, we identified 7 studies (126–132), comprising 4354 patients, that addressed the harms of physical activity. The tables in the **Supplement** (available at www.annals.org) provide study details for counseling trials.

Of the 66 counseling trials, only 13 were good-quality trials (31, 45, 53–55, 57, 59, 82, 96, 99, 116, 118, 125). Fair-quality trials often did not report randomization procedures, allocation concealment, or blinding of outcomes assessment. Many fair-quality trials also limited analyses to persons who completed the study. Some trials did not have allocation concealment of randomization or blinded outcome assessment. Some fair-quality trials, as opposed to good-quality trials, had higher attrition (for example, >20%), differential attrition, or differences in baseline characteristics between groups. Most trials, including the good-quality ones, did not report fidelity of or adherence to counseling interventions.

Trials included a representative range of persons. Men accounted for approximately 17% of all trial participants, or about 35% of trial participants excluding the largest trial that enrolled only women (99). Eleven trials included only women (48, 54, 61, 69, 70, 78, 92, 99, 115, 118, 121), and 5 trials included only men (42, 59, 64, 65, 103). Trials were primarily conducted in middle-aged adults (weighted mean age, 59 years [range, 20 to 78 years]). Nine trials (37, 39, 45, 53, 59, 64, 66, 75, 87) were explicitly conducted in older adults, and most of these trials involved only physical activity counseling (37, 39, 45, 53, 59, 64, 66). Among the 38 trials conducted in the United States, approximately 18% of participants were nonwhite (range in individual trials, 3% to 100%).

Counseling interventions ranged from low-intensity (such as those conducted in a single session or by mail alone) to very high-intensity (such as those with up to 20 sessions over 2 years). Trials were not evenly distributed across categories of study population risk (**Table 1**).

Among diet counseling trials, low-intensity interventions were almost all conducted in general-risk persons and medium- to high-intensity interventions were mostly conducted in selected persons. In contrast, almost all of the physical activity counseling trials were conducted in persons who did not meet recommended levels of physical activity, and only 1 counseling intervention was high-intensity. The combined lifestyle counseling interventions showed a very different distribution, in that medium-intensity trials tended to target patients selected for risk factors related to cardiovascular disease, whereas high-intensity trials primarily involved unselected populations.

Key Question 1: Health Outcomes

Data on the morbidity or mortality related to cardiovascular disease were limited to 3 large, good-quality trials (**Table 2**). In the Women's Health Initiative Dietary Modification Trial (48 835 participants), postmenopausal women who were randomly assigned to intensive low-fat dietary counseling had no difference in major coronary heart disease events (hazard ratio [HR], 0.97 [95% CI, 0.90 to 1.06]), stroke (HR, 1.02 [CI, 0.90 to 1.15], or death (HR, 0.98 [CI, 0.91 to 1.07]) after approximately 8.1 years of follow-up (100, 101). Long-term observational follow-up of TOHP (Trials of Hypertension Prevention) I and II (3126 participants) showed that persons with mildly elevated diastolic blood pressure (80 to 89 mm Hg) who were randomly assigned to intensive sodium restriction counseling had fewer cardiovascular events and revascularization (2415 participants; HR, 0.70 [CI, 0.53 to 0.94]), but no difference in total mortality (3126 participants; HR, 0.80 [CI, 0.51 to 1.26]) after 10 to 15 years of follow-up (134). A more conservative cardiovascular disease composite outcome (without revascularization) was not statistically significant, although the point estimate was similar (2415 participants; HR, 0.72 [CI, 0.50 to 1.03]). Visual inspection of cumulative incidence curves of cardiovascular disease events in TOHP I and II suggests that the intervention and control groups began to diverge at approximately 8 to 9 years of follow-up.

Key Question 2: Intermediate Outcomes

Medium- to high-intensity dietary interventions (with or without concomitant physical activity counseling) decreased body mass index at about 12 months. Statistical heterogeneity was high ($I^2 > 70\%$), making interpretation of pooled effect sizes questionable (**Table 3**). Two thirds of the trials of high-intensity dietary interventions, however, reported statistically significant group differences, suggesting that although the amount of weight change varied greatly from study to study, these interventions are likely to reduce weight (decrease in body mass index of approximately 0.3 to 0.7 kg/m^2). Physical activity counseling trials were limited to primarily medium-intensity interventions for this outcome and generally did not reduce adiposity. Five trials evaluating high-intensity counseling had follow-up longer than 12 months; the reduction in body mass index persisted up to 72 months, although this result was slightly attenuated (99, 113, 117, 118, 121).

Table 1. **Counseling Trials, by Intervention Intensity and Population Risk**

Intervention Intensity and PCP Role	Unselected Population	Population Selected for Suboptimal Diet or Exercise Behavior	Population Selected for Increased Cardiovascular Risk
Low-intensity intervention (estimated 0–30 min)			
Substantial PCP role in intervention	Beresford et al, 1997 (74)* Sacerdote et al, 2006 (90)* Katz et al, 2008 (47)†	Aittasalo et al, 2006 (27)† Goldstein et al, 1999 (33)† Grandes et al, 2009 (35)†	
No PCP role in intervention			
Conducted in or recruited from primary care or health plan	Carpenter et al, 2004 (77)* Fries et al, 2005 (81)* John et al, 2002 (85)* Kristal et al, 2000 (86)* Lutz et al, 1999 (87)* Roderick et al, 1997 (89)*	Prochaska et al, 2005 (88)* Halbert et al, 2000 (39)†	
Not conducted in or recruited from primary care or health plan	De Vet et al, 2009 (28)† Stensel et al, 1994 (65)† Jeffery and French, 1999 (114)‡	Marcus et al, 2007 (55)† Marshall et al, 2003 (56)† Napolitano et al, 2006 (61)† Pekmezi et al, 2009 (70)†	
Medium-intensity intervention (estimated 31–360 min)			
PCP role in intervention	Baron et al, 1990 (73)* Green et al, 2002 (36)† Norris et al, 2000 (63)†	Elley et al, 2003 (31)† Lawton et al, 2008 (54)† Pinto et al, 2005 (64)†	Kallings et al, 2009 (45)†
No PCP role in intervention			
Conducted in or recruited from primary care or health plan	Morey et al, 2009 (59)†	Delichatsios et al, 2001 (29)*† Harland et al, 1999 (41)† Kinmonth et al, 2008 (51)† Kolt et al, 2007 (53)†	Hellénius et al, 1993 (42)*†‡ Stevens et al, 2003 (92)* Yates et al, 2009 (133)† Babazono et al, 2007 (106)‡ Eakin et al, 2007 (108)‡ Hardcastle et al, 2008 (111)‡ Keyserling et al, 2008 (115)‡ Mosca et al, 2008 (116)‡ Wister et al, 2007 (125)‡
Not conducted in or recruited from primary care or health plan	Connell and Janevic, 2009 (69)† Martinson et al, 2008 (57)† Franko et al, 2008 (110)‡ Vandelanotte et al, 2005 (124)‡	Greene et al, 2008 (37)*† Bernstein et al, 2002 (75)* King et al, 2002 (48)*† King et al, 2007 (50)† Marcus et al, 2007 (55)†	Brekke et al, 2005 (76)*‡ Watanabe et al, 2003 (103)*
High-intensity intervention (estimated >360 min)			
No PCP role in intervention			
Conducted in or recruited from primary care or health plan		Stewart et al, 2001 (66)†	Edelman et al, 2006 (109)‡ Oldroyd et al, 2001 (117)‡
Not conducted in or recruited from primary care or health plan	Carpenter et al, 2004 (77)* Aldana et al, 2006 (104)‡ Hivert et al, 2007 (113)‡ Simkin-Silverman et al, 1995 (119)‡ Thompson et al, 2008 (121)‡	Coates et al, 1999 (78)* Tinker et al, 2008 (99)*	Shah et al, 1990 (83)* TOHP, phase I, 1992 (93)* TOHP, phase II, 1997 (96)* Stefanick et al, 1998 (91)* Anderson et al, 1992 (72)*

PCP = primary care provider; TOHP = Trials of Hypertension Prevention.
* Healthful diet counseling.
† Physical activity counseling.
‡ Combined healthful diet and physical activity counseling.

High-intensity diet and lifestyle interventions decreased systolic and diastolic blood pressure by 1.5 mm Hg (CI, 0.9 to 2.1 mm Hg) (78, 82, 91, 93, 96, 99, 104, 118, 121) and 0.7 mm Hg (CI, 0.6 to 0.9 mm Hg) (78, 82, 91, 93, 96, 99, 104, 117, 118, 121), respectively, at 12 months (**Table 3**). The largest reduction in blood pressures occurred in 3 intensive salt-restriction counseling interventions in persons with mildly elevated diastolic blood pressure, resulting in a change of approximately −1.9 mm Hg (CI, −1.2 to −2.5 mm Hg) in systolic blood pressure and −1.0 mm Hg (CI, −0.5 to −1.6 mm Hg) in diastolic blood pressure at 12 months (**Table 3**) (82, 93, 96). Reductions in blood pressure were still statistically significant, although slightly attenuated, at up to 36 months (82, 93, 96). Four other trials reported follow-up beyond 12 months, but none showed a statistically significant reduction by the end of the trials (99, 113, 118, 121). Meta-analyses of 6 trials showed that medium-intensity physical activity interventions did not improve blood pressure.

High-intensity trials targeting diet and combined lifestyle counseling decreased total and low-density lipoprotein

Table 2. **Summary of Evidence**

Key Question	Studies and Participants	Design	Overall Quality	Consistency	Applicability	Summary of Findings
1. Do primary care–relevant behavioral counseling interventions for physical activity or healthful diet reduce CVD in adults?						
	3 studies, 51 961 participants	RCT	Fair; only 3 HD trials, all of good quality; 2 trials with observational follow-up after trials were completed	Fair; trials evaluated different interventions in different populations	Fair; largest trial in postmenopausal women; 2 trials in prehypertension	In WHI, high-intensity general low-fat counseling did not significantly decrease major CVD events at 8.1 y. Observational follow-up of TOHP I and II showed that high-intensity sodium reduction counseling in prehypertensive patients decreased CVD events and revascularization at 10 to 15 y.
2. Do primary care–relevant behavioral counseling interventions for physical activity or healthful diet improve intermediate outcomes (e.g., adiposity, blood pressure, lipids) in adults?						
Evidence for physical activity counseling alone	PA only: 8 studies, 3731 participants	RCT	Fair; intermediate outcomes not commonly reported; limited evidence beyond 12 mo	Good	Fair; only 1 trial conducted in the United States	Sparsely reported findings. Pooled estimates showed that mostly medium-intensity counseling did not improve adiposity, blood pressure, or lipid levels. Two trials showed statistically significant group differences in adiposity, blood pressure, or lipid levels; however, the remaining trials did not.
Evidence for healthful diet counseling, with or without physical activity counseling	HD only: 16 studies, 58 557 participants CL: 14 studies, 3855 participants	RCT	Fair; very high I^2 value for adiposity meta-analyses; limited evidence beyond 12 mo	Fair; HD and CL trials were not distributed consistently by intervention intensity and population risk	Good	High-intensity counseling for healthful diet resulted in statistically significant reductions in adiposity, blood pressure, and total and LDL cholesterol. Body mass index was reduced by approximately 0.3 to 0.7 kg/m^2. Systolic and diastolic blood pressure were reduced by 1.5 and 0.7 mm Hg. Total and LDL cholesterol were reduced by 0.17 and 0.13 mmol/L (6.56 and 5.02 mg/dL). No statistically significant changes were seen for HDL cholesterol or triglycerides.
3. Do primary care–relevant behavioral counseling interventions for physical activity or healthful diet change associated health behaviors in adults?						
Evidence for change in physical activity	PA only: 30 studies, 15 265 participants CL: 15 studies, 4975 participants	RCT	Fair; wide variety in measurement of physical activity; mostly self-reported measures; positive Egger result; limited evidence beyond 12 mo	Fair; PA and CL trials were not distributed consistently by intervention intensity and population risk	Good; most trials conducted in persons selected for sedentary behavior or some increased risk for CVD	Medium- to high-intensity interventions improved self-reported measures of physical activity by approximately 38 min/wk. This modest increase meant that most persons exercised for at least 1 h/wk. Results for the effectiveness of low-intensity counseling were mixed. Although the pooled estimate was not statistically significant, 4 trials (2 of which were not in the meta-analysis) showed statistically significant improvements in self-reported activity levels.

Continued on following page

Table 2—Continued

Key Question	Studies and Participants	Design	Overall Quality	Consistency	Applicability	Summary of Findings
Evidence for change in dietary intake	HD only: 25 studies, 71 267 participants CL: 16 studies, 4951 participants	RCT	Fair; high I^2 value for all dietary intake meta-analyses; mostly self-reported measures; positive Egger result for total fat dietary intake; limited evidence beyond 12 mo	Fair; HD and CL trials were not distributed consistently by intervention intensity and population risk	Good	High-intensity counseling resulted in moderate to large reductions in self-reported fat intake, a 5.9% to 11% decrease in energy from total fat, and a 2.8% to 3.7% decrease in energy from saturated fat. Low- to medium-intensity interventions resulted in smaller changes. Low- to high-intensity counseling yielded moderate to large increases in fruit and vegetable intake ranging from about 0.4 to 2 servings/d.
4. What are the adverse effects of primary care–relevant behavioral counseling interventions for physical activity or healthful diet in adults?						
Evidence for harms of physical activity or counseling to improve physical activity	Trials: 2 studies, 483 participants Observational studies: 7 studies, 4354 cases	RCT (case-crossover)	Fair; adverse events rarely reported in trials; case-crossover design; difficult to measure habitual PA; only 1 study reported absolute risk for cardiac event during vigorous physical activity	Good	Fair; observational studies often limited to nonfatal cases; most case patients were men	In 2 trials, almost 25% of participants reported mild muscular fatigue, strain, or soreness. In observational studies, risk for serious cardiac events was increased during vigorous physical activity. This increased risk was much greater in people with low levels of habitual physical activity. However, the absolute risk for a cardiac event is very small.
Evidence for harms of healthful diet or counseling to improve diet	HD only: 25 studies, 71 267 participants CL: 16 studies, 4951 participants	RCT	Fair; explicit adverse events not reported in trials	Good	Good	No specific examination of adverse effects; however, 2 trials showed an increased intake of carbohydrates with no increase in overall energy intake. Overall, few trials reported dietary intake of monounsaturated or polyunsaturated fats, carbohydrates, or sugars.

CL = combined lifestyle counseling; CVD = cardiovascular disease; HD = healthful diet counseling; HDL = high-density lipoprotein; LDL = low-density lipoprotein; PA = physical activity counseling; RCT = randomized, controlled trial; TOHP = Trials of Hypertension Prevention; WHI = Women's Health Initiative.

cholesterol levels; changes were −0.17 mmol/L (CI, −0.09 to −0.25) (−6.56 mg/dL [CI, −3.47 to −9.65 mg/dL]) and −0.13 mmol/L (CI, −0.06 to −0.21) (−5.02 mg/dL [CI, −2.32 to −8.11 mg/dL]), respectively (**Table 3**) (72, 91, 104, 117, 118, 121). Of the 3 trials that reported follow-up beyond 12 months, 2 trials conducted exclusively in women demonstrated a persistent decrease in total cholesterol or low-density lipoprotein cholesterol levels at 18 or 54 months (118). There was no statistically significant increase in high-density lipoprotein cholesterol levels. Medium-intensity trials did not improve lipid levels on average. Very few trials that targeted physical activity alone reported lipid levels.

We found no evidence of statistically significant publication bias for any of the intermediate outcomes, on the basis of the Egger test and visual inspection of funnel plots. Trials that focused on physical activity–only counseling did not often report measures of adiposity, blood pressure, or lipids (8 studies; 3731 participants).

Key Question 3: Behavioral Outcomes

In general, counseling resulted in small increases in participants' physical activity levels, especially in trials that provided at least medium-intensity interventions. Twenty-four (27–29, 31, 33, 35–37, 42, 47, 48, 50, 51, 53–55, 57, 59, 61, 63, 64, 69, 70, 133) of the 30 trials of physical activity interventions (12 938 participants) and 13 (42, 104, 106, 108, 111, 113–116, 118, 121, 124, 125) of the 17 combined lifestyle trials (4150 participants) were included in the meta-analyses of physical activity level. Pooled standardized mean differences for medium- and high-intensity interventions at approximately 12 months were 0.18 (CI, 0.12 to 0.24) and 0.26 (CI, 0.14 to 0.37), respectively (**Table 4**). These pooled estimates represent small changes in physical activity levels: for example, an increase in physical activity level by 38.3 min/wk (CI, 25.9 to 50.7 min/wk) (**Table 4**). Longer-term follow-up was very rare, but changes in activity level were maintained in 1 trial of medium-

intensity physical activity (71) and 1 trial of high-intensity physical activity plus lifestyle counseling that reported follow-up beyond 12 months (118). The data for low-intensity interventions were mixed. Although the meta-analysis of the trials of low-intensity physical activity showed no overall effect, 4 of the 11 trials of low-intensity interventions increased some measure of physical activity (35, 39, 55, 65); 2 of these 4 trials were not included in the meta-analysis because of limitations in reporting of outcomes at the individual study level. Only 1 of the combined lifestyle trials with this outcome involved a low-intensity intervention, and it showed no effect (114). The Egger test of small study effects was statistically significant for the medium-intensity trials; however, sensitivity analyses without the smallest trials showed similar results.

Meta-analyses showed statistically significant reductions in self-reported total fat intake at all levels of intervention intensity; however, statistical heterogeneity was high ($I^2 > 70\%$) (**Table 4**). For high-intensity trials, 7 of 10 trials showed statistically significant reductions in total fat, suggesting a robust finding of group differences. High-intensity counseling resulted in moderate to large reductions in self-reported fat intake, ranging from a 5.9% to 11% decrease in energy from total fat and a 2.8% to 3.7% decrease in energy from saturated fat (72, 78, 91, 99, 104, 117, 118). Four trials had longer-term follow-up (up to 72 months), during which reductions in total fat and saturated fat were still significant (99, 117, 118, 121). Low- and medium-intensity interventions resulted in smaller reductions in fat intake (42, 48, 74–77, 81, 86, 89, 92, 111, 114, 116, 124). None of the low- or medium-intensity counseling trials had follow-up beyond 12 months.

Healthful dietary counseling increased fruit and vegetable consumption at all levels of intervention intensity, although statistical heterogeneity was high in some subgroups (**Table 4**). Three fair-quality trials of behavioral counseling interventions focusing on fruit and vegetable consumption were successful in increasing

Table 3. **Pooled Effect Sizes for Intermediate Outcomes**

Intervention Target	Low-Intensity Interventions			Medium-Intensity Interventions			High-Intensity Interventions		
	Effect Size (95% CI)	Trials, *n*	I^2, %	Effect Size (95% CI)	Trials, *n*	I^2, %	Effect Size (95% CI)	Trials, *n*	I^2, %
Adiposity (standardized effect size)									
All	−0.10 (−0.22 to 0.02)	5*	69.6	−0.14 (−0.27 to −0.01)†	12‡	71.2	−0.48 (−0.64 to −0.32)†	9	89.8
Physical activity	−0.15 (−0.66 to 0.36)	1	–	−0.09 (−0.24 to 0.06)	7	72.2	–	0	–
Healthful diet (general)	−0.16 (−0.33 to 0.00)	2	77.0	−0.57 (−0.93 to −0.21)†	2	0.0	−0.37 (−0.52 to −0.22)†	4	85.4
Combined lifestyle	−0.04 (−0.17 to 0.10)	1	–	−0.34 (−0.61 to −0.07)†	6	78.1	−0.54 (−0.82 to −0.25)†	5	80.9
Systolic blood pressure, *mm Hg*									
All	−1.2 (−3.3 to 1.0)	3*	79.5	−0.5 (−1.8 to 0.8)	13	46.5	−1.5 (−2.1 to −0.9)†	10	49.0
Physical activity	–	0	–	−0.57 (−1.9 to 0.7)	6	14.0	–	0	–
Healthful diet (low-salt)	–	0	–	–	0	–	−1.9 (−2.5 to −1.2)†	3	0.0
Healthful diet (general)	0.1 (−0.8 to 1.0)	2	0.0	−6.0 (−11.0 to −1.0)†	1	–	−1.0 (−1.6 to −0.3)†	3	26.0
Combined lifestyle	–	0	–	−0.8 (−3.0 to 1.5)	6	59.4	−1.9 (−3.2 to −0.5)†	4	2.7
Diastolic blood pressure, *mm Hg*									
All	−0.5 (−1.2 to 0.2)	3	7.3	−0.3 (−1.4 to 0.8)	9‡	63.2	−0.7 (−0.9 to −0.6)†	10	0.0
Physical activity	–	0	–	−0.5 (−1.9 to 0.8)	5	58.5	–	0	–
Healthful diet (low-salt)	–	0	–	–	0	–	−1.0 (−1.6 to −0.5)†	3	0.0
Healthful diet (general)	−0.2 (−0.9 to 0.6)	2	0.0	−5.0 (−7.8 to −2.2)†	1	–	−0.7 (−0.8 to −0.6)†	3	0.0
Combined lifestyle	–	0	–	−0.3 (−2.3 to 1.7)	5	71.9	−1.1 (−2.4 to 0.2)	4	36.5
Total cholesterol level, *mmol/L*§									
All	0.02 (−0.09 to 0.13)	1	–	−0.04 (−0.11 to 0.02)	14‡	44.6	−0.17 (−0.25 to −0.09)†	6	30.9
Physical activity	–	0	–	−0.05 (−0.13 to 0.04)	6	23.9	–	0	–
Healthful diet (general)	–	0	–	−0.05 (−0.11 to 0.01)	4	0.0	−0.23 (−0.35 to −0.11)†	2	0.0
Combined lifestyle	–	0	–	−0.05 (−0.20 to 0.10)	7	64.5	−0.13 (−0.25 to 0.00)	4	50.0
Low-density lipoprotein cholesterol level, *mmol/L*§									
All	–	0	–	−0.01 (−0.10 to 0.08)	9‡	34.4	−0.13 (−0.21 to −0.06)†	6	32.1
Physical activity	–	0	–	−0.02 (−0.18 to 0.14)	3	31.2	–	0	–
Healthful diet (general)	–	0	–	−0.08 (−0.23 to 0.07)	3	20.3	−0.19 (−0.31 to −0.08)†	2	11.7
Combined lifestyle	–	0	–	0.00 (−0.13 to 0.12)	6	46.5	−0.10 (−0.20 to 0.00)	4	38.1

* Includes an additional trial of healthful diet counseling that targeted fruit and vegetable intake (not shown separately).
† $P \leq 0.05$.
‡ Total number of trials is fewer than the sum of the subgroups because some trials had multiple groups with different intervention targets and are therefore included in multiple subgroups.
§ To convert mmol/L to mg/dL, divide by 0.0259.

Table 4. **Pooled Effect Sizes of Behavioral Outcomes**

Intervention Target	Low-Intensity Interventions			Medium-Intensity Interventions			High-Intensity Interventions		
	Effect Size (95% CI)	Trials, *n*	I^2, %	Effect Size (95% CI)	Trials, *n*	I^2, %	Effect Size (95% CI)	Trials, *n*	I^2, %
Self-reported physical activity, standardized									
All	0.07 (0.0 to 0.15)*	9	32.2	0.18 (0.12 to 0.24)*	24†	41.9	0.26 (0.14 to 0.37)*	4	0.0
Physical activity	0.08 (−0.01 to 0.18)	8	40.7	0.19 (0.12 to 0.27)*	17	49.9	–	0	–
Combined lifestyle	0.06 (−0.08 to 0.19)	1	–	0.20 (0.08 to 0.33)*	8	45.7	0.26 (0.14 to 0.37)*	4	0.0
Self-reported physical activity in the subset reporting min/wk, *min/wk*									
All	33.6 (1.7 to 65.6)*	6	38.6	40.9 (19.5 to 62.3)*	12	78.7	51.5 (−62.6 to 165.8)	1	–
Physical activity	33.6 (1.7 to 65.6)*	6	38.6	38.3 (25.9 to 50.7)*	9	0.0	–	0	–
Combined lifestyle	–	0	–	50.4 (−23.9 to 124.6)	3	82.4	51.5 (−62.6 to 165.8)	1	–
Self-reported fat intake, standardized									
All	−0.23 (−0.29 to −0.18)*	6	0.0	−0.28 (−0.61 to 0.04)*	8†	91.5	−0.81 (−1.13 to −0.50)*	10	97.5
Healthful diet (general)	−0.25 (−0.31 to −0.19)*	5	0.0	−0.46 (−0.81 to −0.11)*	5	73.3	−1.05 (−1.36 to −0.74)*	5	96.3
Combined lifestyle	−0.15 (−0.29 to −0.01)*	1	–	−0.24 (−0.65 to 0.16)	5	91.7	−0.61 (−1.11 to −0.11)*	5	93.6
Self-reported fruit and vegetable intake, standardized									
All	0.34 (0.17 to 0.52)*	6	92.2	0.36 (0.10 to 0.62)*	6	88.0	0.57 (0.33 to 0.81)*	5	94.9
Healthful diet (fruit and vegetable intake)	0.60 (0.08 to 1.11)*	2	93.8	0.36 (0.22 to 0.50)*	1	–	–	0	–
Healthful diet (general)	0.19 (0.14 to 0.23)*	4	0.0	0.65 (0.38 to 0.92)*	3	44.0	0.68 (0.37 to 0.99)*	3	96.8
Combined lifestyle	–	0	–	0.00 (−0.14 to 0.14)	2	0.0	0.40 (−0.16 to 0.96)	2	90.0

* $P \leq 0.05$.
† Total number of trials is fewer than the sum of the subgroups because some trials had multiple groups with different intervention targets and therefore are included in multiple subgroups.

fruit and vegetable intake (37, 85, 87). Meta-analyses of the low- and medium-intensity general low-fat/heart-healthy counseling trials had low to modest heterogeneity and were statistically significant (48, 75, 77, 86, 88, 90, 92). Although statistical heterogeneity was very large in the high-intensity trials, intervention group participants showed greater increases in fruit and vegetable consumption in 4 of the 5 trials (77, 78, 99, 104, 121). Overall, the mean change in fruit and vegetable intake ranged from 0.4 to 2 servings per day. Only 2 trials had follow-up beyond 12 months; these showed a persistent increase in fruit and vegetable intake at 24 and 72 months (37, 99).

Key Question 4: Harms

Adverse effects were rarely noted in physical activity counseling trials. Two trials reported minor muscular symptoms (27, 50), and 3 trials reported falls related to physical activity (31, 53, 54). We also found 7 case-crossover analyses, which showed that the risk for a cardiac event is increased 2-fold to 17-fold during vigorous exercise (126–132). This increased risk was much greater for people with low baseline levels of regular activity. Nevertheless, the absolute risk for a cardiac event during physical activity was very low. One of these studies estimated that the incidence of sudden death associated with vigorous physical activity was 1 per 1.42 million person-hours of exercise (126).

We found no studies designed to assess the adverse effects of dietary counseling or the adverse effects of increasing intake of fruits and vegetables or fiber and decreasing intake of sodium or fat. None of the healthful diet counseling trials reported specific adverse events.

Discussion

Medium- to high-intensity dietary behavioral counseling, with or without physical activity counseling, resulted in small but statistically significant improvements in adiposity, blood pressure, and cholesterol level, as well as moderate to large changes in self-reported dietary and physical activity behaviors. The evidence for changes in physiologic outcomes was strongest for high-intensity counseling interventions. The reductions in blood pressure, about 1.5 mm Hg (systolic) and 0.7 mm

Hg (diastolic), were smaller than those seen in hypertension drug trials and feeding trials (134, 135). However, epidemiologic data suggest that even changes as small as 2 mm Hg in systolic blood pressure can decrease the risk for coronary heart disease by 6% or stroke by 16% (136). Direct evidence from observational follow-up of the large hypertension prevention trials that used sodium reduction counseling suggest that these small changes in blood pressure can result in a 30% reduction in cardiovascular disease events and revascularization in persons with mildly elevated diastolic blood pressure (137). Reductions in cholesterol level were also small (about 0.17 mmol/L [5.02 mg/dL] in total cholesterol level). On the basis of randomized, controlled trials in primary prevention, a sustained reduction of 0.6 mmol/L (23.17 mg/dL) in total serum cholesterol level—an average decrease of 10%—can reduce coronary heart disease by about 25% (138). However, it is unclear whether smaller reductions in total cholesterol level due to dietary changes can affect cardiovascular disease.

Medium- to high-intensity physical activity counseling also resulted in small changes in self-reported physical activity (an increase of about 40 minutes per week). Evidence suggests that even low-intensity dietary counseling results in moderate increases in fruit and vegetable intake (up to 2 servings a day) and small decreases in dietary fat intake (about 1.5% decrease in energy intake from total fat). Evidence for low-intensity physical counseling interventions for increasing self-reported physical activity was mixed.

Evidence for maintenance of any behavioral or physiologic effects beyond 12 months was very limited. The interventions with significant benefit beyond 12 months were all high-intensity counseling interventions with group, phone, or mail contact throughout the trial. Most trials for high-intensity interventions that had follow-up beyond 12 months showed persistent beneficial changes in adiposity and lipid levels (but not blood pressure), as well as improvements in self-reported behavioral outcomes.

Intervention intensity was the most important factor for differences in effect size among different trials. However, the effects of counseling intensity could not be fully disentangled from the risk among the populations studied. Although trials in populations with known traditional cardiovascular risk factors or risk equivalents were excluded, many of the medium- to high- intensity interventions were conducted in participants selected for suboptimal lifestyle behaviors or factors associated with increased cardiovascular disease (**Table 2**). In multivariate meta-regression, both intervention intensity and risk in the population predicted larger effects. In addition, some participant populations were volunteers. Exploratory meta-regressions suggested that use of volunteer participants was also predictive of larger effect sizes, although in multivariate analyses this was significant only for dietary fat intake. Almost all of the effective medium- to high-intensity interventions were delivered by specially trained health educators or nurses, counselors or psychologists, dietitians or nutritionists, or exercise instructors or physiologists; very few involved the primary care provider (**Table 2**). Many of the high-intensity interventions used 12 or more sessions and therefore required resources that may not be available or paid for in the current health care system (in addition to raising issues of real-world patient adherence).

No increase in serious injuries occurred from physical activity or unintended adverse changes in dietary intake, on the basis of available counseling trials (**Table 3**). Two trials reported a paradoxical increase in carbohydrate intake but not overall caloric intake. The clinical significance of these dietary changes is unclear. In the Women's Health Initiative, the replacement of fat intake with complex carbohydrates over 6 years was not associated with adverse effects on lipid profiles (139). Observational studies suggest an increased risk for serious cardiac events during vigorous physical activity, primarily in persons with low levels of habitual activity. However, the absolute risk for serious cardiac events related to physical activity seems very small. The U.S. Department of Health and Human Services' 2008 report on physical activity (6) details additional information regarding harms of physical activity.

In addition to limited confidence in the pooled estimates of effect sizes for some outcomes due to the heterogeneity of the trials, this body of evidence has other limitations. Our updated review represents only a subset of the diet and physical activity counseling literature; important omissions include counseling in persons with known disease (including hypertension, dyslipidemia, diabetes, or coronary heart disease); diet or physical activity counseling for other types of disease prevention or weight management; trials to evaluate the comparative effectiveness of different types of counseling interventions; related behavioral interventions conducted through worksites, schools, and communities; and public health, economic- and policy-oriented, or media-based interventions (140).

Most of the trials relied on self-reported behavioral outcome measures; only 36% of trials reported any objectively measured intermediate outcomes. Measurement of behavioral outcomes varied across trials, and both dietary and physical activity behaviors can be difficult to measure validly and reliably (**Table 4**). Dietary intake was generally measured by food-frequency questionnaires, food diaries, and 24-hour food recalls, each of which can be prone to bias (141). For physical activity, the various forms of physical activity, the episodic nature of some types of activity, and the subjective nature of a person's assessment of intensity make it diffi-

cult to get precise information on physical activity levels. Only 7 of the studies that reported physical activity outcomes used objective measures, such as a pedometer, accelerometer, or actigraph (45, 48, 50, 64, 67, 106, 115, 118), and this measure was always used in addition to a self-reported measure. However, the behavioral outcome results in our review were generally consistent with those that used intermediate outcomes.

Other limitations include risk for bias due to inclusion only of published data, potential selective reporting of outcomes, and inclusion of trials that used volunteer participants. The Egger statistical test for small-study effects was significant only for self-reported total dietary fat intake and self-reported physical activity level among the physical activity counseling trials. However, sensitivity analyses that excluded the small studies with large effects still demonstrated a positive effect of physical activity counseling.

Although the body of literature is already very large, good-quality trials that fully evaluate the longer-term health effects of these types of counseling interventions across a range of patients and use counseling interventions that are most applicable to primary care are needed. More trials are needed to evaluate low-intensity counseling interventions that could be more readily implemented in primary care, or medium-intensity interventions that could be referred to from primary care. The effective high-intensity interventions should be studied for reproducibility, to determine whether they would work in other populations and what intensity of intervention is effective in lower-risk populations. More trials with longer-term follow-up are crucial to understanding how to maintain behavioral change and changes in physiologic outcomes over time. In addition to self-reported behavioral outcomes, trials should also collect and report objectively measured physiologic outcomes. Greater use of objective measures to assess physical activity would probably provide more accurate estimates of changes in physical activity level, which is especially important when the changes are small.

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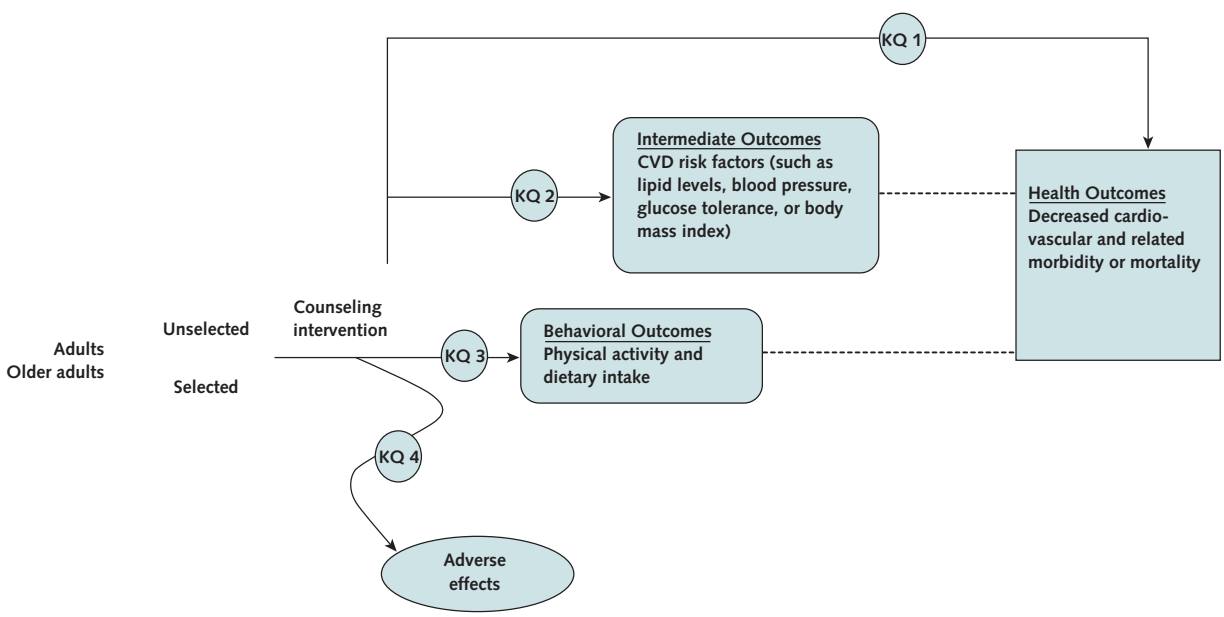
Appendix Figure. **Analytic framework and key questions.**



Key Questions

1. **Do primary care–relevant behavioral counseling interventions for physical activity or healthful diet improve cardiovascular disease health outcomes (prevent morbidity and mortality) in adults?**
2. **Do primary care–relevant behavioral counseling interventions for physical activity or healthful diet improve intermediate outcomes associated with cardiovascular disease (such as lipid levels, blood pressure, glucose tolerance, weight, or body mass index) in adults (including older adults)?**
3. **Do primary care–relevant behavioral counseling interventions for physical activity or healthful diet change associated health behaviors in adults?**
4. **What are the adverse effects of primary care–relevant behavioral counseling interventions for physical activity or healthful diet in adults?**

CVD = cardiovascular disease; KQ = key question.