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Annals of Internal Medicine | Review

Behavioral Counseling to Promote a Healthy Lifestyle in Persons With Cardiovascular Risk Factors

A Systematic Review for the U.S. Preventive Services Task Force

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Background: Most Americans do not meet diet and physical activity recommendations despite known health benefits.

Purpose: To systematically review the benefits and harms of lifestyle counseling interventions in persons with cardiovascular risk factors for the U.S. Preventive Services Task Force.

Data Sources: MEDLINE, PsycINFO, the Database of Abstracts of Reviews of Effects, and the Cochrane Central Register of Controlled Trials (January 2001 to October 2013); experts; and existing systematic reviews.

Study Selection: Two investigators independently reviewed 7218 abstracts and 553 articles against a set of inclusion and quality criteria.

Data Extraction: Data from 74 trials were abstracted by one reviewer and checked by a second.

Data Synthesis: At 12 to 24 months, intensive lifestyle counseling in persons selected for risk factors reduced total cholesterol levels by an average of 0.12 mmol/L (95% CI, 0.16 to 0.07 mmol/L) (4.48 mg/dL [CI, 6.36 to 2.59 mg/dL]), low-density lipoprotein cholesterol levels by 0.09 mmol/L (CI, 0.14 to 0.04 mmol/L) (3.43 mg/dL [CI, 5.37 to 1.49 mg/dL]), systolic blood pressure by 2.03 mm Hg (CI, 2.91 to 1.15 mm Hg), diastolic blood pressure by 1.38 mm Hg (CI, 1.92 to 0.83 mm Hg), fasting glucose levels by 0.12 mmol/L (CI, 0.18 to 0.05 mmol/L) (2.08 mg/dL [CI, 3.29 to 0.88 mg/dL]), diabetes incidence by a relative risk of 0.58 (CI, 0.37 to 0.89), and weight outcomes by a standardized mean difference of 0.25 (CI, 0.35 to 0.16). Behavioral changes in dietary intake and physical activity were generally concordant with changes in physiologic outcomes.

Limitation: Sparse reporting of patient health outcomes, longer-term follow-up of outcomes, and harms.

Conclusion: Intensive diet and physical activity behavioral counseling in persons with risk factors for cardiovascular disease resulted in consistent improvements across various important intermediate health outcomes up to 2 years.

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Decreases in cardiovascular mortality rates in recent decades have been attributed, in part, to improvements in modifiable risk factors (1). A substantial portion of the U.S. population has at least one modifiable risk factor for cardiovascular disease (CVD) (such as hypertension, dyslipidemia, impaired fasting glucose, the metabolic syndrome, and cigarette smoking) (2–7). Despite convincing evidence that healthy diet and physical activity are associated with important health outcomes, including reduction in cardiovascular events and mortality rates (8–17), U.S. adults are not meeting recommendations for healthy diet and physical activity (18–20). Likewise, nutrition and exercise counseling practices in primary care remain suboptimal, even for persons at high risk for CVD (21–24).

In 2012, the U.S. Preventive Services Task Force (USPSTF) recommended that clinicians consider selectively providing or referring adults without preexisting CVD or risk factors for intensive behavioral counseling interventions (C recommendation) (25). The USPSTF subsequently recommended that clinicians screen all adults for obesity and offer or refer obese patients to intensive, multicomponent behavioral interventions (B recommendation) (26). This systematic review was designed to complement the existing reviews that supported the 2012 USPSTF recommendations and to support the USPSTF in updating its 2002 and 2003 recommendations on healthy diet and physical activity counseling in persons with known cardiovascular risk factors (27, 28). To conduct this review, we developed an analytic framework with 4 key questions (**Supplement 1**, available at www.annals.org) that included the effect of dietary or physical activity counseling on patient health outcomes (question 1), intermediate cardiovascular disease–related outcomes (question 2), behavioral outcomes (question 3), and the harms of counseling (question 4).

Methods

Detailed methods, including search strategies; detailed inclusion criteria; and excluded studies are publically available in our full evidence report (29).

Data Sources and Searches

We searched MEDLINE, PubMed, PsycINFO, the Database of Abstracts of Reviews of Effects, and the

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Cochrane Central Register of Controlled Trials from January 2001 to October 2013. We supplemented our searches with suggestions from experts and reference lists from other relevant systematic reviews.

Study Selection

Two investigators independently reviewed 7218 abstracts and 553 full-text articles against a priori–specified inclusion criteria (**Supplement 2**, available at www.annals.org). We included studies in adults who had at least 1 cardiovascular risk factor, including hypertension, dyslipidemia, impaired fasting glucose or glucose tolerance, the metabolic syndrome, and cigarette smoking. We excluded studies limited to persons with known diabetes (considered a CVD risk equivalent), coronary artery disease, cerebrovascular disease, peripheral artery disease, or severe chronic kidney disease. We also excluded populations at increased risk for CVD (such as those with obesity, physical inactivity, and prehypertension) but without other CVD risk factors because these bodies of evidence were considered in previous reviews (30, 31) and USPSTF recommendations (25, 26). We included behaviorally based counseling interventions to promote a healthy diet or physical activity, delivered alone or as part of a multicomponent intervention. We excluded interventions that provided controlled diets or supervised exercise, as opposed to interventions aimed at evaluating whether counseling could change behavior.

We limited studies of efficacy or effectiveness to fair- or good-quality randomized, controlled trials or controlled clinical trials that had at least 6 months of follow-up, were done in developed countries, and published their results in 1990 or later. Included trials had to include a control group (such as usual care, a minimal intervention, or attention control). We examined health outcomes (such as morbidity or mortality related to CVD), intermediate health outcomes (such as physiologic measures of blood pressure, lipid and glucose, and weight; diabetes incidence; medication use; and composite CVD risk scores), and behavioral outcomes (such as self-reported dietary intake and physical activity or objectively measured markers of behavior change [such as VO_2max or urinary sodium]). We also included observational studies that reported serious harms (that is, adverse events resulting in unexpected or unwanted medical attention).

Data Extraction and Quality Assessment

One reviewer extracted population characteristics, study design elements, intervention and control characteristics, and study results into standardized evidence tables. A second reviewer checked the data for accuracy. Articles that met our inclusion criteria were critically appraised by 2 reviewers independently using the USPSTF and National Institute for Health and Care Excellence criteria (32, 33). We rated articles as good-, fair-, or poor-quality. Good-quality studies generally met all criteria, whereas fair-quality studies did not meet all criteria but had no known important limitation that could invalidate its results. Poor-quality studies had important limitations that were considered fatal flaws (for example, they had greater than 40% attrition with or without differential attrition between intervention groups; a lack of randomization with biased assignment of participants to intervention groups, often with differences in baseline characteristics or no reporting of baseline characteristics; per-protocol analyses only; and very poor reporting about description of methods, which did not allow for adequate assessment of quality); thus, they were excluded from this review.

Data Synthesis and Analysis

Because of the clinical heterogeneity across this body of evidence, we stratified our analyses according to the type of intervention (that is, a focus on dietary counseling alone, physical activity alone, or combined diet and physical activity counseling) and according to how study populations were targeted or defined (that is, dyslipidemia, hypertension, impaired fasting glucose or glucose tolerance, or mixed risk factors). We did random-effects meta-analyses for 5 or more studies using the DerSimonian–Laird method to estimate the effect size of counseling on intermediate health outcomes (that is, systolic and diastolic blood pressure; total, high-density lipoprotein, and low-density lipoprotein cholesterol; triglycerides; fasting blood glucose; diabetes incidence; and weight or body mass index) (34). We did qualitative synthesis for health outcomes, behavioral outcomes, and harms. Outcome analyses were also stratified by length of follow-up after randomization (short term was less than 12 months, intermediate term was 12 to 24 months, and long term was greater than 24 months).

We used stratified analyses, visual inspection of forest plots arranged by effect size, and/or meta-regressions to examine the effect of a priori–specified primary sources of heterogeneity on effect size: study population, intervention type, overall intervention intensity (low was less than 30 minutes of total contact, medium was 30 to 360 minutes, and high was more than 360 minutes), number of intervention contacts, duration of intervention, length of follow-up, overall study quality, year of publication, country setting, type of control group, and population risk (including average age; percentage of persons who smoke, have hypertension, have dyslipidemia, or have diabetes; average systolic blood pressure; average low-density lipoprotein cholesterol level; average body mass index; and use of medications).

We assessed the presence of statistical heterogeneity among the studies using standard chi-square tests, and the magnitude of heterogeneity was estimated using the I^2 statistic (35). In instances of 10 or more studies, we formally assessed for publication bias and whether the distribution of the effect sizes was symmetrical with respect to the precision measure by using funnel plots and the Egger linear

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regression method (36, 37). We did all analyses using Stata, version 11.2.

Role of the Funding Source

Agency for Healthcare Research and Quality staff provided oversight for the project and assisted in external review of the companion draft evidence synthesis. Liaisons for the USPSTF helped to resolve issues about the scope of the review but were not involved in the conduct of the review.

Results

Description of Included Trials

Seventy-four fair- or good-quality healthy lifestyle counseling trials in persons with cardiovascular risk factors met our inclusion criteria (**Supplements 3 and 4**, available at www.annals.org). Forty-nine trials evaluated combined lifestyle counseling interventions, 18 diet-only interventions, and 10 physical activity–only interventions. Of the interventions evaluated, only 2 were low-intensity, 48 were medium-intensity, and 37 were high-intensity. Medium-intensity interventions had a median of 5 contacts (interquartile range [IQR], 3 to 8 contacts) with a median duration of 9 months (IQR, 4 to 11 months). High-intensity interventions had a median of 16 contacts (IQR, 9 to 31 contacts) with a median duration of 12 months (IQR, 8 to 18 months). Counseling interventions included didactic education, as well as individualized care plans, problem-solving skills, and audit and feedback. Many trials included weight loss or weight goals for participants who were overweight. Some counseling interventions included cointerventions (such as smoking cessation counseling when applicable, protocols for medication adjustment, and provision of free or low-cost exercise options). Interventions were delivered by dietitians, nutritionists, physiotherapists, exercise professionals or consultants, or trained interventionists (such as health educators, psychologists, nurses, or case managers).

Included trials recruited persons on the basis of individual risk factors (such as dyslipidemia [17 trials], hypertension [15 trials], impaired fasting glucose or glucose tolerance [16 trials]), or a combination of risk factors (26 trials), which commonly included dyslipidemia, hypertension, elevated glucose levels, the metabolic syndrome, obesity, and smoking. Trials included both persons who had not yet started antihypertensive and lipid-lowering medications as well as those already receiving these medications. The mean ages of populations studied ranged from 40.5 to 71.0 years. Both men and women were well-represented in included trials, most of which included both sexes. Twenty-eight trials were done in the United States, whereas most of the other trials were done in Western Europe (33 trials). More than one third of participants were nonwhite in 12 of the U.S.-based trials. The average body mass index in all but 2 trials (38, 39) was in the range of overweight to obese. The median baseline body mass index was 29.8 kg/m^2 (IQR, 28.4 to 31.2 kg/m^2).

We included 11 good-quality and 63 fair-quality trials. In general, the limitations for these fair-quality studies included a lack of reporting of details around randomization, small differences in baseline characteristics between intervention groups, a lack of blinding of outcomes assessment, attrition greater than 20% or differential attrition between study groups, evidence or inability to assess for attrition bias, a lack of reporting on how missing data were handled, or having completed-only analyses.

Effectiveness of Counseling

Only 16 included trials (7053 participants) reported measures of patient health outcomes (**Supplement 4**). Five trials (4470 participants) reported CVD events, including death (40–44), and 11 trials (2583 participants) (45–55) reported self-reported quality-of-life (QOL) or depression symptom outcomes (**Supplement 3**). Overall, there was no reduction in CVD events or mortality rates at 6 to 79 months across 4 (3962 participants) of 5 trials reporting these outcomes. Event rates, however, were generally low. Only 1 good-quality early trial, the Risk Factor Intervention Trial (508 participants), found a reduction in a composite measure of all CVD events at 6.6 years of follow-up (relative risk, 0.71 [95% CI, 0.51 to 0.99]) (56). This trial used a high-intensity behavioral counseling intervention in conjunction with a protocol to start medication for dyslipidemia or increased glucose levels or to start nicotine replacement therapy for cigarette smoking in a relatively sick population of Swedish men (29% smoked, 22% had diabetes, and 8% had a previous myocardial infarction), approximately 20% of whom had died at 6.6 years of follow-up (56). Overall, combined lifestyle interventions do not seem to improve self-reported depression symptoms (4 trials) in persons with impaired fasting glucose or glucose tolerance at 6 to 12 months (49–51, 53). Findings of benefit on self-reported QOL measures were mixed. Although 3 combined lifestyle counseling interventions seemed to improve selected QOL measures (45, 48, 52), 2 combined lifestyle counseling interventions (46, 47), and 2 physical activity–only counseling interventions (54, 55) showed no benefit on self-reported QOL at 6 to 12 months. However, sparse reporting of both CVD events and self-reported measures of depression symptoms or QOL do not allow for definitive conclusions regardless of whether behavioral counseling interventions can improve patient health outcomes.

Seventy-one (32 734 participants) of the 74 included trials reported intermediate health outcomes (**Supplements 4 and 5**, available at www.annals.org). Of the 71 trials, only 14 could not be included in meta-analyses of intermediate health outcomes, primarily due to limitations in data reporting (39, 43, 46, 57–67).

Medium- or high-intensity combined lifestyle counseling interventions in persons selected for risk factors can

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Table 1. **Pooled Effect Sizes for Intermediate Cardiovascular Health Outcomes, by Intervention Type**

Outcomes, by Follow-up Period	All Interventions			Combined Lifestyle		
	Effect Size (95% CI)	Trials, *n*	I^2, %	Effect Size (95% CI)	Trials, *n*	I^2, %
Total cholesterol level*, *mmol/L*						
<12 mo	−0.12 (−0.19 to −0.04)	12	23	NA	4	–
12–24 mo	−0.12 (−0.16 to −0.07)	34	56	−0.14 (−0.21 to −0.07)	22	61
>24 mo	NA	4	–	NA	4	–
LDL cholesterol level*, *mmol/L*						
<12 mo	−0.06 (−0.12 to −0.01)	12	10	−0.06 (−0.14 to 0.01)	6	0
12–24 mo	−0.09 (−0.14 to −0.04)	25	47	−0.10 (−0.15 to −0.04)	17	43
>24 mo	NA	2	–	NA	2	–
HDL cholesterol level*, *mmol/L*						
<12 mo	0.01 (−0.02 to 0.04)	7	17	NA	3	–
12–24 mo	0.02 (0 to 0.04)	19	46	0.02 (0.01 to 0.04)	14	56
>24 mo	NA	4	–	NA	4	–
Triglyceride level†, *mmol/L*						
<12 mo	−0.17 (−0.28 to −0.07)	5	0	NA	3	–
12–24 mo	−0.10 (−0.16 to −0.04)	14	32	−0.09 (−0.16 to −0.03)	10	38
>24 mo	NA	2	–	NA	2	–
SBP, *mm Hg*						
<12 mo	−2.36 (−4.78 to 0.06)	11	77	−2.20 (−4.39 to −0.02)	8	67
12–24 mo	−2.03 (−2.91 to −1.15)	31	48	−2.06 (−3.03 to −1.08)	27	50
>24 mo	NA	4	–	NA	4	–
DBP, *mm Hg*						
<12 mo	−1.67 (−3.30 to −0.04)	7	61	−1.82 (−3.67 to 0.03)	5	69
12–24 mo	−1.38 (−1.92 to −0.83)	24	41	−1.30 (−1.93 to −0.68)	21	48
>24 mo	NA	4	–	NA	4	–
Fasting glucose level‡, *mmol/L*						
<12 mo	−0.08 (−0.16 to 0)	8	36	NA	4	–
12–24 mo	−0.12 (−0.18 to −0.05)	22	80	−0.10 (−0.18 to −0.03)	18	74
>24 mo	NA	4	–	NA	4	–
Incidence of diabetes mellitus, *RR*						
<12 mo	NA	1	–			
12–24 mo	0.58 (0.37 to 0.89)	8	32	0.54 (0.34 to 0.88)	6	40
>24 mo	0.61 (0.46 to 0.79)	6	61	0.61 (0.46 to 0.79)	6	61
Adiposity, *SMD*						
<12 mo	−0.30 (−0.42 to −0.17)	20	71	−0.36 (−0.56 to −0.16)	10	84
12–24 mo	−0.25 (−0.35 to −0.16)	34	80	−0.24 (−0.35 to −0.14)	25	77
>24 mo	−0.40 (−0.73 to −0.07)	6	92	−0.40 (−0.73 to −0.07)	6	92

DBP = diastolic blood pressure; HDL = high-density lipoprotein; LDL = low-density lipoprotein; NA = not applicable; RR = relative risk; SBP = systolic blood pressure; SMD = standard mean difference.
* To convert from mmol/L to mg/dL, divide by 0.0259.
† To convert from mmol/L to mg/dL, divide by 0.0113.
‡ To convert from mmol/L to mg/dL, divide by 0.0555.

decrease total cholesterol and low-density lipoprotein cholesterol levels, blood pressure, fasting glucose levels, diabetes incidence, and weight (**Table 1**). Overall, benefits in these intermediate health outcomes seem to be most robust at 12 to 24 months, with limited trials reporting follow-up beyond 24 months. Intensive combined lifestyle counseling interventions reduced total cholesterol levels (22 trials) by 0.14 mmol/L (CI, 0.21 to 0.07 mmol/L) (5.43 mg/dL [CI, 7.97 to 2.89 mg/dL]), low-density lipoprotein cholesterol levels (17 trials) by 0.10 mmol/L (CI, 0.15 to 0.04 mmol/L) (3.69 mg/dL [CI, 5.98 to 1.40 mg/dL]), and triglyceride levels (10 trials) by 0.09 mmol/L (CI, 0.16 to 0.03 mmol/L) (8.33 mg/dL [CI, 13.80 to 2.86 mg/dL]) and increased high-density lipoprotein cholesterol levels (14 trials) by 0.02 mmol/L (CI, 0.01 to 0.04 mmol/L) (0.97 mg/dL [CI, 0.25 to 1.70 mg/dL]) at 12 to 24 months in persons selected for dyslipidemia or any of many CVD risk factors (**Supplements 6** to **8**, available at www.annals.org). However, very few trials reported follow-up after 24 months, and the reported effects generally did not seem to last at longer-term follow-up. Intensive diet–only counseling interventions also reduced total cholesterol levels (9 trials) by 0.10 mmol/L (CI, 0.17 to 0.03 mmol/L) (3.75 mg/dL [CI, 6.50 to 1.01 mg/dL]) and low-

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Table 1—Continued

Diet Only			Physical Activity Only		
Effect Size (95% CI)	Trials, *n*	I^2, %	Effect Size (95% CI)	Trials, *n*	I^2, %
−0.11 (−0.22 to 0)	5	38	NA	3	–
−0.10 (−0.17 to −0.03)	9	24	NA	3	–
NA	0	–	NA	0	–
NA	4	–	NA	2	–
−0.11 (−0.20 to −0.02)	7	40	NA	1	–
NA	0	–	NA	0	–
NA	2	–	NA	2	–
NA	3	–	NA	2	–
NA	0	–	NA	0	–
NA	0	–	NA	2	–
NA	3	–	NA	1	–
NA	0	–	NA	0	–
NA	0	–	NA	3	–
NA	2	–	NA	2	–
NA	0	–	NA	0	–
NA	0	–	NA	2	–
NA	2	–	NA	1	–
NA	0	–	NA	0	–
NA	0	–	NA	4	–
NA	2	–	NA	2	–
NA	0	–	NA	0	–
NA	0	–	NA	0	–
NA	0	–	NA	2	–
NA	0	–	NA	0	–
−0.20 (−0.36 to −0.05)	6	29	NA	4	–
−0.44 (−0.87 to −0.01)	6	88	NA	3	–
NA	0	–	NA	0	–

density lipoprotein cholesterol levels (7 trials) by 0.11 mmol/L (CI, 0.20 to 0.02 mmol/L) (4.27 mg/dL [CI, 7.84 to 0.70 mg/dL]). Combined lifestyle interventions also reduced blood pressure, glucose levels, diabetes incidence, and weight at both intermediate and longer-term follow-up. At 12 to 24 months, intensive combined lifestyle counseling reduced systolic blood pressure (27 trials) by 2.06 mm Hg (CI, 3.03 to 1.08 mm Hg) and diastolic blood pressure (21 trials) by 1.30 mm Hg (CI, 1.93 to 0.68 mm Hg). It also reduced fasting glucose levels (18 trials) by 0.10 mmol/L (CI, 0.18 to 0.03 mmol/L) (1.86 mg/dL [CI, 3.24 to 0.49 mg/dL]), incidence of diabetes (6 trials) by a risk ratio of 0.54 (CI, 0.34 to 0.88), and weight (25 trials) by a standardized mean difference of 0.24 (CI, 0.35 to 0.14) (**Supplements 9 to 13**, available at www.annals.org).

Pooled effect sizes for blood pressure, glucose levels, and weight were similar for medium- versus high-intensity counseling (data not shown). Trials reporting a reduction in incidence of diabetes were mostly high-intensity counseling interventions. Although fewer trials reported follow-up after 24 months, reductions in these outcomes persisted at longer-term follow-up.

Ten trials (4848 participants) evaluated physical activity–only counseling interventions (54, 55, 62, 65, 66, 68–72). Most of these interventions were medium-intensity (8 trials) rather than high-intensity (2 trials) interventions. Four trials specifically targeted older adults (55, 65, 68, 70). Six trials were done in populations with mixed CVD risk factors, 2 were done in persons with impaired fasting glucose, and 2 were done in persons with

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hypertension. Only 5 trials (4209 participants) reported outcomes at 12 to 24 months. Overall, we found no consistent evidence of benefit on intermediate health outcomes, but based on the limited number of trials and clinical heterogeneity among populations, interventions, and outcomes measured, it is still unclear whether medium- or high-intensity counseling interventions aimed at increasing physical activity alone can improve lipid levels, blood pressure, glucose levels, and weight in persons with CVD risk factors.

Based on visual inspection of forest plots and subsequent exploratory meta-regressions, we found no sources of population, intervention, or study characteristic heterogeneity that consistently influenced effect sizes across outcomes. However, year of publication seemed to explain some statistical heterogeneity for effects on low-density lipoprotein cholesterol levels, blood pressure, and weight, such that more recent studies had smaller effects than earlier studies. High-intensity interventions seemed to explain some statistical heterogeneity for effects on low-density lipoprotein cholesterol outcomes only (higher-intensity interventions had greater effects), and study quality seemed to explain some statistical heterogeneity for effects on systolic blood pressure (better-quality studies had smaller effects). Overall, the differences in effect sizes, as modified by these variables, were very small and likely not clinically meaningful. We found no evidence for significant publication bias except for triglyceride-level outcomes (Egger test; $P = 0.02$).

Sixty-one of the included trials (31 751 participants) reported behavioral outcomes (**Supplements 4** and **14**, available at www.annals.org). Three of these trials (4223 participants) reported only behavioral outcomes (that is, they did not report any intermediate health outcomes) (71, 73, 74). Overall, the direction of effect in dietary intake and physical activity were concordant with intermediate outcome findings. In several instances in which trials did not find any benefit in intermediate health outcomes, trials demonstrated statistically significant improvements in dietary intake (such as fat, saturated fat, fruit and vegetable, and total energy) and various measures of self-reported physical activity in the short and intermediate term. In selected trials that were done in persons who were already receiving medications to lower cholesterol levels or blood pressure, counseling interventions seemed to improve dietary intake and self-reported physical activity despite a lack of benefit in lipid levels or blood pressure. Four (3439 participants) of 5 physical activity–only counseling trials that reported behavioral outcomes at 12 to 24 months found statistically significant improvements in self-reported physical activity (that is, minutes per week or percentage of persons meeting exercise goal) (55, 69–71).

Harms of Counseling

We examined the 74 counseling trials for harms, as defined by the study authors, or any paradoxical change in outcomes (such as decreases in blood pressure, lipid and glucose levels, weight, dietary intake, and physical activity). Although we searched for additional observational studies examining harms of these counseling interventions, we did not find any such studies. In general, we found no evidence for serious harms, although the harms of included counseling interventions were not commonly reported. Only 10 of the included trials explicitly mentioned harms or lack of harms. Although 4 trials reported increased symptoms in persons receiving behavioral counseling attributed to an increase in physical activity (41, 55, 65, 70), there were generally no serious injuries, except for 1 trial targeting older adults (55). We found no consistent evidence for paradoxical changes in intermediate or behavioral outcomes. Although 9 of the 13 trials reported an increase in carbohydrate intake, this increase was generally accompanied by dietary improvements in fat, saturated fat, fiber, and fruit and vegetables without an overall increase in sugar or total calories consumed (41, 44, 75–81).

DISCUSSION

Based on a large body of evidence (74 trials), we found that intensive combined lifestyle counseling in persons with CVD risk factors improved dietary and physical activity behaviors and also reduced cholesterol levels, blood pressure, weight, glucose levels, and incidence of diabetes at 12 to 24 months (**Table 2**). Although the average effect of these reductions were modest (such as reduction in total cholesterol levels by approximately 0.08 to 0.21 mmol/L [3.0 to 8.0 mg/dL], low-density lipoprotein cholesterol levels by 0.04 to 0.16 mmol/L [1.6 to 6.0 mg/dL], systolic and diastolic blood pressure by 1 to 3 mm Hg, and weight by 2 to 3 kilograms), observational studies suggest that modest changes can be associated with clinically meaningful reductions in CVD events (82–84). The magnitude of effect is consistent with changes seen in other reviews of behavioral counseling on diet and exercise (31, 85). However, we found more limited information about longer-term benefits. Benefits for blood pressure, weight, and glucose reduction seemed to persist after 24 months but were based on only 11 trials. A reduction in diabetes incidence seemed to persist for 3 to 4 years. In the Diabetes Prevention Program, for example, at 3 years, an approximate 0.22-mmol/L (4-mg/dL) lower fasting blood glucose level in the intensive counseling group corresponded to a number needed to treat of approximately 7 persons to prevent one case of diabetes (roughly 29% of persons in the control group developed diabetes), which was more effective than metformin alone. Based on our review's estimates, even in populations with lower rates of progression to diabetes than those seen in the Diabetes Prevention Program, the number needed to treat is 13 (CI, 9 to 24) if 20% of persons progress to diabetes or 26 (CI, 19 to 48) if only 10% of persons progress to diabetes over 3 to 6 years. Our review found a reduction in progression to diabetes similar

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Table 2. **Overall Summary of Evidence, by Outcome**

Outcome	Trials and Participants, *n*	Overall Quality	Consistency	Applicability	Summary of Findings
Health outcomes	Trials: 16 Participants: 7053	Fair: sparse reporting of health outcomes or use of clinically important self-reported health outcomes (i.e., QOL, low CVD event rates, and variation in QOL instruments used)	Consistent findings of no benefit on reduction of CVD events, mixed findings for benefit on QOL	Persons with any number of CVD risk factors, no major limitations in populations studied. Mainly high-intensity combined lifestyle counseling interventions.	No reduction in CVD events (including mortality) at 6–79 mo and at 10 y (4 trials); no reduction in depression symptoms at 6–12 mo (4 trials); mixed findings on self-reported measures of QOL at 6–12 mo (7 trials). One earlier trial found a reduction in CVD events at 6.6 y; RR, 0.71 (95% CI, 0.51–0.99) using a high-intensity intervention including a protocol to initiate medication in Swedish men at high risk for CVD (29% smoked and 22% had diabetes).
Intermediate outcomes	Trials: 71 Participants: 32 734	Fair to good: high statistical heterogeneity for fasting glucose and weight outcomes; sparse reporting of outcomes beyond 24 mo; limited number of trials with significant clinical heterogeneity among physical activity–only counseling trials	Consistent findings of benefit across intermediate health outcomes; trials not included in meta-analyses consistent with trials that could be included	Persons with any number of CVD risk factors, no major limitations in populations studied. Medium- to high-intensity combined lifestyle counseling; diet-only counseling, mostly in persons with dyslipidemia not yet receiving medications.	Across all trials reporting each specific outcome, overall reduction in total cholesterol levels (34 trials) by 0.12 mmol/L (95% CI, 0.16 to 0.07 mmol/L) (4.48 mg/dL [CI, 6.36–2.59 mg/dL]), LDL cholesterol levels (25 trials) by 0.09 mmol/L (CI, 0.14 to 0.04 mmol/L) (3.43 mg/dL [CI, 5.37–1.49 mg/dL]), SBP (31 trials) by 2.03 mm Hg (CI, 2.91–1.15 mm Hg), DBP (24 trials) by 1.38 mm Hg (CI, 1.92–0.84 mm Hg), fasting glucose levels (22 trials) by 0.12 mmol/L (CI, 0.18 to 0.05 mmol/L) (2.08 mg/dL [CI, 3.29–0.88 mg/dL]), diabetes incidence (8 trials) by an RR of 0.58 (CI, 0.37–0.89), and weight outcomes (34 trials) by an SMD of 0.26 (CI, 0.35–0.16) at 12–24 mo. Overall evidence for longer-term (>24 mo) findings are limited, with the exception of a reduction in diabetes incidence in persons with impaired fasting glucose or glucose tolerance (5 trials) by an RR of 0.55 (CI, 0.45–0.67). No consistent finding of benefit on intermediate health outcomes for physical activity–only counseling interventions.
Behavioral outcomes	Trials: 61 Participants: 31 751	Fair: heterogeneity in dietary and physical activity outcome measures, mainly use of self-reported outcomes	Consistent with intermediate outcome findings	Persons with any number of CVD risk factors, no major limitations in populations studied. Medium- to high-intensity combined lifestyle counseling and diet-only counseling.	Findings of improvement, or lack of improvement, in behavioral outcomes consistent with findings on intermediate health outcomes. Overall improved dietary intake and physical activity outcomes in trials in persons receiving lipid- or blood pressure–lowering medications that did not demonstrate a benefit on intermediate health outcomes (6 trials). Trials only reporting behavioral outcomes (no intermediate outcomes) found small but significant improvement in diet (fat, saturated fat, fiber, and fruit/vegetable intake) and total physical activity (approximately 35–50 min more per week) at 12–18 mo (3 trials).
Adverse effects	Trials: 10 Participants: 6381	Fair: sparse reporting of harms	Consistent findings of no significant harms	Finding of serious harm applicable to high-intensity physical activity counseling in older adult VA population	No findings of serious harms (i.e., requiring unexpected/unwanted medical attention), except in 1 trial (302 participants) targeting older adults (2 persons with a serious adverse event attributed to physical activity). No findings of paradoxical changes in intermediate or behavioral outcomes. Increased self-reported carbohydrate intake accompanied by dietary improvements in fat/saturated fat, fiber, and fruit/vegetable intake without an overall increase in energy intake (9 trials).

CVD = cardiovascular disease; DBP = diastolic blood pressure; LDL = low-density lipoprotein; QOL = quality of life; RR = relative risk; SBP = systolic blood pressure; SMD = standardized mean difference; VA = Veterans Affairs.

to other existing systematic reviews on diabetes prevention in persons with impaired fasting glucose or glucose intolerance (86–89).

Most evidence supports combined lifestyle messages (49 trials); however, we also found consistent evidence that diet-only counseling (18 trials) reduced cholesterol levels in persons with dyslipidemia. In general, effective counseling interventions were intensive and involved several hours of contact (median, 13 hours [IQR, 9 to 19 hours]) in multiple contacts (median, 8 contacts [IQR, 5 to 16 contacts]) and over several months (median, 12 months duration [IQR, 6 to 12 months]). Adherence and, therefore, effec-

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tiveness in these trials may be greater than in real-world practice, especially given the intensity of these types of interventions. We found more limited information about physical activity–only counseling interventions (10 trials). Mostly medium-intensity physical activity–only counseling in persons with CVD risk factors did not seem to have consistent benefits on intermediate health outcomes; however, the limited number of studies and heterogeneity across trials limits our ability to make any definitive conclusions about the benefits, or lack thereof, of these types of counseling interventions.

Only 16 trials reported health outcomes, which prevented us from drawing any definitive conclusions about whether these types of interventions can decrease CVD events or improve QOL or depression symptoms (40–55). Overall, there does not seem to be a reduction in CVD events in the long term, but event rates in these trials, even after 10 years of follow-up, are generally quite low. Our review found a reduction in blood pressure and cholesterol levels similar to a Cochrane review of multiple risk factor interventions for the primary prevention of CVD by Ebrahim and colleagues (90). However, this review also found a decrease in mortality rates, primarily due to the inclusion of early CVD prevention trials. Our review was restricted to trials published after 1990, given the poor applicability of many earlier trials due to progress in the understanding and management of CVD risk, as well as trends in the distribution of CVD and CVD risk factors over time. Recent lifestyle intervention trials have not been shown to decrease CVD events. For example, the Look AHEAD (Action for Health in Diabetes) trial (5145 participants) that evaluated a high-intensity lifestyle intervention in overweight or obese persons with diabetes found no reduction in the rate of CVD events at approximately 10 years despite reductions in intermediate health outcomes (such as weight and glucose) and improvements in physical activity levels (91).

We did not hypothesize a priori any serious harms for counseling interventions. Overall, a limited number of trials reported on adverse effects of interventions, and only 1 trial in older adults found 2 events of serious harms as a result of physical activity (55). Based on observational studies and additional information on harms of physical activity from the 2008 Physical Activity Guidelines for Americans report (31, 92), focusing on low-impact activities and increasing activity in small increments can mitigate serious harm or injury from counseling interventions in older adults or persons at high risk for injury.

Our review focused narrowly on persons with risk factors for CVD; therefore, it is only a small subset of a much larger body of literature on lifestyle counseling in other populations (such as persons with prehypertension, physical inactivity, diabetes, and existing CVD disease) or for other purposes (such as disease management and falls or disability prevention). Our review was also limited to trials with a true control group; therefore, we did not explicitly address the comparative effectiveness of different types of behavioral counseling and intervention components. There were also limitations posed by the quantitative pooling of results. Fourteen trials could not be included in meta-analyses due to limitations in reporting at the primary study level. We used the DerSimonian–Laird method for random-effects meta-analyses, which has known limitations (93); therefore, we ran sensitivity analyses using the profile likelihood methods, which found concordant estimates with occasional wider CIs. In 2 instances, results were no longer statistically significant for short-term (less than 12 months) blood pressure outcomes. For most outcomes, the statistical heterogeneity was moderate, therefore allowing for the interpretation of pooled estimates. However, the statistical heterogeneity for fasting blood glucose and weight outcomes was very high and should be interpreted with caution. Despite examining many factors that may explain the heterogeneity of findings across trials, we could not identify additional characteristics (other than the type of intervention or population) that consistently explained the statistical heterogeneity in pooled analyses. Other potential sources of bias in our review include limiting to English-only publications, including only published trials, and potential selective reporting of outcomes. Trials with volunteer participants (16 trials), low recruitment rates (10 trials), or high attrition (16 trials) may have limited applicability to real-world findings.

Despite a large body of trial evidence, well-conducted trials are still needed to understand the full effect of these behavioral interventions on important health outcomes. Although intensive combined lifestyle and diet-only interventions are effective, many would require resources that are not currently available or paid for in the current health system. Additional research on the best way to disseminate and implement these types of intensive behavioral counseling interventions into current practice is needed. Details about fidelity of and adherence to counseling interventions should be routinely reported to better understand the applicability of behavioral counseling trial findings. We found a wide range of intensity for effective interventions ranging from 2 hours to more than 30 hours of contact time. Future research should also evaluate whether lower-intensity counseling interventions are as effective as higher-intensity counseling or whether there is a minimum intensity, frequency, or duration of contacts required to maintain effectiveness. Future research on different methods that require minimal health care resources (such as technology-based counseling) is advisable. Additional trials are needed to determine whether benefits in intermediate health outcomes persist in the long term. Many trials with longer-term follow-up had high-intensity interventions with ongoing maintenance sessions throughout the trial. Therefore, relatively little is known about the maintenance of benefits after an active intervention ends. Self-reported patient outcomes (namely measures of health-related QOL) are underused, and future research would benefit

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from measuring and consistently reporting QOL and related self-reported patient outcomes.

In general, intensive diet and physical activity behavioral counseling in persons with risk factors for CVD resulted in consistent improvements across various important physiologic measures of cardiovascular health up to 2 years and reduction in diabetes up to 4 years. Very limited evidence exists on patient health outcomes or harmful effects of these counseling interventions, although it is unlikely that counseling interventions have serious patient harms.

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