JAMA Clinical Guidelines Synopsis

Healthy Lifestyle Counseling in Persons With Cardiovascular Risk Factors

Lorrie Elliott, MD; Adam S. Cifu, MD

GUIDELINE TITLE Behavioral Counseling to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors

DEVELOPER US Preventive Services Task Force

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PRIOR VERSIONS November 2002, January 2003

FUNDING SOURCE Agency for Healthcare Research and Quality

TARGET POPULATION Adults in primary care settings who are overweight or obese and have known cardiovascular (CVD) risk factors (hypertension, dyslipidemia, impaired fasting glucose, or metabolic syndrome)

MAJOR RECOMMENDATION For adults who are overweight or obese and have known CVD risk factors, offer or refer for intensive behavioral counseling interventions to promote a healthful diet and physical activity (B recommendation: high certainty that the net benefit is moderate or moderate certainty that the net benefit is moderate to substantial).

Summary of the Clinical Problem

Cardiovascular disease is a leading cause of death in the United States. Nearly half of US adults have at least 1 risk factor for CVD,[1,2] and 70% are overweight or obese.[1,3] Recent decreases in CVD mortality rates are in part attributed to modification of risk factors.[4] Physical activity and a healthy diet are associated with decreased CVD event rates and mortality, but most US adults do not meet current recommendations for physical activity levels and a healthy diet.[4,5]

Characteristics of the Guideline Source

The guideline was developed by the US Preventive Services Task Force, which is an independent volunteer panel of nonfederal experts in prevention and evidence-based medicine (**Table**). The task force is composed of primary care clinicians and experts in methodology and health behavior. This guideline was developed in coordination with a systematic review sponsored by the Agency for Healthcare Research and Quality (AHRQ). A conflict of interest disclosure is completed by task force members prior to each meeting to provide information to AHRQ on potential financial, business/professional, and intellectual conflicts of interest related to the topics addressed.

Evidence Base

The authors identified 74 trials that examined healthy lifestyle counseling interventions in adults with CVD risk factors. These trials were all considered of fair or good quality. Of the 74 trials, 49 combined lifestyle counseling (diet and physical activity) interventions, 18 included dietary counseling interventions, and 10 included counseling interventions for physical activity only. Counseling was generally medium to high intensity. Medium-intensity interventions had a median of 5 contacts (interquartile range, 3-8 contacts), a median duration of 9 months (interquartile range [IQR], 4-11 months), and 31 to 360 minutes of interaction time with a clinician. High-intensity interventions had a median of 16 contacts (IQR, 9-31 contacts), a median duration of 12 months (IQR, 8-18 months), and more than 360 minutes of contact time with a health care practitioner.

Only 5 trials reported CVD events including mortality. Four trials found no reduction in CVD events. Event rates for cardiovascular outcomes or death in 3 of these trials were low, averaging less than 1%. Only 2 trials had event rates higher than 10% and only 1, the Risk Factor Intervention Trial,[6] reported a benefit in CVD events (relative risk, 0.71; 95% CI, 0.51-0.99; absolute risk reduction of 8%) at 6.6 years of follow-up. Participants in this trial had high rates of smoking, diabetes, and previous myocardial infarction and a mortality rate of 21% during the trial; importantly, the intervention included medical management of cardiovascular risk factors.

The remaining 69 trials assessed intermediate health outcomes (such as lipid levels, glucose levels, blood pressure, composite cardiovascular risk scores, medication use, and diabetes incidence) and/or health behavior outcomes (such as self-reported dietary intake and physical activity or objective markers of behavioral change, such as maximum oxygen consumption or urinary sodium excretion). Given the heterogeneity of the study populations

Table. Guideline Rating

Rating Standard	Rating
1. Establishing transparency	Good
2. Management of conflict of interest in the guideline development group	Good
3. Guideline development group composition	Good
4. Clinical practice guideline–systematic review intersection	Good
5. Establishing evidence foundations and rating strength for each of the guideline recommendations	Fair
6. Articulation of recommendations	Good
7. External review	Good
8. Updating	Fair
9. Implementation issues	Poor

and type of intervention, the authors stratified their analysis and conducted a meta-analysis (using 59 trials for which there were primary data on health outcomes) to estimate the effect size of counseling on intermediate health outcomes.

Benefits and Harms

Combined lifestyle interventions were modestly effective in changing intermediate health outcomes, with reductions in total cholesterol (22 trials) of 5.43 mg/dL (95% CI, 7.97-2.89 md/dL), low-density lipoprotein cholesterol (17 trials) of 3.69 mg/dL (95% CI, 5.98-1.40 mg/dL), and triglycerides (10 trials) of 8.33 mg/dL (95% CI, 13.80-2.86 mg/dL) and an increase in high-density lipoprotein cholesterol (14 trials) of 0.97 mg/dL (95% CI, 0.25-1.70). (To convert cholesterol to mmol/L, multiply by 0.0259.) Systolic blood pressure (27 trials) decreased by 2.06 mm Hg (95% CI, 3.03-1.08 mm Hg) and diastolic blood pressure (21 trials) decreased by 1.30 mm Hg (95% CI, 1.93-0.68 mm Hg). Weight (25 trials) decreased by an average of 2 to 3 kg (4.4-6.7 lb). Fasting glucose (18 trials) decreased by 1.86 mg/dL (95% CI, 3.24-0.49 mg/dL), and diabetes incidence (6 trials) decreased by a risk ratio of 0.54 (95% CI, 0.34-0.88). Effect sizes for blood pressure, glucose, and weight were similar for medium- and high-intensity interventions. Improvements in health behavior outcomes were concordant with improved intermediate health outcomes. Benefits peaked at 12 to 24 months, with only a few trials reporting longer-term results. In those, the reported effects generally did not seem to last at longer-term follow-up. A reduction in diabetes incidence persisted for more than 3 years, based primarily on the results of the Diabetes Prevention Program,[7] a high-intensity intervention, which showed a 58% reduction in diabetes incidence at 3 years.

Eighteen trials studied diet-only counseling interventions and 10 trials assessed physical activity interventions. In the diet-only counseling interventions, a positive effect was found on lipid levels, decreasing total cholesterol (9 trials) by 3.75 mg/dL (95% CI, 6.50-1.01 mg/dL) and low-density lipoprotein cholesterol (7 trials) by 4.27 mg/dL (95% CI, 7.84-0.70 mg/dL). In the 10 trials that assessed counseling for physical activity only, there was no consistent benefit on intermediate health outcomes; 8 of these interventions were medium intensity and 2 were high intensity.

There was no evidence for serious harms of counseling interventions in the 10 trials that specifically assessed this. Most reported harms were minor musculoskeletal or gastrointestinal concerns.

Discussion

Studies of combined lifestyle counseling interventions have primarily analyzed intermediate health outcomes, with few data on clinical end points. These interventions, when applied to adults who were overweight or obese, had small effects on intermediate markers. The results, however, are potentially applicable to a large segment of the US population. The intensity of the interventions may be difficult to replicate in a primary care setting, as adherence to interventions is typically higher in a clinical trial setting. Many interventions require resources that are currently not available or not commonly reimbursed in the current health system (such as dieticians, exercise physiologists, or trained health educators).

Areas in Need of Future Study or Ongoing Research

Comparisons of less-intensive combined lifestyle counseling with the intermediate- to high-intensity counseling studied would be welcome. The types of counseling (didactic education, problem-solving skills, audit and feedback) that are most effective remain in question, as do the type and frequency of contact. The effectiveness of and adherence to counseling delivered in the primary care setting are also not presently known. It is unclear whether results persist past 24 months or whether ongoing maintenance interventions are necessary. Most importantly, future trials should assess the effect of counseling on actual clinical outcomes, such as CVD events. These studies will be challenging because low event rates will necessitate very large studies. Counseling methods that require minimal health care resources, such as technology-based counseling, should be assessed.

Related guidelines and other resources

American Heart Association 2010 scientific statement on CVD risk factor reduction
http://circ.ahajournals.org/content/122/4/406.full.pdf+html

US Preventive Services Task Force obesity screening and management
http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/obesity-in-adults-screening-and-management

Cochrane Database systematic review of risk factor interventions for prevention of heart disease
http://www.cochranelibrary.com/enhanced/doi/10.1002/14651858.CD001561.pub3

ARTICLE INFORMATION

Author Affiliations: Department of Clinical Medicine, Northwestern University Feinberg School of Medicine, Chicago, Illinois (Elliott); Department of Medicine, University of Chicago, Chicago, Illinois (Cifu).

Corresponding Author: Adam S. Cifu, MD, Department of Medicine, University of Chicago, 5841 S Maryland Ave, MC 3051, Chicago, IL 60637 (adamcifu@uchicago.edu).

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