Does Counseling by Clinicians Improve Physical Activity? A Summary of the Evidence for the U.S. Preventive Services Task Force

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Purpose: To determine whether counseling adults in primary care settings improves and maintains physical activity levels.

Data Sources: The Cochrane Database of Systematic Reviews and Registry of Controlled Trials and the MEDLINE, HealthStar, and Best Evidence databases were searched for papers published from 1994 to March 2002.

Study Selection: Controlled trials, case–control studies, and observational studies that examined counseling interventions aimed at increasing physical activity in general primary care populations were reviewed. The researchers included trials in which 1) a patient’s primary care clinician performed some of the counseling intervention; 2) behavioral outcomes (physical activity) were reported; and 3) the study was of “good” or “fair” quality, according to criteria developed by the U.S. Preventive Services Task Force.

Data Extraction: Data were abstracted on design and execution, quality, providers, patients, setting, counseling intervention, and self-reported physical activity at follow-up.

Data Synthesis: Eight trials involving 9054 adults met the inclusion criteria. Among six controlled trials with a usual care control group, the effects of counseling on physical activity were mixed. Because most studies had at least one methodologic limitation, it was difficult to rigorously assess the efficacy of the interventions. More research is needed to clarify the effect, benefits, and potential harms of counseling patients in primary care settings to increase physical activity.

Conclusion: Evidence is inconclusive that counseling adults in the primary care setting to increase physical activity is effective.


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See related article on pp 205-207.

Sedentary behavior (little to no recreational, household, or occupational physical activity) is one of the strongest risk factors for many chronic diseases and conditions, including cardiovascular disease, hypertension, diabetes, obesity, osteoporosis, colon cancer, and depression (1, 2). Only 25% of Americans achieve the level of physical activity recommended in Healthy People 2010 guidelines, that is, 30 minutes of moderate activity on 5 or more days per week or 20 minutes of vigorous activity three or more times per week (3). Twenty-nine percent report getting no regular physical activity. A recent review of observational studies reported that risk for all-cause mortality was 20% to 30% lower among adults who met the Healthy People 2010 recommendations and somewhat lower for adults who exercised moderately or vigorously at least a few times per month or once per week (4).

Despite inconclusive evidence that counseling by primary care clinicians improves patient activity levels, in 1996 the U.S. Preventive Services Task Force (USPSTF) recommended counseling to promote regular physical activity for all children and adults based on evidence of the benefits of increased physical activity. Surveys of patients suggest that a minority of clinicians follow this recommendation. In the 1997 Behavioral Risk Factor Surveillance System, 42% of adult respondents reported receiving clinician advice to increase physical activity levels (5, 6). Approximately three fourths of the patients who reported receiving clinician advice also reported increasing physical activity levels, compared with only half of the patients who reported receiving no clinician advice.

Two recent systematic reviews came to different conclusions about the efficacy of counseling (7, 8). One review focused on eight studies published between 1988 and 1998 in which primary care clinicians directly advised patients to increase physical activity (8). The authors rated only two of these studies as good quality; in four studies, counseling led to small, short-term increases in self-reported activity levels. The other review summarized 15 studies published between 1979 and 1999 of interventions initiated or conducted in the primary care setting, regardless of whether the primary care clinician played any role (7). This review concluded that counseling was “moderately effective” but did not use study quality as a criterion for inclusion. Neither review sought evidence about the potential harms associated with increasing physical activity.

Since these reviews were published, results of several additional trials of counseling have been made available. In consultation with members of the USPSTF, we performed a new systematic review that focused on controlled trials published since the 1996 USPSTF guidelines and addressed these questions: 1) Do adults counseled by primary care clinicians improve or maintain physical activity behavior? 2) If so, what types of interventions are most effective? From the trials on physical activity counseling, we also assessed the harms associated with increased physical activity.

METHODS

Search Strategy and Study Selection

The scope of the two previous systematic reviews (7, 8) differed sharply: One included only studies of counseling by the clinician alone (8), while the other included studies of interventions performed in the primary care setting even when clinicians did not interact with patients.
in any way (7). In consultation with members of the USPSTF, we took the middle ground of including all controlled clinical trials in which some components of the intervention were performed by the patient’s primary care clinician (nurse practitioner, nurse, physician, or physician assistant). To describe the clinician’s role as well as other components of interventions consistently, we used an abstraction tool developed by the Behavioral Counseling Work Group of the current USPSTF (9). The tool is based on a practical “5-A” framework (Assess, Advise, Agree, Assist, and Arrange/Adjust) originally developed to describe the elements of brief provider tobacco-cessation interventions (10). We limited our review to trials that had been published since the last USPSTF review (1994 and later) and that reported behavioral outcomes of an intervention to increase physical activity.

We searched the Cochrane Database of Systematic Reviews and Registry of Controlled Trials through March 2002 using the term “physical activity” and found abstracts for 49 reviews and 966 controlled trials. We searched the MEDLINE and HealthStar database from 1994 to March 2002, using the Medical Subject Headings “exercise,” “physical fitness,” “counseling,” “patient education,” and “health education,” and found 549 abstracts. Experts and reference lists of pertinent articles provided an additional 145 references.

We excluded two randomized, controlled trials that reported physical activity outcomes but did not mention counseling to increase physical activity (11, 12). We excluded one ongoing trial that has not yet reported results for the physical activity intervention in the treatment groups (13). We excluded four randomized, controlled trials (14–17) in which all components of the intervention were provided by a research staff member or exercise specialist. For example, in one study (15), a research associate recruited patients from waiting rooms or from lists provided by the general practitioners. The patients were mailed an invitation to participate in an intervention conducted by health educators at a fitness center. As a team, we reviewed this study and excluded it because no components of the intervention were performed by a primary care clinician.

Data Abstraction and Synthesis

A single reviewer abstracted information about setting, patient participants, providers, interventions, adherence, and outcomes. The outcome of primary interest was the proportion of patients who met the Healthy People 2010 goal in the “long term,” which we defined as at least 6 months after randomization. When this outcome was not available, we recorded mean changes in activity levels. We also recorded short-term results if reported. At least two reviewers summarized the quality of each study using criteria developed by the current USPSTF (18). In applying the USPSTF criteria to trials that used randomization by practice rather than by individual patient, we placed particular importance on the methods used to create comparable groups, such as matching and stratification, and on whether the groups were similar at baseline. We also placed emphasis on whether the interventions were clearly described and whether most patients were retained throughout the study. The internal validity of each trial was rated “good,” “fair,” or “poor.” A rating of “good” means that the trial met all criteria and was likely to be valid. A “fair” rating means that the study was possibly or probably valid, depending on the nature or severity of its flaws. “Poor” studies have fatal flaws rendering the results invalid; such studies were excluded from further consideration.

We summarized the design, quality, and results of each included trial in an evidence table, focusing on the magnitude of change in and duration of physical activity. We examined the consistency of results among studies and the relationship between effects and specific components of the interventions, discussing studies that compared an intervention with usual care separately from those that compared two interventions.

Role of the Funding Source

This review was funded by the U.S. Agency for Healthcare Research and Quality under a contract to support the work of the USPSTF. Task Force members participated in the initial design of the review and reviewed interim summaries as well as the final manuscript. The funding source had no role in the study design, data collection, or data synthesis; however, representatives of the Agency for Healthcare Research and Quality reviewed interim summaries and copies of the manuscript. Since our report was prepared for the current USPSTF, it was distributed for review to 13 outside experts and representatives of professional societies and federal agencies.

RESULTS

Seven randomized, controlled trials (19–25) and one nonrandomized controlled trial (26) met our inclusion criteria (Table). A pilot study for one of the trials (20) was excluded (29). Five other trials (30–34) were excluded because they received a quality rating of poor according to criteria developed by the current USPSTF (18). (See the Appendix Table, available at www.annals.org, for a description of the excluded studies.)

Most of the trials were conducted in typical primary care practices, and all included multiple sites. Clinicians delivered advice themselves but usually did not perform the initial assessment. In some trials, the patients completed a self-report tool on physical activity levels (20, 22, 26) or answered selected questions from larger validated health-assessment tools administered by telephone, in the office waiting area, or in the home (19, 21, 23). Often, a nurse or research assistant conducted a baseline assessment and placed it on the medical chart for review during the clinician’s visit (20, 22, 26). The clinician used the assessment information to exclude patients for whom physical activity...
Table. Summary of Controlled Trials of Counseling for Physical Activity*

<table>
<thead>
<tr>
<th>Study, Year (Reference)</th>
<th>Study Design</th>
<th>Patients</th>
<th>Theory</th>
<th>Provider Education and Materials</th>
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<tbody>
<tr>
<td>Counseling vs. usual care</td>
<td>RCT of 24 community-based primary care practices matched by size (34 physicians); PA only</td>
<td>Sedentary adults (not meeting HP) 50 y; intervention group: 181 patients; mean age, 65 y; baseline stages: 13% precontemplative, 31% contemplative, 56% preparation stage; 12% nonwhite. Control group: 174 patients; mean age, 66 y; baseline stages: 17% precontemplative, 33% contemplative, 50% preparation stage; 20% nonwhite</td>
<td>Transtheoretical (5 stages), social cognitive, health education</td>
<td>Training, pretested manual, and poster for patients</td>
</tr>
<tr>
<td>Norris et al., 2000 (22)</td>
<td>RCT of 32 primary care physicians in a staff-model HMO, stratified by clinic; PA only</td>
<td>Adults &gt;30 y scheduled for well visits. Intervention group: 384 adults; mean age, 53 y; baseline stages: 2.6% precontemplative, 51.3% contemplative, 46.3% action; 11% nonwhite. Control group: 463 patients; mean age, 57 y; baseline stages: 3.4% precontemplative, 46.8% contemplative, 49.8% action; 8% nonwhite</td>
<td>Transtheoretical (3 stages)</td>
<td>1-h training, follow-up calls with providers</td>
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<tr>
<td>Smith et al., 2000 (26)</td>
<td>Nonrandomized controlled trial of patients in 27 general practices in Australia; controls recruited first; PA only</td>
<td>Active and inactive adults 25–65 y. Prescription-only intervention group: 380 patients; mean age, 43 y; median total PA, 95 min. Prescription + booklet intervention group: 376 patients; mean age, 43 y; median total PA, 120 min. Control group: 386 patients, mean age, 42 y; total PA, 145 min</td>
<td>Transtheoretical (5 stages)</td>
<td>20–30 min of training</td>
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<tr>
<td>Kese et al., 1999 (21)</td>
<td>RCT of 42 metropolitan general practices (42 physicians); PA, social activity</td>
<td>Adults ≥65 y. Intervention group: 135 patients; mean age, 73 y; total activity, 281 min/wk. Control group: 132 patients; mean age, 74 y; total activity, 328 min/wk</td>
<td>Not reported</td>
<td>3-h seminar with exercise physiologist, sociologist, and geriatrician; 15 min follow-up detailing; prompt card</td>
</tr>
<tr>
<td>Change of Heart, 1999 (23)</td>
<td>RCT of 20 general practices (20 nurse practitioners), minimization technique; PA, smoking, diet</td>
<td>Adults 18–69 y with ≥1 CHD risk factor. Intervention group: 316 patients; mean age, 48 y, 80% BMI &gt;25 kg/m² = sedentary. Control group: 567 patients; mean age, 46 y; 79% BMI &gt;25 kg/m² = sedentary</td>
<td>Transtheoretical (5 stages)</td>
<td>3-d training with refresher day at 6 mo</td>
</tr>
<tr>
<td>Burton et al., 1995 (19)</td>
<td>RCT of 4195 Medicare patients in 119 practices; PA, immunization, smoking, drinking</td>
<td>Sedentary Medicare beneficiaries. 65–74 y, 61%; 75–84 y, 33%; ≥85 y, 6%. Intervention group: 2105 patients. Control group: 2090 patients</td>
<td>Suggested but not directed</td>
<td>CME credits on preventive and counseling visits, educational materials</td>
</tr>
<tr>
<td>Comparison of different interventions (no usual care) Activity Counseling Trial, 2001 (25, 27, 28)</td>
<td>RCT of 874 adult patients from 11 primary care settings (51 physicians, 2 physician assistants, 1 nurse practitioner); PA only</td>
<td>Inactive adults 35–75 y in stable health. Advised intervention group: 292 patients; average age, 51 y. Assisted intervention group: 293 patients; average age, 52 y. Counseled group: 289 patients; average age, 52 y</td>
<td>Social cognitive</td>
<td>Advice training (clinicians) assist and behavioral counseling training (health educators)</td>
</tr>
<tr>
<td>Swinburn et al., 1998 (24)</td>
<td>RCT of 491 patients of 37 providers in 2 New Zealand urban centers; PA only</td>
<td>Sedentary adults. 50% had ≥1 CHD risk factor. Intervention group: 239 patients. Control group: 252 patients</td>
<td>Self-management (goal setting)</td>
<td>1 training session on assessing and prescribing physical activity</td>
</tr>
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</table>

* BMI = body mass index; CHD = coronary heart disease; CME = continuing medical education; HMO = health maintenance organization; HP = Healthy People 2010 recommendation (30 min of moderate physical activity ≥5 d/wk or 20 min of vigorous activity ≥3 d/wk); PA = physical activity; RCT = randomized, controlled trial. Values in square brackets are 95% CIs.
### Table—Continued

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Provider Adherence</th>
<th>Short Term (&lt;6 mo)</th>
<th>Long Term (≥6 mo)</th>
<th>Quality Comments</th>
</tr>
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<tbody>
<tr>
<td>5-min stage-based advice on benefits; assisted with self-efficacy barriers; community resources; written PA prescription; follow-up visit at 1 mo for adjusted prescription</td>
<td>Intervention group: 99% received PA prescription, 77% received follow-up prescription. Control group: 1% received PA prescription</td>
<td>At 6 wk, 28% of intervention patients vs. 21% of controls met HP goal (difference, 7 percentage points (CI 3 to 15 percentage points))</td>
<td>At 8 mo, 28% of intervention patients vs. 23% of controls met the HP goal (difference, 5 percentage points (CI –6 to 14 percentage points))</td>
<td>Good quality. Met all criteria. 95% follow-up at 6 wk, 88% at 8 mo</td>
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<tr>
<td>Stage-based advice on benefits; PA preferences; assisted with barriers, self-efficacy, and self-management. Gave stage-based handouts; agreed on written goal. Follow-up call at 1 mo + mailed education materials</td>
<td>Intervention group: 94% were counseled and 90% of these received PA prescriptions. Control group: 65% were counseled and 81% of these received a PA prescription</td>
<td>Follow-up call at 1 mo mailed education materials</td>
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<tr>
<td>Advice, provided PA prescription; stage-based booklets sent to random sample</td>
<td>Intervention group: 62% received PA prescription. Inferred 468 of 471 sedentary patients for 99% adherence. Control group: not reported</td>
<td>Among inactive patients at 6–10 wk in the prescription + booklet vs. control groups, 31% vs. 27% met the HP goal (difference, 4 percentage points (CI 5 to 12 percentage points)); 46% vs. 35% increased to 60 min/wk (difference, 11 percentage points (CI 2 to 20 percentage points)); P = 0.02. In the prescription only vs. control groups, 26% vs. 27% met the HP goal (difference, –1 percentage point (CI –10 to 7 percentage points)); 41% vs. 35% increased to 60 min/wk (difference, 6 percentage points (CI 3 to 15 percentage points))</td>
<td>Among inactive patients at 7–8 mo in the prescription only vs. control groups, 24% vs. 17% met the HP goal (difference, 7 percentage points (CI 0 to 21 percentage points)); P = 0.05) and 36% vs. 27% increased to 60 min/wk (difference, 9 percentage points (CI 0 to 17 percentage points); P = 0.06). In the prescription only vs. control groups, 23% vs. 17% met the HP goal (difference, 5 percentage points (CI –3 to 12 percentage points)); 32% vs. 27% increased to 60 min/wk (difference, 4 percentage points (CI 4 to 13 percentage points)); P = 0.11</td>
<td>Fair quality. 93% follow-up at 6 wk, 97% at 6 mo. Baseline differences in previous PA counseling. Not reported</td>
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<tr>
<td>Counseling for PA and social activity. Other counseling techniques not reported</td>
<td>Intervention group: 32% of intervention group vs. 21% of control group reported discussing PA with physician</td>
<td>At 1 y, intervention patients increased walking 44 min/wk (4 to 84 min/wk) more than control patients (P = 0.03)</td>
<td>At 1 y, intervention patients performed 14 sessions/4 wk vs. 9 sessions/4 wk in controls (difference, 3.9 sessions/4 wk (CI 1.0 to 6.8 sessions/4 wk); P &lt; 0.05)</td>
<td>Fair quality. 90% intervention group follow-up at 1 y, 85% control follow-up at 1 y. Counseling interventions not clearly defined, low provider adherence</td>
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<td>Stage-based advice on benefits and attitudes; assisted with community resources. 20-min follow-up counseling sessions as needed. Most counseling details not reported</td>
<td>Not reported</td>
<td>At 4 mo, intervention patients had 13 (20-min) activity sessions/4 wk vs. 9 sessions/4 wk in controls (difference, 3.7 sessions/4 wk (CI 1.3 to 6.3 sessions/4 wk); P &lt; 0.05)</td>
<td>At 1 y, intervention patients performed 14 sessions/4 wk vs. 9 sessions/4 wk in controls (difference, 3.9 sessions/4 wk (CI 1.0 to 6.8 sessions/4 wk); P &lt; 0.05)</td>
<td>Fair quality. 65% intervention group follow-up at 4 mo, 54% at 1 y; 74% control follow-up at 4 mo, 62% at 1 y</td>
</tr>
<tr>
<td>Feedback and advice from pre-visit risk screen, assisted with community resources. 20-min weekly counseling</td>
<td>Intervention group: 89% of physician encounter forms contained PA discussion note. Inferred that up to 39% of patients attended follow-up counseling visit that included PA. Control group: not reported</td>
<td>At 2 y, 42% of intervention patients in good health and 20% of patients in poor health increased PA vs. 42% of controls in good health and 18% of controls in poor health (difference for poor health, 3 percentage points (CI –9 to 4 percentage points)); P = 0.025)</td>
<td>At 6, 12, and 24 mo, male or female patients did not differ in total energy expenditure, with one exception. Women in the counseling group had an average total energy expenditure of 33.3 kcal × kg−1 × day−1 at 6 mo vs. 32.7 kcal × kg−1 × day−1 for women in the guided group (difference, 0.54 kcal × kg−1 × day−1 (CI 0.07 to 1.0 kcal × kg−1 × day−1); P = 0.01 (adjusted)</td>
<td>Fair quality. 75% follow-up at 2 y, 73% control follow-up at 2 y. Counseling interventions not clearly defined</td>
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<td>Advised group: 3 min of initial advice. Assisted group: initial advice and 30–40 min of behavioral counseling + telephone follow-up. Counseled group: initial advice, behavioral counseling, and biweekly telephone counseling for first 6 wk, monthly calls thereafter, weekly class offerings.</td>
<td>99% received initial 3 min of advice; documented for 97%. Average contact time: advised group, 18 min over 24-mo study; assisted group, 2.7 h; counseled group, 8.9 h for women, 5.6 h for men</td>
<td>At 6 mo, 22% of intervention patients vs. 10% of controls increased to 60 min/wk (difference, 12 percentage points (CI 6 to 18 percentage points); P = 0.004). Groups did not differ in number of increased minutes spent in PA (156 min/2 wk)</td>
<td>At 6, 12, and 24 mo, male or female patients did not differ in total energy expenditure, with one exception. Women in the counseled group had an average total energy expenditure of 33.3 kcal × kg−1 × day−1 at 6 mo vs. 32.7 kcal × kg−1 × day−1 for women in the assisted group (difference, 0.54 kcal × kg−1 × day−1 (CI 0.07 to 1.0 kcal × kg−1 × day−1); P = 0.01 (adjusted)</td>
<td>Good quality. Met all criteria. 91% follow-up at 24 mo, 78% completed fitness test (VO2max) at 24 mo</td>
</tr>
<tr>
<td>Advice (average, 5 min) and written PA prescription. Stage-based booklets sent to random sample. Control group received advice only</td>
<td>Not reported</td>
<td>More patients receiving advice and a written PA prescription performed any activity (51% vs. 86%, an increase of 35 percentage points) at 6 wk vs. patients who received only advice (56% to 77%, an increase of 21 percentage points) (difference, 14 percentage points (CI 6 to 22 percentage points); P = 0.004). Groups did not differ in number of increased minutes spent in PA (156 min/2 wk)</td>
<td>More patients receiving advice and a written PA prescription performed any activity (51% vs. 86%, an increase of 35 percentage points) at 6 wk vs. patients who received only advice (56% to 77%, an increase of 21 percentage points) (difference, 14 percentage points (CI 6 to 22 percentage points); P = 0.004). Groups did not differ in number of increased minutes spent in PA (156 min/2 wk)</td>
<td>Fair quality. 91% intervention group follow-up at 6 wk; 94% control follow-up at 6 wk. Intervention not well defined. Adherence not reported</td>
</tr>
</tbody>
</table>
was contraindicated or to tailor the intervention to each patient’s needs. In most trials, the clinician advised sedentary or minimally active patients to achieve regular, moderate-intensity physical activity; in some trials, clinicians recommended vigorous activity as an option.

Five studies (20, 22, 24–26) targeted physical activity alone, while three (19, 21, 23) also had other behavioral targets (for example, diet change, smoking cessation). In three of the trials, the primary care clinicians condensed advice and counseling on behavior change into a single 3- to 5-minute encounter and, for some patients, a follow-up session with the clinician or another member of the health care team (20, 24, 25). Five trials did not report the amount of time that the clinician spent with patients for the intervention (19, 21–23, 26).

Two of the trials met all USPSTF criteria and were rated as good quality (20, 25) (Table). The remaining trials were rated as fair quality because treatment and control groups differed significantly in physical activity levels at baseline (22, 26), the counseling intervention was not clearly defined (19, 21, 24), or attrition was high (19, 23).

### Efficacy of Counseling

#### Interventions Compared with a Usual Care Control

In six controlled trials that contained a usual care control group (19–23, 26), the effects of counseling on physical activity after 6 to 24 months were mixed (Table). Only one of the trials (20) met all of our criteria for a quality rating of “good.” In this trial, clinicians provided sedentary patients with a brief (5-minute) message, a prescription for exercise, and a follow-up visit to adjust the prescription 1 month later. After 8 months, 28% of 181 intervention patients met the Healthy People 2010 goal compared with 23% of 174 patients who received usual care (difference, 5 percentage points [95% CI, −6 to 14 percentage points]).

Of the five fair-quality trials, two showed no effect of counseling on physical activity levels after 6 or more months (19, 22) and three showed statistically significant increases in activity (21, 23, 26). In the latter three trials, two randomized trials reported increases in the average number of exercise sessions (23) or in time spent walking (21) but did not report the proportion of patients who increased physical activity. The third trial (26), which was nonrandomized, reported that an increased proportion of inactive patients added 60 minutes or more of physical activity per week.

Among the studies we rated as fair quality, two had relatively serious threats to validity. One was a nonrandomized trial in which a significantly greater proportion of the intervention patients (62%) were inactive at baseline compared with the usual care group (54%) (P < 0.05) (26). In the other, a randomized trial in which counseling was ineffective, more control patients than intervention patients reported receiving physical activity counseling in the 6 months before the trial began (55% vs. 42%; P = 0.02) (22). Although the groups were otherwise similar, this imbalance raises the possibility that randomization was not conducted properly (22). Also, control physicians counseled 81% of their patients, greatly reducing the trial’s ability to show a difference between groups.

Components of the interventions included advice (20, 22, 26), assistance with perceived self-efficacy (19) and barriers (20, 22), mailed educational materials (22, 26), referral to community resources (20), and written exercise prescriptions (20, 22, 26). There were too few studies and too few details to discern any relationship between the components of the interventions and the reported efficacy. None of the fair-quality trials reported the time the clinician spent with the patient. The four studies that applied the “stages of change” (trantheoretical) model of behavior change had mixed results (20, 22, 23, 26).

Three of the trials addressed physical activity only (20, 22, 26), while the other three addressed multiple behavior changes (19, 21, 23). Within each of these categories, results of the trials were mixed. The trials addressing multiple behavior changes reported few details about the intervention components and either did not report adherence (19, 23) or reported poor adherence to the physical activity component (39%) (21).

#### Interventions Compared with Other Interventions

We identified two trials that compared the efficacy of different interventions and had no usual care group (Table) (24, 25). The results of these trials suggested that a written prescription was more effective than advice alone (24) and that women may need more intensive counseling interventions (that is, more contact and time with the clinician) than men to increase physical activity in the long term (25).

In the larger, methodologically stronger study, the Activity Counseling Trial (25), more intense counseling programs were better than brief advice for women, but not for men. In this trial, 874 sedentary adults in stable health were randomly assigned to one of three interventions: clinician advice and educational materials (advice group); clinician advice, educational materials, and 30 to 40 minutes of behavioral counseling and interactive mail (assistance group); or all of the above plus counseling telephone calls and class offerings (counseling group) (25). At 6, 12, and 24 months, men in all groups did not differ in expended energy or fitness levels (25). After 6 months, women in the counseling group had increased self-reported physical activity compared with women in the assistance group. At 6 months, women in the counseling group achieved a total energy expenditure of 33.3 kcal × kg⁻¹ × day⁻¹ compared with 32.7 kcal × kg⁻¹ × day⁻¹ for women in the assistance group (difference, 0.54 kcal × kg⁻¹ × day⁻¹ [CI, 0.07 to 1.0 kcal × kg⁻¹ × day⁻¹]; P = 0.01 [adjusted]). For a woman weighing 50 to 55 kg, this difference corresponds to walking an extra 2 miles per week. At 12 and 24 months, women in the different intervention groups did not differ significantly in total energy expenditure. At the 24-month examination,
women in the counseling and assistance groups were more fit than women in the advice group. For counseling compared with advice, difference in maximal oxygen uptake (VO₂max) was 73.9 mL/min (99.2% CI, 0.9 to 147.0 mL/min; P = 0.046). For assistance compared with advice, the difference in VO₂max was 80.7 mL/min (99.2% CI, 8.1 to 153.2 mL/min; P = 0.02).

Potential Harms of Counseling

Potential harms of physical activity counseling have not been well defined. Harms of physical activity probably include musculoskeletal injuries, fall-related injuries, and cardiovascular events. Whether counseling decreases or increases such events is not clear. Only the Activity Counseling Trial reported rates of physical harm in the 2 years following counseling (25). Although patients were instructed to gradually increase physical activity, approximately 60% of all patients reported musculoskeletal events and 3% of all patients required hospitalization during the study. Twenty-nine percent of patients reported potential cardiovascular events during the 2 years. Nineteen percent of all patients saw a physician about these events and 5% required hospitalization. Since there was no usual care group in this trial, it is difficult to know whether or how much the interventions contributed to the harms. Although patients with preexisting heart disease or a positive result on a submaximal treadmill test were excluded from the trial before randomization, the sample included patients taking medication for chronic conditions, including hypertension. Many patients were overweight (average body mass index, 29.5 kg/m²), and 9% smoked (28).

To avoid injury, most trials excluded patients at risk or offered moderate rather than vigorous activity. Five of the eight trials specifically stated that patients were excluded for medical reasons (20, 22, 23, 25, 26). Six of the eight trials offered a moderate activity option (20–25). However, these trials did not provide sufficient detail about harms to judge the efficacy of these precautions.

Feasibility and Costs

Assessment and counseling take patient and staff time, which may explain why only three trials reported that more than 90% of patients received the intended intervention (20, 22, 23). Some of the counseling efficacy studies used additional staffing for assessments (20, 21, 23). One trial reported that a research staff member spent 5.8 minutes assessing each patient using the Physical Activity Scale for the Elderly (PASE) assessment tool (20).

The Activity Counseling Trial reported that patients who received both advice and counseling (the assistance group) spent an average of an additional 2.7 hours with a clinician or health educator over 2 years compared with patients who were simply advised to increase physical activity (18 minutes of contact time over 2 years) (25). Women who received advice, counseling, follow-up counseling telephone calls, and classes (the counseling group) spent 9 more hours with a clinician or an educator than women who received only advice. Similarly, men in the counseling group spent an extra 5 hours with a clinician or an educator over 2 years.

Discussion

We performed this review to determine whether adults who receive counseling in primary care settings improve and maintain physical activity behavior. Several recent good- and fair-quality trials on efficacy of counseling for physical activity in primary care demonstrated modest or no increases in physical activity; these trials were extremely heterogeneous. Previous reviews (7, 8) found that interventions targeting physical activity were effective in the short term. However, we found mixed, inconclusive evidence to support this finding. Two of three trials in our review that addressed multiple behaviors reported increased activity in the short and long term.

Most trials in our review provided limited details on the counseling intervention and had only fair follow-up rates; highly motivated providers; differences in physical activity levels at baseline between intervention and control groups; uncertain or low provider adherence; or inadequate power to detect differences because of high baseline activity levels, small numbers of participants (patients and physicians), or inclusion of some counseling advice in usual care control groups. In several trials, it was difficult to assess whether patients had actually received a physical activity behavioral intervention.

Many people are sedentary or active at different times in their lives (35). Since most physical activity interventions in primary care focus on changing sedentary behavior to active behavior, studies with very long follow-up periods are needed to evaluate which strategies best encourage maintenance of physical activity (36). These long-term interventions may be more feasible for clinicians and more effective if the larger health systems provide support for initiation and maintenance, such as telephone-based interventions and mailed support. For example, a recent trial of health system–sponsored telephone support by trained health educators reported increased physical activity in patients committed to increasing activity (37). Clinical interventions may also be more effective if patients are referred to community programs that provide ongoing social support, such as established walking groups (38).

Only one trial in this review reported harms (25). Understanding the potential harms and revising future interventions to reduce them may improve patient adherence. We need large prospective studies that report the type of intervention, including the recommended intensity of physical activity, and injuries in the long term (for example, >2 years). Such trials should document the reasons why patients drop out of studies. It is possible that some nonresponders stop exercising because they experience harm.

Because of the methodologic limitations described earlier, we found it difficult to assess the efficacy or effectiveness of the interventions examined. Although research sug-
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Appendix Table. Studies Rated as Poor Quality*

<table>
<thead>
<tr>
<th>Study, Year (Reference)</th>
<th>Reasons for Poor Rating</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bull and Jamrozik, 1998 (33)</td>
<td>Maintenance of comparison groups in question. Nonrandomized trial design (same providers for control and intervention patients based on days of the week during 3-wk recruitment) had high potential for contamination. Fair to poor rates of follow-up assessments (70% at 1 mo, 57% at 6 mo, 56% at 12 mo).</td>
<td>Increased proportion of active intervention patients (40%) at 1 mo vs. 31% of controls (difference, 9 percentage points). Increased proportion of active intervention patients (38%) at 6 mo vs. 30% of controls (difference, 8 percentage points). No difference in active proportion at 1 y (36% intervention patients vs. 31% control patients; difference, 5 percentage points).</td>
</tr>
<tr>
<td>Calfas et al., 1996 (32)</td>
<td>Establishment and maintenance of comparison groups in question. Nonrandomized trial design with intervention physicians selected based on personal interest in physical activity. Suggests that control physicians had less interest in physical activity and may have had lower than expected usual care counseling rates at baseline. During study, 17% of intervention physicians and 30% of control physicians were lost.</td>
<td>Intervention patients reported higher metabolic rate (432) at 4 y vs. 388 for controls (P &lt; 0.001).</td>
</tr>
<tr>
<td>Elder et al., 1995 (30)</td>
<td>High loss to follow-up. 45% of intervention patients responded at 4 y vs. 44% of control patients. Patients who did not complete the follow-up assessment were excluded from analysis.</td>
<td>Not reported based on randomization.</td>
</tr>
<tr>
<td>Graham-Clarke and Oldenburg, 1994 (31)</td>
<td>Unclear whether randomization was adequate because a greater proportion of intervention patients were at “intended to change” stage (53% vs. 37% of controls; difference, 16 percentage points [13–19 percentage points]). Achieved poor rates of follow-up assessments (44% at 4 mo, 50% at 12 mo). Insufficient information to abstract needed results relative to randomization.</td>
<td>Intervention patients who received physician advice to exercise before receiving education materials were more likely to change behavior than patients who received no advice (OR, 1.51 [0.95–2.4]).</td>
</tr>
<tr>
<td>Kreuter et al., 2000 (34)</td>
<td>Unclear whether randomization was adequate because no baseline demographic characteristics were provided. No mention of an intention-to-treat analysis. Used a new physical activity tool with no validity analysis reported.</td>
<td></td>
</tr>
</tbody>
</table>

* These studies were rated poor according to the U.S. Preventive Services Task Force quality criteria (18). Poor-quality studies have fatal flaws rendering them invalid. HP = Healthy People 2010 recommendation (30 min of moderate physical activity ≥5 d/wk or 20 min of vigorous activity ≥3 d/wk); OR = odds ratio; PACE = Physician-based Assessment and Counseling for Exercise. Values in square brackets are 95% CIs (provided when available).

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References

Note: This manuscript is based on a longer systematic evidence review that was reviewed by outside experts and representatives of professional societies. A complete list of peer reviewers is available on line at www.ahrq.gov/clinic/uspstfx.htm.

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