

# Does Counseling by Clinicians Improve Physical Activity? A Summary of the Evidence

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## Epidemiology

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.<sup>1,2</sup> 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 3 or more times per week.<sup>3</sup> 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* recommendation and somewhat lower for adults who exercised moderately or vigorously at least a few times per month or once per week.<sup>4</sup>

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.<sup>5,6</sup> 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.<sup>7,8</sup> One review focused on 8 studies published between 1988 and 1998 in which primary care clinicians directly advised patients to increase physical activity.<sup>8</sup> The authors rated only 2 of these studies as good quality; in 4 studies, counseling led to small, short-term increases in self-reported activity levels. The other

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The USPSTF recommendations based on this evidence review can be found in Behavioral Counseling in Primary Care to Promote Physical Activity: Recommendations and Rationale (which precedes this chapter), available on the AHRQ Web site and through the AHRQ Publications Clearinghouse.

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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.<sup>7</sup> 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 2 previous systematic reviews<sup>7,8</sup> differed sharply: 1 included only studies of counseling by the clinician alone,<sup>8</sup> while the other included studies of interventions performed in the primary care setting even when clinicians did not interact with patients in any way.<sup>7</sup> 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.<sup>9</sup> 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.<sup>10</sup> We limited the 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 databases 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 2 randomized, controlled trials<sup>11,12</sup> that reported physical activity outcomes but did not mention counseling to increase physical activity. We excluded 1 ongoing trial that has not yet reported results for the physical activity intervention in the treatment groups.<sup>13</sup> We excluded 4 randomized, controlled trials<sup>14-17</sup> in which all components of the intervention were provided by a research staff member or exercise specialist. For example, in one study<sup>15</sup> 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 2 reviewers

summarized the quality of each study using criteria developed by the current USPSTF.<sup>18</sup> 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 very 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 separately studies that compared an intervention with usual care and those that compared 2 interventions.

## Role of the Funding Source

This review was funded by the U.S. Agency for Healthcare Research and Quality (AHRQ) 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 synthesis; however, representatives of AHRQ 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<sup>19-25</sup> and 1 non-randomized controlled trial<sup>26</sup> met the inclusion criteria (Table 1). A pilot study for 1 of the trials<sup>20</sup> was excluded.<sup>27</sup> Five other trials<sup>28-32</sup> were excluded because they received a quality rating of poor according to criteria developed by the current USPSTF (Table 2).<sup>18</sup>

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<sup>20,22,26</sup> or answered selected questions from larger validated health-assessment tools administered by telephone, in the office waiting area, or in the home.<sup>19,21,23</sup> Often, a nurse or research assistant conducted a baseline assessment and placed it on the medical chart for review during the clinician’s visit.<sup>20,22,26</sup> The clinician used the assessment information to exclude patients for whom physical activity 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<sup>20,22,24-26</sup> targeted physical activity alone, while 3<sup>19,21,23</sup> also had other behavioral targets (eg, diet change, smoking cessation). In 3 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.<sup>20,24,25</sup> Five trials did not report the amount of time that the clinician spent with patients for the intervention.<sup>19,21-23,26</sup>

Two of the trials met all USPSTF criteria and were rated as good quality (Table 1).<sup>20,25</sup> The remaining trials were rated as fair quality because treatment and control groups differed significantly in physical activity levels at baseline,<sup>22,26</sup> the

Table 1. Summary of controlled trials for physical activity

Study, authors, year	Study design	Patients	Theory	Provider education and materials	Protocol
<b>Counseling vs. usual care</b>					
Physically Active for Life, Goldstein, 1999 <sup>20</sup>	<b>RCT</b> of 24 community-based primary care practices matched by size (34 physicians), PA only.	Sedentary adults (not meeting HP) who were 50 years and older. Intervention: n=181; mean age, 65 years; baseline stages: 13% precontemplative, 31% contemplative, 56% preparation stage; 12% nonwhite. Control: n=174; mean age, 66 years; baseline stages: 17% precontemplative, 33% contemplative, 50% preparation stage; 20% nonwhite.	Transtheoretical (5 stages), social cognitive theory, health education.	Training, pretested manual, and poster for patients.	5 min. stage-based advice on benefits; assisted with self-efficacy and barriers; community resources; written PA prescription; follow-up visit at 1 mo. for adjusted prescription.
Norris, 2000 <sup>22</sup>	<b>RCT</b> of 32 primary care physicians in a staff-model HMO, stratified by clinic. PA only.	Adults over age 30 scheduled for well visits. Intervention: n=384 adults; mean age, 53; baseline stages: 2.6% precontemplative, 51.3% contemplative, 46.3% action; 11% nonwhite. Control: n=463; mean age, 57; baseline stages: 3.4% precontemplative, 46.8% contemplative, 49.8% action; 8% nonwhite.	Transtheoretical (3 stages).	1 hour training, follow-up calls with providers.	Stage-based advice on benefits; PA preferences; assisted with barriers, self-efficacy, and self-management. Gave stage-based hand-outs; agreed on written goal. Follow-up call at one month and mailed educational materials.
Smith, 2000 <sup>26</sup>	<b>Non-randomized controlled trial</b> of patients in 27 general practices in Australia. Recruited controls first. PA only.	Active and inactive adults ages 25 to 65 years old. Prescription only intervention: n=380; mean age, 43 years; median total PA, 95 minutes; prescription and booklet intervention: n=376; mean age, 43 years; median total PA, 120 minutes; control: n=386, mean age, 42 years; total PA, 145 minutes.	Transtheoretical (5 stages).	20-30 mins of training.	Advice, provided PA prescription. Stage-based booklets sent to random sample.
Kerse, 1999 <sup>21</sup>	<b>RCT</b> of 42 metropolitan general practices (42 physicians), PA, social activity.	Adults age 65 and older. Intervention: n= 135; mean age, 73 yrs; total activity, 281 minutes/week. Control: n= 132; mean age, 74 years; total activity, 328 minutes/week.	Not reported	3 hour seminar with exercise physiologist, sociologist, and geriatrician; 15 minutes follow-up detailing; prompt card.	Counseling for PA and social activity. Other counseling techniques not reported.

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Table 1. Summary of controlled trials for physical activity (cont.)

Study, authors, year	Study design	Patients	Theory	Provider education and materials	Protocol
<b>Counseling vs. usual care</b>					
Change of Heart, Steptoe, 1999 <sup>23</sup>	RCT of 20 general practices (20 nurse practitioners), minimization technique. PA, smoking, diet.	Adults 18-69 years with 1 or more CHD risk. Intervention: n=316; mean age, 48; 80% BMI >25 kg/m <sup>2</sup> plus sedentary. Control: n=667; mean age, 46; 79% BMI > 25 kg/m <sup>2</sup> plus sedentary.	Transtheoretical (5 stages).	3 day training with refresher day at 6 months.	Stage-based advice on benefits and attitudes; assisted with incentives, self monitoring, relapse prevention, barriers. Telephoned patients between counseling sessions. Mailed educational materials.
Burton, 1995 <sup>19</sup>	RCT of 4,195 Medicare patients in 119 practices. PA, immunization, smoking, drinking.	Sedentary Medicare beneficiaries. 61% age 65 to 74 years; 33% age 75 to 84 years; 6% age 85+ years. Intervention:n=2,105; Control: n=2,090.	Suggested but not directed.	Continuing medical education credits on preventive and counseling visits. Educational materials.	Feedback and advice from pre-visit risk screen, assisted with community resources. 20 minute follow-up counseling sessions as needed. Most counseling details not reported.
<b>Comparison of different interventions (no usual care)</b>					
Activity Counseling Trial, 2001 <sup>25,33,34</sup>	RCT of 874 adult patients from 11 primary care settings (51 physicians, 2 physician assistants, 1 nurse practitioner). PA only.	Inactive adults (ages 35 to 75 years) in stable health. Intervention: Advised group: n=292; avg age, 51 years; Assisted group: n=293; avg age 52 years; Counseled group: n=289; avg age 52 years.	Social cognitive theory.	Clinicians received advice training; health educators received assist and behavioral counseling training.	3 minutes of initial advice (Advised Group); initial advice and 30-40 minutes of behavioral counseling plus telephone follow-up (Assisted Group); initial advice, behavioral counseling, and biweekly telephone counseling for first 6 weeks, monthly calls thereafter, weekly class offerings (Counseled Group).
Swinburn, 1998 <sup>24</sup>	RCT of 491 patients of 37 providers in 2 New Zealand urban centers. PA only.	Sedentary adults. 50% had at least one coronary heart risk factor. Intervention: n=239; Control: 252.	Self-management (goal setting).	1 training session on assessing and prescribing physical activity.	Advice (avg. 5 minutes) and written PA prescription. Stage-based booklets sent to random sample. Control group received advice only.

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Table 1. Summary of controlled trials for physical activity (cont.)

Study, authors, year	Provider adherence	Short-term: less than 6 months	Long-term: 6 months or more	Quality comments
<b>Counseling vs. usual care</b>				
Physically Active for Life, Goldstein, 1999 <sup>20</sup>	Intervention: 99% received PA prescription, 77% received follow-up prescription. Control: 1% received PA prescription.	At 6 weeks, 28% of intervention patients met HP goal vs 21% of controls (difference of 7%; CI, -3% to 15%).	At 8 months, 28% of intervention patients met HP goal vs 23% of controls (difference of 5%; CI, -6% to 14%).	Good quality Met all criteria. Follow-up: 95% at 6 weeks, 88% at 8 months.
Norris, 2000 <sup>22</sup>	Intervention: 94% were counseled, 90% of these received PA prescription. Control: 65% were counseled, 81% of these received a PA prescription.			Fair quality Follow-up: 93% at 6 weeks, 97% at 6 months. Baseline differences in prevelous PA counseling. During the trial, control clinicians increased PA counseling rate.
Smith, 2000 <sup>26</sup>	Intervention: 62% received PA prescription. Inferred 468 of 471 sedentary patients for 99% adherence. Control: Not reported.	Among inactive patients at 6-10 weeks in the prescription plus booklet goal vs control: 31% met HP goal vs. 27% control (difference of 4%; CI, -5% to 12%); 46% increased 60 minute weekly vs. 35% control (difference of 11%; CI, 2% to 20%; P=0.02). In the prescription only vs control: 26% met HP goal vs. 27% (difference of -1%; CI, -10% to 7%); 41% increased 60 minutes weekly vs 35% control (difference of 6%; CI, -3% to 15%).	Among inactive patients at 7-8 months in the prescription plus booklet vs control: 24% met HP goal vs 17% (difference of 8%; CI, 0% to 15%; P=0.053); 36% increased 60 minute weekly vs 27% control (difference of 9%; CI, 0% to 17%; P=0.06). In the prescription only vs control: 22% met HP goal vs 17% (difference of 5%; CI, -3% to 12%); 32% increased 60 minutes weekly vs 27% control (difference of 4%; CI, -4% to 13%).	Fair quality Follow-up: 92% at 6-10 week, 83% at 7-8 months. Baseline differences in PA levels.
Kerse, 1999 <sup>21</sup>	Intervention: 32% of patients reported discussing PA with physician. Control: 21% reported discussing PA with physician.		At 1 year, intervention patients increased walking 44 min/week more than control patients (CI, 4 to 84 min/week; P=0.03).	Fair quality Follow-up: intervention, 90% at 1 year; control, 85% at 1 year. Counseling interventions not clearly defined, low provider adherence.

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Table 1. Summary of controlled trials for physical activity (cont.)

Study, authors, year	Provider adherence	Short-term: less than 6 months	Long-term: 6 months or more	Quality comments
<b>Counseling vs. usual care</b>				
Change of Heart, Steptoe, 1999 <sup>23</sup>	Not reported.	At 4 months, intervention patients had 13 (20-minute) activity sessions/4 weeks vs 9 sessions/4 weeks in controls (difference of 3.7; CI, 1.3 to 6.3 sessions/4 weeks; $P<0.05$ ).	At 1 year, intervention patients performed 14 sessions/4 weeks vs 9 sessions/4 weeks in controls (difference of 3.9; CI, 1.0 to 6.8 sessions/4 weeks; $P<0.05$ ).	Fair quality Follow-up: intervention, 65% at 4 months, 54% at 1 year; control, 74% at 4 months, 62% at 1 year.
Burton, 1995 <sup>19</sup>	Intervention: 89% of physician encounter forms contained PA discussion note. Inferred that up to 39% of patients attended follow-up counseling visit that included PA.		At 2 years, 42% of intervention patients in good health vs 42% control group patients in good health increased PA. 20% of intervention patients in poor health increased PA vs 18% of control patients in poor health (difference of 3%; CI, -4% to 9%).	Fair quality Follow-up: intervention, 75% at 2 years; control, 73% at 2 years. Counseling interventions not clearly defined.
<b>Comparison of different interventions (no usual care)</b>				
Activity Counseling Trial, 2001 <sup>26,35,34</sup>	99% received initial 3 minutes of advice; documented for 97%. Avg contact time: Advised Group: 18 minutes over 24 month study; Assisted Group: 2.7 hours; Counseled Group: 8.9 hours for women, 5.6 hours.		At 6, 12, and 24 months, no difference in total energy expenditure for male or female patients with one exception. Women in the counseled group had an average total energy expenditure of 33.3 kcal*kg-1*day-1 at 6 months vs 32.7 kcal*kg-1*day-1 for women in the assisted group (difference of 0.54 kcal*kg-1*day-1; CI, 0.07 to 1.0; adjusted $P=0.01$ ).	Good quality Follow-up: 91% at 24 months, 78% completed fitness test (Vo2 max) at 24 months Met all criteria.
Swinburn, 1998 <sup>24</sup>	Not reported.	More patients receiving advice and a written PA prescription performed any activity (51% to 86%, an increase of 35%) at 6 weeks vs patients who received only advice (56% to 77%, an increase of 21%) (difference of 14%; CI, 6% to 22%; $P=0.004$ ). No difference in the number of increased minutes spent in PA for the groups, 156 minutes per 2 weeks.		Fair quality. Follow-up: Intervention: 91% at 6 weeks; Control: 94% at 6 weeks. Intervention not well defined. Adherence not reported.

**Note:** HP indicates Healthy People 2010 recommendation (30 minutes of moderate physical activity on at least 5 days per week or 20 minutes of vigorous activity on at least 3 days per week); PA, physical activity.

counseling intervention was not clearly defined,<sup>19,21,24</sup> attrition was high.<sup>19,23</sup>

## Efficacy of Counseling

### Interventions Compared with a Usual Care Control

In 6 controlled trials that contained a usual care control group,<sup>19,23,26</sup> the effects of counseling on physical activity after 6 to 24 months were mixed (Table 1). Only 1 of the trials<sup>20</sup> met all of our criteria for a good quality rating. 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 of 5%; 95% CI, -6% to 14%).

Of the 5 fair-quality trials, 2 showed no effect of counseling on physical activity levels after 6 or more months<sup>19,22</sup> and 3 showed statistically significant increases in activity.<sup>21,23,26</sup> In the latter 3 trials, 2 randomized trials reported increases in the average number of exercise sessions<sup>23</sup> or in time spent walking<sup>21</sup> but did not report the proportion of patients who increased physical activity. The third trial, which was non-randomized, reported that an increased proportion of inactive patients added 60 minutes or more of physical activity per week.<sup>26</sup>

Among the studies we rated as fair quality, 2 had relatively serious threats to validity. One was a non-randomized trial in which a significantly greater proportion of the intervention patients (62%) were inactive at baseline compared with the usual care group (54%) ( $P < 0.05$ ).<sup>26</sup> In the other, a randomized trial in which counseling was ineffective, more control patients (55%) than intervention patients (42%) reported receiving physical activity counseling in the 6 months before the trial began ( $P = 0.02$ ).<sup>22</sup> Although the groups were otherwise similar, this inequality raises the possibility that randomization was not conducted properly.<sup>22</sup> 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,<sup>20,22,26</sup> assistance with perceived self-efficacy<sup>20</sup> and barriers,<sup>20,22</sup> mailed educational materials,<sup>22,26</sup> referral to community resources,<sup>20</sup> and written exercise prescriptions.<sup>20,22,26</sup> 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 4 studies that applied the "stages of change" (transtheoretical) model of behavior change had mixed results.<sup>20,22,23,26</sup>

Three of the trials addressed physical activity only,<sup>20,22,26</sup> while the other 3 addressed multiple behavior changes.<sup>19,21,23</sup> 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<sup>19,23</sup> or reported poor adherence to the physical activity component (39%).<sup>21</sup>

### Interventions Compared with Other Interventions

We identified 2 trials that compared the efficacy of different interventions and had no usual care group (Table 1).<sup>24,25,33,34</sup> The results of these trials suggested that a written prescription was more effective than advice alone<sup>24</sup> 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.<sup>25</sup>

In the larger, methodologically stronger study, the Activity Counseling Trial,<sup>25</sup> 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 1 of 3 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).<sup>25</sup> At 6, 12, and 24 months, men in all groups did not differ in expended energy or fitness levels.<sup>25</sup> After 6 months, women in the counseling group had



Table 2. Studies rated as poor quality\*

Study	Reasons for poor rating *	Result
Bull and Jamrozik, 1998 <sup>31</sup>	Maintenance of comparison groups in question. Nonrandomized trial design (same providers for control and intervention patients based on days of the week during 3 week recruitment) had high potential for contamination. Fair to poor rates of follow-up assessments (70% at 1 month, 57% at 6 months, 56% at 12 months).	Increased proportion of active intervention patients (40%) at 1 month compared with 31% of control patients (a difference of 9%). Increased proportion of active intervention patients (38%) at 6 months compared with 30% of control patients (a difference of 8%). No difference in the active proportion at 1 year, 36% intervention patients compared with 31% control patients (a difference of 5%).
Calfas et al, 1996 <sup>30</sup>	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. Trial lost 17% of intervention physicians and 30% of control physicians during study.	Increased proportion of intervention patients (52%) achieved PACE active stage (meets HP) at 4-6 weeks compared with 12% of control patients ( a difference of 40%; CI, 28% to 52%).
Elder et al, 1995 <sup>28</sup>	High loss to follow-up. 45% of intervention patients responded at 4 years compared with 44% of control patients. Patients who did not complete the follow-up assessment were excluded from the analysis.	Intervention patients reported increased metabolic rate (432) at 4 years compared with 388 for control patients ( $P=0.0006$ ).
Graham-Clarke and Oldenburg, 1994 <sup>29</sup>	Unclear whether randomization was adequate because a greater proportion of intervention patients were at "intended to change" stage (53% compared with 37% of control patients; a difference of 16%; CI, 13% to 19%). Achieved poor rates of follow-up assessments (44% at 4 months and 50% at 12 months). Paper didn't give sufficient results to abstract needed results relative to randomization.	Not reported based on randomization.
Kreuter et al, 2000 <sup>32</sup>	Unclear whether randomization was adequate because no baseline demographic characteristics were provided. The analysis made no mention of an intention-to-treat analysis. Used a new PA tool with no validity.	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; CI, 0.95 to 2.4).

\*These studies were rated poor using the USPSTF quality criteria.<sup>18</sup> Poor quality studies have fatal flaws rendering the studies invalid.

**Note:** CI indicates 95% confidence interval; HP, Healthy People 2010 recommendation: Moderate activity 30 min./5 times/week (or) vigorous activity 20 min./3 times/week; OR, odds ratio; PA, physical activity; PACE, Physician-based Assessment and Counseling on Exercise.

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<sup>-1</sup>\*day<sup>-1</sup> compared with 32.7 kcal\*kg<sup>-1</sup>\*day<sup>-1</sup> for women in the assistance group (difference of 0.54 kcal\*kg<sup>-1</sup>\*day<sup>-1</sup>; 95% CI, 0.07 to 1.0; adjusted *P*=0.01). 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 (Vo<sub>2</sub>max) 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 Vo<sub>2</sub>max 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.<sup>25</sup> 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/m<sup>2</sup>) and 9% smoked.<sup>34</sup>

To avoid injury, most trials excluded patients at risk or offered moderate rather than vigorous activity. Five of the 8 trials specifically stated that patients were excluded for medical reasons.<sup>20,22,23,25,26</sup> Six of the 8 trials offered a moderate activity option.<sup>20-25</sup> 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 3 trials reported that more than 90% of patients received the intended intervention.<sup>20,22,23</sup> Some of the counseling efficacy studies used additional staffing for assessments.<sup>20,21,23</sup> 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.<sup>20</sup>

The Activity Counseling Trial reported that patients who received both advice and counseling (the assistance group) spent an average of an extra 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).<sup>25</sup> Women who received advice, counseling, follow-up counseling telephone calls, and classes (the counseling group) spent 9 more hours with a clinician or educator than women who received only advice. Similarly, men in the counseling group spent an extra 5 hours with a clinician or 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<sup>7,8</sup> found that

interventions targeting physical activity were effective in the short-term. However, we found mixed, inconclusive evidence to support this finding. Two of 3 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 move between being sedentary and being active at different times in their lives.<sup>35</sup> 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.<sup>36</sup> 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 physical activity.<sup>37</sup> Clinical interventions may also be more effective if patients are referred to community programs that provide ongoing social support, such as established walking groups.<sup>38</sup>

Only 1 trial in this review reported harms.<sup>25</sup> Understanding the potential harms and revising future interventions to reduce them may improve patient adherence. We need large prospective studies that report type of intervention, including the recommended intensity of physical activity, and also report injuries in the long term (eg, more than 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 methodological limitations described earlier, we found it difficult to assess the efficacy or effectiveness of the interventions examined. Although research suggests that counseling can be effective in some specific situations, the evidence is insufficient to generally conclude that counseling is effective. Existing studies do not provide a clear picture of the specific features of counseling that relate to its effectiveness.

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