Effectiveness of Physical Activity Advice and Prescription by Physicians in Routine Primary Care

A Cluster Randomized Trial

Gonzalo Grandes, MD, MS; Alvaro Sanchez, PhD; Ricardo Ortega Sanchez-Pinilla, MD; Jesus Torcal, MD; Imanol Montoya, MS; Kepa Lizarraga, MD; Javier Serra, MD; for the PEPAF Group

Background: Physical activity promotion is a priority, but contribution of physicians' interventions is unclear. The effectiveness of the PEPAF ("Experimental Program for Physical Activity Promotion"), which was implemented exclusively by physicians in routine primary care from October 2003 to December 2004, was assessed.

Methods: Fifty-six Spanish family physicians were randomized to either the intervention (n=29) or standard care (n=27) arm of the trial. The physicians recruited 4317 physically inactive patients (2248 for intervention and 2069 for control protocols) from a systematic sample after assessing their physical activity in routine practice. Intervention physicians provided advice to all patients and a physical activity prescription to the subgroup attending an additional appointment (30%). The main outcome measure was the change in physical activity measured by blinded nurses using the 7-Day Physical Activity Recall. Secondary outcomes included cardiorespiratory fitness and health-related quality of life.

Results: At 6 months, intervention patients increased physical activity more than controls (adjusted difference, 18 min/wk [95% confidence interval, 6-31 min/wk]; metabolic equivalent tasks × hours per week, 1.3 [95% CI, 0.4-2.2]). The proportion of the population achieving minimal physical activity recommendations was 3.9% higher in the intervention group (1.2%-6.9%; number needed to treat, 26). No differences were found in secondary outcomes. The effect of intervention was positively modified in subjects older than 50 years ($P \leq .01$) and in the prescription subgroup ($P < .001$).

Conclusions: Family physicians were effective for increasing physical activity of primary care patients. Overall clinical effect was small but relevant for population public health. Within the intervention program, clinically relevant effects were seen in patients receiving a physical activity prescription.

Trial Registration: clinicaltrials.gov Identifier: NCT00131079

Arch Intern Med. 2009;169(7):694-701

HEALTH BENEFITS OF PHYSICAL activity are undisputed, but the majority of the population in developed countries is insufficiently active.[1-3] Therefore, physical activity promotion represents a public health priority, and there is a need for action at the individual, family, health care, community, and governmental levels.[2] The potential contributions by primary care physicians could be substantial because they can take advantage of the ongoing care they provide to a large sector of the population and be influential in changing patients' behaviors.[4] However, while current evidence provides strong support for communitywide interventions, it is inconclusive for physicians' interventions.[5-7]

Although some clinical trials conducted in North America and New Zealand reported positive long-term results, they included staff (allied health care professionals, health educators, and exercise specialists) in addition to family physicians to conduct physical activity assessments of patients and participate in their recruitment, counseling, prescription of physical activity, or follow-up, or they required excessive time or other resources (sports foundations) not usually available in primary care.[8-11] Moreover, 3 of the studies did not include a standard care group and did not directly address the central question of whether physician counseling increases physical activity.[8,9,11,12] Therefore, these studies have a limited generalizability, and the effect attributable to primary care physicians in routine family practice remains unclear.[7,12] The objective of this study was to assess the effectiveness of family physicians to increase physical activity in inactive patients using a new "Experimental Program for Physical Activity Promotion" (PEPAF, following the Spanish translation) implemented exclusively by family physicians in routine practice.

Author Affiliations: Primary Care Research Unit of Bizkaia, Basque Health Service–Osakidetza (BHS), Bilbao, Spain (Drs Grandes and Sanchez and Mr Montoya); Santa Barbara Primary Care Center, Castilla–La Mancha Health Service, Toledo, Spain (Dr Ortega Sanchez-Pinilla); Basauri–Ariz Primary Care Center, BHS, Basauri, Spain (Dr Torcal); and Sports Medicine Service of the Provincial Government of Bizkaia, Bilbao (Drs Lizarraga and Serra).
Group Information: The PEPAF ("Experimental Program for Physical Activity Promotion") Group members are listed at the end of this article.

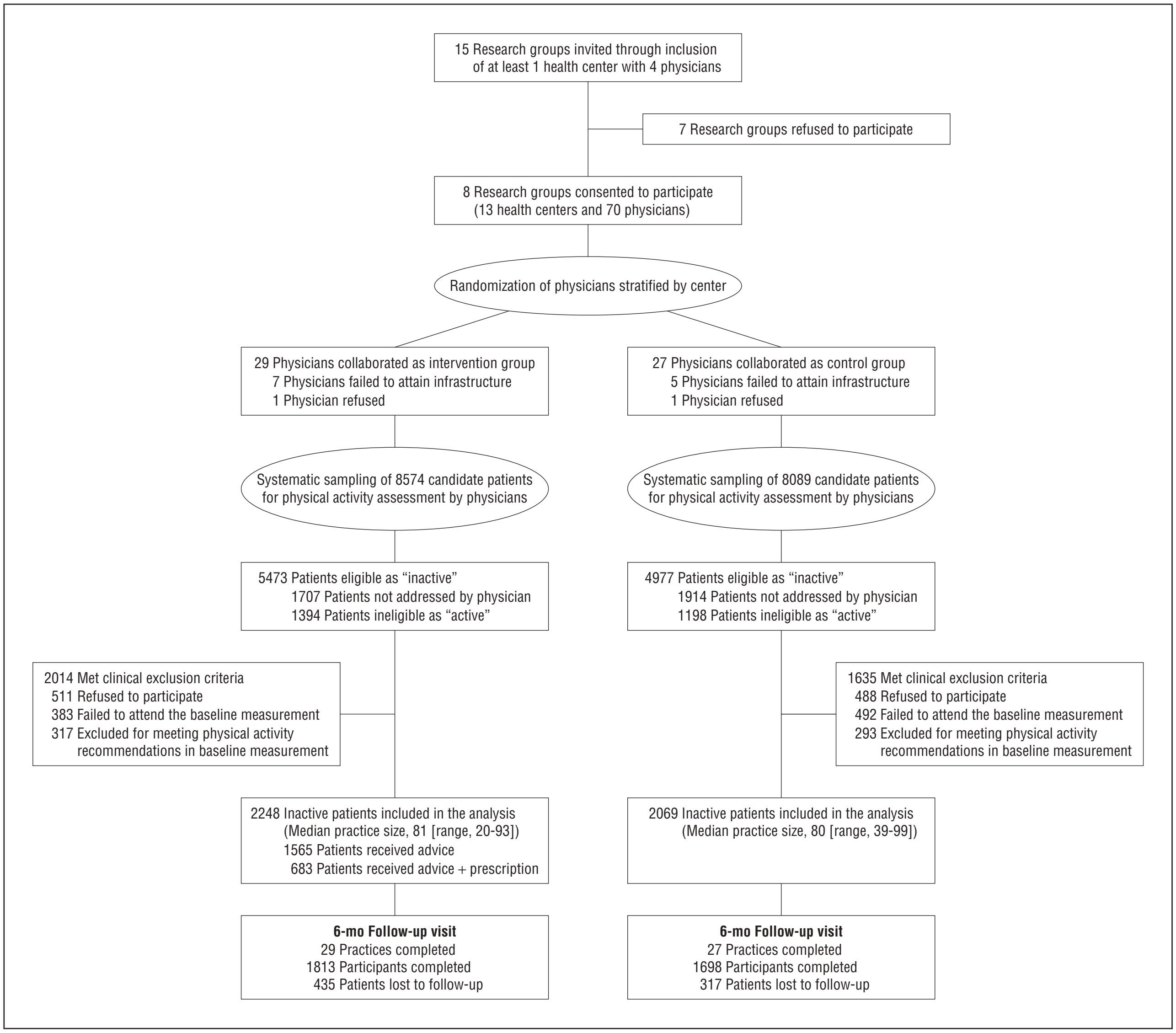

Figure 1. Study flowchart of the PEPAF ("Experimental Program for Physical Activity Promotion") trial.

METHODS

STUDY DESIGN

We conducted a pragmatic, cluster randomized controlled clinical trial in Spain from October 2003 to December 2004 at 11 public primary care centers, with family physicians as allocation units.[13] The protocol was approved by the institutional ethical research committees of all participating centers.

PARTICIPANTS

All 15 research groups of the Spanish Preventive Services and Health Promotion Primary Care Research Network were invited to participate. A collaboration of at least 4 physicians per center was required for eligibility. Seventy family physicians from 13 primary care centers belonging to 8 research groups agreed to participate. After signing a collaboration consent form, physicians were randomized to either the PEPAF or usual care (control) arm of the trial in a 1:1 ratio using computer-generated random numbers stratified by center and provided by a central site. Two centers (12 physicians) dropped out before the start of the study because of technical complaints, and 2 physicians failed to participate. Finally, 56 physicians (29 allocated to the PEPAF arm and 27 to the control arm) performed the study at 11 primary care centers (**Figure 1**).

Family physicians recruited patients aged 20 to 80 years, who did not meet the recommended aerobic physical activity levels (moderate-intensity physical activity for ≥30 minutes 5 d/wk or vigorous intensity activity for ≥20 minutes 3 d/wk).[1] To avoid recruitment bias, candidates to be assessed by their physicians were systematically sampled by research nurses from the list of patients scheduled for consultation. After dealing with the reason for consultation, physicians assessed the patients' physical activity with assistance of a computerized algorithm. Computer screen shots guided physicians to review exclusion criteria, which included unstable or chronic conditions that would preclude safe participation in regular physical activity, as well as severe emotional distress, complicated pregnancy, and follow-up difficulties. Patients signed a consent form before the baseline measurement. The study was managed online using Web-based software designed to help physicians follow the research protocol and control the recruitment process of each eligible patient. A detailed description of the recruitment process, physical activity screening algorithm and its predictive value, exclusion criteria, and patient characteristics is given elsewhere.[13,14]

Intervention process and components	Behavior change technique (theoretical model)
Advice:	
Structured physician advice to all intervention patients using Web-based software that prompted open questions to elicit patients' beliefs about physical activity benefits, graphical information about risks of inactivity, and sample sentences to provide medical advice	Provide information about behavior-health link (HBM) Provide information on consequences (HBM)
Immediately after the advice, physicians asked patients if they were ready to increase their physical activity level and offered an additional 15-min consultation to develop an individualized physical activity plan	Prompt intention identification (HBM and SCT) Prompt intention formation (HBM and SCT)
A 4-page pamphlet summarizing the aforementioned information on benefits, risks, motivation, and help offered by a general practitioner	Printed information about behavior-health link, consequences, and providing general encouragement (HBM, SCT)
Prescription in addition to advice:	
15-min Educational session in which physicians accomplished the following:	
• Reinforced patients' reasons and intention to change	Provide general encouragement (HBM and SCT)
• Negotiated a goal for patient's physical activity change	Agree on behavioral goals (SCT)
• Addressed potential barriers and anticipated solutions for change using Web-based tools for lack of time (review of patients' timetable and identification of free time), community resources (database with community resources' contact information), and health problems (evidence-based information for physical activity benefits related to a variety of health problems)	Prompt barrier and solution identification (SCT) using the following: Time management Community resource information Information adapted to health problem
• Cooperatively designed a 3-mo physical plan	Prompt specific goal setting (SCT)
• Standardized a printed prescription of the frequency, duration, intensity, and a progression of a selected activity or exercise, including the keeping of a self-monitoring log	Printed prescription (SCT) Prompt self-monitoring of behavior (SCT)
• Provided a folder containing a brief guide for increasing physical activity in which the printed prescription was attached	Provide printed instruction (SCT)

Figure 2. Intervention process and components and behavior change techniques in the PEPAF ("Experimental Program for Physical Activity Promotion") trial. HBM indicates Health Belief Model[15]; SCT, Social Cognitive Theory.[16]

INTERVENTION AND CONTROL PROTOCOLS

Physicians allocated to the PEPAF arm provided brief advice and educational materials to all patients and offered an additional 15-minute appointment to prescribe an individualized physical activity plan. Patients attending and not attending this appointment formed the prescription and advice subgroups, respectively (**Figure 2**). Physicians received 24-hour training on the study protocol, counseling, and prescription of physical activity. The quality of the intervention was ensured by the Web-based software, which assisted and obliged physicians to advance through the standardized steps of the intervention and recorded the process followed with each patient.

Control group physicians delivered standard care and delayed any new systematic intervention related to physical activity until the end of the study, unless the reason for consultation or the patients' health problems were directly related to inactivity. They received training similar to that of the intervention group physicians on research procedures and on the use of the Web-based software to assess patients' physical activity and to perform recruitment.

MEASUREMENTS AND FOLLOW-UP

The primary outcome measure was the change in physical activity from baseline to 6 months, using the 7-Day Physical Activity Recall (PAR) semistructured interview,[17] whose validity is well accredited, including among Hispanic populations.[18] In the PAR, minutes in the week prior to the interview pertaining to leisure and occupational moderate or vigorous activity and the proportion of participants who achieve the minimum recommended physical activity levels are directly calculated. Weekly activity dose in metabolic equivalent tasks (METs) $\times$ hours per week (MET-h/wk) is estimated by multiplying the hours devoted to activities of moderate, hard, and very hard intensity by 4, 6, and 10 METs, respectively. The PAR findings were the reference standard used to exclude patients identified as inactive by the physician but who actually met the minimum physical activity recommendations at baseline.

Secondary outcome measures were maximum oxygen uptake ($\dot{V}O_{2max}$), estimated by the YMCA cycle ergometer submaximal exercise test,[19] and health-related quality of life using the 36-Item Short Form Health Survey (SF-36) questionnaire (version 1).[20] Age, sex, and baseline motivational stage of change, as assessed by a self-administered questionnaire,[21] were considered as predictor variables. Potential confounders included social class and education[22]; alcohol risky drinker using the Alcohol Use Disorders Identification Test (AUDIT) questionnaire ($\geq$8 points)[23]; self-reported smoking status; and risk factors taken from clinical records.

Research nurses blinded to the allocation group of participants and working in exercise laboratories performed measurements at baseline after patient recruitment by the physician and at the 6-month follow-up visit. Measurement quality was assured by 3 days of training in the research protocol (8 h/d), questionnaire administration, exercise test, and online double-data entry into a central database. A pilot study was conducted at each center, followed by a 1-day review training. A telephone recall system was used to improve patient follow-up rates. Quality control was performed by the coordinating center (Primary Care Research Unit of Bizkaia), with daily online supervision and feedback on study process and data entry, monthly progress reports, and meetings with the collaborating investigators and research nurses every 4 months.

STATISTICAL ANALYSIS

Differences between the PEPAF and control groups in changes in outcome variables over 6 months were analyzed on an intention-to-treat basis. In the event of missing data, baseline values were carried forward. The Mann-Whitney Wilcoxon rank sum test was used for continuous variables owing to the known skewed nature of outcome data,[6] and the χ^2 test was used for categorical variables. Multilevel analysis, ie, generalized mixed-effects models, were used to estimate baseline and multivariate-adjusted between-group differences, adjusted odds ratios (AORs), and 95% confidence intervals (CIs) at the patient level, taking into account the hierarchical and multicenter structure of data, with patients clustered by physician and physicians nested in centers. These models were linear for changes in physical activity, $\dot{V}O_{2max}$, and quality of life (SAS PROC MIXED version 9.1, 2003; SAS Institute Inc, Cary, North Carolina); and logistic for achievement of the minimum-recommended physical activity levels and readiness to change (SAS PROC

GLIMMIX). Treatment group, baseline values, known determinants of physical activity, and physician characteristics were considered as fixed effects. Centers and physicians were included as random effects on the intercept and on treatment effect. Likelihood ratio tests (significance criterion, $P < .05$) were used to simplify the models following a backward strategy. Sensitivity analyses were repeated excluding potential outliers, ie, those beyond 2 standard deviations.

A predefined subgroup analysis was performed to test the hypothesis that the program was more successful in more motivated people, older people, or male participants, testing interaction terms between these covariates and the intervention arm (significance criteria, $P \leq .01$). To describe the effect of prescription in addition to advice, a predefined per-protocol analysis was performed by testing an "intervention group by prescription" interaction effect. Empirical Bayesian estimators were calculated for each center, followed by a sensitivity analysis to evaluate changes after excluding centers whose populations or effects attributable to the PEPAF program significantly differed from the overall average.

Statistical power based on mixed-effects models adjusted to the final sample size, actual data variability, and clustering was greater than 95% to detect statistically significant differences between the intervention and control groups of 1.75 MET-h/wk in physical activity change, 0.63 mL/kg/min in $\dot{V}O_{2max}$, and at least 3.5 points in SF-36 health-related quality of life scores.

RESULTS

PARTICIPANTS

Among the 16 663 sampled patients, 3621 were not assessed by their primary care physician because of nonattendance, severity, technical difficulties, or lack of time, and 2592 were identified as active. Among the remaining patients, 5473 in the intervention group and 4977 in the control group were identified as inactive by their physicians, therefore meeting eligibility criteria. In the intervention and control groups, 2014 and 1635 eligible patients, respectively, had some exclusion criterion; 511 and 488, respectively, refused to participate; and 383 and 492, respectively, failed to attend the baseline measurement. From the 4927 patients who completed the baseline measurement, 317 intervention patients and 293 control patients were excluded because they met the minimum recommended levels of physical activity, as confirmed in the PAR interview. Finally, 2248 intervention patients and 2069 controls were included in the analyses (Figure 1). At baseline, both groups had similar values of outcome variables: 34 min/wk devoted on average to moderate or vigorous physical activity, a mean weekly activity dose of 2.4 MET-h/wk, and 24.5 mL/kg/min of $\dot{V}O_{2max}$ (correlation with activity dose, $r = 0.11$; $P < .001$). Quality of life, clinical, and sociodemographic variables were also equally balanced between the groups. Because a greater proportion of patients in the PEPAF group reported to be in the "preparation" stage of change, subsequent analyses were adjusted for baseline stage of change (**Table 1**).

INTENTION-TO-TREAT COMPARISONS

The 6-month follow-up visit was completed by 81% of patients. Patients lost to follow-up did not differ between the groups, except by age and social class ($P = .02$ for both).

Table 1. Baseline Characteristics of the 4317 Primary Care Patients Not Meeting the Minimum Recommended Physical Activity Levels Included in the PEPAF Trial[a]

	PEPAF Group (n=2248)	Control Group (n=2069)
Primary outcome measures		
Moderate and vigorous activity, min/wk	34.4 (90.9)	33.2 (79.5)
Moderate and vigorous activity, MET-h/wk	2.37 (5.96)	2.36 (5.94)
Secondary outcome measures		
$\dot{V}O_{2max}$, mL/kg/min[b]	24.37 (8.10)	24.66 (8.41)
Health-related quality of life, score (range, 0-100)[c]		
Physical functioning	85.80 (14.38)	85.14 (15.88)
Role physical	69.38 (42.85)	68.58 (43.37)
Bodily pain	62.31 (27.07)	62.15 (26.98)
General health	64.56 (19.45)	63.92 (19.86)
Vitality	58.32 (21.20)	59.84 (21.28)
Social functioning	85.01 (22.51)	85.75 (21.85)
Role emotional	75.69 (40.07)	77.32 (39.32)
Mental health	65.48 (19.41)	66.29 (19.62)
Sociodemographic variables		
Age, y	49.47 (14.88)	50.65 (15.10)
Female, No. (%)	1505 (66.9)	1328 (64.2)
Work situation, No. (%)		
Works outside of home	1153 (51.3)	1031 (49.8)
Homemaker	546 (24.3)	491 (23.7)
Retired	313 (13.9)	358 (17.3)
Student	58 (2.6)	35 (1.7)
Unemployed	115 (5.1)	97 (4.7)
Other	63 (2.8)	57 (2.8)
Educational level, No. (%)		
None	100 (4.5)	164 (7.9)
Elementary school	670 (29.8)	625 (30.2)
Middle or high school	1077 (47.9)	955 (46.2)
University studies	401 (17.8)	325 (15.7)
Social class, No. (%)[d]		
Manager large enterprise	154 (6.9)	143 (6.9)
Manager small enterprise	264 (11.7)	203 (9.8)
Intermediate employee	662 (29.5)	622 (30.1)
Manual worker	1167 (51.9)	1100 (53.2)
Risk factors, No. (%)		
Diabetes	167 (7.7)	188 (9.3)
Hypertension	524 (24.1)	528 (26.3)
Dyslipidemia	411 (18.9)	463 (23.0)
BMI, No. (%)	27.33 (4.74)	27.34 (4.85)
Normal, BMI <25	734 (32.6)	684 (33.1)
Overweight, BMI 25-29	933 (41.5)	846 (40.9)
Obese, BMI ≥30	581 (25.8)	537 (26.0)
Smoking, No. (%)		
Current smoker	703 (31.3)	609 (29.4)
Former smoker	423 (18.8)	390 (18.9)
Nonsmoker	1122 (49.9)	1070 (51.7)
At-risk drinker, No. (%)	116 (5.3)	102 (5.0)
Physical activity stage of change, No. (%)		
Precontemplation	480 (21.3)	749 (36.2)
Contemplation	746 (33.2)	696 (33.6)
Preparation	730 (32.5)	380 (18.4)
Action	105 (4.7)	65 (3.1)
Maintenance	187 (8.3)	179 (8.7)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); MET-h/wk, metabolic equivalent tasks × hours per week; PEPAF, "Experimental Program for Physical Activity Promotion"; $\dot{V}O_{2max}$, maximum oxygen uptake.

[a] Values are given as means (standard deviations) unless otherwise stated.

[b] Variables derived from the cycle ergometer test at baseline (n=3603).

[c] Sample sizes for baseline Medical Outcomes 36-Item Short Form Health Survey scales: physical functioning (n=4308); role physical (n=4300); bodily pain (n=4315); general health (n=4304); vitality (n=4308); social functioning (n=4313); role emotional (n=4300); mental health (n=4306).

[d] Social class classification based on occupation and work position[24]: class IV to V includes nonqualified and qualified manual workers; class III includes the administrative workforce, supervisors, and freelance workers; class II includes managers of enterprises with less than 10 employees, professionals with first-level university degree, senior technicians, artists, and sportsmen/women; and class I includes managers of public organizations or private enterprises with more than 10 employees, professionals with second- and third-level university degrees.

Table 2. Change in Primary and Secondary Outcome Measures From Baseline to the 6-Month Follow-up: Intention-to-Treat Analysis

			Baseline Adjusted Change (95% CI)		
Outcome Measure	IPC	ICC	PEPAF Group (n=2248)	Control Group (n=2069)	Multivariate-Adjusted Attributable Difference[a] (95% CI)
Primary outcome measures					
Moderate and vigorous activity, min/wk	0.035	0.031	82.58 (59.94 to 105.23)	65.14 (42.40 to 87.88)	18.15 (5.66 to 30.65)
Moderate and vigorous activity, MET-h/wk	0.038	0.033	5.70 (4.07 to 7.32)	4.42 (2.78 to 6.05)	1.27 (0.38 to 2.16)
Proportion meeting physical activity recommendations at 6 mo, %	0.036	0.032	18.8 (13.8 to 25.0)	15.0 (10.8 to 20.3)	3.9 (1.2 to 6.9)
Secondary outcome measures					
$\dot{V}O_{2max}$, mL/kg/min[b]	0.011	0.007	1.18 (0.84 to 1.52)	1.09 (0.74 to 1.43)	0.11 (−0.20 to 0.43)
Health-related quality of life (SF-36)[c]					
Physical functioning	0.018	0.014	0.70 (−0.35 to 1.75)	0.42 (−0.63 to 1.48)	0.12 (−0.42 to 0.65)
Role physical	0.010	0.010	7.25 (4.06 to 10.44)	7.16 (3.95 to 10.37)	0.43 (−1.35 to 2.20)
Bodily pain	0.035	0.031	4.25 (2.57 to 5.92)	4.34 (2.65 to 6.03)	0.07 (−1.19 to 1.23)
General health	0.016	0.016	2.18 (0.75 to 3.62)	2.05 (0.61 to 3.49)	−0.06 (−0.86 to 0.74)
Vitality	0.014	0.014	1.47 (−0.25 to 3.19)	1.21 (−0.51 to 2.94)	0.12 (−0.84 to 1.08)
Social functioning	0.034	0.034	3.26 (1.17 to 5.35)	3.00 (0.90 to 5.10)	0.17 (−0.77 to 1.11)
Role emotional	0.005	0.005	2.60 (−1.09 to 6.30)	1.19 (−2.51 to 4.90)	1.92 (−0.08 to 3.93)
Mental health	0.010	0.010	1.46 (0.10 to 2.89)	1.41 (−0.02 to 2.85)	−0.02 (−0.80 to 0.76)

Abbreviations: CI, confidence interval; ICC, intracenter correlation; IPC, intraphysician correlation; PEPAF, "Experimental Program for Physical Activity Promotion"; SF-36, Medical Outcomes 36-Item Short Form Health Survey; $\dot{V}O_{2max}$, maximum oxygen uptake.

[a] Adjusted for baseline measurement; age; sex; stage of change; social class; work situation; smoking; body mass index; and physicians' sex, age, and previous training in healthy lifestyles promotion.

[b] Sample size for $\dot{V}O_{2max}$, n=3603.

[c] Scores in health-related quality of life scales coded as 0 to 100: physical functioning (n=4308); role physical (n=4300); bodily pain (n=4315); general health (n=4304); vitality (n=4308); social functioning (n=4313); role emotional (n=4300); mental health (n=4306).

All 4317 participants were analyzed, with baseline observations of patients lost to follow-up carried forward and adjusting for these variables. Between-group changes in physical activity significantly favored the PEPAF group (Mann-Whitney Wilcoxon rank sum test, $P<.001$; χ^2 test, $P=.001$). Compared with controls, the PEPAF group showed adjusted differences of 18 minutes of physical activity per week (95% CI, 6-31 minutes) and 1.3 MET-h/wk (95% CI, 0.4-2.2 MET-h/wk), as well as a 3.9% (95% CI, 1.2%-6.9%) higher proportion of patients achieving the minimum recommended physical activity level (AOR, 1.3; 95% CI, 1.1-1.6) (**Table 2**). Sensitivity analyses excluding outliers did not influence these effects, and analyses not imputing missing data yielded similar but slightly higher differences: 24 min/wk (95% CI, 9-39 min/wk), 1.7 MET-h/wk (95% CI, 0.6-2.7 MET-h/wk), and 4.4% (95% CI, 1.6%-7.5%) meeting physical activity recommendations.

Both groups showed a similar dose-response relationship between physical activity change and $\dot{V}O_{2max}$ improvement ($r=0.06$; $P<.001$), but no significant differences were seen between the groups in $\dot{V}O_{2max}$ ($P=.45$) (Table 1). No significant differences were found either in health-related quality of life ($P>.05$) (Table 1). Irrespective of the baseline stage of change, the proportion of patients in the preparation, action, or maintenance stages of change at 6 months was 10.8% (95% CI, 5.9%-15.5%) higher in the PEPAF group (AOR, 1.5 [95% CI, 1.3-1.9]).

SUBGROUP ANALYSES

As shown in **Figure 3**, the effect of the program on physical activity was modified by age (intervention group by age, P value for interaction, $\leq .01$). In the subgroup 50 years and older, patients exposed to the PEPAF program devoted 34.5 more minutes (95% CI, 18.4-50.6 minutes) per week to moderate or vigorous physical activity, with an adjusted difference of 2.2 MET-h/wk (95% CI, 1.1-3.3 MET-h/wk) in the improvement of weekly activity dose and were 7.3% (adjusted difference [95% CI, 3.4%-11.7%]) more successful at achieving physical activity recommendations (AOR, 1.6 [95% CI, 1.3-2.0]). By contrast, no significant effect of the PEPAF program was shown in patients younger than 50 years. Age-stratified subgroups were matched in all baseline characteristics, except for the aforementioned higher proportion of prepared patients in the PEPAF group for which analyses are adjusted.

In addition, within the PEPAF program effects were significantly higher in the 30% of patients receiving advice plus prescription (PEPAF by prescription subgroup, P value for interaction, $<.001$). Older patients who received a physical activity prescription increased their activity by 131 min/wk (95% CI, 105-157 min/wk) and 8.9 MET-h/wk (95% CI, 7.1-10.8 MET-h/wk), and, compared with control patients, they doubled the minutes per week devoted to moderate or vigorous physical activity (adjusted difference, 67 min/wk [95% CI, 47-87 min/wk]) and the weekly activity dose (adjusted difference, 4.4 MET-h/wk [95% CI, 3.1-5.8 MET-h/wk]) and showed an 11.0% (95% CI, 5.4%-17.4%) difference in the probability of meeting the recommended physical activity levels (AOR, 2.0 [95% CI, 1.4-2.7]). Patients younger than 50 years who were given a physical activity prescription also significantly overcame their control counterparts (adjusted differences of 31.50 min/wk [95% CI, 11.23-51.77 min/wk] and 2.45 MET-h/wk [95% CI, 1.05-3.85 MET-h/wk]), with an adjusted difference of 7.0% (95% CI, 2.2%-12.8%) in the probability of meeting recommendations (AOR, 1.7 [95% CI, 1.2-2.3]). However, the advice subgroup only showed a small

	No.	Baseline-adjusted change: PEPAF	Baseline-adjusted change: Control	Multivariate-adjusted differences (95% confidence interval) between groups and subgroups
Moderate and vigorous activity, min/wk				
Overall	4317	82.6	65.1	18.1
Age <50 y	2050	64.4	63.4	0.0
Advise	771	51.0		−12.9
Prescription	339	94.4		31.5
Age ≥50 y	2267	100.8	67.1	34.5
Advise	794	87.7		22.5
Prescription	344	131.1		67.0
Moderate and vigorous activity, MET-h/wk				
Overall	4317	5.70	4.42	1.3
Age <50 y	2050	4.62	4.21	0.3
Advise	771	3.66		−0.7
Prescription	339	6.75		2.4
Age ≥50 y	2267	6.78	4.62	2.2
Advise	794	5.85		1.3
Prescription	344	8.94		4.4
Proportion meeting physical activity recommendations, %				
Overall	4317	18.8	15.0	3.9
Age <50 y	2050	14.2	13.3	0.5
Advise	771	11.1		−2.4
Prescription	339	21.0		7.0
Age ≥50 y	2267	23.6	16.3	7.3
Advise	794	22.1		5.8
Prescription	344	27.1		11.0

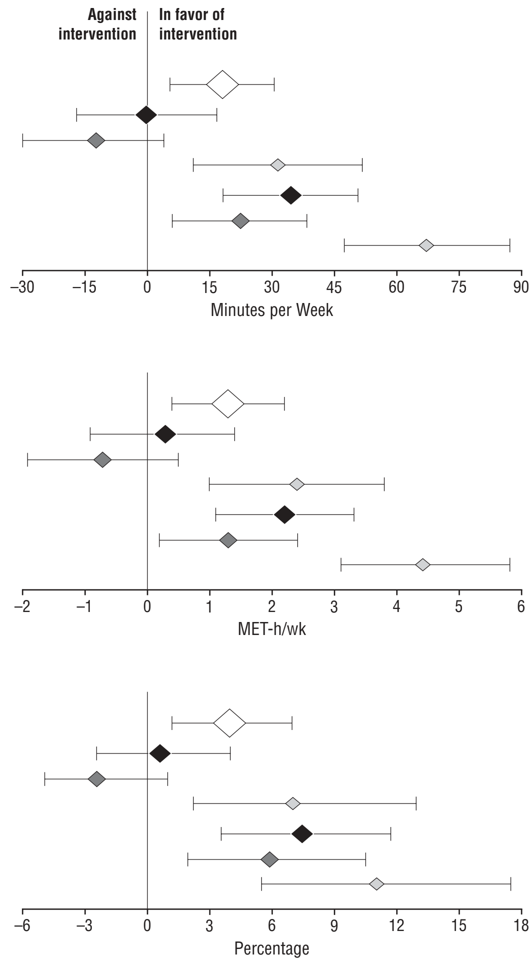

Figure 3. Change in physical activity from baseline to the 6-month follow-up examination: intention-to-treat, subgroup, and "as-treated" analyses. Intervention group by age subgroup, *P* value for interaction, ≤.01; PEPAF ("Experimental Program for Physical Activity Promotion") group by prescription subgroup, *P* value for interaction, <.001. MET-h/wk indicates metabolic equivalent tasks × hours per week.

effect in the older patients' strata and no significant effect among participants younger than 50 years (Figure 3).

Contrary to what was hypothesized, the effects attributable to the PEPAF program and differences associated with physical activity prescription were independent from patients' baseline stage of change and sex. While there was a significant variability in changes in physical activity between the populations from the different collaborating centers ($P<.001$), the within-center effect attributable to the intervention did not vary across centers ($P=.75$). The sensitivity analyses excluding population from centers that significantly differed from the average showed no relevant changes in either the magnitude or the direction of the observed effects.

COMMENT

The PEPAF program implemented by family physicians in routine primary care significantly increased physical activity in patients. While the quantitative effect of the program may be considered of little clinical relevance at an individual level, to our knowledge this is the first randomized clinical trial in primary care to show a significant effect on the proportion of the population achieving the recommended physical activity levels.[6] Such proportion is within the range reported for other lifestyle interventions, such as counseling for smoking cessation or alcohol abstinence,[25,26] considered relevant for the public health.

In addition, a clinically relevant effect was associated with physical activity prescription by physicians. Recent studies have reported decreases in cardiovascular risk associated with as little as 45 to 60 minutes of walking per week or 2.6 to 3.9 MET-h/wk,[1] figures similar to the effect associated with physical activity prescription in our study. Such prescription can be considered an efficient intervention, since only 9 subjects older than 50 years or 13 younger subjects need to be treated for one of them to meet the minimal recommendations. Although these results are consistent with previous randomized clinical trials,[10,11] inferences based on these subgroup analyses require assumptions similar to those in observational studies. For this reason, analyses were adjusted for potential confounding covariates but require confirmation in future clinical trials. These findings are useful for illustrating applicability of the PEPAF intervention strategy across patient subgroups and show what physicians might expect when patients accept their offer of a prescription of a physical activity plan.

Although intragroup increases in physical activity were associated with improvements in cardiorespiratory fitness similar to those reported in other clinical trials,[8,9] they did not translate into between-group differences, probably because most patients who increased physical activity carried out activities of moderate intensity, such as walking or dancing, with a small impact on physical fitness. Nevertheless, it should be taken into account that physical activity per se has an influence on health that is not mediated by an increase in fitness or by an improvement in the risk factor profile.[27] No effect on quality of life was seen, which is consistent with results in previous studies.[28] Adverse effects were not considered because there is no evidence that physical activity interventions will cause harm.[6]

Self-reported measurement of physical activity may be associated with recall and social desirability bias. Although nowadays objective measurement is desirable in clinical trials,[29] structured self-reported measurements are an accepted method in population-based and clinical studies, and this has been the method used in epidemiological studies linking physical activity and health.[1,30] Use of accelerometers was not feasible when our study was designed because they were expensive and time consuming owing to the large number of participants. Nevertheless, the PAR has shown a high correlation with accelerometers,[24,31] and because intervention and control subjects performed the same interview with blinded nurses, measurement error is expected to be nondifferential.

Randomization of physicians before patient recruitment prevented concealment of the patient enrolment process. To minimize a potential recruitment bias, patients to be assessed for inclusion in the study were randomly selected. Even then, a higher proportion of "prepared" patients was observed in the PEPAF group, and baseline stage of change was subsequently considered as a confounder and all analyses were adjusted for it. Since this was the only unbalanced variable at baseline, the proportions of people in action and maintenance were similar, and physician counseling has shown an immediate effect on patients' readiness to change,[32,33] another explanation could be the effect of medical advice received by this group immediately before the baseline measurement, causing a transfer of "precontemplators" toward the self-reported "preparation" stage of change.

As in other reported trials, significant increases in physical activity were shown in both the intervention and control groups.[6] This might be owing to the effect of physical activity assessment and performance of research procedures by physicians; the seasonal effect resulting from baseline measurements in winter and follow-up measurements during spring and summer; and especially, the effect of repeated measurement of physical activity and fitness.[34,35] There is also a possibility of contamination of control physicians. Although randomization by center would have been more effective to avoid such contamination, randomization of physicians stratified within centers was decided because it was important to control heterogeneity from center to center, and because there was some intracenter correlation, within-center randomization also increased the statistical power of the study.

The present study, to our knowledge the largest one to evaluate the effectiveness of physical activity advice and prescription by primary care physicians, recruited a large sample of randomly selected inactive patients not especially motivated to change. Patient characteristics are representative of the common sociodemographic and clinical characteristics seen in primary care.[14] The study was performed in the "real world," and program intensity was high, forcing family physicians to work hard to address and recruit a large number of inactive patients, which markedly increased physicians' workload. A significant variability between physical activity changes seen in the populations from the different centers, along with homogeneity of the intervention effect across centers and their null influence in the sensitivity analysis, supports the generalizability of the results to other similar public primary care centers and populations.

In conclusion, family physicians may enable inactive patients to increase their physical activity levels, producing significant results at population level and clinically relevant results when physical activity is prescribed. This supports the prescription of a physical activity plan specifying the frequency, intensity, duration, and progression over time instead of minimal advice, which yields poor results but is predominant in primary care.[36] Although prescriptions are rarely given by primary care physicians because they require more time, support, and training than minimal advice, primary care physicians may play a much greater role by devoting more time to patients who are prepared to address the objectives of a physical activity plan. Further efforts for dissemination of effective prescription tools and a call to action for primary care practitioners to use them are needed.[36]

Accepted for Publication: November 15, 2008.
Correspondence: Gonzalo Grandes, MD, MS; Basque Health Service–Osakidetza, Primary Care Research Unit of Bizkaia, Luis Power, 18-4ª Planta, Bilbao E-48014, Spain (gonzalo.grandes@osakidetza.net).
Author Contributions: Dr Grandes is the guarantor of the study and had full access to all study data and takes responsibility for data integrity and accuracy of the data analysis. *Study concept and design:* Grandes, Sanchez, Ortega Sanchez-Pinilla, Torcal, Lizarraga, and Serra. *Acquisition of data:* Grandes, Sanchez, and Montoya. *Analysis and interpretation of data:* Grandes, Sanchez, Ortega Sanchez-Pinilla, Torcal, and Montoya. *Drafting of the manuscript:* Grandes, Sanchez, and Ortega Sanchez-Pinilla. *Critical revision of the manuscript for important intellectual content:* Grandes, Sanchez, Ortega Sanchez-Pinilla, Torcal, Lizarraga, and Serra. *Statistical analysis:* Grandes, Sanchez, and Montoya. *Obtained funding:* Grandes and Sanchez. *Administrative, technical, and material support:* Grandes, Sanchez, Ortega Sanchez-Pinilla, Torcal, Lizarraga, and Serra. *Study supervision:* Grandes, Sanchez, Ortega Sanchez-Pinilla, Torcal, Lizarraga, and Serra.
PEPAF Group Members: *Director Team: Primary Care Research Unit of Bizkaia, Basque Health Service–Osakidetza*

(principal investigator: Gonzalo Grandes; coinvestigators: Jesús Torcal, Ricardo Ortega Sánchez-Pinilla, Alvaro Sánchez, Kepa Lizarraga, Javier Serra, and Imanol Montoya). *Basque Health Service–Osakidetza:* Basauri–Aríz Health Center (Angel Fernández, Victor Manuel López, Lourdes Marijuán, Begoña Etxeguren, Victor Landa, Jesús Martínez, María Mercedes Díez, Juan Ramón Lejarza, and Judith González), Galdakao Health Center (Vidal Salcedo, Idoia Ibáñez, Agurtzane Ortego, Pedro Iraguen, Pilar Echevarria, and Virginia Villaverde), Algorta Health Center (Amaia Ecenarro, María Teresa Uribe, Carmen Moral, Eguskiñe Iturregui, and Ana Belén Fernández). *Andalucia Health Service:* Camas Health Center–Seville (José María Páez, María Ángeles Tarilonte, Concepción Molina, Vicente Rodríguez, Isabel Villafuente, and Mercedes Álvarez). *Balearic Islands Health Service:* Dalt Sant Joan Health Center–Mahón (Andreu Estela, Jose María Coll, Angels Llach, Josep María Masuet, Ana Moll, and Monica Pons). *Catalonian Health Service:* Serraparera Health Center–Barcelona (Bonaventura Bolibar, Agusti Guiu, Amadeu Díaz, Xavier Martínez, María Dolores Hernández, José Ignacio Olivares, Francisco Hernansanz, Rita Ayala, and Ana Cascos). *Castilla–la Mancha Health Service:* San Fernando Cuenca III Health Center–Cuenca (Vicente Martínez, María del Carmen García, María Ángeles Gabriel, María Luscinda Velázquez, Natividad Ortega, María Jesús Segura, Rodrigo Cerrillo, and Patricia López). *Castilla y León Health Service:* Casa Barco Health Center–Valladolid (Carmen Fernández, Amparo Gómez, Miguel Angel Díez, Ruperto Sánz, Luis Miguel Quintero, and Jose Ignacio Recio), La Alamedilla Health Center–Salamanca (Luis García, José Antonio Iglesias, Manuel Gómez, Emilio Ramos, Pilar Moreno, Yolanda Castaño, and Nadia Carrillo). *Galicia Health Service:* Sardoma Health Center–Vigo (Pilar Gayoso, Luciano Casariego, Manuel Domínguez, Jose Ramón Moliner, Fernando Lago, María Concepción Cruces, and Marisa Enríquez). *Madrid Health Service:* Guayaba Health Center–Madrid (Tomás Gómez Gascón, Javier Martínez, José Antonio Granados, María Ángeles Fernández, María Isabel Gutiérrez, Carlos San Andrés, Concepción Vargas-Machuca, and Cristina Díaz).
Financial Disclosure: None reported.
Funding/Support: This project was supported by The Carlos III Institute of Health of the Ministry of Health of Spain, and cofinanced by funds from the European Fund For Regional Development (FEDER) of the European Union (FIS PI02/0015, RETICS G03/170 and RD06/0018/0018).
Role of the Sponsors: The authors are totally independent of the sponsors and have full responsibility for the study conduct and the publication.
Additional Contributions: We thank all patients who participated in this study. James F. Sallis, PhD, San Diego State University, assisted with measurement issues, and Mina T. Levenson, PhD, helped in manuscript translation.

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