Effects of Physical Activity Counseling in Primary Care

The Activity Counseling Trial: A Randomized Controlled Trial

The Writing Group for the Activity Counseling Trial Research Group

Context Physical activity is important for health, yet few studies have examined the effectiveness of physical activity patient counseling in primary care.

Objective To compare the effects of 2 physical activity counseling interventions with current recommended care and with each other in a primary care setting.

Design The Activity Counseling Trial, a randomized controlled trial with recruitment in 1995-1997, with 24 months of follow-up.

Setting Eleven primary care facilities affiliated with 3 US clinical research centers.

Participants Volunteer sample of 395 female and 479 male inactive primary care patients aged 35 to 75 years without clinical cardiovascular disease.

Interventions Participants were randomly assigned to 1 of 3 groups: advice (n=292), which included physician advice and written educational materials (recommended care); assistance (n=293), which included all the components received by the advice group plus interactive mail and behavioral counseling at physician visits; or counseling (n=289), which included the assistance and advice group components plus regular telephone counseling and behavioral classes.

Main Outcome Measures Cardiorespiratory fitness, measured by maximal oxygen uptake ($\dot{V}O_2$max), and self-reported total physical activity, measured by a 7-day Physical Activity Recall, compared among the 3 groups and analyzed separately for men and women at 24 months.

Results At 24 months, 91.4% of the sample had completed physical activity and 77.6% had completed cardiorespiratory fitness measurements. For women at 24 months, $\dot{V}O_2$max was significantly higher in the assistance group than in the advice group (mean difference, 80.7 mL/min; 99.2% confidence interval [CI], 8.1-153.2 mL/min) and in the counseling group than in the advice group (mean difference, 73.9 mL/min; 99.2% CI, 0.9-147.0 mL/min), with no difference between the counseling and assistance groups and no significant differences in reported total physical activity. For men, there were no significant between-group differences in cardiorespiratory fitness or total physical activity.

Conclusions Two patient counseling interventions differing in type and number of contacts were equally effective in women in improving cardiorespiratory fitness over 2 years compared with recommended care. In men, neither of the 2 counseling interventions was more effective than recommended care.

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PHYSICAL ACTIVITY IS IMPORTANT for health,[1] and many national organizations recommend that physicians and other health care practitioners counsel patients on physical activity.[2-8] The US adult averages about 3 medical office visits annually,[9] and patients report that they want information about physical activity from physicians.[10] Health care practitioners do not routinely counsel patients about physical activity,[11] although they are more likely to counsel patients at high risk for or with a known disease.[12-17] Studies of physical activity interventions in primary care have been short term or have lacked control groups,[18-20] and effectiveness of patient education and counseling in primary care on physical activity and fitness has been inadequately tested.

The Activity Counseling Trial (ACT) was sponsored by the National Heart, Lung, and Blood Institute to test patient education and counseling approaches for physical activity in the primary care setting.[21-23] The objective was to determine the effects of 2 patient education and counseling interventions compared with current recommended care, and with each other, on cardiorespiratory fitness and

For editorial comment see p 717.

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physical activity in inactive adult patients.

METHODS

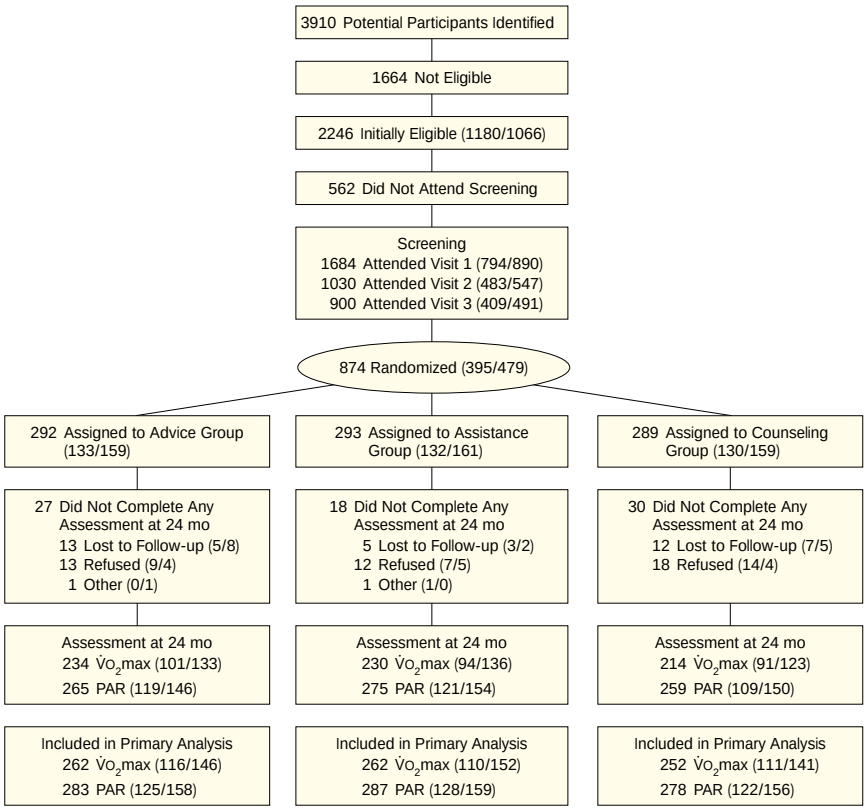
Design

The ACT was a multicenter randomized clinical trial with 3 randomized groups: 2 patient education and counseling groups, termed "assistance" and "counseling," and a recommended care "advice" comparison group. There were 2 primary outcome measures: cardiorespiratory fitness measured as maximal oxygen uptake ($\dot{V}O_2max$) by a treadmill exercise test and self-reported physical activity measured by the 7-day Physical Activity Recall (PAR) interview.[24,25] The study was designed to answer the research question separately in men and women, because of the possibility that effects of interventions to promote physical activity may vary by sex, and to test the effects of interventions delivered for 24 months.[22,23]

Setting

Participants were adult patients at 11 primary care facilities (ie, hospital-associated outpatient clinics, multispecialty group practices, internal medicine clinics, and family practice clinics) seen by 51 physicians, 2 physician assistants, and 1 nurse practitioner. The primary care facilities were affiliated with 3 clinical centers, which were Stanford University, Palo Alto, Calif; University of Tennessee, Memphis; and the Cooper Institute in conjunction with the University of Texas Southwestern Medical Center, Dallas; the coordinating center was Wake Forest University School of Medicine, Winston-Salem, NC; and the project office was the National Heart, Lung, and Blood Institute, Bethesda, Md. Participants gave written informed consent, institutional review boards of all institutions approved the study, and a National Heart, Lung, and Blood Institute–appointed data and safety monitoring board reviewed study progress twice a year.

Figure 1. Screening/Baseline, Randomization, and Follow-up



Data are reported as number of women/men.

Participants

Participants were inactive (daily energy expenditure $\leq$35 kcal·kg^{-1}·day^{-1} from the 7-day PAR), 35 to 75 years old, and in stable health, defined as an absence of serious chronic disease. If the participants were taking medication for chronic disease, they had to be continuing a stable dosage for at least 3 months. Patients with a history of coronary heart disease or findings of ischemia during the study treadmill test were excluded. Participants had to be planning or scheduled to see a study clinician during the recruitment phase, able to read and write English, independent in daily living, and able to increase their physical activity. Recruitment took place over 18 months in 1995-1997.

Methods for identifying potential participants (N=3910) included computerized databases, appointment logs, medical record reviews, questionnaires, and responses to invitation letters.[26] Staff initiated prescreening by telephone to elicit interest, obtain or verify demographic information, and to determine potential study eligibility. Three screening/baseline visits were implemented (FIGURE 1). At the first visit, study requirements were described, informed consent for screening was obtained, and a 7-day PAR was administered. Questionnaires on demographics, medical history, psychosocial factors, and nutrition and a second informed consent for randomization were given to participants for review and completion. At the second visit, clinic staff reviewed the questionnaires, a cardiovascular-oriented medical examination was conducted, a second 7-day PAR was administered, and clinical measurements were performed, including a maximal treadmill exercise test. The third visit included a submaximal treadmill test.

Eligible and consenting participants (N=874) were randomized to the 3 groups (advice, assistance, or coun-

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seling) stratified by clinical center and race/ethnicity. Randomization was performed by a computer-automated system at the coordinating center accessed by touchtone telephone when participants arrived at their appointments with their physicians, which were the first intervention visits. Physicians were masked to randomized assignment.

Similar data collection was conducted at baseline and at 6 and 24 months after the participants' randomization date. An interim 7-day PAR was administered at 12 months by telephone.

At each follow-up contact, possible adverse events were assessed by questionnaire (mailed at 18 months), including musculoskeletal injuries during or following exercise and any potential cardiovascular events.

Measurement Methods

Physical activity was assessed as total energy expenditure estimated by the 7-day PAR,[24,25] a structured interview in which participants recall specific activities to estimate amount of time spent each 24-hour period during the previous 7 days in the following 5 categories of activity intensity: sleep (1.0 metabolic equivalent tasks [METs]), light (1.1-2.9 METs), moderate (3.0-5.0 METs), hard (5.1-6.9 METs), and very hard (≥7.0 METs). The amount of time in each category was multiplied by that category's average MET value and the results for the categories summed to obtain an estimate of total energy expenditure ($kcal \cdot kg^{-1} \cdot day^{-1}$). Calories expended in and duration of moderate activity and hard plus very hard (vigorous) activity were determined.

Interviewers were trained to use a standardized protocol for administering the 7-day PAR. To improve precision at each time point, the 7-day PAR was administered twice at least 7 days apart at baseline, 6 months (once in person and once by telephone), and 24 months, with values for the 2 interviews at each time point averaged.[27]

Cardiorespiratory fitness was assessed as measured maximal oxygen uptake ($\dot{V}O_2max$, mL/min) by a graded maximal exercise test on a treadmill. After a short walking warm-up at 0% grade, the speed was increased until steady-state heart rate of 60% of age-predicted maximum or a rating of perceived exertion (RPE) of 11 to 13 (fairly light to somewhat hard physical activity) on the Borg scale[28] was maintained for 4 minutes. The grade was elevated 2% in 2-minute stages and subsequently increased 1% when the RPE was 17 (very hard physical activity) or above, until the participant reached volitional fatigue or standard stopping criteria.[29] The $\dot{V}O_2max$ was calculated as the mean of the highest consecutive two 30-second oxygen uptake values near the end of the test.

To determine baseline characteristics of participants, conventional cardiovascular disease risk factors were assessed. Blood pressure was recorded using standard procedures and hypertension was defined as a systolic blood pressure of 140 mm Hg or higher and/or a diastolic blood pressure of 90 mm Hg or higher; participants also were considered to be hypertensive if they were taking antihypertensive medication.[5] Body weight and height were measured and body mass index (BMI; calculated as the weight in kilograms divided by the height in meters squared) was determined; overweight was a BMI of 25 to 29.9 kg/m^2 and obesity was a BMI of 30 kg/m^2 or more.[30] Fasting blood lipid levels were measured and analyzed by a central laboratory; low-density lipoprotein cholesterol (LDL-C) concentrations were calculated.[31] Hypercholesterolemia was defined as an LDL-C of 160 mg/dL or higher or if the participant was taking lipid-lowering medication.[4] Smoking status was assessed by self-report.

The staff who took the measurements were masked to participants' treatment assignments and were trained at a central location and certified for measuring primary and key secondary outcomes. Experts on the assessement of the 7-day PAR and treadmill exercise test conducted yearly site visits to verify adherence to measurement procedures and for refresher training and recertification. Investigators at the coordinating center and in a study-wide measurement committee monitored measurement quality.

Interventions

The ACT interventions[23] were designed for feasible implementation in a primary care setting. Social cognitive theory was used to select key personal (eg, self-efficacy), social (eg, social support for exercise), and environmental (eg, access to facilities and resources) factors as mediators of physical activity participation,[32] which the interventions targeted using previously successful strategies, such as goal setting, supportive feedback, and active problem solving.[33] Except for the provision of physician advice, the interventions were delivered by ACT health educators placed in the clinics by the study.

All 3 groups were given the same physical activity targets based on current national recommendations: 5 or more days a week of 30 minutes of moderate-intensity physical activity (equivalent to brisk walking)[34] or 3 or more days a week of 30 minutes of vigorous-intensity physical activity (equivalent to running).[35] This amount of activity is equivalent to 2 $kcal \cdot kg^{-1} \cdot day^{-1}$ or more in moderate-to-vigorous activity or approximately 1.5 to 2 miles/d depending on body weight. Participants could choose the moderate or vigorous activity and were advised to gradually increase their physical activity to avoid injury.

A hierarchical design was used in which additional strategies were added in the assistance group above those in the advice group, with further strategies added in the counseling group.

Advice Group. Participants in the advice group received physician advice based on national recommendations.[7] Physicians received training on a brief (2-4 minutes) advice process, consisting of assessing activity level using a simple self-assessment tool; providing advice to increase activity and select a long-term goal; and referring the par-

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ticipant to an on-site health educator for further education or counseling.[36] The health educator provided existing educational materials on physical activity,[37] answered questions about the recommendations made by the physician, and was available to be called with questions. At follow-up physician visits, the physician gave advice and the health educator briefly met with the participants. The advice from the health educator was limited to information on the type and amount of physical activity; behavioral counseling was not provided.

Assistance Group. Participants in the assistance group received the same physician advice and educational materials as those in the advice group. In addition, the health educator conducted an initial 30- to 40-minute behavioral counseling session, which included showing a motivational videotape, confirmation of physical activity goals, discussion of benefits specific to the participant, and development of an individualized physical activity plan. The health educators telephoned the participants 1 week after the initial visit to provide advice and support. An interactive-mail component consisted of a monthly newsletter to increase cognitive and behavioral skills for physical activity; the newsletter included a postage-paid mail-back card for reporting weekly physical activity, current goals, and barriers to participation. Participants were given an electronic step-counter (Digi-Walker, Model SW-200; Yamax, Kansas City, Mo) and a magnetic, erasable monthly calendar, and they were instructed to record daily steps and minutes of physical activity and to provide this information on their monthly mail-back cards. Health educators then mailed back brief information sheets addressing items submitted by participants on their mail-back cards. The health educator called participants who returned less than 70% of mail-back cards in a 6-month period to encourage involvement in the interactive mail exchange. Inexpensive items, such as sports water bottles, were given as incentives for returning mail-back cards. At the time of physician visits, participants received brief behavioral counseling from health educators to assess activity level, to provide feedback and reinforcement, and to problem-solve barriers to activity.

Counseling Group. Participants in the counseling group received all of the components of the assistance intervention and in addition received health educator–initiated telephone counseling biweekly, then monthly after 6 weeks during the first year of intervention, with telephone contacts during the second year at a negotiated frequency. Telephone counseling incorporated information from the mail-back cards, evaluated and updated physical activity goals, problem-solved barriers to adherence, planned for future barriers, and provided reinforcement and social support. Weekly classes were provided at the centers by the health educators on behavioral skills for adopting and maintaining physical activity.

Nine health educators were trained at a central location, with annual retraining, by ACT behavioral scientists in intervention implementation and documentation of intervention activities. Turnover of health educators was low, and new health educators were trained using the same approach. Checklists, structured scripts, and central auditing of session audiotapes were used for intervention quality control. The ACT physicians and clinic staff were trained in intervention procedures by trainers from each clinical center who also monitored protocol adherence by physicians and clinic personnel.[36]

A computerized tracking system to prompt the health educators to deliver protocol-specified intervention components to the appropriate participants and to document participant contacts was developed by ACT. Total duration of intervention contact was estimated by adding the durations of all health educator visits and telephone calls, initial physician advice (estimated at 4 minutes), classes (1 hour each), and mail-back cards from the newsletters (estimated at 5 minutes).

Statistical Power and Analysis Methods

Sample size calculations for $\alpha = .05$, 2-sided, conducted separately for men and women and adjusted for multiple comparisons for 3 pairwise comparisons resulted in sample size estimates of 393 women and 417 men for 90% power to detect a 1.1-kcal $\cdot$ kg^{-1} $\cdot$ day^{-1} difference in total energy expenditure between any 2 of the randomized groups, based on the goal of 2-kcal $\cdot$ kg^{-1} $\cdot$ day^{-1} average increase in the assistance and counseling groups with some expected increases in the advice (comparison) group.[22] These sample sizes provided 91% and 93% power to detect a 7% difference in $\dot{V}O_2$max in women and men, respectively.

The a priori primary analysis method was repeated measures analyses of covariance[38] conducted separately for men and women comparing the 3 randomized groups on each of the 2 primary end points. All participants were analyzed according to the group to which they were assigned, regardless of intervention attendance or compliance. Dependent variables were $\dot{V}O_2$max or total physical activity by 7-day PAR. Independent variables were randomization stratification factors (center and race/ethnicity), intervention group, follow-up visit, and intervention $\times$ follow-up visit interaction. Baseline level of $\dot{V}O_2$max was included when $\dot{V}O_2$max was the dependent variable, and baseline level of total physical activity was included when physical activity was the dependent variable. All participants with a postrandomization measure at 6 months and/or 24 months were analyzed, and all follow-up values were included in the analysis. The analysis takes into account correlations between follow-up measures in the same person, and 6-month data contribute to the 24-month estimations. This analysis approach provides unbiased estimates of the intervention effect even if the chance of an observation being missing is de-

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pendent on other observed data, such as participant baseline characteristics, baseline level of the outcome measure, or interim value of the outcome measure. Intervention effect was tested by contrasting adjusted means at the 24-month visit. *P* values used to judge significance were adjusted for 6 multiple comparisons (2 primary outcomes × 3 group pairwise comparisons), and 99.2% confidence intervals (CIs) were calculated, which are consistent with the adjusted *P* value. Unadjusted *P* values and standard 95% CIs also were calculated, as were percentages of the adjusted baseline mean for between-group differences at 24 months.

The a priori statistical procedure assumes that missing data at 24 months may be related to baseline characteristics and outcomes at 6 months.[38,39] In case this assumption was not met, 2 secondary analyses were conducted in which data were imputed for participants missing 24-month values. One analysis imputed 24-month data using a regression model assuming missing data in all groups had the same distribution as observed data in the advice group, and a second analysis carried forward baseline values to 24 months assuming participants who did not return for follow-up measurement had no change from baseline values. In addition, baseline-to-24-month within-group changes, 95% CIs of the changes, and percentage change were calculated for unadjusted differences in participants with 24-month data, and these results also were calculated using each of the 2 imputation strategies in all participants randomized.

To examine physical activity level in relation to current national recommendations, the proportion of participants meeting physical activity goals (ie, 30 minutes of moderate-to-vigorous physical activity [≥3 METs] at least 5 days a week, 30 minutes of vigorous activity [>5 METs] at least 3 days a week, or at least 2 $kcal \cdot kg^{-1} \cdot day^{-1}$ in moderate-to-vigorous activity) and total calories expended in moderate-to-vigorous activity were compared at 24 months as secondary outcomes.

For all outcome analyses, a Bonferroni procedure was used to preserve an overall $\alpha = .05$ type I error rate within sex, with *P* values adjusted for 6 comparisons within sex (2 primary outcome measures and 3 pairwise comparisons).

RESULTS

Baseline characteristics were similar in the 3 randomized groups (**TABLE 1**). Mean age was approximately 51 to 52 years for both men and women. Nearly one third of the participants were of minority race/ethnicity. More than 75% of women and approximately 90% of men had some college education, and more than 40% of participants had annual household incomes of $75 000 or more. By design, none of the participants had a history of coronary heart disease. Approximately 85% of participants had 1 or more cardiovascular disease risk factors in addition to being physically inactive (ie, smoking, overweight/obesity, hypertension, hypercholesterolemia, or history of diabetes mellitus).[40] Mean (SD) energy expenditure was 32.4 (0.9) $kcal \cdot kg^{-1} \cdot day^{-1}$ in women and 32.9 (1.0) $kcal \cdot kg^{-1} \cdot day^{-1}$ in men, mean $\dot{V}O_2max$ was 1628 (380) mL/min in women and 2585 (552) mL/min in men. Less than 1% of women and approximately 1.5% of men met the physical activity goals.

During the 2 years of intervention, the advice group averaged 3 intervention contacts totaling 18 minutes, and the assistance group averaged 22 contacts totaling almost 3 hours. The counseling group averaged 44 contacts totaling 9 hours for women and 38 contacts totaling 5.6 hours for men (**TABLE 2**).

Follow-up measurement rates at 24 months were 91.4% for the 7-day PAR and 77.6% for $\dot{V}O_2max$, with rates of 90.7%, 93.9%, and 89.6% for the 7-day PAR and 80.1%, 78.5%, 74.0% for $\dot{V}O_2max$ in the advice, assistance, and counseling groups, respectively (Figure 1). There were no significant differences in demographic characteristics between participants with and those without 24-month measurements.

Results for cardiorespiratory fitness are shown in **FIGURE 2** and **TABLE 3**. For women, the a priori primary analysis resulted in an adjusted difference at 24 months between the assistance and advice groups of 80.7 mL/min (99.2% CI, 8.1-153.2; adjusted *P* = .02), between the counseling and advice groups of 73.9 mL/min (99.2% CI, 0.9-147.0; adjusted *P* = .046), and between the assistance and counseling groups of –6.7 mL/min (99.2% CI, –80.9 to 67.5; adjusted *P* = .99). For women, obtained differences between groups using imputation strategies were consistent with the primary analysis (Table 3). Unadjusted within-group analyses from baseline to 24 months showed a decrease of 16.2 mL/min (95% CI, –58.2 to 25.8) in the advice group, an increase of 58.5 mL/min (95% CI, 11.5-105.4) in the assistance group, and an increase of 62.9 mL/min in the counseling group (Table 3), for a net unadjusted difference between the assistance and advice groups of 74.7 mL/min, between counseling and advice groups of 79.1 mL/min, and between assistance and counseling groups of –4.4 mL/min. For men (data from the primary analysis are shown in Table 3) there were no significant differences between groups in cardiorespiratory fitness at 24 months. Imputation strategies were not performed for men because the a priori analysis did not result in any significant between-group differences.

For both men and women, there were no significant differences in self-reported total physical activity, except for in women at 6 months there was a significantly higher value of 0.54 $kcal \cdot kg^{-1} \cdot day^{-1}$ in the counseling than in the assistance group (95% CI, 0.07-1.00; adjusted *P* = .01) (**FIGURE 3**).

At 24 months, the secondary outcomes classifying participants according to physical activity recommendations show that percentage of participants engaging in 30 minutes of moderate-to-vigorous physical activity at least 5 days a week or 30 minutes of vigorous activity at least 3 days a week for women were 25.7% (28/109) in the counseling group, 9.9% (12/121) in the assistance group, and 14.3% (17/119) in the advice group

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(counseling vs assistance, $P=.005$; other comparisons not significant), and for men were 18.5% (28/151) in the counseling group, 29.9% (46/154) in the assistance group, and 16.4% (24/146) in the advice group (assistance vs advice, $P=.02$; other comparisons not significant). There were no significant differences between groups in proportion of participants engaging in 2 $kcal \cdot kg^{-1} \cdot day^{-1}$ or more of moderate-to-vigorous activity or energy expended in moderate-to-vigorous activity (data not shown; available from the authors on request).

Safety assessment showed that musculoskeletal injuries related to exercise, possible cardiovascular events, and physician visits and hospitalizations due to these were similar in magnitude between the 3 randomized groups (TABLE 4). There was approximately a 60% rate of musculoskeletal events during the 2 years, or approximately 30% per year. The difference in number of hospitalizations for possible cardiovascular events was significant across all 3 groups ($P=.04$), with the pairwise comparison between the highest rate in the assistance group and the lowest rate in the counseling group also significant ($P=.05$).

COMMENT

The role of physicians and other health care practitioners in advising sedentary patients to become physically active is recognized by national organizations,[2-8] but there are numerous barriers to counseling these patients.[12-17] The ACT was designed to address this problem by developing and testing 2 patient education and counseling interventions (received by the assistance and counseling groups) feasible for use in primary care settings and comparing them with current recommended care (received by the advice group).

For women, the assistance and the counseling interventions were similar in significantly increasing cardiorespiratory fitness, resulting in an approximately 5% higher $\dot{V}O_2$max at 2 years

Table 1. Baseline Characteristics of Activity Counseling Trial Participants by Randomized Group and Sex*

Characteristic	Women				Men			
	Advice (n = 133)	Assistance (n = 132)	Counseling (n = 130)	Total (n = 395)	Advice (n = 159)	Assistance (n = 161)	Counseling (n = 159)	Total (n = 479)
Age, mean (SD), y	51.3 (9.6)	52.4 (9.4)	51.9 (9.4)	51.9 (9.7)	50.4 (9.7)	52.1 (10.0)	51.6 (9.1)	51.4 (9.6)
Race/ethnicity, No. (%)								
White/Asian/other	87 (65)	87 (66)	85 (65)	259 (66)	123 (77)	122 (76)	122 (77)	367 (77)
Black/African American	40 (30)	40 (30)	40 (31)	120 (30)	31 (19)	32 (20)	32 (20)	95 (20)
Hispanic	6 (5)	5 (4)	5 (4)	16 (4)	5 (3)	7 (4)	5 (3)	17 (3)
Education, No. (%)								
High school or less	33 (25)	30 (23)	31 (24)	94 (24)	19 (12)	13 (8)	12 (7)	44 (9)
Some college	47 (35)	58 (44)	53 (41)	158 (40)	25 (16)	27 (17)	35 (22)	87 (18)
College graduate or more	53 (40)	44 (33)	46 (35)	143 (36)	115 (72)	121 (75)	112 (70)	348 (73)
Employment status, No. (%)								
Employed	91 (68)	91 (69)	93 (72)	275 (70)	141 (89)	129 (80)	139 (87)	409 (85)
Retired	17 (13)	13 (10)	13 (10)	43 (11)	14 (9)	21 (13)	11 (7)	46 (10)
Unemployed or homemaker	25 (19)	27 (31)	24 (19)	76 (20)	4 (3)	11 (7)	9 (6)	23 (5)
Smokers, No. (%)	14 (11)	13 (10)	13 (10)	40 (10)	13 (8)	16 (10)	9 (6)	38 (8)
Overweight or obese, No. (%)	92 (71)	91 (70)	96 (76)	279 (72)	130 (83)	115 (72)	119 (77)	364 (78)
BMI, mean (SD), kg/m^2	30 (8)	30 (7)	31 (8)	30 (7)	29 (5)	28 (5)	29 (6)	29 (5)
Hypertensive, No. (%)	45 (34)	51 (39)	47 (36)	143 (36)	54 (34)	61 (38)	54 (34)	169 (35)
BP, mean (SD), mm Hg	117/75 (14/8)	119/76 (14/9)	119/75 (17/9)	118/75 (15/9)	121/80 (12/8)	122/80 (13/9)	120/79 (13/8)	121/80 (13/8)
Hypercholesterolemic, No. (%)	27 (22)	20 (16)	33 (26)	80 (21)	37 (24)	39 (25)	44 (29)	120 (26)
LDL-C, mean (SD), mmol/L [mg/dL]	3.30 (0.91) [127 (35)]	3.30 (0.78) [127 (30)]	3.23 (0.94) [124 (36)]	3.28 (0.88) [126 (34)]	3.46 (0.91) [133 (35)]	3.33 (0.81) [128 (31)]	3.46 (0.81) [133 (31)]	3.41 (0.86) [131 (33)]
History of diabetes, No. (%)	6 (5)	13 (10)	11 (8)	30 (8)	8 (5)	19 (12)	11 (7)	38 (8)
Physical activity								
Total activity, mean (SD), $kcal \cdot kg^{-1} \cdot day^{-1}$	32.4 (0.9)	32.4 (0.8)	32.5 (0.9)	32.4 (0.9)	32.9 (0.8)	32.8 (1.0)	33.0 (1.1)	32.9 (1.0)
At physical activity goal, No. (%)†	2 (1.5)	1 (0.8)	1 (0.8)	3 (0.8)	1 (0.6)	4 (2.5)	2 (1.3)	7 (1.5)
$\dot{V}O_2$max, mean (SD), mL	1634 (376)	1624 (359)	1628 (359)	1628 (380)	2592 (555)	2548 (530)	2615 (570)	2585 (552)

*Note: percentages are within group and sex. BMI indicates body mass index; BP, blood pressure; and LDL-C, low-density lipoprotein cholesterol. Race/ethnicity was not known for 1 man; employment status was not known for 1 man; overweight/obesity and BMI not available for 9 women and 10 men; LDL-C not available for 18 women and 14 men. Denominators for percentages are those for whom data were available.

†Thirty minutes of moderate-to-vigorous activity at least 5 days a week or 30 minutes of vigorous activity at least 3 days a week.

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than in the advice group. The assistance intervention achieved significant effects with about 3 hours of total contact time over 2 years, divided over approximately 22 contacts. Despite more frequent and longer total contact time, the counseling intervention did not obtain significantly higher fitness levels than the assistance intervention. Neither of these interventions had a greater effect on total reported physical activity than that observed in the advice group. For men, neither the assistance nor counseling intervention improved cardiorespiratory fitness or total physical activity significantly above the level achieved by the advice group. There was no evidence of increased adverse events, such as injuries, in the assistance and counseling groups compared with the advice group. We conclude that the assistance and counseling intervention programs were equally effective in women, but for men these interventions were not more effective than the recommended care of physician and health educator advice alone. Participants were volunteers interested in increasing their physical activity levels who met various eligibility criteria and had a relatively high socioeconomic status as defined by education level, so the results may not be generalizable to the broader primary care patient population.

The primary outcomes for ACT were total self-reported physical activity and cardiorespiratory fitness. Physical activity reflects the behavioral aims of the interventions, structured self-report instruments are an accepted method for quantifying physical activity in population-based studies,[41] and self-reported physical activity is associated with cardiovascular disease in epidemiologic studies.[1] Self-report measures, however, may be biased or imprecise. Thus, the increases in self-reported physical activity from baseline to 2 years seen in this study may not be attributable to the interventions, although between-group comparisons are valid. Cardiorespiratory fitness is measured more objectively, is correlated with change in physical activity, and is inversely associated with cardiovascular disease mortality.[42-44] Fitness measures reflect longer-term activity levels than do 1-week activity recalls. Increases in cardiorespiratory fitness were seen in men from baseline to 6 months, and it may be that all of the interventions, including the recommended care received by the advice group, increased fitness in men short-term.

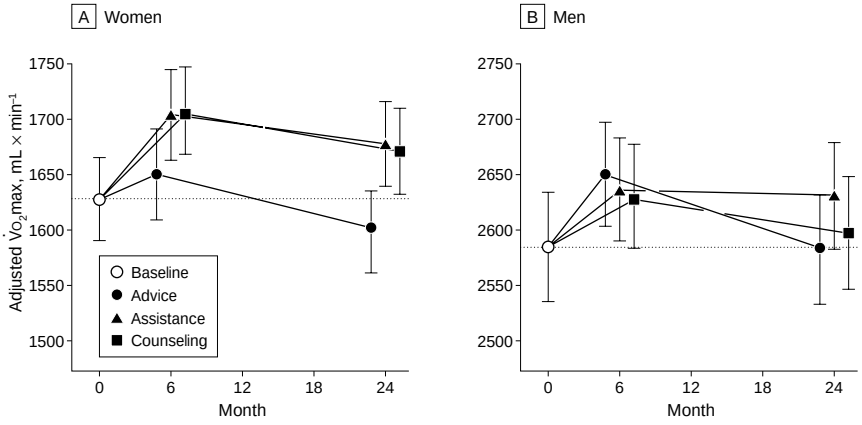
Secondary analyses were conducted to determine the proportion of participants meeting the physical activity recommendations regarding frequency, duration, and intensity of activity, that is, 30 minutes of moderate-to-vigorous activity 5 or more days a week or 30 minutes of vigorous activity 3 or more days a week. At the 24-month assessment, the highest group-specific percentages meeting the recommendations were 26% in the counseling group for women and 30% in the assistance group for men, compared with 1% to 2% at baseline. These

Table 2. Number, Type, and Total Duration of Contacts Over 24 Months of Intervention, by Sex and Randomized Group in the Activity Counseling Trial

	Women			Men		
	Advice	Assistance	Counseling	Advice	Assistance	Counseling
No. randomized	133	132	130	159	161	159
Individual visits						
Mean No.	2.9	3.1	3.7	2.7	3.1	3.0
Mean aggregated time, h	0.3	1.1	1.2	0.3	1.1	1.0
Telephone calls						
Mean No.	0.4	3.8	21.0	0.3	2.9	19.4
Mean aggregated time, h	0.02	0.4	2.5	0.02	0.3	2.0
Classes						
Mean No.	0	0	4.1	0	0	1.4
Mean aggregated time, h	0	0	4.1	0	0	1.4
Newsletters						
Mean No.	0	14.8	15.1	0	16.0	14.5
Mean aggregated time, h	0	1.2	1.3	0	1.3	1.2
Total contacts*						
Mean No.	3.3	21.7	43.8	3.0	22.0	38.2
Mean aggregated time, h	0.3	2.7	8.9	0.3	2.7	5.6

*Components do not sum exactly to total due to rounding.

Figure 2. Cardiorespiratory Fitness



Maximal oxygen uptake, $\dot{V}O_2$max in mL/min, for women and men by intervention group, adjusted for clinical center, race/ethnicity, and baseline value; measurements at months 0, 6, and 24. Error bars indicate 95% confidence intervals. Baseline marker represents the adjusted mean for all participants.

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proportions are slightly higher than that achieved in Project Active, in which after 2 years of intervention, about 20% of participants achieved the target of 30 minutes of moderate-intensity physical activity on 5 or more days a week.[45] National data indicate that approximately 20% of US adults report participation in regular, sustained physical activity for 30 minutes 5 or more days a week.[1] If interventions, such as the assistance and counseling interventions in our study, could result in 20% of the remaining sedentary population also meeting these targets, it would have important public health implications.

Exercise training with vigorous aerobic exercise has been shown to result in a 10% to 15% increase in $\dot{V}O_2$max.[46] A smaller effect can be expected from physical activity counseling interventions, such as in ACT, targeting more modest activity intensities. The 5% net increase in $\dot{V}O_2$max achieved in women in the ACT is similar to increases in other physical activity counseling trials targeting initially sedentary, middle-aged women and men.[45,47,48] Given the strong inverse gradient of mortality across levels of cardiorespiratory fitness in epidemiologic studies, a 5% improvement in fitness should lower mortality risk. Analyses of men have shown that a 1-minute increase in treadmill time on tests 5 years apart, which is comparable with a 5% improvement in $\dot{V}O_2$max in sedentary persons, is associated with a 9% reduction in multivariable-adjusted mortality risk.[49] In a

Table 3. Effects of Patient Education and Counseling Interventions on $\dot{V}O_2$max in Women and Men*

Measures	A Priori Analysis†		Imputation Strategy for Women‡	
	Men (n = 439)	Women (n = 337)	Strategy 1 (n = 395)	Strategy 2 (n = 395)
Comparisons Between Groups§				
Assistance vs advice				
Adjusted 24-month difference (%)	49.5 (1.9)	80.7 (4.9)	56.0 (3.4)	52.5 (3.2)
Adjusted *P* value (99.2% CI) of difference	.66 (−44.6 to 143.6)	.02 (8.1 to 153.2)	.04 (2.0 to 110.1)	.07 (−2.7 to 107.6)
P value (95% CI) of difference	.17 (−20.5 to 119.5)	.004 (26.7 to 134.6)	.006 (15.9 to 96.2)	.01 (11.5 to 93.4)
Counseling vs advice				
Adjusted 24-month difference (%)	15.3 (0.6)	73.9 (4.5)	55.8 (3.4)	55.5 (3.4)
Adjusted *P* value (99.2% CI) of difference	.99 (−81.1 to 111.7)	.046 (0.9 to 147.0)	.04 (1.6 to 110)	.049 (0.2 to 110.9)
P value (95% CI) of difference	.68 (−56.4 to 87.0)	.008 (19.7 to 128.2)	.007 (15.5 to 96.1)	.008 (14.4 to 93.6)
Counseling vs assistance				
Adjusted 24-month difference (%)	−34.2 (−1.3)	−6.7 (−0.4)	−0.2 (−0.01)	3.1 (0.2)
Adjusted *P* value (99.2% CI) of difference	.92 (−130.1 to 61.6)	.99 (−80.9 to 67.5)	.99 (−54.4 to 54.0)	.99 (−52.4 to 58.5)
P value (95% CI) of difference	.35 (−105.5 to 37.0)	.81 (−61.9 to 48.4)	.99 (−40.5 to 40.0)	.88 (−38.1 to 44.3)

Measures	Unadjusted Analysis		Imputation Strategy for Women‡	
	Men	Women	Strategy 1 (n = 395)	Strategy 2 (n = 395)
Within Group Changes by Randomized Group				
Advice				
Baseline mean	2627.2	1617.2	1634.1	1634.1
24-month mean	2607.8	1601.0	1602.2	1621.7
Baseline to 24-month change (%)	−19.4 (−1.0)	−16.2 (−1.0)	−31.8 (−1.9)	−12.3 (−0.8)
95% CI of change	−69.9 to 31.1	−58.2 to 25.8	−64.4 to 0.8	−44.1 to 19.5
Assistance				
Baseline mean	2539.9	1588.9	1623.5	1623.5
24-month mean	2579.3	1647.3	1647.3	1665.1
Baseline to 24-month change (%)	39.4 (1.6)	58.5 (3.7)	23.8 (1.5)	41.6 (2.6)
95% CI of change	−14.1 to 92.9	11.5 to 105.4	−11.9 to 59.4	8.1 to 75.2
Counseling				
Baseline mean	2615.0	1580.2	1627.5	1627.5
24-month mean	2609.7	1643.1	1650.2	1671.5
Baseline to 24-month change (%)	−5.4 (−0.2)	62.9 (4.0)	22.7 (1.4)	44.0 (2.7)
95% CI of change	−66.6 to 41.8	20.5 to 105.2	−9.7 to 55.0	14.1 to 73.9

*Values are expressed in mL. CI indicates confidence interval.
†The a priori analysis is for all participants for whom there are follow-up data and uses all follow-up data available.
‡Imputation strategy 1 assumes that participants missing 24-month data were like the advice group participants who were measured. Imputation strategy 2 assumes that participants missing 24-month data had no change from baseline.
§When comparing groups, adjustment is for baseline value, clinical center, and race/ethnicity. Adjusted *P* values are adjusted for 6 multiple comparisons (2 primary outcomes and 3 group pairwise comparisons).

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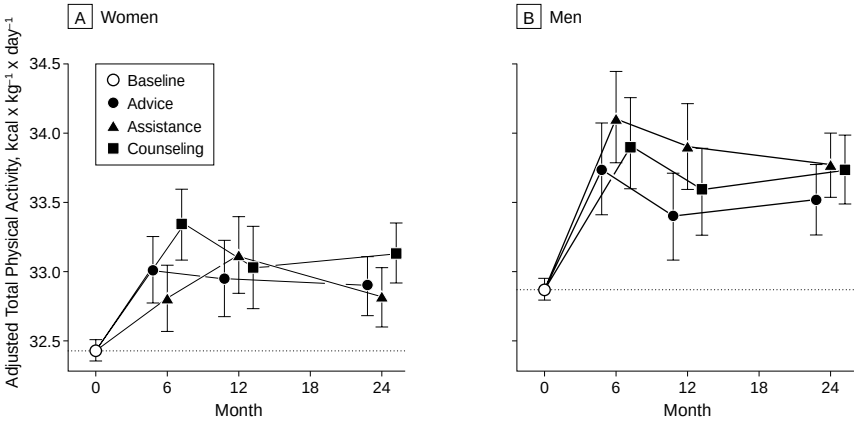
study that examined the association between cardiorespiratory fitness and mortality in men and women, the 20% of women who were the least physically fit were more than twice as likely to die during follow-up as the women who were most fit.[50]

The 30% annual rate of musculoskeletal problems seen in ACT is higher than in other moderate-intensity physical activity intervention trials with community-based populations of comparably aged sedentary adults.[47,48,51] The difference could be due to differences in health status between community vs primary care samples or to different ascertainment approaches. It is possible that more musculoskeletal problems were reported in ACT because of the active participation of primary care practitioners. The 24-month rates of serious events requiring hospitalization were relatively low (2%-7%) and did not differ appreciably between the randomized groups. There was no usual care or no-treatment comparison group, so it is not possible to determine whether all 3 interventions increased musculoskeletal problems.

In the ACT, the comparison group was the advice group; these participants received physician advice regarding physical activity, which is recommended by the US Preventive Services Task Force,[7] and patient education materials. It is important to recognize, however, that many primary care physicians do not follow these recommendations and do not advise their patients regarding physical activity.[11] Since all participants in ACT received physician advice regarding physical activity, it was not possible to adequately determine effects of physician advice per se. Given the 6-month fitness increases seen in men, it is possible that the men in the advice group were receptive to this advice; however, it would be useful to test physician advice itself further in randomized controlled studies to determine its effectiveness. The ACT health educators placed in primary care practices effectively delivered the interventions, and ACT clinicians were able to incorporate the physical activity advice into their clinical practice, which they report did not cause a burden.[36] The time needed to provide advice was designed to be readily adaptable to primary care settings,[36,52-54] although it is longer than physicians report they spend on exercise advice[55] and up to 5 times longer than was found in an analysis of audiotaped patient encounters in a different sample.[56] Compared with the advice intervention, the incremental cost of the assistance intervention was approximately $500 per participant, and the incremental cost of the counseling intervention was approximately $1100 per participant over the 2 years of ACT. It is unknown whether the assistance and counseling interventions could be incorporated feasibly into primary care practices using existing resources.

The ACT assistance and counseling interventions demonstrated discernable success with women but not with men. It would seem advisable to use these, or similar, interventions for inactive women patients interested in increasing their physical activity, while delivering physician advice and educational materials to men, which is the current recommended care.

Figure 3. Total Self-reported Physical Activity for Women and Men by Intervention Group



Adjusted for clinical center, race/ethnicity, and baseline value; measurements at months 0, 6, 12, and 24. Error bars indicate 95% confidence intervals. Baseline marker represents the adjusted mean for all participants.

Table 4. Possible Adverse Events Reported by Participants as Occurring During 24 Months of Intervention and Follow–up, by Randomized Group*

	Advice Group (n = 292)	Assistance Group (n = 293)	Counseling Group (n = 289)
Musculoskeletal event during or following exercise†			
Any event	161 (55)	181 (62)	184 (64)
Event requiring a physician visit	89 (30)	109 (37)	103 (36)
Event requiring hospitalization	10 (3)	13 (5)	7 (2)
Potential cardiovascular event‡			
Any event	80 (27)	89 (30)	82 (28)
Event requiring a physician visit	55 (19)	53 (18)	57 (20)
Event requiring hospitalization	17 (6)	21 (7)	8 (3)

*All values are expressed as No. (%).
†Includes leg or arm pain, swollen or sore joint, strained muscle, tendon, or ligament, and fractured bone.
‡Includes chest pain, difficulty breathing, and dizziness or loss of consciousness.

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A pen is certainly an excellent instrument to fix a man's attention and to inflame his ambition.
—John Adams (1735-1826)

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