Enhanced Fitness: A Randomized Controlled Trial of the Effects of Home-Based Physical Activity Counseling on Glycemic Control in Older Adults with Prediabetes Mellitus

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OBJECTIVES: To determine whether a home-based multicomponent physical activity counseling (PAC) intervention is effective in reducing glycemic measures in older outpatients with prediabetes mellitus.

DESIGN: Controlled clinical trial.

SETTING: Primary care clinics of the Durham Veterans Affairs (VA) Medical Center between September 29, 2008, and March 25, 2010.

PARTICIPANTS: Three hundred two overweight (body mass index 25–45 kg/m^2), older (60–89) outpatients with impaired glucose tolerance (fasting blood glucose 100–125 mg/dL, glycosylated hemoglobin (HbA1c) <7%) randomly assigned to a PAC intervention group (n = 180) or a usual care control group (n = 122).

INTERVENTION: A 12-month, home-based multicomponent PAC program including one in-person baseline counseling session, regular telephone counseling, physician endorsement in clinic with monthly automated encouragement, and customized mailed materials. All study participants, including controls, received a consultation in a VA weight management program.

MEASUREMENTS: The primary outcome was a homeostasis model assessment of insulin resistance (HOMA-IR), calculated from fasting insulin and glucose levels at baseline and 3 and 12 months. HbA1c was the secondary indicator of glycemic control. Other secondary outcomes were anthropometric measures and self-reported physical activity, health-related quality of life, and physical function.

RESULTS: There were no significant differences between the PAC and control groups over time for any of the glycemic indicators. Both groups had small declines over time of approximately 6% in fasting blood glucose ($P < .001$), and other glycemic indicators remained stable. The declines in glucose were not sufficient to affect the change in HOMA-IR scores due to fluctuations in insulin over time. Endurance physical activity increased significantly in the PAC group ($P < .001$) and not in the usual care group.

CONCLUSION: Home-based telephone counseling increased physical activity levels but was insufficient to improve glycemic indicators in older outpatients with prediabetes mellitus. **J Am Geriatr Soc 60:1655–1662, 2012.**

Key words: diabetes mellitus; aging; randomized clinical trial; counseling; physical activity; veterans; obesity

Type 2 diabetes mellitus is reaching epidemic proportions in the United States, paralleling increases in overweight and obesity. Approximately 11 million older adults in the United States have diabetes mellitus. Diabetes mellitus is the leading cause of new cases of blindness, kidney failure, and nontraumatic limb amputation in the

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United States. An estimated 79 million people in the United States are considered to have prediabetes mellitus.[1]

Type 2 diabetes mellitus often can be prevented with lifestyle modifications, particularly in older adults. The Diabetes Prevention Program (DPP) showed that an intervention advocating weight loss and physical activity reduced the development of diabetes mellitus approximately 71% in adults aged 60 and older.[2] Subsequent research has confirmed the independent benefit of physical activity in preventing diabetes mellitus after controlling for weight loss,[3] but the direct costs of lifestyle interventions such as the DPP may be prohibitive. Alternative approaches involving telephone counseling and mailed interventions may provide a comparable intervention effect with greater outreach for older adults not able to attend facility-based interventions at a lower cost.

The research program reported on herein has focused on delivery of home-based physical activity and lifestyle interventions for older adults.[4,5] Given the findings from the DPP that development of type 2 diabetes mellitus can be significantly reduced in older adults with a lifestyle intervention,[2] a home-based physical activity counseling (PAC) intervention trial aimed at improving glycemic indicators in older veterans was developed. The Enhancing Fitness in Older Overweight Veterans with Impaired Glucose Tolerance (Enhanced Fitness) Trial was a randomized controlled trial with an adaptive randomization design that compared the effects of a 1-year home-based physical activity telephone counseling intervention with usual care (control).

METHODS

Study Design

The Enhanced Fitness Trial was originally designed as an adaptive randomization design with allocation to PAC or usual care. Adaptive design studies identify intermediate markers of response to treatment and re-randomize, at a predetermined time point, to additional or alternate therapies based on responses to initial treatment.[6] The design initially included an interim 3-month assessment of physical activity uptake, with a planned reassignment to more or less counseling based on progress toward achievement of prescribed physical activity goals. The protocol was amended to eliminate allocation to added cognitive behavioral therapy for nonadherence when one-third of the sample had been accrued, and no study participants met the predefined objective parameters for nonadherence. Nonadherence was defined as failing to meet up to 75% of the exercise prescription, in minutes per week, agreed upon between the health counselor and participant during the counseling sessions. Thus, all participants in the PAC group were reallocated to higher or lower doses of telephone follow-up at 3 months. The Durham Veterans Affairs (VA) institutional review board reviewed and approved the research protocol annually.

Study Participants

Figure 1 depicts the screening and enrollment process. Research staff prescreened the medical records of all age-eligible (≥ 60) individuals from the Durham and Raleigh VA clinics (n = 10,221). Eligible individuals were required to be followed by a primary care provider (PCP) in VA primary care, geriatrics, or women's health clinics and have had at least one visit in the previous 12 months. They had to have impaired glucose tolerance (fasting glucose 100–125 mg/dL), be free from a diagnosis of diabetes mellitus, have a glycosylated hemoglobin (HbA1c) of less than 7%, and not be taking diabetes mellitus medications. A body mass index between 25 and 45 kg/m^2 was required. Other exclusion criteria, described previously,[7] assessed overall health for safe participation in this study. Individuals who exceeded current physical activity recommendations were excluded.[8] Eight thousand four hundred forty-three individuals did not meet initial eligibility criteria, and the PCP excluded another 15. Recruitment packages were mailed to 1,763 individuals; 1,398 of these were contacted by telephone, and enrollment appointments were made for 561 potentially eligible individuals. Three hundred two of these met full eligibility criteria and were randomized between September 29, 2008, and March 25, 2010. A statistician with no participant contact delivered sealed randomization assignments to the project coordinator that were kept in a locked cabinet until randomization.

Because of the adaptive design, individuals were not equally allocated to groups. Thus, a priori, participants were allocated so that approximately 60% of the sample was in the intervention arm (81 received monthly follow-up telephone calls; 82 received monthly follow-up calls during Months 3–6 and then every other month during Months 6–12), and 40% of the sample (122) received usual care.

Procedures

Individuals blinded to intervention status assessed all of the outcomes at baseline 3 and 12 months. Each visit followed a structured format that lasted approximately 90 minutes.

Enhanced Fitness Intervention

The Enhanced Fitness intervention was designed to enhance self-efficacy for physical activity by integrating self-monitoring, goal-setting, reinforcement, modeling, and cognitive reframing into an ongoing individualized counseling program of physical activity for endurance and strengthening activities.[9] Consistent with recommendations from the American Diabetes Association,[10] the American College of Sports Medicine, the American Heart Association,[8] and the U.S. Physical Activity Guidelines,[11] each individual was given the long-term goal of engaging in 30 or more minutes of lower extremity aerobic exercise, preferably walking, on five or more days of the week and 15 minutes of exercises to increase lower extremity strength on three nonconsecutive days each week.

The intervention has been described previously.[7,12] Individuals assigned to the PAC arm received an in-person baseline counseling consultation with a trained health counselor. Using a structured protocol, the counselor assessed current activity status and established a realistic 2-week physical activity prescription. Individuals were

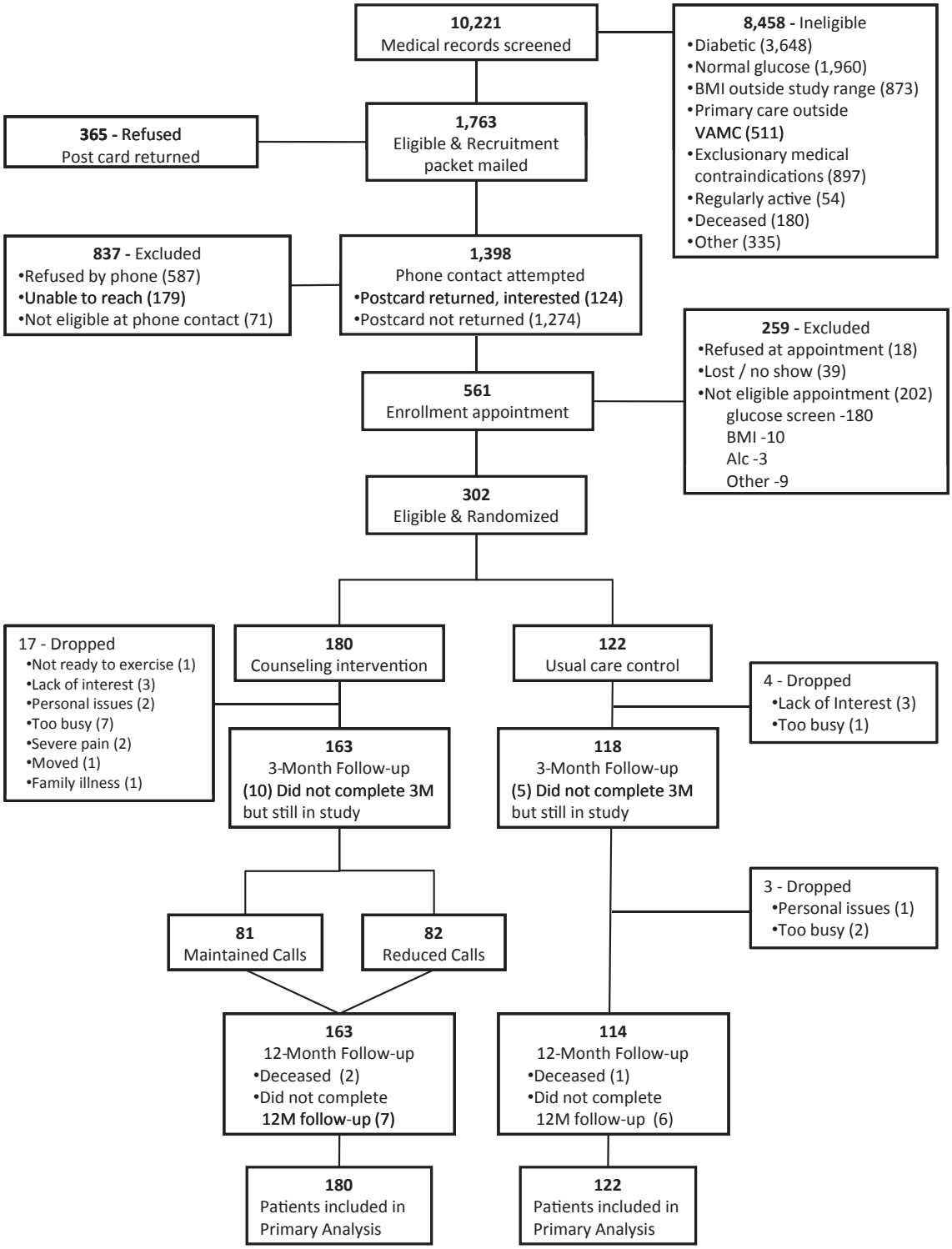

Figure 1. CONSORT diagram for clinical trial. BMI = body mass index; VAMC = Veterans Affairs Medical Center.

given a notebook containing handouts on the health benefits of exercise, tips for exercising safely, a poster with specific exercises, elastic bands of different resistances, and a pedometer. The baseline counseling was supplemented with regular telephone counseling every 2 weeks for 6 weeks followed by monthly calls over the entire 1-year intervention period. Individuals assigned to fewer telephone calls received telephone calls every other month during the final 6 months. To enhance partnership with primary care, the PCP endorsed physical activity and involvement in the study at the next clinic visit. This was followed by regular PCP encouragement using an automated telephone system. The final component of the intervention was a quarterly individualized feedback report that summarized progress toward each long-term goal of endurance and strengthening exercise.

Usual Care Plus MOVE!

Participants randomized to the usual care group received the standard of care as provided in their usual VA primary, women's health, or geriatrics clinic. PAC within the context of a clinic visit varies considerably according to provider, with some providers endorsing physical activity routinely at each visit and others not. In addition to provider discretionary approaches to care, the VA also has a nationally mandated weight management program for veterans called MOVE!, a voluntary program that offers various levels of support for veterans desiring to lose weight and includes interactive self-management programs, classroom sessions, and individualized counseling. MOVE! provides guidance on nutrition and physical activity using a step-level approach coupled with individualized goal setting. Therefore, participants were informed at randomization that they would be referred to the MOVE! program. Once a consultation was submitted, MOVE! personnel would send each participant a lifestyle questionnaire, and it was up to the individuals to decide whether they would participate in the various MOVE! activities offered at the VA. The current study tracked participation in MOVE!

Outcomes

The primary outcome was change in insulin action between groups as measured according to fasting insulin and glucose levels, using the homeostasis model assessment of insulin resistance (HOMA-IR) with HbA1C as a secondary indicator of improved glycemic control. Participants were instructed to refrain from eating or drinking anything, except for water and medications, past midnight the evening before their appointment. A reminder call was placed the night before the scheduled appointment, and study personnel verified fasting before drawing blood. Technicians not affiliated with the study analyzed blood chemistries, which included lipids, except for fasting insulin, at the VA central laboratory. Blood samples for measurement of fasting insulin were sent to a private laboratory.

Secondary outcomes included self-reports of physical activity, health-related quality of life, and physical function. Physical activity was assessed using a modified version of the Community Healthy Activities Model Program for Seniors (CHAMPS) questionnaire.[13] CHAMPS was developed specifically for older adults, has good construct validity and reliability, and is sensitive to change.[14] Modification consisted of exclusion self-reports of heavy household work or heavy gardening from the calculations of total minutes of moderate-intensity endurance physical activity per week because of previous experience with substantial overreporting of these activities. Health-related quality of life was measured using the Medical Outcomes Study 36-item Short-Form Survey (SF-36),[15] a widely used measure of general health and function that has been validated in many populations and is considered to be a reliable indicator of health status and is sensitive to change.[16,17]

Other information collected on the questionnaires included baseline assessment of race, ethnicity, and education level. Race and ethnicity was determined according to self-report of the participants during the baseline questionnaire using the following categories: Caucasian, African-American, Hispanic, and other. At each wave of data collection, chronic conditions were assessed using the Older Americans Resources and Services (OARS) Comorbidity and Symptom Index.[18] The OARS requires an affirmative or negative response to questions about unique medical conditions and symptoms.

Statistical Analyses

The sample size was set at 300, with allocation of 60% of the sample to the intervention PAC arm (n = 178) and 40% of the sample (n = 122) to usual care to adjust for the adaptive design. Power estimates were calculated using data from the studies of a targeted risk reduction intervention through defined exercise,[19] in which a group receiving a low dose of moderate exercise, equivalent to the dose of moderate exercise advocated for the Enhanced Fitness Trial, reduced fasting insulin by 1.3 U, whereas the control group experienced an increase in fasting insulin of 0.92 U with a pooled standard deviation of 3.9. With correction for multiple comparisons between adaptive strategies and a projected 12.5% attrition rate based on previous experience, the sample size was 80% powered to detect a standardized difference of 0.39 in fasting insulin for a two-tailed test.

Analyses were performed under the intention-to-treat criteria. With three data points (baseline, 3-month, 12-month) and to accommodate missing values (due to dropout, lost to follow-up, death), mixed models were used.[20] Data were analyzed according to good clinical practices.[21] The baseline value of the particular outcome was entered as a covariate to adjust residual baseline differences between the groups at baseline. A series of contrasts was defined to assess group differences after baseline that compared PAC with usual care. Where necessary, data were log transformed for analysis. For the primary outcomes, the statistical significance of the group and time by group interactions were assessed. The interpretation of the level of significance was adjusted to reflect three outcomes for the glycemic indicators using a Bonferroni correction.[22]

RESULTS

Characteristics of the study sample are presented in Table 1. The average age of the sample was 67 (range 60–89). In contrast to most behavioral interventions, which tend to enroll individuals with higher educational status, 46% of the sample had a high school degree or less. Physical function, obtained from the SF-36 (mean score 72) was comparable with that of the general population of men aged 65 and older.[23] Participants had normal usual walking speeds for their age but were at the tenth percentile in norms for 6-minute walk distance, indicating poor aerobic capacity for their age.[24,25]

Of 302 participants randomized, 262 (86.8%) completed a 12-month follow-up visit, which was what had been projected (87.5%). Reasons for withdrawal or attrition are listed in Figure 1. Sensitivity analyses between dropouts and those who completed the 12-month assessment revealed no baseline differences between groups in

Table 1. Baseline Characteristics of Participants

Characteristic	Intervention (n = 180)	Usual Care (n = 122)
Age, mean ± SD (range)	67.1 ± 6.3 (60–89)	67.7 ± 6.2 (60–80)
Aged ≥75, n (%)	27 (15.0)	24 (19.7)
White, n (%)	129 (71.7)	83 (68.0)
Male, n (%)	173 (96.1)	119 (97.5)
Some college education or trade school, n (%)	107 (59.4)	65 (53.3)
Number of comorbidities, mean ± SD	4.2 ± 2.4	3.9 ± 2.4
Number of symptoms, mean ± SD	2.3 ± 1.7	2.0 ± 1.6
Gait speed, m/s, mean ± SD	1.24 ± 0.3	1.25 ± 0.3

SD = standard deviation.

age, race, number of symptoms, general health, or physical function. Body mass index was slightly higher in dropouts (32.2 vs 31.0 kg/m^2, $P = .04$).

Change in Glycemic Indicators

There were no significant differences between the PAC and usual care groups over time for any of the glycemic indicators (Table 2). Both groups had small declines over time of approximately 6% in fasting blood glucose ($P < .001$), and other glycemic indicators remained relatively stable. The modest declines in fasting glucose were not sufficient to affect the change in HOMA-IR scores due to fluctuations in insulin over time. HbA1c remained stable throughout the year. Four percent of the sample (seven PAC, four usual care) was diagnosed with diabetes mellitus during the 1-year intervention period. Post hoc analyses examining dose response and potential thresholds suggestive of improved glycemic indicators did not yield significant findings.

Table 2. Group Means and Differences Between Group Means for All Outcomes

Outcome	Intervention			Usual Care			*P*-Value[a]
	Baseline	3 Months	12 Months	Baseline	3 Months	12 Months	
Primary							
Insulin, μIU/mL	10.26 ± 6.09	10.04 ± 7.21	11.4 ± 6.84	10.39 ± 8.58	10.45 ± 7.82	10.28 ± 5.59	.43[b]
Glucose, mg/dL	110.51 ± 6.95	106.96 ± 9.59	104.35 ± 9.62	110.60 ± 7.10	107.63 ± 9.62	104.38 ± 11.97	.91[b]
Homeostasis model assessment of insulin resistance	1.41 ± 0.83	1.35 ± 0.82	1.49 ± 0.94	1.45 ± 1.20	1.42 ± 1.14	1.37 ± 0.86	.58
Secondary Metabolic							
Glycosylated hemoglobin	5.89 ± 0.41	5.93 ± 0.42	5.90 ± 0.44	5.91 ± 0.41	5.91 ± 0.43	5.93 ± 0.36	.08
Total cholesterol, mg/dL	171.1 ± 33.8	167.5 ± 31.5	167.9 ± 32.7	179.0 ± 36.7	176.5 ± 34.1	171.6 ± 33.9	.68
High-density lipoprotein cholesterol, mg/dL	39.2 ± 12.6	40.0 ± 11.8	45.3 ± 13.2	38.5 ± 11.1	40.0 ± 11.7	44.8 ± 13.3	.87[b]
Low-density lipoprotein cholesterol, mg/dL	105.7 ± 30.5	103.1 ± 28.7	98.1 ± 30.0	113.7 ± 31.3	111.4 ± 31.1	102.2 ± 31.5	.84[b]
Triglycerides, mg/dL	131.8 ± 69.5	121.1 ± 64.3	131.4 ± 74.0	144.6 ± 139.7	133.3 ± 114.9	123.2 ± 64.2	.25
Physical activity, min/wk							
Endurance	73.39 ± 119.81	124.30 ± 127.15	133.60 ± 136.47	115.29 ± 183.66	92.87 ± 115.01	112.62 ± 135.45	<.001
Strength	19.19 ± 74.97	20.92 ± 33.46	28.44 ± 57.62	25.11 ± 75.68	27.42 ± 68.69	40.15 ± 93.35	.11
Health-related quality of life, range 0–100							
General health	61.39 ± 39.40	59.84 ± 42.59	58.12 ± 42.29	65.78 ± 39.52	66.37 ± 42.75	61.68 ± 41.82	.92
Physical function	62.94 ± 20.97	63.97 ± 21.30	62.52 ± 21.79	66.88 ± 20.60	67.08 ± 19.86	66.24 ± 20.91	.09
6-minute walk, m	495.7 ± 119.9	516.5 ± 128.2	518.3 ± 127.4	500.9 ± 109.3	526.4 ± 113.9	517.2 ± 129.1	.81
Anthropometric							
Body mass index	31.35 ± 3.75	30.90 ± 3.73	30.74 ± 3.88	30.97 ± 3.45	30.89 ± 3.60	30.64 ± 3.62	.31
Weight, kg	94.08 ± 13.03	92.89 ± 12.69	92.60 ± 13.62	94.51 ± 12.81	94.28 ± 13.10	93.67 ± 13.13	.34
Waist circumference, cm	104.22 ± 9.04	104.23 ± 8.53	103.92 ± 10.02	103.98 ± 8.51	104.03 ± 8.10	104.43 ± 11.73	.68

[a] *P*-values are for the group by time interactions indicating between-group differences.
[b] $P < .001$ for time effect, with no between-group differences.

Change in Physical Activity

Walking and other endurance physical activity increased significantly over time for the PAC group, from an average 73 minutes per week at baseline to an average 133 minutes per week at 12 months (+82%), in comparison with the usual care group, whose endurance physical activity remained constant, from 115 minutes per week at baseline to 112 minutes per week at 12 months ($P < .001$ for between-group difference) (Table 2). The prevalence of individuals meeting the goal of 150 minutes of endurance exercise increased in the PAC group over time from 16% to 42%, in contrast to the usual care group, whose prevalence of individuals meeting the 150-min/wk marker was stable over time (31%; odds ratio (OR) = 1.65, 95% confidence interval (CI) = 1.08–2.53). Both groups increased strength training activities over time, with no between-group differences noted. Validation of self-reported activity was performed in two ways. A subset of study participants wore ankle step count activity monitors for 1 week after each assessment; a modest correlation ($P = .11$, n = 39) between mean number of step counts per day and mean minutes of moderate-intensity endurance activities from the CHAMPS was observed at the 3-month assessment point only. In the PAC group, individuals were asked to record pedometer counts as part of their self-monitoring of physical activity and were encouraged to mail these to the investigative team. Of respondents, individuals averaged 5,241 steps for the baseline assessment (n = 90), 5,585 steps for the 3-month assessment (n = 76), and 5,643 steps for the 12-month assessment (n = 48), which mirrors the self-reported changes in minutes of endurance activity. Seventy-two percent of the total PAC group stated that receiving the pedometer motivated them to walk quite a bit or very much.

Change in Health-Related Quality of Life and MOVE! Program Outcomes

Self-reports of health-related quality of life and physical function were stable throughout the intervention period (Table 2). There were no changes over time or between groups for any of the subscales of the SF-36.

Only 15% of the randomized sample enrolled in MOVE! On average, MOVE! enrollees attended six interactive classroom sessions. Weight loss was higher in individuals choosing to engage in MOVE! activities (−1.55 kg) than in those who did not (−0.89 kg). There were no other differences between MOVE! participants in glycemic or physical activity outcomes.

Adverse events

Changes in health status were identified at each telephone contact during the follow-up survey, the telephone counseling, or according to self-report. Six hundred ninety-one adverse events were reported, reviewed, and classified as serious or nonserious. Nonserious adverse events (n = 650) included aches and pains, sore muscles, muscle cramps, headaches, colds and influenza, and minor injuries or cuts. Of these nonserious adverse events, 36 were attributed to increased physical activity: pain related to preexisting joint or back pain exacerbated by exercise (n = 20), fall that caused a minor injury (n = 5), sore or pulled muscle (n = 4), heat exhaustion (n = 3), knee injury (n = 1), finger injury (n = 1), injury to head by exercise equipment (n = 1), and developed blisters while walking (n = 1). The remaining 41 health changes were classified as serious (life threatening or resulting in a hospitalization). Two of these, both in the PAC group, were attributed to the increased physical activity. One person experienced radiating shoulder pain while walking on a treadmill that resulted in a hospitalization, and one person fell from a treadmill, which resulted in a broken femur. Two events were considered possibly attributable to increased physical activity. One person had a transient ischemic attack with symptoms of right-sided numbness that resulted in a hospitalization, and one person experienced shortness of breath and was subsequently diagnosed with myocardial infarction. The remaining 37 health changes and illnesses, although serious, were not related to physical activity.

DISCUSSION

The Enhanced Fitness Trial included a theory-based PAC intervention with components known to increase physical activity. Although substantial increases in physical activity were reported, there were no notable improvements in the primary endpoints pertaining to glycemic control. Although participants in the PAC group reported gradual and significant gains in physical activity over the 12-month intervention period, they largely did not attain the recommended therapeutic dose of 150 minutes of moderate physical activity per week necessary to affect insulin resistance.

These results are analogous to a clinic-based health lifestyle intervention provided to overweight individuals with diabetes mellitus in which individuals reported substantial gains in physical activity (78%) and modest weight loss, with no change in diabetic control.[26,27] A recent meta-analysis comparing structured exercise with telephone advice concluded that telephone advice for physical activity alone was insufficient to achieve significant improvements in HbA1c in individuals with type 2 diabetes mellitus, whereas structured exercise or telephone advice for physical activity and diet were.[28] Another meta-analysis focused on lifestyle interventions aimed at reducing diabetic risk in routine clinical practice.[29] Results reported modest reductions in weight and waist circumferences, with no clear effect on biochemical or clinical parameters. The authors concluded that, given the positive changes observed and the apparent successful feasibility of integrating lifestyle intervention without excessive cost into the system, it seemed worthy to continue supporting these efforts along with rigorous evaluations in these settings.[29]

The magnitude of change in physical activity observed in individuals in the PAC group is meaningful from a public health perspective in that the participants were largely sedentary at baseline and made continuous strides in increasing physical activity throughout the counseling period. Reducing sedentary behaviors, independent of physical activity, has known cardiovascular, metabolic, and functional benefits in older adults.[30,31] Moreover, the PAC

intervention was designed to be lower in cost and more convenient to participants, which increases its appeal to providers and participants alike.

This study was directed at outpatients receiving care in VA primary care clinics. This presents numerous challenges. As a whole, veterans receiving care at the VA tend to have more chronic diseases, poorer health, lower income, and higher levels of unemployment than individuals receiving health care in the private sector.[32,33] The health counselors noted, in comparison to prior research on older veterans, which had been heavily dominated by World War II Veterans, a higher prevalence of depressive disorders and posttraumatic disorder syndromes as more Vietnam-era veterans aged into geriatric care. As noted in the results, changes in physical activity were gradual, from a baseline of 73 min/wk for endurance activities to 124 min/wk at 3 months and 133 min/wk at 12 months; a near doubling. One can only speculate whether a longer intervention period would have yielded continued gains in physical activity, with a concomitant improvement in insulin resistance. Most of the studies that have observed meaningful results in reducing diabetes mellitus incidence and other glycemic indicators have been of longer duration.[3,34]

Although the results of this study were largely stable regarding the primary outcome, there are numerous positives. Most health outcomes did not worsen throughout the year, and several showed trends in positive directions (fasting glucose, weight, and low-density lipoprotein cholesterol declined, and high-density lipoprotein cholesterol increased). The budget, which did not allow oral glucose tolerance tests to be conducted, which might have been more sensitive to change, also constrained the study. Six-minute walk distance improved modestly from baseline to 12 months; the raw mean change observed in the PAC group was not statistically significant but is considered a small meaningful change relative to clinical outcomes using anchor-based methods of responsiveness to change analysis.[35] Integration with primary care providers was successful; 74% of individuals in the PAC group reported that their provider encouraged physical activity during a clinic visit, and 84% believed that the study gave them necessary tools to lower their risk of developing disease. Using a combined mailing and telephone counseling approach made the program more accessible, given that 50% of the sample lived more than 25 miles from their VA clinic. An inherent challenge of integrating research-based methods into routine clinical care has to do with maximizing uptake of these programs. The entire sample in the study (PAC and usual care) were given a consultation on the VA MOVE! Program, yet only 15% of the sample chose to participate. How to get the other 85% of at-risk people involved in these voluntary programs remains unknown. Although not officially documented, many participants acknowledged that they were not physically active and were overweight but did not perceive themselves as being at risk for diabetes mellitus. Another smaller proportion of individuals expressed concern that, if they engaged in health-promoting activities, they might be at risk of losing their disability (monetary) benefits. Although 87% of participants in the PAC group felt that they had gained tools to help them reduce their risk of diabetes mellitus, only 24% of them expressed a willingness to pay for an individual PAC session. All of these issues are important as attempts are made to promote adherence to a healthier lifestyle.

There are obvious limitations to this study. Physical activity was determined according to self-report. A small subset of the study sample wore step count monitors as validation of self-reported activity. As noted in the results, a modest correlation was found between self-report and step counts at 3 but not 12 months. As more technology to assess physical activity becomes readily available and less costly, future studies of this nature can include more-thorough assessment of physical activity. It was not possible to implement the most-attractive feature of the original design, which included group therapy for nonadherent participants; the difference between self-report and directly measured physical activity may have been a result of a lack of objective measurement of physical activity. Another limitation was that, despite randomization, there were substantial differences in physical activity at baseline between the two groups, which may have affected some of the between-group outcomes.

In conclusion, this study highlights the challenges faced in promoting physical activity and lifestyle changes in primary care. The fact that positive change was observed in the usual care group attests to the efforts that the VA has put forth in managing its at-risk patients. Unfortunately, the low levels of physical activity observed in the participants also highlight the failure of the system to fully integrate physical activity promotion into these efforts. Although a promising intervention has been successfully implemented, low physical activity remains pervasive in this population. Additional efforts are needed to maintain long-term improvement and maintenance of these efforts. Future research will probably include more emphasis on combined lifestyle changes (physical activity and diet) and seek to explore ways of increasing long-term uptake in these at-risk populations.

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