Translating Weight Loss and Physical Activity Programs Into the Community to Preserve Mobility in Older, Obese Adults in Poor Cardiovascular Health

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**Background:** Limitations in mobility are common among older adults with cardiovascular and cardiometabolic disorders and have profound effects on health and well-being. With the growing population of older adults in the United States, effective and scalable public health approaches are needed to address this problem. Our goal was to determine the effects of a physical activity and weight loss intervention on 18-month change in mobility among overweight or obese older adults in poor cardiovascular health.

**Methods:** The study design was a translational, randomized controlled trial of physical activity (PA) and weight loss (WL) on mobility in overweight or obese older adults with cardiovascular disease (CVD) or at risk for CVD. The study was conducted within the community infrastructure of Cooperative Extension Centers. Participants were randomized to 1 of 3 interventions: PA, WL + PA, or a successful aging (SA) education control arm. The primary outcome was time to complete a 400-m walk in seconds (400MWT).

**Results:** A significant treatment effect (P = .002) and follow-up testing revealed that the WL + PA group improved their 400MWT (adjusted mean [SE], 323.3 [3.7] seconds) compared with both PA (336.3 [3.9] seconds; P = .02) and SA (341.3 [3.9] seconds; P < .001). Participants with poorer mobility at baseline benefited the most (P < .001).

**Conclusion:** Existing community infrastructures can be effective in delivering lifestyle interventions to enhance mobility in older adults in poor cardiovascular health with deficits in mobility; attention should be given to intervening on both weight and sedentary behavior since weight loss is critical to long-term improvement in mobility.

**Trial Registration:** clinicaltrials.gov Identifier: NCT00119795


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ability to walk 400 m predicts multiple adverse outcomes such as morbidity, worsening disability, CVD, institutionalization, and mortality.\textsuperscript{12-14} Clearly, the ability to walk without assistance is a critical factor in an older person’s capacity to function independently in the community.\textsuperscript{15} Our primary aim was to compare the effects of 3 treatment arms on 18-month change in time (in seconds) to complete the 400MWT. The 3 treatments included a successful aging (SA) control arm, PA, and WL + PA. Our secondary aims included examining the effects of the treatments on WL, level of PA, and adverse events.

METHODS

OVERVIEW

The study recruited 288 participants ages 60 to 79 years from 3 counties (Forsyth, Davidson, and Guilford Counties) in North Carolina. After baseline assessment and randomization to SA, PA, or WL + PA, participants returned for assessments at 6, 12, and 18 months. Participants were treated in 8 waves, with all sessions being conducted indoors at the NCCE centers. Each wave within counties consisted of approximately 39 participants with approximately 13 in each treatment arm. A data safety and monitoring board routinely evaluated the execution of the study protocol and adverse events. Electronic copies of the intervention manuals are available on request from the corresponding author (W.J.R.).

All interventionists had degrees in the health sciences and were trained by the study investigators. A registered dietitian provided oversight for the dietary intervention arm. The SA arm and portions of the WL + PA arm were delivered by Cooperative Extension agents—also known as Family and Consumer Sciences (FCS) educators—who are field faculty from North Carolina State University. These educators have degrees in Home Economics and/or Nutrition Education. Cooperative extension specialists provide unbiased, research-based information to the public in such areas as agriculture, human nutrition, diet and health, food safety, gerontology, and human development.

ELIGIBILITY

The eligibility criteria identified ambulatory, overweight or obese, community-dwelling older adults who either had CVD or cardiometabolic dysfunction and evidence of self-reported limitations in mobility using the following inclusion criteria: (1) age 60 to 79 years; (2) having less than 60 minutes/week of moderate intensity physical activity (PA), body composition, and balance; (3) unstable angina, symptomatic congestive heart failure, or exercise-induced complex ventricular arrhythmias; (4) resting blood pressure greater than 160/100 mm Hg; (5) diagnosis of systemic diseases that precluded participants from safely participating in the interventions; (6) a fasting blood glucose level higher than 140 mg/dL (7.77 mmol/L), type 1 diabetes mellitus (DM), or type 2 DM with insulin therapy; (7) active treatment for cancer; (8) clinically significant visual or hearing impairment; (9) dementia, delirium, or impaired cognitive function; (10) participation in another medical intervention study; (11) having more than 21 alcoholic drinks per week; (12) inability to walk unassisted; and (13) inability to speak or read English.

RECRUITMENT, ENROLLMENT, AND RANDOMIZATION

Recruitment occurred over 2.5 years. The first person was enrolled on January 17, 2005, and the last person was closed out on April 6, 2010. Recruitment strategies included newspaper advertisements and direct mailings. Each participant was randomized to treatment using a permuted block randomization scheme with stratification by wave.

MEASURES

Demographics, medical history, and comorbidities were collected by self-report. Height without shoes was measured to the nearest 0.1 cm using a stadiometer and weight to the nearest 0.1 kg using a calibrated electronic scale.

Mobility

The 400MWT was used to assess mobility.\textsuperscript{17} In a study of middle-to older-aged women, the 400MWT had excellent stability (intraclass correlation [ICC], 0.95) and was significantly related to measured VO\textsubscript{2peak} (the highest oxygen value achieved during an exercise test to exhaustion), PA, body composition, and balance.\textsuperscript{18} Moreover, prospective data analyses in healthy older adults have shown that performance on the 400MWT is predictive of mortality, incident cardiovascular disease, and disability.\textsuperscript{19}

Physical Activity

The Lifecorder-EX accelerometer (New-Lifestyles Inc, Lees Summit, Missouri) was used to assess PA.\textsuperscript{19,20} Intensity levels 3 to 9 were classified as moderate to vigorous (M-V); this is consistent with the metabolic demands of activity for this age group.\textsuperscript{20} At baseline and at the 6-month and the 18-month follow-up assessments, all participants were asked to wear the accelerometer for 7 days. More than 97% of the activity for M-V was of a moderate intensity, and the data were processed consistent with established protocols.\textsuperscript{19,20}

PA INTERVENTION

The PA intervention (48 total sessions) was based on an evidence-based program for older adults that is conceptually driven by principles from Bandura’s social cognitive theory and the group dynamics literature.\textsuperscript{21} A primary goal was to gradually increase or shape PA in a home-based environment to more than 30 minutes of moderately intense activity on most days of the week for a total of more than 150 minutes/wk. Participants walked at a moderate intensity of “somewhat hard—13” as assessed by the Borg Rating of Perceived Exertion scale.\textsuperscript{22} Weekly trackers (written self-monitoring logs) were used to document walking behavior.

The PA intervention involved 2 phases: intensive and maintenance. The 6-month intensive phase involved counseling sessions in a mix of 3 group sessions and 1 individual session per month. Group sessions lasted 90 minutes, and individual sessions lasted 30 minutes. Each group session started with a 30-
to a 45-minute period of walking followed by an interactive, group-mediated, behavioral-focused session.

During the first 2 months of the intensive phase, participants were asked to identify their primary motivations for becoming more active, and group leaders emphasized the risk of disability with aging. In addition, participants were introduced to the concepts of goal setting and self-monitoring, documenting minutes of walking in activity logs, and learning how to adjust goals when warranted.

During months 3 and 4, discussions focused on creating a PA program that had the flexibility to accommodate the multiple barriers that inevitably occur. During this period, strategies focused on the development of self-regulatory skills and a network of social support. During months 5 and 6, discussions focused on the concept of participants perceiving themselves as physically active, independent older adults. They were taught how to use environmental cues to facilitate activity goals and how to avoid or deal with relapses when they occurred.

Months 7 to 18 formed the maintenance phase with a reduction in the frequency of contact to 2 times per month. One contact was a group session and the second was a telephone contact that lasted approximately 10 to 20 minutes. Discussion mirrored the check-in during the intensive phase in that PA goals were discussed, specific plans of action were implemented, and self-regulatory skills were reinforced.

**WL and PA Intervention**

The combined treatment arm (48 total sessions) involved the PA program in conjunction with dietary WL. Using the same conceptual model as PA, the WL goal was to reduce caloric intake to produce a WL of approximately 0.3 kg per week for the first 6 months for a total loss in mass of 7% to 10%. During maintenance, participants were encouraged to continue WL as long as their BMI was 20 or greater; however, the primary focus was on weight maintenance. At program inception, participants were assigned a daily energy intake goal based on their baseline weight. A 1200- to 1500-kcal goal was used for those weighing less than 250 lbs (113.4 kg), and a 1500- to 1800-kcal goal for those weighing 250 lbs or more. Recommendations for choices of foods were based on the MyPyramid Food Guidance System. Participants were given food tracking booklets and, at the end of each week, they were asked to identify their primary motivations for being WL and to share their personal triggers to eating. Participants did not receive a progressive, supervised program of PA or diet for WL; however, both PA and nutrition for aging were addressed as separate and distinct topics.

**Statistical Analyses**

Using a 2 df test for our primary outcome, we calculated that 300 participants would provide 94% power to detect a difference in the 400MWT of 13 seconds between SA and PA and 26 seconds between SA and WL + PA. This allowed for a 25% dropout rate and the ICC due to the group-based intervention. Descriptive statistics were used to describe the sample. The primary analysis used a linear mixed model with covariates, including the baseline 400MWT, county, wave within county, visit (at 6, 12, and 18 months), and sex. “Participant” was included as a random effect to account for the within-participant correlation. Adjusted means were used to account for the variables in the primary model. Fisher exact test was used to compare adverse event rates by treatment group. The potential impact of missing data on our conclusions was examined by comparing the proportion of missing primary outcome data between treatments using a generalized linear mixed model similar to the primary analysis model and by use of multiple imputation. Analyses were conducted using SAS statistical software (version 9.2; SAS Institute, Cary, North Carolina).

**RESULTS**

The Consolidated Standards of Reporting Trials (CONSORT) diagram (Figure 1) shows that 86.5% of the participants completed the 18-month follow-up; using a mixed-model in SAS we were able to conduct analyses for the primary outcome on 93.4% of those randomized. Participants in SA attended a mean (SD) of 70.9% (26.3%) of the scheduled sessions, whereas for PA it was 79.8% (24.6%), and for WL + PA it was 88.2% (25.2%). Women made up 67.0% of this cohort, and 81.9% were white. As shown in Table 1, the participants were to provide feedback and reinforcement to participants. As in the PA arm, maintenance involved 2 contacts each month: 1 group contact and 1 telephone counseling call.

**SA Education Intervention**

The SA treatment was developed by faculty at North Carolina State University, Raleigh, who serve as extension specialists for NCCE. Each scripted lesson was taught by an FCS agent in each county and was tailored for older adults. The purpose and structure of the SA group was to (1) control for general levels of staff and participant interactions, (2) optimize recruitment and to ensure participants’ ongoing cooperation and retention, (3) select a control intervention that would have minimal effects on the primary outcome, and (4) use an intervention that had tangible benefit. Participants in the SA arm met weekly for the first 2 months, monthly through the sixth month, and then bi-monthly until the end of the study—a total of 18 sessions.

In the SA treatment, participants were taught how to actively “take charge” of their health. Examples of topics covered included the following: how the body changes with aging, preventing or delaying disease, eating for good health, positive attitudes toward aging, family relationships and care giving, and talking to health care providers. The SA intervention differed from the other 2 arms of the study in that participants did not receive a progressive, supervised program of PA or diet for WL; however, both PA and nutrition for aging were addressed as separate and distinct topics.
socioeconomically diverse, had multiple comorbidities, and all were overweight or obese.

400-m WALK TIME

Table 2 and Figure 2 provide descriptive data for the primary outcome by treatment group. A statistically significant overall treatment effect (P = .002) was observed, and follow-up testing revealed that the WL + PA group improved their 400MWT performance over time compared with both SA (P < .001) and PA (P = .02). Baseline
it was 13.0 seconds (95% CI, 2.5-23.5). Clearly, WL + PA resulted in improved walking performance compared with either SA or PA. There was no evidence of differential missingness of the primary outcome (P=.13). The multiple imputation analyses confirmed the complete case analyses.

**WL, LEVELS OF PA, AND ADVERSE EVENTS**

Participants in SA and PA experienced very small decreases in weight, approximately 1.0% after randomization, whereas the WL + PA group had lost 8.5% at 6 months and essentially retained this level at 18 months (7.7%) (P < .001) (see Table 3 for means and 95% CIs for adjusted means).

There were significant group differences (P < .01) for minutes of M-V PA (see Table 4 for means and 95% CIs for adjusted means), with those in the PA and WL + PA group increasing their minutes of M-V over time compared with those in the SA group (P < .02). In addition, adverse events are presented in Table 5. There were 28 people with adverse events in the WL + PA group, 16 in the PA group, and 14 in the SA group (P = .04). The pattern was similar for serious adverse events (17 in the PA + WL group, 13 in the PA group, and 9 in the SA group), although the differences were not statistically significant (P = .33). It is important to note that most adverse events in the WL + PA group and PA group involved musculoskeletal complaints that were transient, whereas only 2 of the serious adverse events were definitely related to treatment.

**COMMENT**

There were 2 major findings in this study. First, the results illustrate that to improve mobility in older, functionally compromised, obese adults with either CVD or...
cardiometabolic dysfunction, PA must be coupled with WL. And second, the WL + PA intervention was successfully translated into a community setting with results for WL and increased PA comparable with those observed in the best randomized controlled trials conducted in academic health centers.26,27 Although PA was effective at improving 400MWT performance at 6 months compared with SA, this benefit disappeared at 18 months. We surmise that the benefit of WL + PA over PA alone was due either to the increased motivation to be physically active when one has lost weight, and/or that being physically active is perceptually or objectively less demanding once one has lost weight.

As evident from the 95% CI of the 400MWT data, the magnitude of the treatment difference between WL + PA and SA was substantial. Of course, readers may question the clinical meaningfulness of this difference, given that Kwon et al.,28 using data from the Lifestyle Interventions and Independence for Elders Pilot (LIFE-P) Study, proposed that a 20-second change in 400MWT represents the lower end of the range for clinical significance. There are 2 important points to consider. First, LIFE-P targeted older adults (>70 years) who had poor mobility. As observed in the current study, change in function is affected dramatically by baseline performance such that those who perform worse at baseline experience greater improvement. Thus, a clinically significant change in 400MWT for more functionally able older adults has yet to be determined but will clearly fall below what Kwon et al. observed. Second, it is likely that the clinical significance of a change in 400MWT depends on the outcome of interest. Interestingly, the 12-month outcome data for the 400MWT in LIFE-P yielded a change in gait speed of 0.003 m/s for the PA group (from 0.854 m/s to 0.857 m/s), which equates to an improvement of 1.64 seconds, whereas those in the SA group experienced a decline in gait speed of 0.031 m/s (from 0.854 m/s to 0.823 m/s)—17.56 seconds worse. Moreover, the functional changes observed in LIFE-P and power estimates based on failure to complete the 400MWT led to the largest PA trial of older adults ever funded by the National Institute on Aging. Thus, it would be premature to dismiss an 18-second treatment change for the 400MWT in the current study as clinically irrelevant, particularly recognizing that this value was obtained while adhering to the principle of intent-to-treat. Further research on this question is warranted.

Compared with the SA group, both the PA and WL + PA treatment groups experienced statistically significant increases in PA, whereas the WL + PA group lost considerable weight—7.7% at 18 months—compared with either the SA or PA groups. In addition, there was little evidence that the interventions posed a safety risk for participants. It is now well known that older adults with various existing comorbidities respond favorably to PA interventions.29-32 Although the number of trials focusing on the management of obesity in older adults has been limited,6 the Obesity Society has underscored the need for research in this area.33 The current study is unique given the target population investigated, the interventions, and the fact that the research was conducted within a translational context partnering with the NCCE and faculty at North Carolina State University who serve as extension specialists for this organization.

In summary, this investigation revealed that a community-based WL + PA intervention can have a favorable effect on preserving the mobility of older, obese adults who are at risk for or have CVD. The magnitude of change that we observed in both the WL and PA groups was comparable with data from highly successful, center-based intervention research.5,26,27 Future studies are needed to expand this line of investigation to other community jurisdictions to examine the generalizability of these findings.

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Author Contributions: Dr Rejeski had full access to all of the data, and Dr Ambrosius takes responsibility for the integrity and accuracy of all data analyses. Study concept and design: Rejeski, Bearon, McClelland, Perri, and Ambrosius. Acquisition of data: Rejeski, Brubaker, Goff, and Ambrosius. Analysis and interpretation of data: Rejeski, Brubaker, Goff, Bearon, McClelland, and Ambrosius. Drafting of the manuscript: Rejeski and Ambrosius. Critical revision of the manuscript for important intellectual content: Rejeski, Brubaker, Goff, Bearon, McClelland, Perri, and Ambrosius. Statistical analysis: Ambrosius. Obtained funding: Rejeski, Goff, Bearon, McClelland, Perri, and Ambrosius. Administrative, technical, and material support: Rejeski, Brubaker, and Ambrosius. Study supervision: Rejeski, Brubaker, Perri, and Ambrosius.

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REFERENCES


Correction

Error in Correspondence. In the Letter to the Editor titled “Considering Selection Bias When Developing a Search Strategy” by Nakao et al, published in the March 14, 2011, issue of the Archives (2011;171[5]:471–472), an incorrect e-mail address appeared in the Correspondence section. The correct e-mail address is as follows: kenji.ueshima@at3.ecs.kyoto-u.ac.jp.