A Randomized Trial of Weighted Vest Use in Ambulatory Older Adults: Strength, Performance, and Quality of Life Outcomes

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BACKGROUND: Lower extremity weakness is a major risk factor for falls and hip fractures. Aging muscle is capable of responding to strengthening techniques. Strategies for providing accessible, inexpensive, safe, and effective strengthening programs for older adults are needed.

OBJECTIVE: To evaluate whether use of a weighted vest improved strength, physical performance, markers of bone turnover, or health-related quality of life.

DESIGN: A 27-week randomized, controlled, unmasked clinical trial. The primary outcome was peak isokinetic knee extensor strength at follow-up, adjusted for baseline strength.

SETTING: Home-based program.

PARTICIPANTS: A total of 62 women and men, mean age 74 years.

INTERVENTIONS: Subjects were randomized to: no vest (n = 21), 3% body weight (BW) vest (n = 19), or 5% BW vest (n = 22). The vest is a nylon garment with pockets that are loaded with adjustable weights. The vest was prescribed for 2 hours daily, 4 days per week. No specific physical activities were mandated.

MEASUREMENTS: All measures were made at baseline and 27 weeks. These included: knee strength and endurance by isokinetic dynamometer; timed physical performance tests; serum osteocalcin and urinary N-telopeptides; and health-related quality of life scales.

RESULTS: Follow-up values of muscular strength and endurance, physical performance, bone turnover markers, and health-related quality of life did not differ by treatment assignment. The final study visit was attended by 19 (90%), 15 (80%), and 20 (91%) of the control, 3%, and 5% groups, respectively. Three permanent discontinuations of vest use occurred.

CONCLUSIONS: Weighted vest use did not result in improvement in multiple domains of strength and function and did not affect bone turnover markers. We conclude that the training stimulus afforded by the vest (at the dosage tested) was below the required amount to produce strength gains or bone stimulation. **J Am Geriatr Soc 48:305–311, 2000.**

Key words: physical activity; strength; physical performance; quality of life; older people

Lower extremity weakness predicts development of disability in older men and women.[1] Although maximal muscle plasticity declines with age,[2,3] several studies have established that resistance training produces substantial muscle strengthening in older women and men.[4–6] Even in the oldest old, resistance training can produce up to 200% gains in strength.[7]

Despite their success at producing increases in strength, resistance training programs generally require specialized equipment, close supervision, and participant travel, making wide-scale implementation difficult. Attempts to minimize these barriers to physical training include the use of simpler equipment (e.g., sandbags, therabands),[8,9] low-[10] and ultra-low-[11] intensity training regimens, and home-based programs.[12] Although these interventions make exercise relatively more accessible than attendance at a gym, the participants must, nevertheless, engage in a formal set of exercises. However, older persons often prefer not to do specific exercises; the most common form of self-selected physical exercise in one large survey of middle-aged and older individuals was walking.[13] The ready availability, ease of performance, and economy of walking likely contribute to its popularity.

A major geriatrics research challenge, therefore, is to devise physical activity programs that achieve their desired benefits while remaining easily accessible to older persons. An intervention that does not require travel, expensive equipment, or any specific set of exercises and that can be incorporated effortlessly into one's daily routine might meet the goal of maximizing ease of use. To this end, we developed an intervention using a weighted vest, designed to be worn several hours a day while performing the usual weight-bearing activities of daily life. The vest is a nylon garment with front and rear pockets. The pockets are loaded with adjustable weights, which are prescribed as a percent of body weight. The intended benefits of this intervention were mod-

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est gains in lower extremity strength and/or bone tropism. Pilot studies with the weighted vest revealed possible improvements in bone mineral density, better health-related quality of life,[14] and increases in knee extensor strength.[15]

Based on these encouraging results, we designed a 27-week, randomized controlled trial that compared two doses of a weighted vest (3% or 5% of body weight) with no vest use. Specifically, we asked whether use of the weighted vest improved: (a) knee extensor or flexor strength and endurance; (b) selected measures of physical performance; (c) markers of bone turnover; and (d) indices of health-related quality of life. For each of these outcomes, we hypothesized a potential dose-response effect, with greater benefit at the higher vest dose. Finally, we considered the possibility that higher toxicity (i.e., more side effects) could occur in the 5% compared with the 3% vest-using group.

METHODS

Overview

This was a 27-week, randomized, controlled, non-masked trial during which subjects wore one of two doses of a weighted vest compared with no vest use. Outcome measures (described in detail below) were knee extensor and flexor strength, selected measures of physical performance, serum and urine markers of bone turnover, and indices of health-related quality of life. All measurements were made before randomization (baseline), and again at 27 weeks (follow-up) by the same research staff using identical protocols. The study was approved by the University of California at Los Angeles and University of Southern California IRBs. All participants gave written informed consent.

Participants

Men and women volunteers aged 60 years or older were recruited from community sites. Safety-related exclusion criteria were self-report of angina or coronary artery disease; congestive heart failure; systolic blood pressure greater than 160 or diastolic blood pressure greater than 95; use of anticoagulants, antiseizure medications, or more than two antihypertensive medications; cancer other than nonmelanoma skin cancer; long-term musculoskeletal pain that limited physical function; history of injurious falls; use of assistive devices; history of hip fracture; and history of falls associated with injury. Use of any bone-active drug or the presence of disease related to bone metabolism were also causes for exclusion.

Questionnaires

Self-report standardized questionnaires collected demographic, behavioral, and medical history. Usual physical activity was assessed with the PEPI survey.[16] The Medical Outcomes Study (MOS) Short-Form 36 (SF-36) and the 5-item MOS pain scale were used to measure both global and specific domains of perceived health.[17,18] A modified (self-reported format) falls efficacy scale[19] and the multiple health locus of control scale[20] were also collected.

Physical Measures

Body weight (kg) and height (cm) were measured with subjects in uniform lightweight clothing (gym shorts and a tee shirt, without shoes).

Physical Performance

The 8- and 50-foot walk tests (normal pace),[21] five timed chair stands,[22] timed stair climb (13 stairs),[23] one-leg stand (eyes open),[24] and functional reach[25] tests were performed using standardized protocols.

Strength and Endurance

Bilateral isokinetic, isometric, and endurance tests were performed using a Kin-Com isokinetic dynamometer (Model 500H; Chattecx, Chattanooga TN) using standard protocols; tests were done in the same order (isokinetic, isometric, and endurance). Five maximal effort concentric knee isokinetic flexions and extensions were performed at 60°/second. The maximal values of five measurements (peak extension torque and peak flexion torque) are the strength outcomes used in this report. One isometric measure was taken at each of three angles (100°, 120°, and 140°, measured posteriorly); the 120° measure is used as the isometric strength outcome. (see data analysis, below, for justification of choice of isokinetic and isometric measures). A modified endurance protocol required subjects to perform 20 continuous concentric flexions and extensions at 60°/second.[26,27] Endurance was calculated as [(greatest extension value, repetitions 15 through 19) − (greatest extension value, repetitions 2 through 6)].

Bone Turnover Markers

Blood for serum osteocalcin (OC) determination was collected between 7 a.m. and 11 a.m. Samples were processed and frozen at −70°C within 1 hour of collection. OC was measured using an immunoassay[28] by Endocrine Sciences (Calabasas, CA). Urine for N-telopeptides (NTX) was collected between 7 a.m. and 11 a.m. (first or second morning void) and stored at −70°C. NTX was measured using an enzyme-linked immunosorbent assay (ELISA)[29] by Endocrine Sciences. All samples for OC and NTX were run in single-batch mode at the end of the study.

Intervention

Subjects were randomized by computer program to one of three treatments: no vest, 3% vest, or 5% vest use. Those in the 3% and 5% vest groups were asked to wear a vest that contained weight in the amount of 3% or 5% of their body weight, respectively. The vest is a lightweight nylon garment with pockets in the front and back; weight is loaded symmetrically among the anterior and posterior pockets. After a 3-week graduated break-in period, during which participants wore the vest for increasing periods of time, participants were asked to wear the vest for 2 hours daily, 4 days per week, for 24 additional weeks. No specific physical activities were prescribed; rather, participants were asked to wear the vest during usual weight-bearing activities. These included recreational activities (e.g., walking), home chores (e.g., housekeeping), or any other nonrecumbent or nonsitting activity. Because of concern about potential back injury, participants were advised not to wear the vest during activities that involved substantial forward bending or twisting, such as gardening or vacuuming. All participants were asked to maintain a daily diary of physical activity; vest-using groups recorded activity with and without the vest separately. Staff made monthly phone calls to remind participants to fill out diaries, to answer questions regarding diary completion, and (for vest users) to assess any problems related to wearing the vest. Participants were encouraged to call with any questions or problems.

Data Analysis

First, data reduction of the multiple strength outcomes was performed by examination of baseline strength data before breaking the randomization code. Because baseline values for the right- and left-sided measures of strength did not differ (data not shown), only right-sided values were analyzed as outcomes. Isometric knee extensor and flexor strength were measured at 100°, 120°, and 140°. To minimize multiple testing, we determined (before examining the follow-up values) that we would use peak extension torque at only one of these angles as the primary isometric outcome. We first evaluated the Pearson correlation coefficients among the values at 100°, 120°, and 140°. All were highly correlated (all r's > 0.8). We also calculated Pearson correlation coefficients between the strength values at each angle and each of the performance-based functional measures. Of the three angles, peak torque at 120° demonstrated the highest correlations with the functional performance tests (data not shown). Therefore, the 120° measure was chosen as the primary isometric strength outcome.

Baseline differences among the no vest, 3% vest, and 5% vest groups with respect to demographics, anthropometric measures, strength, bone turnover markers, health-related quality of life, and falls efficacy were compared using chi-squared tests and analysis of variance. Analysis of covariance (ANCOVA) was used to examine treatment-related differences among no vest, 3% vest, and 5% vest groups at follow-up. For each outcome, using an intent-to-treat approach, the 27-week value of the outcome variable was modeled as a function of the treatment group, controlling for the baseline value of that variable. Because of the known relations between age, body size, and muscular strength, all models were also adjusted for age and body mass index. Models restricted to adherent participants were also run.

Several of the outcome measures were not normally distributed. Therefore, nonparametric Kruskal-Wallis tests were also performed. Parametric and nonparametric test results did not differ; thus, parametric results are reported. All analyses were performed using the Statistical Analysis System (SAS) Version 6.12 (SAS Institute, Cary NC 27513).

RESULTS

Three hundred eleven men and women were screened for potential participation, 201 of whom were excluded. Major reasons for ineligibility were back problems (37%), gait disorders (21%), anticoagulant use (13%), and angina (10%). Of the 110 persons eligible, 62 (56%) enrolled in the study. The mean age was 74 years, 74% were female, 87% were white, and 89% had more than a high school education. Characteristics of participants randomized to each of the study treatments were similar, except for education. The percentage of participants with more than a high school education varied from 74% (3% BW group) to 100% (no vest group) (P = .03).

Study retention was high; 19 (90%), 15 (80%), and 20 (91%) of the of the control, 3%, and 5% groups, respectively, attended the follow-up study visit. There were three permanent discontinuations of vest use, one in the 3% group and two in the 5% group. Permanent cessations were due to loss of interest in the study, back pain, and a severe contact dermatitis related to wearing the vest in water.

Baseline and follow-up values of Kin-Com measured muscular strength and endurance are shown in Table 1. No significant differences were evident among the randomized groups in any strength measure at baseline. Treatment with the weighted vest did not have a significant impact on any strength parameter: follow-up isometric, isokinetic, and endurance values were similar among all study arms.

Table 1 also summarizes the effect of the intervention on measured physical performance. Groups were similar at baseline, except for differences in timed chair stands (P = .02). No statistically significant group differences in any of the performance measures were evident at follow-up.

Initial mean values of serum osteocalcin were within the manufacturer's normal range and were similar across groups (Table 1). Values for urinary NTX were also age-appropriate and comparable across groups at baseline. Neither osteocalcin (P = .36) nor NTX (P = .48) changed significantly with treatment.

Table 2 outlines baseline and follow-up values of the health-related quality of life scales. At the start of the study, participants rated their physical functioning and emotional well-being highly, with initial values of approximately 87 and 86, respectively. Almost no role limitations in the physical domain (mean score = 92) or the emotional domain (mean score = 97) were evident at baseline. Participants also began the study with strikingly high (internal) health locus of control scores. Fear of falling was virtually absent at baseline, indicated by an average score of approximately 94 out of 100. Only the Powerful Others HLOC scores differed among treatment groups at follow-up (P = .04). Contrary to our predictions, at follow-up, the 5% vest group rated themselves as having less control over their health, compared with the no vest group (P = .02).

Participants who did not complete at least 75% of their diaries with interpretable data were deemed nonadherent. (We did not accept verbal reports of physical activity and vest use as indicators of protocol adherence). Based on diary completion, 81% of the no vest group was adherent. An additional condition for ideal adherence was applied to the vest-assigned participants: They were required to record that they had accomplished 100 ± 30% of the prescribed number of weekly minutes of vest use (i.e., 480 ± 144 minutes per week). Fifty-eight percent of the 3% group and 55% of the 5% group achieved ideal vest adherence by this definition. In both vest groups, walking (25% of recorded vest-wearing minutes) and light housework (25% of recorded vest-wearing minutes) were the leading activities reported. Patterns of vest wearing over time were examined to evaluate whether either active treatment group was waning or increasing in adherence over time. The median number of minutes remained stable at 480 per week for the duration of the study.

Diary-recorded physical activity did not differ among groups at the start of the study, nor was there a statistically significant time trend of increasing or decreasing activity over time. The median number of minutes of physical activity during weeks 4 to 12 of the project (after the 3-week break-in period for the vest users) averaged 965, 1260, and 980 in the 0%, 3%, and 5% groups, respectively. During weeks 19 through 26, median physical activity minutes averaged 918, 1268, and 1208 in the same respective groups.

Table 1. Baseline and 27-Week Mean Values (Standard Deviations) of Muscular Strength, Physical Performance, and Bone Turnover Measures by Treatment Assignment*†

	All Participants	No Vest	3% Vest	5% Vest	*P* Value§
Muscle Strength‡					
Isometric‖					
Peak Extension					
Baseline	81.2 (4.18)	78.4 (6.66)	87.5 (7.23)	78.6 (6.66)	0.58
Follow-up		82.9 (3.78)	78.7 (4.33)	86.4 (3.66)	0.41
Isokinetic¶					
Peak Extension					
Baseline	64.5 (3.93)	56.2 (5.95)	69.8 (6.30)	68.3 (6.10)	0.23
Follow-up		70.7 (3.82)	63.1 (4.14)	69.6 (3.56)	0.37
Peak Flexion					
Baseline	43.8 (2.27)	38.2 (3.57)	47.8 (3.77)	45.9 (3.66)	0.15
Follow-up		47.7 (2.40)	43.7 (2.63)	45.9 (2.26)	0.55
Endurance#					
Peak Difference					
Baseline	6.0 (1.76)	3.9 (3.16)	6.0 (3.18)	8.0 (3.00)	0.65
Follow-up		11.2 (2.70)	10.3 (2.87)	11.5 (2.47)	0.95
Physical Performance**					
Walk, 8 feet					
Baseline	2.6 (0.06)	2.6 (0.10)	2.5 (0.10)	2.6 (0.09)	0.75
Follow-up		2.5 (0.11)	2.4 (0.12)	2.5 (0.10)	0.81
Walk, 50 feet					
Baseline	12.3 (0.21)	12.3 (0.33)	12.2 (0.34)	12.5 (0.31)	0.80
Follow-up		12.8 (0.32)	12.9 (0.43)	12.3 (0.36)	0.48
Chair stands					
Baseline	14.1 (0.41)	15.1 (0.64)	12.5 (0.67)	14.5 (0.62)	0.02
Follow-up		14.3 (0.59)	13.6 (0.65)	14.4 (0.54)	0.74
Functional reach††					
Baseline	31.0 (0.80)	30.4 (1.24)	31.0 (1.31)	31.5 (1.18)	0.81
Follow-up		32.7 (1.10)	33.3 (1.14)	31.5 (0.97)	0.45
Stair climb					
Baseline	9.4 (0.36)	9.7 (0.55)	9.5 (0.58)	9.1 (0.52)	0.72
Follow-up		9.3 (0.38)	9.7 (0.40)	9.8 (0.34)	0.63
Single leg stand‡‡					
Baseline	15.9 (1.48)	13.2 (2.12)	17.6 (2.23)	17.1 (2.02)	0.29
Follow-up		12.8 (1.96)	16.2 (2.09)	14.5 (1.76)	0.52
Bone Markers§§					
Osteocalcin					
Baseline	12.24 (0.80)	11.62 (1.42)	13.26 (1.51)	11.98 (1.33)	0.71
Follow-up		11.38 (0.80)	12.72 (0.86)	12.87 (0.75)	0.36
N-telopeptides					
Baseline	38.89 (2.98)	38.22 (4.93)	38.57 (5.76)	39.74 (4.79)	0.97
Follow-up		38.42 (2.95)	33.43 (3.45)	38.15 (2.86)	0.49

* For strength and performance outcomes, sample sizes at baseline were 19, 19, and 21 for no vest, 3% vest, and 5% vest, respectively. At follow-up sample sizes were 18, 16, and 21 in the same respective groups.
† Osteocalcin sample size were 17, 15, and 19 for no vest, 3% vest, and 5% vest at baseline and follow-up. N-telopeptide sample size were 19, 14, and 20 at baseline and follow-up in the same respective groups.
‡ All values are mean torque in Newton-meters (± standard error).
§ *P* value for F-test of equivalence of distributions among treatment groups at baseline or follow-up; models are adjusted for age and body mass index; follow-up models are also adjusted for baseline values of each outcome.
‖ Isometric strength measured at 120°.
¶ Peak isokinetic measure is the highest single value of 5 trials. All measures presented as absolute (positive) value.
\# Peak endurance difference is calculated as the highest value among repetitions (15 through 19) minus highest value among repetitions (2 through 6).
** All values are mean number of seconds (± standard error) except for functional reach, which is measured in centimeters.
†† Value given is maximum of three attempts.
‡‡ Single leg stand performed with eyes open.
§§ Units for osteocalcin are in ng/mL, units for N-telopeptides are nm BCE/mg creatinine. All measures are reported (± standard error).

Table 2. Baseline and 27-Week Mean Values (Standard Deviations) of Health-Related Quality of Life Measures by Treatment Assignment*

Measurements†	All Participants	No Vest	3% Vest	5% Vest	*P* Value‡
Physical Function					
Baseline	87.2 (1.7)	88.7 (2.9)	83.3 (3.0)	89.1 (2.8)	0.31
Follow-up		79.8 (3.2)	80.6 (3.6)	84.4 (3.2)	0.57
Emotional Well-Being					
Baseline	85.6 (1.5)	82.1 (2.6)	87.8 (2.7)	85.6 (2.5)	0.30
Follow-up		86.3 (1.6)	82.4 (1.7)	85.2 (1.6)	0.26
Role Limitations, Physical					
Baseline	92.3 (2.9)	92.2 (4.9)	83.4 (5.2)	100.2 (4.8)	0.07
Follow-up		78.5 (6.4)	77.0 (7.1)	81.7 (6.4)	0.89
Role Limitations, Emotional					
Baseline	96.8 (2.0)	97.4 (3.4)	93.9 (3.5)	98.6 (3.3)	0.61
Follow-up		95.1 (2.1)	100.2 (2.2)	100.0 (2.0)	0.16
Energy					
Baseline	69.5 (2.1)	68.5 (3.6)	71.6 (3.8)	68.7 (3.5)	0.81
Follow-up		67.2 (2.6)	66.4 (2.8)	66.5 (2.6)	0.97
Social Function					
Baseline	57.7 (1.8)	60.3 (3.2)	57.2 (3.4)	55.6 (3.1)	0.57
Follow-up		51.0 (3.0)	60.1 (3.3)	54.1 (3.0)	0.13
Pain					
Baseline	25.9 (2.9)	19.4 (5.0)	29.2 (5.0)	28.9 (4.7)	0.29
Follow-up		28.6 (4.7)	40.7 (4.8)	35.5 (4.4)	0.21
Internal HLOC					
Baseline	16.5 (0.6)	17.8 (1.1)	16.1 (1.2)	15.4 (1.1)	0.29
Follow-up		17.6 (1.1)	18.1 (1.2)	20.0 (1.1)	0.30
Powerful Others HLOC					
Baseline	27.9 (0.9)	29.1 (1.5)	27.1 (1.6)	27.5 (1.5)	0.60
Follow-up		30.4 (1.1)	29.0 (1.1)	26.5 (1.1)	0.04
Chance HLOC					
Baseline	29.3 (1.0)	29.8 (1.6)	27.5 (1.7)	30.3 (1.6)	0.45
Follow-up		29.9 (1.0)	30.8 (1.1)	29.9 (1.0)	0.78
Falls Efficacy					
Baseline	93.7 (1.0)	92.7 (1.7)	93.5 (1.8)	94.9 (1.4)	0.67
Follow-up		91.1 (1.8)	91.1 (2.0)	90.7 (1.8)	0.99

* Sample sizes at baseline were 21, 19, and 22 for no vest, 3% vest, and 5% vest, respectively. At follow-up, sample sizes were 21, 18, and 22 in the same respective groups.
† All values except HLOC are scaled 0–100, where higher values indicate better function or less pain. Some mean values exceed 100 because they are least squares estimates; adjustment for covariates and balancing may cause values that exceed the crude maximum. HLOC scales range from 6 to 42; higher values indicate better (more internal) locus of control.
‡ *P* values for F-test of equivalence of distributions among groups; follow-up models are adjusted for age, body mass index, and baseline values of each measure.

The analyses of strength, endurance, physical performance, bone turnover markers, and health-related quality of life were repeated for those participants who were adherent. No substantive differences between the intention-to-treat and adherent analyses were evident (data not shown).

DISCUSSION

Despite previous data from our group[14,15] and from other researchers[9,10] supporting the thesis that low intensity training stimulus can increase muscle strength in older persons, the present study found that wearing a weighted vest had no discernible effect on strength or physical performance. To produce strength gains, the required stimulus is relative; it must be tailored to the condition of the participants at the start of training. The higher the individual's initial strength or performance, the greater the required stimulus; the magnitude of the necessary stimulus is also determined by the desired degree of strength increase.[30]

That our volunteers were too fit at the outset to derive benefit from the vest stimulus may explain this study's null results. Our participants were not extraordinarily strong compared with other, similarly aged men and women volunteers in previous, successful, low-to-moderate intensity strength training experiments.[9,10,26,31,32] Using isokinetic dynamometry at 60°/second, baseline knee extensor strength in these studies ranged between 50 and 89 Nm, quite comparable to the peak extension torques that we observed. These programs employed light to moderate resistance training with specified exercises and resistive devices such as ankle weights, sandbags, and therabands, resulting in 10 to 20% strength improvements. The current study applied a novel stimulus—wearing a small amount of vest weight over a long duration (2 hours) 4 times a week. We conclude, from the absence of any effect on strength or performance, that the vest intervention did not reach the lower limit of a training stimulus for the muscle groups and tasks assessed.

In contrast to our low-intensity vest intervention, Shaw and Snow used a weighted vest as part of a sophisticated program of graduated, cyclical resistance training.[33] At 9 months, lower body muscle strength increased by 16 to 33%. The independent contribution of the vest to strength improvement cannot be determined, however, as it was studied only as a component of a complex weight-bearing exercise intervention. Importantly, the training stimulus provided by Snow et al., the specified nature of the exercise protocol, as well as the degree of participant supervision needed far exceeded those of the present trial.

We also hypothesized that the weighted vest might have a bone preserving effect. The amount and type of physical activity required to prevent bone loss remains uncertain. At the extremes of inactivity, such as immobilization, bone is rapidly lost; conversely, bone density of the dominant arms of competitive tennis players is substantially greater than that of their nonplaying arms.[34] However, the optimum frequency and intensity of bone loading to preserve bone mass has been difficult to determine. From an adherence perspective, particularly among deconditioned older individuals, a low-intensity intervention is attractive. Models suggest that low-intensity, high-frequency stimuli may benefit bone, albeit less so than high intensity stimuli.[35] Notably, a pilot study in 34 early postmenopausal women that used a mechanical device to apply very small, high frequency skeletal loads found that after 12 months, placebo-treated women lost 3.8% of spinal bone density, whereas recipients of mechanical stimulation experienced a statistically significantly smaller loss of 1.0%.[36] We proposed that the vest would be an intense, long-duration musculoskeletal load and could possibly influence bone metabolism via muscular forces or by direct action via biomechanical perturbation of mechanoreceptor cells. Because 6 months time is too short to expect to see increases in bone density, bone turnover markers were used as the outcome measure. Bone turnover assays are sensitive, respond rapidly, and are sensitive to change, decreasing by 30 to 40% within 12 weeks when pharmacological antiresorptive agents are used.[37] There are few published reports of the effect of physical activity interventions on bone markers, and most involved young subjects and were of short duration.[38–41] However, one nonrandomized, 16-week strength training study conducted in middle-aged men found a statistically significant increases of 19% in OC and a 26% increase in bone alkaline phosphatase in the intervention group.[41]

In an earlier study, subjects using a weighted vest for 6 months shifted to a more internal health locus of control and reported less bodily pain compared with an attention control group.[14] Our present study did not reproduce these findings, nor did it affect the domain of falls efficacy. Participants began the study with very little fear of falling, however, making it difficult to observe improvement in falls efficacy. Although the vest did not cause strength gains in the current project, it might nonetheless have led to an improved sense of control on the basis of participation in a "healthy activity". However, in contrast to our expectation, one of the health locuses of control subscales became less internal in the 5% vest group compared with the control group. The magnitude of the difference was small and may have been due to chance, given the multiple statistical tests performed. At baseline, participants rated themselves in the approximate middle of the remaining two health locuses of control scales; thus, it is not likely that the lack of improvement in these subscales was caused by a ceiling effect.

We do not ascribe these negative results to poor adherence, although assessing adherence to a home-based program of vest use is challenging. Many subjects reported accurate vest use verbally, but we accepted only completed diaries as documentation. Using this conservative approach, adherence was low, at 55 to 58%. We believe this likely represents the arduousness of completing a daily record rather than the actual rate of ideal vest wearing. Nonetheless, using this stringent classification, adherent analyses were not different from those performed by randomization.

The limitations of the study must be considered. First, our sample appears modest in size, with 55 subjects (18 no vest, 16 3% BW, and 21 5% BW) completing both pre- and postintervention measures of knee extensor strength. However, sample size and power were planned a priori, and the goal of 16 completed subjects per group was achieved. This permitted an 85% chance (at the 5% level) of detecting a 10% difference in knee extensor strength between the control and the 3% groups and a 20% difference in this measure between the control and the 5% groups. Our sample size also provided 80% power to detect a difference of 20% in bone markers between control and intervention groups. It was not possible to mask this study, as a placebo vest (one without weights) would have been transparent. One would expect, however, that knowledge of the vest-wearing assignment would have led to a bias in favor of the treated group.

In summary, among high functioning ambulatory older adults, we found no effect of a 3% or 5% weighted vest on numerous measures of strength, physical function, bone turnover, and health-related quality of life. We propose that further work with this novel intervention should focus on making the training stimulus greater, without abandoning the accessibility of the intervention. This could be implemented by using the present doses of the vest in less conditioned (frailer) older persons or by employing higher weight loads or longer durations, perhaps in conjunction with walking, among ambulatory older persons similar to these who participated in this project.

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