Group Treatment Improves Trunk Strength and Psychological Status in Older Women with Vertebral Fractures: Results of a Randomized, Clinical Trial

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OBJECTIVES: To assess whether group exercise and coping classes reduce physical and psychological impairments and functional disability in older women with prevalent vertebral fractures (VFs).

DESIGN: Randomized, controlled trial (modified crossover) with site as unit of assignment; testing at baseline and 3, 6, 9, and 12 months.

SETTING: Nine North Carolina retirement communities.

PARTICIPANTS: One hundred eighty-five postmenopausal Caucasian women (mean age 81), each with at least one VFs.

INTERVENTION: The intervention group had 6 months of exercise (3 meetings weekly, 45 minutes each) and coping classes (2 meetings weekly, 45 minutes each) in Phase 1, followed by 6 months of self-maintenance. The control group had 6 months of health education control intervention (1 meeting weekly, 45 minutes) in Phase 1, followed by the intervention described above.

MEASUREMENTS: Change in trunk extension strength, change in pain with activities, and change in psychological symptoms.

RESULTS: Between-group differences in the change in trunk extension strength (10.68 foot pounds, $P<.001$) and psychological symptoms (-0.08, $P=.011$) were significant for Phase 1. Changes in pain with activities did not differ between groups (-0.03, $P=.64$); there was no change in the pain endpoint. In Phase 2, controls showed significant changes in trunk strength (15.02 foot pounds, $P<.001$) and psychological symptoms (-0.11, $P=.006$) from baseline. Change in pain with activities was not significant (-0.03, $P=.70$). During self-maintenance, the intervention group did not worsen in psychological symptoms, but improved trunk extension strength was not maintained.

CONCLUSION: Weak trunk extension strength and psychological symptoms associated with VFs can be improved in older women using group treatment, and psychological improvements are retained for at least 6 months. **J Am Geriatr Soc 52:1471–1478, 2004.**

Key words: osteoporosis; vertebral fractures; exercise; psychosocial; interdisciplinary intervention; quality of life

Osteoporosis is a skeletal disease that diminishes bone strength and increases risk of fracture.[1] Forty-four million Americans have or are at high risk of developing osteoporosis, resulting in 1.5 million new fractures annually.[2] Although hip fractures are devastating, vertebral fractures (VFs) are more prevalent and cause substantial morbidity and mortality.[3] Five percent of 50-year-old and 25% of 80-year-old non-Hispanic Caucasian women have had at least one VF.[4]

The overall effect of VFs on patients is poorly understood. Several studies have shown that clinically diagnosed VFs are associated with pain, trunk weakness, deformity, disability, and impaired psychological function,[5–7] but it has been estimated that two-thirds of VFs do not come to medical attention.[8,9] Results of cross-sectional studies of older women have demonstrated no association,[10,11] a modest association,[12,13] or strong associations[14] between VFs and back pain, functional limitations, or disability, making it difficult to characterize their outcomes, but recent

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studies of VFs suggest that they have a substantial negative effect on health-related quality of life.[12,14]

In recent years, osteoporosis medications have proliferated. Randomized, controlled trials have shown that atraumatic fractures can be prevented with calcium and vitamin D;[15] with antiresorptive agents such as bisphosphonates (alendronate[16] and risedronate[17]), calcitonin,[18] estrogen,[19] and raloxifene;[20] and with anabolic agents (teriparatide[21]), but much less is known about nonpharmacological interventions for women with VFs.[22] Because of this gap in knowledge about effectively treating nonbone sequelae of VFs, a randomized, controlled clinical trial was performed of an intervention designed to improve three specific negative consequences of VFs: weak trunk extension strength, pain with activities, and impaired psychological status. It was hypothesized that a 6-month group exercise and coping class intervention taught by a physical therapist and a social worker would improve these outcomes in older women with prevalent VFs living in continuing care retirement communities (CCRCs) more than the outcomes of women with prevalent VFs who received a general health education intervention. Secondary hypotheses were that the control group, without an intervention, would worsen over 6 months of observation, the control group would improve once they received the targeted intervention, and the intervention group could maintain the positive effects of the intervention during 6 months of self-maintenance. The ultimate objective was to determine the effectiveness of a multidisciplinary intervention that could be used in clinical settings to reduce disability associated with VFs.

METHODS

Study Design

This experiment was a group randomized, modified crossover trial. The unit of randomization was site because of concern about between-group contamination in the unusually close living arrangements of CCRC residents. Randomization was performed using a random number generator with equal allocation to the two arms. All researchers except the biostatistician were masked to allocation status until a site was enrolled. Furthermore, all personnel involved with subject contacts, data collection, and intervention administration were masked to the intervention status of the sites and to the study hypotheses throughout the trial. In addition, participants were unaware of the content of the intervention that they did not receive initially. The trial profile is presented in Figure 1.

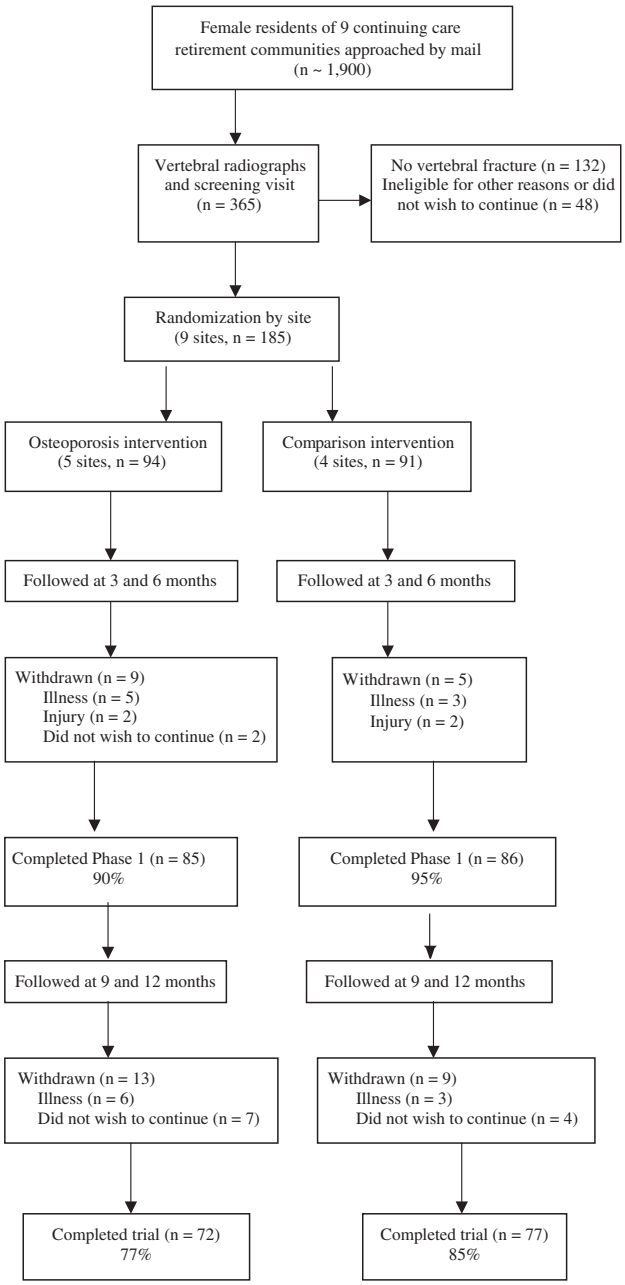

Figure 1. Trial profile.

Recruitment

Retirement communities were sites for this trial because of the high prevalence of osteoporosis and VFs in their residents. This setting also minimized logistical problems for presenting interventions and measuring outcomes and minimized loss to follow-up. The Duke University Medical Center institutional review board approved the study protocol to include women in independent or assisted living CCRCs.

Recruitment strategies were identical at each site. Each woman had three spinal radiographs: a lateral thoracic spine, breathing technique; an anterior-posterior lumbar spine; and a lateral lumbar spine. A clinician with experience in osteoporosis (KWL) and the study's skeletal radiologist (SM) read all films. VFs were identified if a vertebral body had a 20% or greater reduction in anterior, central, or posterior height compared with adjacent vertebrae. When there was disagreement about the presence or absence of a VF, both readers reviewed the films simultaneously and discussed them until consensus was reached. Women without at least one 20% VF were ineligible for the study.

Each subject then underwent a medical history and physical experimentation. Women were excluded if they had had a hip fracture in the last year or a clinical VF in the previous 6 months; more than two errors on the Short Portable Mental Status Questionnaire;[23] corrected vision worse than 20/40; active cardiac, pulmonary, or neurolog-

ical disease or rheumatoid arthritis; or an injurious fall in the previous 6 months or could not ambulate independently (assistive devices acceptable)

Intervention

The content of the interventions is presented in Table 1.

The exercise intervention focused on common physical consequences of VFs: trunk weakness, reduced trunk flexibility in the direction of extension, and difficulty with erect posture both sitting and standing. Specific exercises included stretches to increase cervical dorsal glide, thoracic and lumbar extension, and shoulder flexion to increase the length of the hip flexors, hamstrings, and plantar flexors. Progressive strengthening exercises were used for trunk extensors, lower trapezius, middle trapezius, rhomboids, abdominals via stabilization,[24] hip abductors, and hip extensors. To strengthen the trunk extensors, participants who could tolerate prone positioning (lying face down) performed trunk lifts against gravity in a prone position, progressed to holding small weights in their hands (up to 3 lbs in each hand) as they performed the trunk lifts. Participants who did not tolerate a prone position performed trunk extension seated with the physical therapist exercise instructor providing manual resistance. These participants progressed to prone trunk lifts (against gravity and against gravity holding weights) as tolerated. Rubber bands of varying densities were used for lower trapezius, middle trapezius, and rhomboid strengthening. Exercise sessions also taught subjects about safe exercise, optimal skeletal alignment, body mechanics for activities of daily living and recreational activities, deformity caused by VFs, and avoiding forward bending and twisting to prevent high-risk loading of the vertebral bodies.

The coping intervention focused on reducing psychological problems commonly experienced after VFs: anxiety, depression, and stress. The material concentrated on the appropriate use of specific active and passive coping skills (e.g., direct action and inhibition of action[25]), accessing and accepting social support, and physical and emotional relaxation and stress-reduction strategies.

The control phase included a weekly class that focused on health issues of older women. The content of interventions at all sites was standardized. Instructors followed manuals written by the investigators, and two investigators (KMS and DTG) completed preintervention training.

MEASURES

Measurement sessions had three parts: self-report demographic and health-related measures, physical impairment and performance measures taken by a physical therapist, and psychological measures taken by a research assistant. A standard written protocol was used for all measures, which were taken at baseline, 6 months, and 12 months. In addition, the three primary outcome measures were assessed at 3 months and 9 months. Specific measures are described below.

Primary Outcome Measures

Three primary outcome variables (trunk extension strength, pain with activities, and psychological symptoms) were identified for this study.

Table 1. Study Design: Phase 1 (First 6 Months)

Subject group	Topic	Frequency	Instructor	Content
Intervention	Exercise class	3 × week for 45 minutes	Physical therapist	General osteoporosis education and exercise directed toward improving osteoporosis-related impairments
	Coping class	2 × week for 45 minutes	Psychiatric social worker	General and osteoporosis-specific coping skills, stress reduction/relaxation, social networking skills, and lifestyle modifications appropriate for osteoporosis management
Control	General health concerns of older women	1 × week for 45 minutes	Registered nurse	General information about screening for, preventing, and treating diseases such as hypertension, diabetes mellitus, breast cancer, and urinary incontinence
Intervention	Self-maintenance period (no group class)	Individual volition	None	Participants were instructed to continue their exercises and coping skills as they had learned them in the classes during the previous 6 months; each was given a log to record exercise
Control	Exercise class	3 × week for 45 minutes	Physical therapist	General osteoporosis education and exercise directed toward improving osteoporosis-related impairments
	Coping class	2 × week for 45 minutes	Psychiatric social worker	General and osteoporosis-specific coping skills, stress reduction/relaxation, social networking skills, and lifestyle modifications appropriate for osteoporosis management

Trunk extension strength (peak isometric torque in foot pounds) was measured using a standard protocol with the B-200 Isostation (Isotechnologies, Inc., Hillsborough, NC).[26] In sitting position, subjects performed one submaximal and one maximal 5-second practice trial of thoracic trunk extension, then three maximal 5-second trials with a 45-second rest between each trial. The mean peak torque of the three trials of thoracic trunk extension was used for analysis. Test-retest reliability (interclass correlation coefficient (ICC) = 0.76) and interrater reliability (ICC = 0.93) were determined in healthy older women without VFs over 1 to 2 weeks. Test-retest stability of the measure over 2 months in older women with VFs was correlation coefficient = 0.76.[26] Mechanical problems with the B-200 required that date be excluded from the first three sites (1 control (n = 22) and 2 intervention sites (n = 41)). Because of this problem, all analyses using peak torque have a sample size of 122 (3 intervention sites (n = 53); 3 control sites (n = 69)). Participants did not train or exercise using the B-200; their only exposure to this equipment was during testing sessions.

Pain with activities was measured using the pain subscale of the Functional Status Index (FSI).[27] Test-retest reliability with older adult samples on all subscales of the FSI ranges from 0.65 to 0.81; interrater reliability is higher than test-retest.[26–28] As noted earlier, all subjects lived in CCRCs, where employees at the sites completed many functional tasks that otherwise might be required of an older adult. To accommodate this, minor wording modifications were made to the FSI. The Cronbach alpha for the revised version in the sample was 0.931.

Psychological symptoms were measured using the Global Severity Index (GSI) of the Hopkins Symptom Checklist 90—Revised.[29] This instrument asks 90 questions about the existence of specific psychological symptoms and how much each had distressed the subject during the previous week. Responses range from 0 (not at all) to 4 (all the time). Individual endorsements are summed and divided by 90 to calculate the GSI. This scale has been used previously with older women with osteoporosis, and alpha coefficients range from 0.95 to 0.96.[30–31] Higher scores on the GSI indicate more frequent and severe psychological symptoms.

Because randomization was by site, the following covariates were included: age, education (measured in years), number of VFs (taken from the three radiographs described earlier), back pain (single item that asked "Within the last month, have you had pain in your back?" with yes = 1), number of comorbid symptoms (respondents were asked whether they had experienced 22 symptoms of chronic diseases or serious health conditions; positive responses were coded as 1, and scores were summed).

Analysis

Analyses for this trial were completed on an intention-to-treat basis, and data from all women who entered the trial and who came to measurement sessions were analyzed by initial group assignment, irrespective of compliance or participation in the intervention. A mixed model analysis of variance as implemented under the SAS mixed models procedure was used for the analyses (SAS Institute, Inc., Cary, NC).[32] This allowed us to employ the class of models that extends the standard repeated measures design to include subjects with missing values.[33] Analysis of Phase 2 data from the control group provided potential validation of the results obtained in Phase 1 of the study.

The primary hypotheses involved the three outcome variables discussed earlier: trunk extension strength, pain with activities, and psychological symptoms. Because of randomization by site, parameter estimates for the intervention effect were calculated controlling for site nested within intervention group, assuming that site was random (the unadjusted model). Then adjusted models were estimated incorporating the covariates listed above and controlling for site nested within intervention group. To control the overall type I error rate, a Bonferroni correction of the overall alpha level (0.05) for three outcome variables was calculated (0.05/3 = 0.0167). Because there were no substantive differences between unadjusted and adjusted models, only the adjusted models are presented.

RESULTS

Study Participants

Baseline demographic characteristics for the study sample are shown in Table 2. Baseline values of the dependent variables are shown in Table 3. All 185 participants were non-Hispanic Caucasian women. Each site had several minority residents, but none qualified for the study. Equal proportions of both groups reported back pain in the last month (40% in each group). The only variable on which the intervention and control groups differed significantly was the number of comorbid symptoms, with the control group having a slightly higher mean number of symptoms.

Attendance

The instructors reported attendance at exercise, coping, and health education classes weekly. Mean attendance for the intervention group (Phase 1) was 58% for the exercise class and 57% for the coping class. Mean attendance for control group in Phase 1 was 77% for the health education class. Mean attendance for the control group in Phase 2 was 65% for the exercise class and 62% for the coping class. These means did not differ significantly by site or by treatment group.

Table 2. Baseline Characteristics of Intervention and Control Groups (N = 185)

Characteristic	Intervention Group (n = 94)	Control Group (n = 91)
	Mean ± Standard Deviation	
Age	80.2 ± 4.8	82.0 ± 6.2
Education, years	15.1 ± 2.6	14.5 ± 2.6
Vertebral fractures, n	2.6 ± 2.2	2.8 ± 1.4
Comorbid symptoms, n	4.0 ± 1.8	4.3 ± 2.0*
Effect of health problems (range 1–3)†	1.9 ± 0.7	1.9 ± 0.7

* $P = .04$.
† 1 = no effect to 3 = major effect.

Table 3. Baseline Values of Dependent Variables (N = 185)

Dependent Variable	Intervention Group (n = 94)	Control Group (n = 91)
Trunk-extension strength (n = 122) (foot pounds) (range 0–80)*	27.31 ± 14.34	28.07 ± 11.97
Pain with activity (range 1–4)†	1.34 ± 0.54	1.30 ± 0.50
Psychological symptoms (range 0–4)‡	0.35 ± 0.30	0.31 ± 0.24

Between-group comparison at baseline: * $P = .77$; † $P = .60$; ‡ $P = .24$.

Adverse Events

Four adverse events were associated with the exercise classes during approximately 8,000 contact hours during the trial. One subject fractured a costal cartilage while performing prone exercise, one subject fractured a rib while rolling from supine to prone, and two subjects had increased pain (one reported neck pain, the other reported back pain) so that they missed classes and saw a physician who diagnosed the pain as being of soft tissue origin. In addition, two adverse events occurred during data collection. One subject was diagnosed with a hip fracture after she had her 6-month physical examination and demographic data collection. One subject sustained a metatarsal fracture when a 2-pound weight fell on her foot.

Hypothesis Testing

The results of the trial are shown in Figure 2 and in Tables 4 and 5 (adjusted model).

Test of the Primary Hypothesis

Figure 2 shows changes in trunk extension strength, pain with activities, and psychological symptoms during the 12 months of the trial. During Phase 1 of the trial, the control group decreased in trunk extension strength and increased (worsened) in pain with activities and psychological symptoms. In contrast, the intervention group change scores showed improvement in all three outcomes. After adjusting for covariates, a significance test of the difference between groups in the change scores showed that change was significantly greater in the intervention group than in the control group for trunk extension strength and psychological symptoms but not for pain with activities (Table 4).

Tests of the Secondary Hypotheses

As noted above, trunk extension strength, pain with activities, and psychological symptoms all worsened for the control group during Phase 1 of the trial, but only the decline in trunk strength ($P < .001$) and increase in psychological symptoms ($P = .005$) were statistically significant. The change in pain with activities was not significant ($P = .92$).

During Phase 2, the control group participated in the group intervention, and the intervention group practiced self-maintenance of their new skills for 6 months. Data from this phase are shown in Table 5 and indicate that the control group significantly improved trunk extension strength ($P < .001$) and psychological symptoms ($P = .0064$) relative to its change in Phase 1 but that pain with activities did not change significantly ($P = .68$).

During Phase 2, members of the intervention group practiced self-maintenance. It had been hypothesized that the self-maintenance program would allow this group to

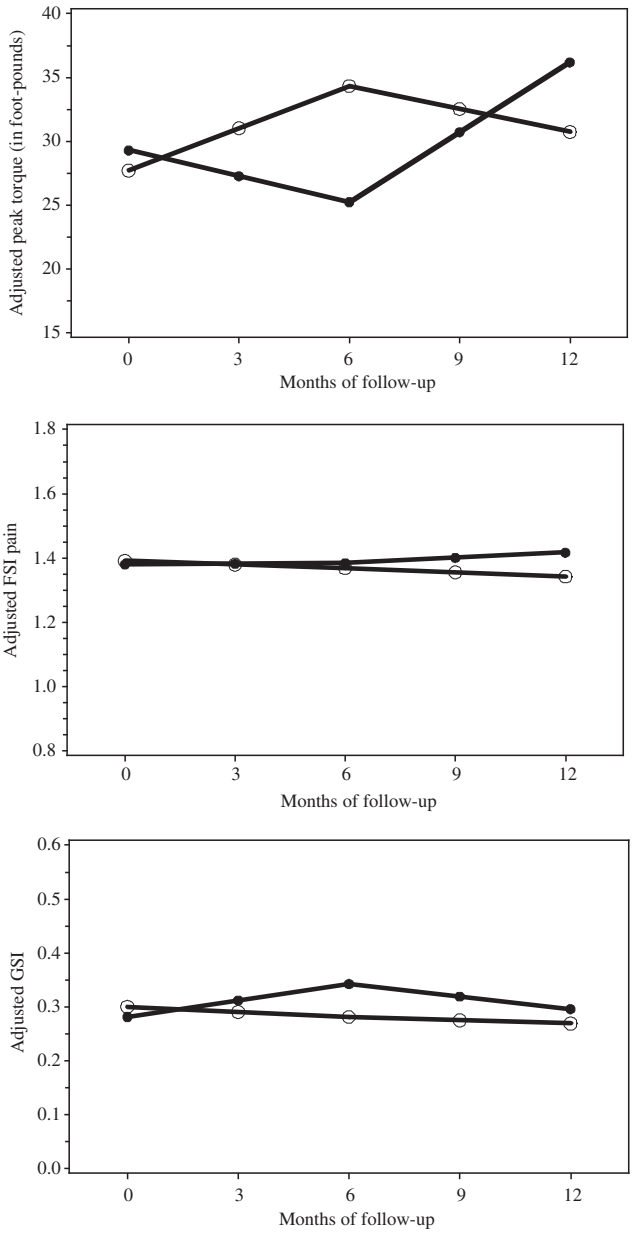

Figure 2. A. Adjusted mean trunk-extension strength, controlling for site, age, number of fractures, number of comorbidities, self-reported back pain, and baseline peak torque. (n = 122). • = control group; ○ = intervention group.
B. Adjusted mean pain with activity, controlling for site, age, number of fractures, number of comorbidities, self-reported back pain, and baseline Functional Status Index (FSI) (n = 185). • = control group; ○ = intervention group.
C. Adjusted mean psychological symptoms, controlling for site, age, number of fractures, number of comorbidities, self-reported back pain, and baseline Global Severity Index (GSI) (n = 185). • = control group; ○ = intervention group.

Table 4. Comparison of Phase 1 Change Scores for Intervention and Control Groups (N = 185)

Variable	Intervention Group Change Score	Control Group Change Score	Difference in Change Score Parameter Estimate (95% Confidence Interval)	*P*-value for Difference in Change Score
Peak torque 0 to 6 months (n = 122)	6.628	−4.560	10.68 (6.98–14.39)	<.001
Pain with activities 0 to 6 months	−0.022	0.004	−0.03 (−0.14 −0.08)	.64
Psychological symptoms 0 to 6 months	−0.018	0.062	−0.08 (−0.2 −0.10)	.01

Note: Adjusted for site, age, number of fractures, number of comorbidities, self-reported back pain, self-reported health problems, and baseline level of the outcome measures.

sustain gains in outcomes from Phase 1, but as seen in Table 5, the intervention group experienced a decline in back strength during Phase 2 ($P = .02$). The improvement in psychological symptoms for the intervention group did not change during Phase 2 ($P = .60$). Pain with activities did not change during Phase 2 ($P = .54$).

DISCUSSION

Data from this trial show that participation in this multidisciplinary group intervention significantly increased trunk extension strength and decreased psychological symptoms of older women with prevalent VFs. Once the intervention was withdrawn, the improvement in psychological symptoms did not change, but trunk extension worsened. The intervention did not change self-reported pain with activities.

This randomized, controlled trial is atypical for osteoporosis, for which trials usually focus on the effectiveness of pharmacological therapies[34] or the benefit of exercise,[35–39] with increased bone density as the objective. Two studies examined the effect of exercise programs on impairments related to VFs, including reduced shoulder flexion range of motion[40] and thoracic kyphosis,[41] but the samples in these studies were limited to postmenopausal women without documented VFs. One study[22] found that a 10-week exercise intervention decreased pain and analgesic use in women (aged 55–75) with at least one VF. Although this study[22] did not include a psychological intervention, quality of life scores improved throughout the study. Although it has been demonstrated that trunk extension strength can be improved in postmenopausal women,[42–44] this is the first work to report an increase in trunk extension strength in older women (mean age = 81) with VFs after an exercise intervention. In addition, no published work of which the authors are aware has combined coping and exercise interventions with VF patients.

In this study, subjects in the control group during Phase 1 experienced declines in trunk extension strength and psychological symptoms. This suggests that, in the absence of intervention, these VF sequelae become worse over time, but once the control group received the intervention in Phase 2, results were similar to those of the intervention group in Phase 1: trunk-extension strength increased, psychological symptoms decreased, and pain with activities did not change. The similarity in outcomes for the two groups strengthens the findings of this investigation.

The magnitude of the mean change in trunk-extension strength at the end of the exercise classes (changes of 24% for the intervention group and 45% for the control group) is comparable with changes reported by other investigators. Another study[45] reported increases in postmenopausal women of 32% in strength over 3 months and 25% per year for 2 years. In these studies, mean age of participants was 56; in the current study, respondents had a mean age of 81. Specific exercises used for trunk-extension strengthening were similar in all three studies, but in the current study, sitting isometric trunk extension was performed in addition to prone hyperextension. People with spinal deformity for whom prone positioning is difficult or impossible often better tolerate seated isometric exercise for extensor strengthening. In addition, this study used strengthening exercises for scapular muscle groups and exercises designed to increase trunk extension flexibility.

The reduction in psychological symptoms after the intervention in both groups may result from multiple components of the coping intervention. First, knowing that others suffer the same negative consequences of osteoporosis and VFs normalizes most women's perception of osteoporosis. In earlier work,[30,31] older osteoporotic

Table 5. Within-Group Comparison of Phase 2 Change Scores for Intervention and Control Groups

Variable	Intervention*		Control†	
	Parameter Estimate (95% CI)	*P*-value	Parameter Estimate (95% CI)	*P*-value
Peak torque (n = 122)	−3.60 (−6.40 −1.71)	.02	15.02 (10.80–19.27)	<.001
Pain with activities	−0.03 (−0.11 −0.06)	.54	−0.03 (–0.11 to –0.17)	.70
Psychological symptoms	−0.01 (−0.06 −0.03)	.60	−0.11 (10.19–10.30)	.006

Note: Adjusted for site, age, number of fractures, number of comorbidities, self-reported back pain, self-reported health problems, and baseline level of the outcome measures.

* Relative to final value at end of Phase 1 (intervention).

† Relative to change during Phase 1 (first 6 months).

women initially reported that the problems they experienced were idiosyncratic, that others without fractures could not relate to or understand the multiple difficulties engendered by VFs. Having the opportunity not only to identify others with similar problems but also to share management techniques and frustration offered these women the benefits of a support group.

A second component of the psychological intervention was stress reduction. Each session began with relaxation exercises designed to gain control over emotions and minimize frustration. Not only people with osteoporosis but also older adults with other chronic diseases can use this technique, but data from this trial do not allow us to test the individual effect of intervention components. Such testing should be done in future research.

Although study subjects showed improvements in two outcomes, the intervention did not change the third primary outcome—pain with activities. Several possible reasons for this exist. First, the sample included all women with one or more radiographically detected VFs, not just women with VFs who had back pain and current disability resulting from back pain or vertebral deformity. At baseline, only 40% of the sample reported pain in any location during the previous month. The low prevalence of VF-related pain in the sample may explain why the outcome of pain with function did not change. Second, the pain with activity subscale of the FSI was designed to measure arthritis disability, not osteoporotic pain. Finally, the CCRC environment in which subjects lived may not have offered sufficient opportunities to detect improvement in pain with function. The scale that measured pain with activities asked only about tasks performed in the previous week. Unless women deliberately sought to apply these skills in their daily functioning, it is possible that the routine of CCRCs never offered them the opportunity to test and sustain such improvements.

Regarding maintenance of improvements after withdrawal of the intervention, it must be asked, "Why did the psychological improvements persist and the physical gains did not?" Attitudes toward exercise and the difficulty in sustaining exercise without structured support may have played a part in this result. Continuing individualized exercise over time requires substantial self-discipline, strong motivation, and a considerable time commitment each week. By comparison, the psychological coping skills these women learned could be used anywhere and could be applied to stresses other than those of osteoporosis. The broader applicability of coping skills may partially explain why postintervention changes on these outcomes differed.

This study had some limitations. First, because subjects were non-Hispanic Caucasian female residents of retirement communities who lived independently or in assisted living, findings cannot be generalized to the entire older population. Second, because the exercise and coping interventions occurred concurrently, their unique effects cannot be differentiated. Had cost not been a concern, each intervention would have been tested separately to see whether both were potent, and then the interventions would have been combined to determine whether the effects were synergistic. Third, this group of women had high levels of education, which may have contributed positively to their ability to understand and apply the psychological coping strategies. This trial did not allow us to test whether women with less education could also benefit from this type of intervention.

This study contributes to the understanding of successful rehabilitation for older women with VFs in several ways. First, group coping skills classes can improve psychological symptoms, and these improvements can be sustained for at least 6 months after the intervention. Second, older women with prevalent VFs can improve trunk-extension strength, but the improvement will not necessarily be sustained without continued intervention. Future investigations should explore whether an increase in trunk-extension strength leads to other favorable outcomes, such as improved function, reduced disability, and reduced VF incidence[46] in this population. Equally important, future research should be done with women of differing races, educational levels, and ages to determine its applicability to a larger number of women with osteoporosis.

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