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A comparison of strength-training, self-management and the combination for early osteoarthritis of the knee

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Abstract

Objective—To assess the relative effectiveness of combining self-management and strength-training for improving functional outcomes in early knee osteoarthritis patients.

Methods—A randomized intervention trial lasting 24 months conducted at an academic medical center. Community dwelling middle-aged adults (N=273), aged 34 to 65 with knee osteoarthritis, pain and self-reported physical disability completed a strength-training program, a self-management program, or a combined program. Outcomes included five physical function tests (leg press, range of motion, work capacity, balance, and stair climbing) and two self-reported measures of pain and disability.

Results—A total of 201 (73.6 %) participants completed the 2-year trial. Overall compliance was modest - strength-training (55.8 %), self-management (69.1 %), and combined (59.6 %) programs. The three groups showed a significant and large increase from pre- to post-treatment in all physical functioning measures including leg press (d =.85), range of motion (d=1.00), work capacity (d=.60), balance (d=.59), and stair climbing (d=.59). Additionally, all three groups showed decreased self-reported pain (d=-.51) and disability (d=-.55). There were no significant differences among groups.

Conclusions—Middle-aged, sedentary persons with mild early knee osteoarthritis benefited from strength-training, self-management, and the combination. These results suggest that both strength-training and self-management are suitable treatments for early onset of knee osteoarthritis in middle-aged adults. Self-management alone may offer the least burdensome treatment for early osteoarthritis.

Osteoarthritis is the most common arthritis form and the second leading cause of long-term disability in the United States [1]. Osteoarthritis of the knee typically affects women more than men and has a prevalence between 10-15% at age 35 to 35-45% at age 65 [2]. Currently the most prevalent chronic condition among women [3], osteoarthritis warrants serious concern.

Aerobic and resistance exercise [4] and self-management [5,6] produce positive changes in objective functional and patient-reported outcomes for knee osteoarthritis. These findings

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led the American College of Rheumatology to support both therapeutic approaches in their updated treatment guidelines [7]. Most studies documenting these effects sample older patients and compare the two treatments with each other [8] or compare one to some form of treatment as usual [9]. Older patient samples have longer disease durations, greater osteoarthritis severity and greater functional impairment, thus do not represent all patients with knee osteoarthritis.

Three questions remain from the literature. First, would strength-training or selfmanagement produce significant improvements with younger, sedentary, and less disabled patients with mild knee osteoarthritis? Although the combination of these characteristics describes the majority of early knee osteoarthritis patients, previous studies have not provided conclusive information on this typical combination, as their samples captured only one or two of these features per study. Second, would combining the two treatments improve functional outcomes more than strength-training or self-management alone? Recent meta-analytic results [10] explicitly omitted studies that combined the treatments, so there is scant evidence on the benefit of multidimensional treatments relative to strength-training and self-management alone. Since both treatments may address physical and psychological functional outcomes. Third, would outcomes differ between objective or self-reported measures? In many cases, patient-reported outcomes differ from objective physical functioning measures [11].

The Multidimensional Intervention for Early Osteoarthritis of the Knee ("Knee Study") was designed to test these questions directly by comparing strength-training, self-management, and their combination for improving patients' physical functioning and pain measured by both objective tests and patient self-report.

Patients and Methods

Design

The Knee Study was a 24-month non-blinded randomized intervention trial to compare the effects of three interventions: a strength-training program, a self-management program, and a combined strength-training and self-management program. The study was conducted with IRB approval in accordance with the Helsinki Declaration at the University of Arizona Arthritis Center in Tucson, AZ. All study participants gave written informed consent prior to randomization. Two-hundred and seventy three (N=273) participants were stratified by sex and randomly assigned by the project coordinator via a random number table to one of three treatment groups.

Participants

Knee Study participant eligibility criteria were (1) between the age of 35 and 64 years; (2) reported pain on most days in 1 or both knees; (3) duration of symptoms of less than 5 years; (4) had Kellgren and Lawrence classification (KL) [12] grade II radiographic evidence of knee osteoarthritis in one or both knees; and (5) self-reported disability due to knee pain for at least 3 of the following: descending or ascending stairs, walking, kneeling, or performing daily activities.

Potential participants were excluded if they had (1) an uncontrolled medical condition that precluded safe participation or prevented completion of the study (e.g., heart disease, blood pressure or respiratory conditions); (2) any neurological condition that could affect coordination; (3) inflammatory arthritis (e.g., rheumatoid or psoriatic arthritis); (4) previous knee surgery; (5) KL grades III or IV radiographic evidence of osteoarthritis in one or both knees; (6) a BMI > 37.5 - individuals over that limit were advised to follow a weight loss

program and achieve stable weight for 6 months prior to participation; (7) a knee corticosteroid injection in the previous 3 months; (8) plans to move from the local area; (9) plans to become pregnant during the study period; (10) more than 120 minutes per week of any vigorous (e.g., exercise, walking, household chores, etc.) physical activity; or (11) participated in any form of resistance training.

Staff recruited participants from the local community by mass mailings, television/ newspaper advertisements, and flyers. After telephone screening by study staff, individuals who met initial eligibility criteria underwent a radiographic exam administered by a staff rheumatologist. Individuals meeting all eligibility criteria were followed for a run-in period (mean = 73 days) after random assignment (via concealed computer generated values) to one of three treatment groups as described above.

Interventions

Strength-training—Participants engaged in two phases of strength-training. The first phase (9 months) of supervised – by expert physical trainers - strength-training sessions targeted improvement in each of three core areas: 1) stretching and balance, 2) range of motion and flexibility, and 3) isotonic muscle strengthening. Subjects reported to the designated facilities for three sessions per week and each session consisted of the following essential components: A) 10 minute walking warm-up at 50% maximum heart rate B) 5-10 minutes of stretching and balance exercises, C) 10 minutes of range of motion/flexibility exercises, D) 30 minutes of strength-training exercises, and E) 5 minutes of cool-down which includes walking and/or static stretching of the muscles. For all strength-training components, subjects completed specified exercises with both limbs.

Isotonic loads were increased through 3 stages (body weight/therabands, free weights, and machine weights) according to each participant's needs, fitness, and current condition. In lieu of basing initial resistance on 3 or 6-rep max, all weights progressed from a comfortable resistance with proper exercise form. Participant load progression followed the following logic - all participants started at two sets of six repetitions and gradually increased to two sets of ten repetitions at the same weight. When participants felt they could increase weight and had completed the exercise for at least two consecutive strength-training days, they would do so and shift back to two sets of six repetitions. Range of motion exercises were increased for each subject when the exercises could be completed with a Borg scale of difficulty ≤ 6 [13]. Throughout the process, trainers emphasized good form and encouraged participants to note soreness or pain during and after exercises.

Phase 2 (15 months) focused on developing self-directed long-term exercising habits. Trainers contacted participants every two weeks during the first 6 weeks of phase two; thereafter, contact reduced to every other month. During the first six weeks, trainers recorded compliance and adjusted exercise schedules to meet each participants' needs. In addition to scheduled sessions, trainers encouraged participants to meet quarterly for "booster" sessions.

Self-management—Based on existing self-help programs [14], the two-phase selfmanagement intervention targeted coping and self-efficacy skills. The 9-month Phase 1 consisted of 12 weekly 90-minute (60% didactic / 40% interactive) classroom sessions facilitated by the program manager and local health professionals; no strength-training treatment staff were involved. These were followed by weekly telephone calls designed to boost knowledge and behaviors from classroom sessions, as well as providing practical, oneon-one problem solving discussions to tailor the treatment to each participant's needs. These weekly phone calls continued through the end of Phase 1 and also through Phase 2, when they were staggered to biweekly, monthly and then bimonthly calls. Coping skills focused

on promoting more adaptive strategies and reducing avoidant or passive strategies. Selfefficacy skills focused on increasing perceptions of control for physical functioning, pain management, and other ancillary arthritis symptoms. One of the 12 lectures covered the lifetime health benefits of a well-balanced exercise program that included strength, flexibility, and aerobic conditioning, as well as suggested strategies for self-motivation to maintain such a regimen. Participants at this session received lists of exercise resources should they wish to establish their own regimens. Self-management group participants, however, received no instructions pertaining to specific exercises, techniques, or routines. Staff taught the self-management skills using educational and behavioral methods including homework assignments and active involvement/practice during treatment sessions.

Combined treatment—The combined group concurrently participated in both the strength-training and self-management courses, with slight alterations to ensure equivalence of contact time across treatment groups. Specifically, staff contacted participants in the combined treatment group less often than participants of the strength-training and self-management programs during the second phase. Otherwise, the combined group participated in the full, independent treatment protocols for both the strength-training and self-management programs.

Primary Outcome Measures

Physical Performance Tests—Objective measures of physical functioning consisted of five discrete physical performance tests measured three times (months 0, 9, and 24). Each test provided several metrics of performance including time to complete, force, number of repetitions, etc., that were combined to a unit weighted z-score average to reduce the number of statistical tests and improve reliability of each test [15]. Higher values reflect greater functional ability. Expert disability assessors, physical trainers and study staff administered the following tests for all groups according to standard protocols.

Leg Press (maximum voluntary isometric lower body strength) [16]: Subjects sat on the quadriceps isometric force test device (test-retest reliability: .99) [16,17] with both hip and knee angles at approximately 90 degrees. Expert disability assessors instructed participants to build up to maximal pressure – over 10 seconds - to one foot as if they were straightening their leg from 90 degrees while keeping their backs flat against the back rest and hips down on the seat. Expert disability assessors recorded the maximum force for three trials with each leg along with perceived exertion at the conclusion of the test for each leg.

Functional Range of Motion (FOCUS): In this timed test (test-retest reliability: .90) [18], subjects moved 18 pegs from one position to another in vertical, horizontal, and diagonal planes of a pegboard to demonstrate range of motion (e.g., from above the shoulders to below the knees, from a standing to a crouching position). Expert disability assessors recorded measures of perceived pain and exertion after testing.

ERGOS Work Simulator: The ERGOS, administered by expert disability assessors, [19] provided a standardized measurement of functional work capacity using computerized delivery of instructions and data collection of time, work load, perceived pain, and perceived work load. The ERGOS exercise consisted of grasping a series of five-pound- steel discs and moving them along a metal bar while in a crouching position (in two parts - from right to left and then left to right). Outcomes reflect the participant's ability to perform lower body and upper body coordinated movements typical in manual labor.

<u>Get up and go:</u> Physical trainers timed participants during while they rose from a seated position, walked three meters, turned 180 degrees, walked back to the chair, and sat down

using regular footwear and customary walking aid [20]. Participants reported pain levels and perceived exertion after testing.

<u>Stair climbing:</u> Physical trainers timed participants as they climbed and descended five steps for three trials [20]. Participants also reported physical discomfort related to knee and quadriceps involvement.

Self-reported Pain and Disability—The patient self-report outcome measures – administered five times (months 0, 3, 6, 9, 18, and 24) - consisted of several scales combined to form standardized indices of pain and disability. Pain measures included a visual analog scale (0-100), the Body Pain subscale from the SF-36 [21], and the pain subscale from the WOMAC osteoarthritis index [22]. Disability measures included the stiffness and disability subscales from the WOMAC, the Physical Function subscale from the SF-36, and a visual analog scale (0-100) for arthritis disability. Similar to the physical performance tests, each set of measures were first standardized and then averaged to form a standardized index score. Higher values indicated greater pain and disability.

Secondary Measures

There were several relevant covariates included prior to testing for treatment effects. Arthritis severity at baseline - measured by self-reported visual analog scale (0-100), age, sex, and body mass index served as covariates. These variables often serve as excellent predictors of treatment outcome in knee osteoarthritis treatment studies.

Statistical Analyses

Our primary objective was to compare both self-reported outcomes (pain and disability) and physical performance test outcomes among the three treatment groups (whether the combined group performed better than the strength-training or self-management groups on both outcomes). The trial was designed to randomize roughly 270 subjects among intervention groups to achieve a post-attrition sample size of 60 in each group at the end of 24 months. A total sample size of 180 was projected to provide 80% power to detect a small effect size ($f^2 = .063$) with alpha set at .05 among groups. Missing data were handled with a multiple-imputation procedure imputing 5 complete datasets [23,24,25] to provide complete data for our intent-to-treat analyses. If the amount of missing information were negligible for the primary predictor of "month," then a single, randomly selected complete dataset would be used for the analysis. Otherwise, all resulting datasets would be averaged and the missing information (γ) reported. All hypothesis tests were two-sided.

The primary analyses consisted of linear mixed-effects regression models using the lmer procedure in the R statistical package [26]. A total of seven regression models were run - one for each dependent variable that included the five physical function tests (leg press, range of motion, ERGOS, get up and go, and stair climbing) and the two self-reported outcomes (pain and disability). Group contrasts were dummy coded *a priori* using self-management as the default comparison category to the combined and strength-training groups. A Benjamini-Hochberg [27] method helped alleviate problems of multiple comparisons across the models.

A general set of covariates (BMI, age, sex, and arthritis severity) were specified prior to testing two primary predictors (effect over time measured by months in treatment and treatment group). Only three repeated measures were available for the physical functioning tests, so those models were restricted to linear effects. The additional repeated measures for the self-reported outcomes allowed us to test for linear and quadratic (i.e., curvilinear) effects for month together with their interactions with group. All models were tested via

standard nested model procedures to account for error structures as well as fixed, random, and independent random effects. Finally, we calculated percentages of participants achieving clinically-relevant improvement criteria of 26% and 40% reductions in WOMAC pain and disability scores, respectively [28].

Results

Staff recruited 1726 potential participants beginning September, 2003, approximately 21 weeks prior to baseline testing and continued recruitment throughout the study (December, 2006). A total of 492 (29%) potential participants met initial screening eligibility criteria and received knee x-ray exams. Of those, 163 (33%) failed x-ray criteria and another 36 failed to enroll for other reasons, leaving 273 who were randomized to one of three treatment groups (see Figure 1). Following randomization, 19 (7%) participants failed to receive the assigned treatment after the run in period due to lack of interest, non-compliance, health problems, or moving from local area resulting in 254 participants are shown in Table 1. All results reflect analyses of the original 273 assigned participants in an intent-to-treat analysis.

Almost three-quarters of the assigned participants finished the trial after two years (201 out of 273 for 73.6% 2-year completion rate). Retention among the groups was not significantly different (see Table 1) and the demographic variables (e.g., age, sex, race, arthritis severity, pain, disability, and comorbid medical conditions) failed to predict dropout.

Treatment compliance varied somewhat by group, treatment, and project phase (see Table 1). Overall compliance was higher during phase 1 (67.5%) compared to phase 2 (50.3%) with negligible differences between groups. The self-management treatment had higher compliance rates than any portion of the strength-training as expected because fewer opportunities existed for non-compliance with the self-management participants compared with the strength-training or combined groups.

A total of 15 adverse events were "definitely" related to the study, 30 adverse events were "possibly" related to the study, and 13 adverse events were "probably" related to the study. These study-related adverse events consisted of increased knee pain (osteoarthritis flare-up), accident/injury related to strength-training, and pain/soreness from strength-training. Of those, only one adverse event "possibly" related to the strength-training intervention resulted in a withdrawal from the study (see Figure 1). Here, a participant in the strength-training group exacerbated a pre-existing lower back injury. One additional adverse event "possibly" related to strength-training was unresolved at study end, however, the participant did not drop out; she ceased exercising but provided follow-up responses to end-study measures. Beyond these last two adverse events, no other study-related adverse events remained unresolved at study end. Adverse events that did not result in withdrawals are not reflected in Figure 1.

Main Outcomes

The multiple imputation procedure produced five complete datasets for each analysis. Comparisons across the five complete datasets indicated that amount of missing information was negligible (mean $\gamma < .00001$); parameters from each imputed dataset were not significantly different, so we utilized a randomly selected imputed data set for analyses rather than averaging the parameter estimates across the five datasets.

All outcomes showed a significant change over time (see Table 2) regardless of treatment assignment. The self-reported outcome measures had sufficient repeated measures to test

both linear (month) and quadratic (month²) parameters; only the linear parameter was significant for all models.

Preliminary correlations among the seven outcomes indicated small relationships (mean r < . 2) among the outcomes, thus we analyzed the outcomes separately for each outcome measure. Figures 2 and 3 show the changes observed by group over time for the seven different outcomes - five objective performance tests and two self-reported outcomes, respectively. The primary hypotheses were tested by the interaction between month and treatment assignment. None of the interactions were significant for any models. Furthermore, no main effect for treatment was significant either indicating that there were no differences over time nor were there pooled differences between treatment groups. Table 3 documents the within-group and between-group effect sizes and 95% confidence intervals for each of the seven outcome measures; all within-group effect sizes were significantly different from zero with the exception of one (strength-training group for the pain outcome). In contrast, no between-group effects were significant. Finally, the majority of participants in all groups achieved clinically-relevant improvements in WOMAC disability (26% criterion) and pain (40% criterion) (see Table 1).

Discussion

These results show that over a 24-month period, physically inactive middle-aged people with symptomatic knee osteoarthritis benefited equivalently from a program of strength-training, self-management, or the two combined. Those benefits were significantly larger for men compared with women, but the beneficial effects for women were still pronounced, as women outnumbered men by a factor of 3 to 1. Men gained significantly more large muscle mass strength, but also tended to report more pain than women. Thus, both men and women benefited from these treatments. Benefits were even more evident in objective physical tests than in self-reported outcomes. Additionally, improvements in disability and pain were clinically relevant for the majority of participants across treatments, reaching 26% improvement in function and 40% improvement in pain scores [28].

The logic behind the combined treatment was that the different factors addressed in physical and psychological treatments might produce an additive effect if administered together. These results suggest otherwise. Instead, the comparison of the three treatment arms showed no differences, suggesting similar benefits for all three over a two-year period.

No-difference findings may not be surprising given the study length. Lengthy exercise studies tend to weigh heavily on participants and their treatment compliance wanes. These no-difference findings might indicate a regression artifact where participants regress back to lower, mean functional levels. While plausible, we are persuaded otherwise because all three groups showed continued improvement over 24 months despite waning compliance and average within group-effect sizes in the medium to high range. Furthermore, an analysis of the pre- versus post-run-in data shows that the participants were quite healthy and pain free prior to treatment - mean scores on an 11-point (0=none to 10=extreme) pain visual analog scale were roughly 5 points at pre-run-in and 3 points at post-run-in (ES=1.66). Furthermore, our sample was younger than typical knee osteoarthritis treatment samples and thus may have been much higher functioning than those in other studies. Higher functioning would mean that there was less opportunity to produce an effect. The self-reported physical functioning scores on the SF-36 compare favorably with a generally healthy sample [29] yet the three treatments still improved functionality. In effect, the study length and sample age might have decreased our ability to see differences among the three groups. Finally, the combined treatment burden may have diluted the effects of both strength-training and selfmanagement and produced no-difference results.

One implication of the negligible gains in combining treatments over either strength-training or self-management alone might be that costs and patient burden would rule out the combined treatment. This implication, however, only pertains to functional outcomes - both directly measured and self-reported. Other outcomes not studied here, such as physical activity level, perceived self-efficacy of controlling treatment, or other long-term relevant outcomes might respond more to combined treatments. At this point, improvements in these other outcomes are purely speculative and deserve further study.

Another implication is that given a relatively young osteoarthritis population, both strengthtraining and self-management result in functional improvement. Patients unwilling or unable to exercise might still benefit from treatment that is less costly [30,31] but equally effective in producing functional gains.

Several limitations warrant mention. First, we did not assess treatment effects on articular cartilage and inflammation. Experts recognize the importance of mechanical loading for maintaining healthy cartilage [32]. Furthermore, chronic exercise has been shown to reduce both local and systemic inflammatory factors [33], which play a central role in knee osteoarthritis onset and progression. Second, omitting a no-treatment arm eliminated a direct test of treatment effectiveness. Most middle-aged people with early knee osteoarthritis symptoms may not seek treatment and thus the no-treatment group would be a suitable comparison. Third, potential differences in self-medication practices (e.g., if the self-management group had used more analgesics and/or non-steroidal anti-inflammatory drugs than the other groups) throughout the study could affect the between-group differences. Fourth, due to difficulties recruiting males, we were not able to perform an adequate sex-stratified analysis. Finally, the sample might have limited the effects of each treatment since participants were high functioning individuals at baseline.

Our results show that two non-pharmacological treatments - strength-training and selfmanagement - produce gains in our unique sample of middle-aged people with knee osteoarthritis. While physical activity is linked with reduced risk for obesity, cardiovascular disease, hypertension, and diabetes [34], self-management may be a less intrusive and equally effective early treatment for knee osteoarthritis. Insofar as physical function is a prerequisite to maintaining health-protective levels of physical activity, our results suggest there may be broad health benefits from strength-training and self-management for early osteoarthritis patients. Healthcare providers may confidently recommend self-management and strength-training for their osteoarthritis patients, constrained only by availability, costs, burden, or preference.

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Figure 1. Consort diagram.

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Figure 2.

The figure represents three repeated measures - measured at baseline, 9-months, and 24months - for five objective functional outcomes for the three treatment groups. Error bars at each point represent 95% confidence intervals. Higher numbers for all outcomes indicate better functioning. McKnight et al.



△ Self–Management ○ Strength Training □ Combined

Figure 3.

Five repeated measures - measured at baseline, 3-months, 9-months, 18-months, and 24-months - for self-reported pain and disability for the three treatment groups. Error bars at each point represent 95% confidence intervals. Lower values for both outcomes indicate less pain and disability.

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Table 1

Summary statistics for baseline data (study design, demographics, and relevant covariates), treatment compliance, and clinically meaningful differences in outcomes.

		Strength Training	Self-Management	Combined
Study Design				
	Randomized	<i>n</i> =91	<i>n</i> =87	<i>n</i> =95
	Completed (24 months)	<i>n</i> =64	<i>n</i> =67	<i>n</i> =70
	% Completed	70.3	77.0	73.7
Demographics				
	Age	53.3 (7.2)	52.6 (6.5)	51.9 (7.7)
	Female	80.2%	74.7%	76.0%
	White (%)	92.6%	96.3%	86.3%
	College Educated	74.1%	55.9%	59.1%
Physical Condition				
	BMI (kg/m ²)	27.9 (4.5)	27.9 (4.1)	27.4 (4.1)
	Arthritis Severity (VAS)	24.0 (22.9)	25.0 (24.6)	23.2 (18.7)
	SF-36	58.4 (17.8)	61.8 (14.7)	
	Physical62.3 (16.0)			
Mental Condition				
	SF-36 Mental	74.4 (15.8)	67.8 (16.8)	71.6 (15.9)
	Depression (CESD)	7.4 (7.5)	10.4 (8.2)	7.8 (6.5)
Compliance				
Phase 1	Strength Training	69.5 (25.2)	NA	72.1 (22.0)
	Self-management	NA	74.8 (43.4)	75.0 (43.3)
Phase 2	Strength Training	39.5 (36.9)	NA	44.1 (32.1)
	Self-management	NA	62.0 (48.5)	61.6 (48.7)
Clinically-Meaningful Change				
	Functioning (26% change from baseline/N)	64/91 (70%)	56/87 (64%)	63/95 (66%)
	Pain (40% change from baseline/N)	59/91 (65%)	49/87 (56%)	62/95 (65%)

Demographic statistics are reported as either means (standard deviations), frequencies (%), or proportions (Count/N) with corresponding percentage in parentheses - depending on the type of data – for all randomized participants. The abbreviation "NA" indicates not applicable. All statistics reported reflect values for the randomized N (N=91, 87, and 95 for the strength-training, self-management, and combined groups, respectively). No significant differences existed between treatment groups on any of the demographic variables, compliance estimates, or clinically meaningful change frequencies.

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Table 2

Unstandardized parameters and standard errors for the linear mixed-effects models.

			Covar	iates			
Outcome	Intercept	BMI	AGE	Male	Arthritis VAS	Predictor month	${{{\mathbb R}}^{2}}_{{\rm adj}}$
Leg Press^{\dagger}	48 (.27)	.03 (.01)*	02 (.003)*	1.26 (.06)*	004 (.001)*	.03 (.004)*	.41
Range of Motion \ddagger	1.05 (.24) [*]	03 (.005)*	01 (.003)	.28 (.05)*	005 (.001)*	.03 (.004)*	.22
ERGOS∱	$1.40(.30)^{*}$	02 (.01)	02 (.003)*	.44 (.07)*	008 (.001)*	.02 (.005)*	.16
Get Up and Go [#]	1.37 (.24) [*]	03 (.005)*	01 (.003)*	.02 (.05)	01 (.001)*	.02 (.004)*	.16
Stair Climbing †	1.27 (.24) [*]	02 (.005)*	01 (.003)	.19 (.05)*	006 (.001)*	.01 (.004)*	.13
Pain≄	10 (.21)	.01 (.004)	003 (.003)	.12 (.05)*	.01 (.001)*	05 (.02)*	.13
Disability≭	65 (.21)*	.01 (.004)*	.006 (.003)	.04 (.05)	.01 (.001)*	04 (.02)*	.12

was not a significant predictor, it was omitted from the table. Each parameter shows how much of a change in the outcome (column 1) would be expected given a unit change in the covariate or predictor (month).

 \dot{r} Best fitting model specified a random intercept parameter with a fixed linear slope parameter for month.

 \sharp Best fitting model specified dependent random intercept and random slope parameters.

p<.0001. All other p-values were greater than .02.

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Table 3

Effect sizes within group and between groups

		Within Group Effect	Sizes*	Betweer	n Group Effect Siz	es **
	Combined	Strength Training	Self-Management	ST+SM vs ST	ST+SM vs. SM	ST vs SM
Outcome	(INS+SM)	(ST)	(N I)			
Leg Press	0.82	0.89	0.84	0.08	0.22	0.15
Range of Motion	1.04	1.16	0.79	0.06	0.36	0.29
ERGOS	0.66	0.66	0.47	-0.01	-0.01	0.00
Get Up and Go	0.66	0.53	0.58	0.01	0.08	0.06
Stair Climbing	0.58	0.56	0.64	0.05	0.17	0.12
Pain	-0.70	-0.24	-0.59	-0.24	-0.15	0.10
Disability	-0.79	-0.43	-0.43	-0.19	-0.33	-0.11

The 95% confidence intervals were +/- .3 for each parameter.

Within group effect sizes are based upon the expected change given the linear mixed-effects model results.

** Between group effect sizes are based upon the observed differences between baseline and 24 months.