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Home-Based Leg Strengthening Exercise Improves Function One Year After Hip Fracture: A Randomized Controlled Study

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Abstract

Objectives—Examine the effectiveness of a short term leg strengthening exercise program compared to attentional control on improving strength, walking abilities, and function one year after hip fracture.

Design—Randomized controlled pilot study.

Setting—Interventions occurred in patients' homes.

Participants—Community-dwelling older adults (n=26) six months post hip fracture at baseline.

Intervention—Exercise and control participants received interventions by physical therapists twice weekly for 10 weeks. The exercise group received high intensity leg strengthening exercises. The control group received transcutaneous electrical nerve stimulation and mental imagery.

Measurements—Isometric force production of lower extremity muscles; usual and fast gait speed, six minute walk (6-MW) distance, modified physical performance test (mPPT), and SF-36 physical function.

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Results—The primary endpoint was at one year post fracture. Isometric force production ($p < .01$), usual and fast gait speed ($p = .02$ & $.03$, respectively), 6-MW ($p < .01$), and mPPT ($p < .01$) improved at one year post fracture with exercise. Effect sizes were 0.79 for strength, 0.81 for mPPT scores, 0.56 for gait speed, 0.49 for 6-MW, and 0.30 for SF-36 scores. More patients in the exercise group made meaningful changes in gait speed and 6-MW distance than control patients (χ^2 : $p = .004$).

Conclusion—A 10-week home-based progressive resistance exercise program was sufficient to achieve moderate to large effects on physical performance and quality of life and may offer an alternative intervention mode for hip fracture patients who are unable to leave home at 6 months after the fracture. The effects were maintained at 3 months after completion of the training program.

Keywords

functional performance; gait speed; six minute walk test; modified physical performance test

INTRODUCTION

Poor functional outcomes are reported for the majority of older adults who sustain a hip fracture.(1) The ability of hip fracture patients to make sustained functional improvements above and beyond natural recovery is unknown. The majority of recovery in ambulation, activities of daily living, and muscle strength occurs within the first six months after fracture.(2) Despite the completion of traditional “Medicare reimbursed rehabilitation,” which includes acute, post-acute care, and home health, the majority of patients do not get outpatient physical therapy and excess disability remains for basic tasks such walking 10 feet, an inability to rise from the floor, and transferring without assistance in and out of bed. (3;4) Systematic reviews of hip fracture practices include very few studies that examined the effects of exercise after the six-month plateau in natural recovery.(5) Sherrington and Lord examined patients seven months post fracture and reported minor improvements in quadriceps strength and gait speed following four weeks of daily step up exercises.(6) Portegijs et al. examined participants several years post fracture and reported improved muscle strength, but not improved muscle power, upright balance, or gait speed after 12 weeks of twice weekly power training in a gym.(7)

Binder and colleagues showed the strongest effects for improving physical performance, strength, balance, and gait speed. The intervention group received a 24 week, two phase, gym-based exercise program.(8) The high intensity strength training (phase two) began approximately six months post fracture and the control group was given an unsupervised home exercise program.(8) It is unclear if these results could be translated into the home setting that lacks the gym-based equipment, or if improvement would be sustainable. Since the number of hip fractures is expected to increase with the aging population,(9) programs are needed for frail older adults to improve function and to reduce the long term disability. Studies with longer term follow up and rigorous control conditions are needed.

The purpose of this small randomized controlled trial was to examine the effectiveness of a short-term leg strengthening exercise program compared to an attentional control group (CON) on improving force production, gait speed and endurance, physical performance, and physical function one year after hip fracture. Effectiveness was defined by statistical significance, effect size, and meaningful change.

METHODS

Overview

Community-dwelling participants were identified by local physical therapists at various healthcare centers in the Bucks and Montgomery county area. Data were collected at baseline (6 months post fracture), immediately after the intervention (10 weeks post-randomization) and at the primary endpoint of 1 year post fracture (26 weeks after randomization). The Arcadia University Committee on Protection of Research Subjects approved the study. The examiner was blinded to group assignment. Intra-rater reliability for the tests included in the assessment was (ICC 3, 1) =0.83–0.99. The trainer was not blinded to exercise group.

Participants

Participants were included if they had successful fixation (partial or total hip replacement or open reduction internal fixation) of a hip fracture within the previous 6 months (5.5–6.5 months post fracture), were 65 years of age or older, were living at home prior to the fracture, had a physician referral and were discharged from physical therapy. Exclusion criteria included a medical history of unstable angina or uncompensated congestive heart failure, ongoing chemotherapy or renal dialysis, history of stroke with residual hemiplegia, Parkinson disease, absence of sensation in the lower extremities due to sensory neuropathy, life expectancy of less than six months, or Mini-Mental State Exam scores < 20.(10) Prior to baseline testing, participants were additionally excluded if they ambulated ≥ 1.0 m/sec (indicating normal walking speed for elders and thus little chance for additional improvement)(11) or walking speeds < 0.3 m/sec (representing the lowest 10th percentile of walking speeds for older adults)(12) to create a more homogenous sample for this small trial. Participants listed demographic characteristics; completed the Pre-Fracture Physical Function scale which is scored from 0–20 with higher scores indicating better function;(13) the Barthel activities of daily living (ADL) index which is a 10 item ADL index scored from 0–100 with 100 being independent in ADL;(14) the Lawton instrumental activities of daily living (IADL) form, an eight item instrument in which eight indicated independence in all IADLs;(15) and the Geriatric Depression Scale which is a 30 point scale with 0 indicating no depressive symptoms.(16) Medical history and medications were obtained from hospital records and verified by the participant. All testing occurred at the academic center and all training occurred in the participants' homes.

Randomization & Intervention

Following baseline testing, subjects were randomized to either the leg strengthening exercise group or the CON by unrestricted randomization method with opaque sealed envelopes. Treatment sessions occurred twice a week for 10 weeks for 20 total sessions, a frequency of visits found to be sufficient for change was established from previous work.(17) Each session lasted approximately 30–40 minutes. Treatment sessions for both groups were conducted by licensed physical therapists (PTs). The leg strengthening group received strengthening exercises for the hip extensors, hip abductors, knee extensors, and ankle plantarflexors bilaterally because of the role of these muscles in gait and transfers.(18–20) Protocols for these exercises have been reported elsewhere.(17) Briefly, subjects were positioned supine for the combination exercise of hip and knee extension (leg press) as well as for the hip abduction exercise. Patients performed an additional hip extension exercise in a standing position as well as performing heel raises to train the ankle plantarflexors. We used a portable progressive resistive exercise (PRE), the Shuttle MiniClinic (Contemporary Design Co, PO Box 5089, Glacier, WA 98244) machine for the hip and knee muscles; body weight was used for the ankle muscles (heel rising exercise). (Online Figure) The machine provides variable resistance via six latex bands, each with a starting load equal to

approximately 2.7 kg and 9 kg at maximal tension. The bands can be engaged separately or together so that the maximal load is approximately 54 kg. The physical therapist determined the amount of resistance the subject could push against in order to complete a maximum of 8 repetitions. Thus the exercise intensity was an 8-repetition maximum,(21) and volume was 3 sets of 8 repetitions. Intensity was re-evaluated every two weeks and the resistance was increased if the participant was able to complete eight repetitions at the higher load in good form. Determining the 8-RM allowed the physical therapist to know the training intensity without further subcalculations (eg, 80% of the 1-RM) for which there would potentially be no corresponding load in elastic tubing bands.

The CON received conventional transcutaneous electrical stimulation (TENS). Conventional TENS uses sensory level stimulation to superficial cutaneous nerve fibers at or above the sensory threshold but below the motor threshold.(22) Bilateral gluteal muscles (hip extensors and abductors), knee extensors, and ankle plantarflexors were stimulated for 7 minutes for a total of 21 minutes each session. The physical therapist adjusted the intensity of the stimulation until the participant reported feeling a comfortable tingling in the muscle bellies. No visible muscle contraction was elicited. The initial intensity was not changed over the course of the study. During the TENS, guided imagery was used to encourage the participant to envision the leg muscles being used in activities involving rising up on the toes, rising from a squatting position, climbing a steep incline.

Outcomes & Follow Up

Isometric force of the hip, knee, and ankle extensors, was measured with an electromechanical dynamometer (Kin Com, Chattanooga Corp., Chattanooga, TN) with velocity set to 0°/sec during all testing procedures. We used isometric testing to avoid testing and training with the same device which may have given an advantage to the experimental group since they would have had more practice with that device. The hip abductors were measured with a portable, hand-held dynamometer (CSD 500, Chatillon Medical Products, P.O. Box 35668, Greensboro, NC 27425) since the patients could not be positioned as described in the literature. (23) Maximal isometric force tests were conducted on each leg for hip extensors (supine with hip at 90 degrees of flexion), hip abductors (supine with hip in neutral), knee extensors (sitting with knee at 75 degree of flexion), and ankle plantarflexors (sitting with ankle in neutral).

Participants performed one practice trial and two data collection trials each for a duration of three to four seconds. At least 60 seconds rest was provided between tests to reduce the effect of muscle fatigue. Torque data were collected on a second computer with custom designed software (Labview, National Instruments, Austin, TX) at a sampling rate of 200 Hz during the isometric testing. The highest torque value achieved was recorded. The training did not target one specific muscle group, but rather the lower extremity as a whole; therefore, the isometric force values for each muscle group were added together to form a summed lower-extremity force score for each limb. Summed force scores have been reported in the geriatric training literature because individual lower-extremity muscle force scores are highly correlated.(24)

Gait speed was measured with the Gait Mat II (E.Q., Inc., Chalfont, PA) This 3.87 meter long mat contains pressure sensitive switches which close upon contact. Participants completed four trials at two speeds. The first speed tested usual speed in which the participant was instructed to "Walk at your normal or comfortable pace." Participants then walked at fast speed for two trials in response to the command to "Walk as quickly as possible without running." Meaningful changes for usual and fast gait speed in older adults with hip fracture(25) and usual gait speed in persons without hip fracture(26) are reported to be 0.1 meters/second. Endurance was measured with Six-Minute-Walk (6-MW) distance

over a 30.48 meter long linoleum floor corridor. Standardized verbal encouragement was given once per minute. Distance was recorded to the nearest meter. Meaningful change for 6-MW test has been reported to be 50 meters for older adults.(26) Physical performance was assessed with the modified Physical Performance Test (mPPT).(27) The mPPT is a timed test consisting of nine tasks measuring static standing balance (progressive Romberg), completing five chair rises, lifting a book and putting it on a shelf, donning and remove a jacket, picking up a penny from floor, turning 360 degrees, walking fast over 50 feet, climbing one flight of stairs, and climbing up to 4 flights of stairs. The maximal score of 36 indicates higher function.(27) The authors of the mPPT used three points to estimate meaningful change when powering exercise trials (personal communication via email with D Sinacore on 9/14/06). The Medical Outcome Studies, Short Form (SF-36) was used to assess physical health status. The physical functioning subscale is scored on a 0–to100 scale with 100 representing excellent health status.(28) Meaningful change has been suggested as 5 points for hip fracture patients;(29) however, we chose a more stringent change score of 15 points since three out of the 10 questions would need to show improvement for this magnitude of difference.

Statistical analysis

Sample size was calculated based on pilot data in which the effect size index (d)(30) for quadriceps strength change was $d=2.2$ and for SF-36 was $d = 1.6$. Since the pilot sample was small and there was no control group, a more conservative estimate of effect size index was used ($d=1.4$). Assuming a power of 0.80, a large effect size ($d=1.40$), an alpha level of 0.05, 12 were needed in each group for a total of 24 subjects.(30) Three additional subjects were recruited to account for potential drop-outs.

Data were analyzed with SPSS software. Descriptive statistics described the sample. Unpaired t-tests compared baseline characteristics for continuous data; and χ^2 tests were used for categorical data. Intention-to-treat analysis with the last observation carried forward was used to assess all outcome measures among the groups. The primary analysis was the comparison between baseline and one year post fracture. Analysis of covariance was used with the 12 month post fracture value as the dependent variable and the baseline value as the covariate. Sex and type of hip fracture repair were also entered as covariates, but the results did not change, and thus are not shown. Post-hoc testing to examine the changes from baseline to post-intervention were examined with ANCOVA with the baseline as the covariate and post-intervention as the dependent variable. Statistical tests were 2-tailed, $p<0.05$ was considered statistically significant. Effect sizes were also calculated as the between-group difference in mean change scores divided by the pooled standard deviation. Finally, we described the outcomes in terms of known meaningful changes. The criteria for meaningful change for each individual was improvement of 0.1m/s for usual and fast gait speed,(25,26) 50 meters in six minute walk (6-MW) distance,(26) three points on the modified physical performance test (mPPT), and 15 points on the physical function subscale of the SF-36.(29) We used the chi square test to determine if the number of patients who made meaningful changes was different between groups.

RESULTS

Flow of participants

Seventy patients were contacted, 26 were randomized, and 21 completed the intervention. Three additional subjects were not able to complete final testing at one year post fracture. The 8 subjects unable to complete the study were younger and had lower ADL scores than those who completed the study (Figure 1). Subjects were recruited beginning June 2003 and follow up data were completed January 2006. Table 1 describes the 26 randomized subjects,

21 of whom were women with an average age of 81. They had an average BMI of 27.4, took 4–5 medications, and had a MMSE score of 28. There were no differences between groups for baseline data (Table 1).

Participants in the strength training program showed gains after training that were maintained one year post fracture. The results of the ANCOVA showed that isometric force production ($p<.01$), usual and fast gait speed ($p=0.02$ & 0.03 respectively), 6-MW distance ($p<.01$), and mPPT scores ($p<.01$) improved. Large effect sizes were demonstrated for strength (0.79) and physical performance test scores (0.81), moderate effects for usual (0.56) and fast (0.41) gait speed and 6-MW (0.49), and smaller changes for SF-36 physical function scores (0.30)(Table 2). Post-hoc analyses reveal that the exercise group made significant improvements in strength and mPPT immediately after the intervention. No significant changes were noted in the CON.

We also examined the number of participants who achieved meaningful changes in the measures for functional outcomes with chi square. Only those people who completed the 1 year post fracture testing, eight for the CON and 10 for the exercise group were included. Five of 10 participants in the exercise group, and no participants in the CON made had meaningful changes in usual and fast gait speed and 6-MW distance one year after fracture ($p=.004$). Seven of the 10 exercisers made meaningful changes in mPPT scores while only one out of eight in the CON did ($p=.015$); six out of 10 exercisers made meaningful changes in SF-36 physical function, while only two out of eight controls did ($p=.188$). It is clear that when comparing the CON to leg strengthening exercise, a greater number of leg strengthening participants improved in a meaningful way for each functional measure.

Adherence to the exercise was excellent in both groups. For the participants who completed the exercise and control interventions, adherence (number of sessions completed divided by possible number of sessions) to the leg strengthening exercise was 99% (237 out of 240 sessions) and 99% (178 out of 180 sessions) to the CON. Subjects reported occasional muscle soreness after exercise, but we had no adverse events directly attributable to the exercise regime. There were no reports of skin irritation or pain from the CON. Of the two participants in the exercise group who stopped exercising, one completed all the exercise sessions, but then developed chest pain and was not able to be retested. The other exercise participant completed 45% of the sessions, and began to complain of groin pain after a weekend walking trip. This participant underwent revision of the hemiarthroplasty. Of the three control participants, one developed heterotrophic ossification in the quadriceps muscle and underwent surgery; another participant experienced medical decline and died in the hospital, and the third experienced the onset of neurological symptoms and was hospitalized for testing.

DISCUSSION

This randomized clinical trial provides evidence that a 10-week leg strengthening program using progressive resistance exercise starting six months after hip fracture was effective in improving muscle strength and functional performance one year after hip fracture. More participants who performed leg strengthening exercise made meaningful changes in walking speed, endurance, and physical function compared to the CON.

Our results demonstrate that an exercise program similar to the intensity provided in Binder's study (leg press exercise 78% of 1 RM)(31) can be translated into the home setting. Since the patients were six months post fracture we assumed that natural recovery was completed, thus the reported gains may have been due to the specific exercises chosen or the frequency, intensity, and duration of the program or to changes the patients made in their

day to day lifestyle. We selected exercises that targeted muscles important for function and attempted to maximize specificity of training by performing the exercise in certain positions and within particular ranges of motion. The effects we measured at one year post fracture are similar and in some cases greater than the effects calculated from Binder's study.(8) Comparing baseline and six month outcomes, Binder's effect sizes were 0.54 for quadriceps torque, 0.56 for fast gait speed, 0.66 for mPPT scores, and 0.38 for SF-36 physical function scores.(8) Despite the fact that the participants in Binder's study had faster baseline walking speeds and higher SF-36 physical function scores suggesting their participants were higher functioning, the participants in our study were able to achieve similar effects with the leg strengthening program (Table 2). Our results are also consistent with the recent Cochrane review on the effects of strength training on physical function.(32) In the report of 121 trials with over 6,700 participants, the effect size for strength training on quadriceps strength was 0.84 and on self-reported function was 0.14. Mean differences associated with training were 52 meters for the six minute walk test, and 0.08 m/sec for gait speed.(32) These values are very similar to what we found for our participants with hip fracture.

Most exercise trials have used either "usual care", (33) education, (17) recommendations for continued unsupervised exercise as the control condition, (34) or nothing at all. (7) We believe that we are the first group to use an attentional control for patients after hip fracture. By having a physical therapist administer the placebo TENS and imagery each treatment session, we were able to control for attention and motivation that physical therapists are known to provide during treatment. (35) Despite the small number in our trial, the strength of the design provides support that the leg strengthening intervention was effective. Other strengths of our study include attempts to minimize bias with concealed randomization and blinded outcome assessors and our attempt to measure outcome several months after the intervention was completed.

The limitations to our study include the small sample size; a single, unblinded interventionist; the high dropout rate; baseline differences in mPPT scores, and a lack of information regarding activities participants performed from the end of the intervention period to the end of the trial. Although the sample was small, we did have sufficient power to detect changes in physical performance at one year. The high dropout rate appears to be more reflective of frail, older adults than to the intervention provided. These varied ailments are typical of many older adults and we do not believe these events suggest that our program was too aggressive or intolerable for older adults. The higher mPPT scores in the exercise group at baseline may suggest that those patients were less disabled and more likely to recover, but the baseline differences were controlled by using the ANCOVA statistical procedure with baseline values as the covariate.

Home-based progressive resistive training programs may be needed for those with accessibility problems such as lack of transportation or fear/inability to leave the home. While Medicare A would not typically provide care six months after fracture, there are rehabilitation companies that provide Medicare B services in the home for persons who have unmet functional goals. This study also showed that effects were achieved in a short amount of time (10 weeks) and were maintained for several months after the end of the training program. Since this was a small pilot trial, a larger, multicenter trial is needed to determine if this kind of program could be started earlier in the course of recovery, what the effects of the program would be if started earlier and whether these changes are of the magnitude that would make the program cost effective. In summary, a 10 week program of twice weekly progressive resistance training for the leg muscles beginning six months after hip fracture was effective in improving force production, gait speed and endurance, and physical performance one year after hip fracture.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Subject Enrollment Diagram

Table 1**Baseline Characteristics of the Participants**

	CON Group (n=12)	Exercise Group (n=14)
Age (years)	82.0 ± 6.0	79.6 ± 5.9
Female, n (%)	9 (75%)	12 (86%)
Married	4 (33%)	7 (50%)
Living alone	6 (50%)	5 (36%)
Pre-fracture Function (0–20)	19.0 ± 1.6	19.7 ± 0.7
MMSE (0–30)	28.1 ± 2.1	28.4 ± 1.3
Fracture type, n (%)		
Intracapsular	4 (33%)	7 (50%)
Intertrochanteric	8 (67%)	7 (50%)
Surgical Repair		
Hemiarthroplasty	2 (17%)	6(43%)
ORIF	10 (83%)	8(67%)
BMI (kg/m ²)	27.3 ± 4.8	27.5 ± 2.5
GDS (0–30)	7.3 ± 3.6	4.9 ± 4.1
ADL (0–100)	92.9 ± 12.3	99.2 ± 1.9
IADL (0–8)	5.8 ± 2.8	7.1 ± 1.7
Prescribed Medications	5.5 ± 2.7	4.4 ± 3.6
Time from hip fracture to enrollment, weeks	26 ± 2	26 ± 2
Medical history, n (%)		
High blood pressure	8 (67%)	10 (71%)
Arthritis	5 (42%)	3 (21%)
Osteoporosis	4 (33%)	6 (43%)
Diabetes	3 (25%)	3 (21%)
Atrial fibrillation	3 (25%)	1 (7%)
Congestive heart failure	2 (17%)	0 (0%)
Hypothyroidism	6 (50%)	2 (14%)
Hypercholesteremia	5 (42%)	5 (36%)

CON=attentional control group

Means ± standard deviations

MMSE = Mini-Mental State Exam (0–30; 30- no cognitive impairment)

ADL- Barthel Index of Activities of Daily Living (0–100; 100-independence in ADL)

IADL- Lawton Index of Instrumental Activities of Daily Living (0–8; 8- independence in IADL)

GDS- Geriatric Depression Scale (0–30; 0-no depressive symptoms)

BMI- Body mass index

ORIF- open reduction internal fixation

Table 2

Primary Outcome Measures

	CON Group (n=12)	Exercise Group (n=14)	p value	Effect Size (sd units)
Summed LE Torque (n)				
Baseline	914 ± 326	853 ± 210		
Post intervention	887 ± 274	949 ± 207	p=.042	
1 yr post fracture	927 ± 354	1073 ± 167	p=.006	0.79
Usual Gait Speed (m/sec)				
Baseline	0.66 ± 0.17	0.70 ± 0.19		
Post intervention	0.70 ± 0.22	0.81 ± 0.17	p=.150	
1 yr post fracture	0.67 ± 0.21	0.81 ± 0.17	p=.020	0.56
Fast Gait Speed (m/sec)				
Baseline	0.89 ± 0.27	1.01 ± 0.27		
Post intervention	0.91 ± 0.25	1.07 ± 0.23	p=.161	
1 yr post fracture	0.89 ± 0.24	1.11 ± 0.22	p=.027	0.41
Six Minute Walk Distance (m)				
Baseline	221.8 ± 73.0	265.1 ± 88.5		
Post intervention	242.7 ± 83.0	295.7 ± 79.8	p=.307	
1 yr post fracture	219.4 ± 67.8	299.5 ± 80.0	p=.005	0.49
Physical Performance Test				
Baseline*	20.4 ± 6.1	24.0 ± 3.5		
Post intervention	21.3 ± 5.8	27.4 ± 3.2	p=.021	
1 yr post fracture	20.3 ± 6.2	27.6 ± 2.6	p=.000	0.81
SF-36 Physical Function				
Baseline	37.5 ± 14.5	50.7 ± 19.6		
Post intervention	40.4 ± 14.2	50.4 ± 15.6	p=.716	
1 yr post fracture	38.3 ± 19.2	56.8 ± 19.6	p=.192	0.30

CON- attentional control group

p values represent the results of ANCOVA testing with baseline values as the covariate and the dependent variable being post intervention or the primary comparison of 1 year post fracture. The effect sizes are reported for the primary comparison of baseline to one year post fracture.

* Indicates p=.04 for baseline differences between groups in mPPT scores; all other baseline comparisons were not statistically different.