Effects of Extended Outpatient Rehabilitation After Hip Fracture

A Randomized Controlled Trial

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Context Hip fractures are common in the elderly, and despite standard rehabilitation, many patients fail to regain their prefracture ambulatory or functional status.

Objective To determine whether extended outpatient rehabilitation that includes progressive resistance training improves physical function and reduces disability compared with low-intensity home exercise among physically frail elderly patients with hip fracture.

Design, Setting, and Patients Randomized controlled trial conducted between August 1998 and May 2003 among 90 community-dwelling women and men aged 65 years or older who had had surgical repair of a proximal femur fracture no more than 16 weeks prior and had completed standard physical therapy.

Intervention Participants were randomly assigned to 6 months of either supervised physical therapy and exercise training (n=46) or home exercise (control condition; n=44).

Main Outcome Measures Primary outcome measures were total scores on a modified Physical Performance Test (PPT), the Functional Status Questionnaire physical function subscale (FSQ), and activities of daily living scales. Secondary outcome measures were standardized measures of skeletal muscle strength, gait, balance, quality of life, and body composition. Participants were evaluated at baseline, 3 months, and 6 months.

Results Changes over time in the PPT and FSQ scores favored the physical therapy group ($P = .003$ and $P = .01$, respectively). Mean change (SD) in PPT score for physical therapy was +6.5 (5.5) points (95% confidence interval [CI], 4.6-8.3), and for the control condition was +2.5 (3.7) points (95% CI, 1.4-3.6 points). Mean change (SD) in FSQ score for physical therapy was +5.2 (5.4) points (95% CI, 3.5-6.9) and for the control condition was +2.9 (3.8) points (95% CI, 1.7-4.0). Physical therapy also had significantly greater improvements than the control condition in measures of muscle strength, walking speed, balance, and perceived health but not bone mineral density or fat-free mass.

Conclusion In community-dwelling frail elderly patients with hip fracture, 6 months of extended outpatient rehabilitation that includes progressive resistance training can improve physical function and quality of life and reduce disability compared with low-intensity home exercise.

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Hip fractures are a common problem among older adults and can have a devastating impact on the ability of older patients to remain independent. A significant functional decline following a hip fracture has been documented even among individuals who were functioning at high levels before the event.[1-3] Between 22% and 75% of hip fracture patients do not recover to their prefracture ambulatory or functional status between 6 and 12 months after the fracture event.[3-6] Many patients require continued supportive services and are at high risk for recurrent hospitalization,[7] fracture,[8] and institutionalization.[9] Individuals at high risk of poor recovery of mobility after hip fracture include those with deficits in skeletal muscle strength during the postfracture period.[10] Medicare and insurance programs usually require that the patient be discharged from treatment once independence in ambulation is achieved, with or without an assistive device. However, many patients have persistent strength and mobility deficits at the end of treatment that impair their capacity for independent function and increase risk of recurrent injury and nursing home placement. Consequently, there is a need to identify strategies to improve functional outcomes for these patients.

This study was designed to test the hypothesis that in community-dwelling, frail, elderly patients with hip fracture,

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6 months of an extended outpatient rehabilitation program that included whole-body progressive resistance exercise training would induce greater improvements in measures of disability and physical performance than low-intensity home exercise that focused primarily on flexibility.

METHODS

Study Population

Men and women aged 65 years or older with a recent proximal femur fracture were recruited from local hospitals, home care programs, and the community at large to participate in this study. Patients were recruited close to the time of discharge from standard physical therapy, which, in most cases, was completed at home. After a brief telephone interview, potential participants were invited to undergo a screening evaluation, which included a medical history, medical record review, physical examination by a physician and a physical therapist, blood and urine chemistry measurements, electrocardiogram, and the Short Blessed Test of Orientation, Memory, and Concentration.[11] We administered a modified version of the Physical Performance Test (PPT), a 9-item objective evaluation of physical function developed by Reuben and Siu.[12] The score on the PPT ranges between 0 and 36 and is associated with degree of disability, loss of independence, and mortality in the elderly.[12,13] Our modified PPT substitutes the timed chair stand and standing balance tasks developed by Guralnik et al[14,15] for the writing and simulated eating items in the original PPT.

Self-reported information regarding activities of daily living (ADLs) was collected using standardized, validated questionnaires that measured difficulty with performance of 9 ADLs (Functional Status Questionnaire [FSQ]; score range, 0-36, with 36 indicating no difficulty with any ADLs),[16] assistance with performance of 7 basic ADLs (BADL scale; score range, 0-14), and 7 instrumental ADLs (IADL scale; score range, 0-14).[17] These procedures have been described in detail elsewhere.[18] A modified version of the ADL questionnaire was used to collect information about prefracture functional status. Written informed consent was obtained from participants in accordance with procedures approved by the Washington University Institutional Review Board, St Louis, Mo.

To be eligible for this study, volunteers had to meet the following criteria: (1) age at least 65 years; (2) community-dwelling (not living in a nursing home) on discharge from physical therapy for the hip fracture; (3) screening evaluation within 16 weeks of hip fracture repair; (4) modified PPT score between 12 and 28; and (5) self-reported difficulty or requirement for assistance with 1 or more ADL. The PPT criterion was devised because we targeted individuals with persistent mobility impairments. Volunteers were ineligible for the study for any of the following: (1) pathological fracture, bilateral femur fractures, or previous contralateral femur fracture; (2) inability to provide informed consent due to dementia or cognitive impairment or a Short Blessed Test score of 11 or greater[11]; (3) inability to walk 50 ft (using an assistive device, if needed); (4) visual or hearing impairments that interfered with following directions or judged to potentially interfere with performing exercises safely; (5) cardiopulmonary disease or neuromuscular impairments that would contraindicate participation in a weight-training program (unstable angina or congestive heart failure, spinal stenosis, symptomatic spondylosis, etc); (6) conditions that would not be expected to improve with exercise training (eg, severe Parkinson disease, cerebrovascular disease with residual hemiparesis); (7) initiation of medication for osteoporosis or hormone therapy within 12 months of screening; or (8) terminal illness with life expectancy of less than 1 year.

Random assignment to the intervention group or the control group was performed on completion of the baseline assessments within strata, defined as the type of surgical repair procedure (hemiarthroplasty vs open reduction internal fixation), using a computer-generated algorithm and a block design. Participants who were unable or unwilling to drive to our research facility were provided transportation for all assessment and exercise sessions.

Outcome Assessments

Participants underwent a series of assessments at baseline and at 3 and 6 months after baseline using standardized procedures and forms. Follow-up data collection at 3 and 6 months was attempted for all participants, even those who had discontinued the therapy to which they had been assigned or who had received less than the full dose of exercise. The primary patient outcomes were the total scores on the modified PPT, FSQ, and ADL instruments.

Participants also underwent assessments of muscle strength, gait, balance, body composition, and quality of life. Maximal voluntary muscle strength for knee extension and flexion of the fractured and unfractured limbs was measured using Cybex isokinetic dynamometry (Cybex International, Medway, Mass). Gait speed was measured for the middle 7 m of a 12-m walkway at the participant's self-selected and maximal gait speed. Balance was measured with the Progressive Romberg Test,[14] Berg Balance Instrument,[19] and a timed single-limb stance.[20] Total body dual-energy x-ray absorptiometry (DEXA) (Hologic QDR1000/W, software version 6.2OD, Waltham, Mass) was used to assess total and regional fat-free mass and bone mineral density (BMD). The Medical Outcomes Study Short-Form 36 (SF-36) instrument[21] and a modified version of the Hip Rating Questionnaire[22] were administered to measure quality of life. The procedures for these measurements have been described in detail.[18,23,24] Except for DEXA measurement, the research staff who conducted the assessments were not involved in exercise training and were blinded to group assignment.

Participants completed 3-day food records at baseline under the supervision of a registered dietitian. Individuals with a body mass index (calculated as weight in kilograms divided by the square of height in meters) below 21 or a food record that documented low calorie and protein intake were instructed about strategies to increase calories and the nutrient density of the foods chosen. Weight was measured monthly, and individuals who experienced weight loss were monitored by a dietitian. To control for variations in micronutrient and calcium intake, all participants were provided with calcium tablets, prescribed at 500 mg twice per day, and a daily multivitamin tablet. Individuals with a baseline serum 25-hydroxyvitamin D level of less than 16 ng/dL were given a single oral bolus dose of vitamin D, 100 000 IU, at baseline.[25]

Supervised Physical Therapy and Exercise Training

The exercise training program was conducted at an indoor exercise facility located at the Washington University Medical Center campus. It consisted of 2 approximately 3-month-long phases of exercise training. The initial phase of exercise was designed to prepare the participants for progressive resistance training and also to minimize injury. Our pilot studies indicated that very few patients were able to perform a program of progressive resistance training with weight-lifting machines at the time of enrollment. Exercises during the first 3-month phase (phase 1) were conducted by a physical therapist using a group format (2-5 participants/group) and were designed to enhance flexibility, balance, coordination, movement speed, and, to some extent, strength of all major muscle groups. Twenty-two exercises formed the basis of this program (protocol available from the authors). The exercises were made progressively more difficult by increasing the number of repetitions and/or by performing the exercises in more challenging ways. The exercises were modified by the physical therapist to accommodate and/or target each participant's specific physical impairments. Common adaptations included increased time and/or attention to flexibility exercises targeted at hip flexors and extensors of the fractured leg, weight-shifting exercises, strengthening exercises for hip flexors, extensors, and abductors, and limitations of the amount of range of motion or weight used due to arthritis. Phase 1 exercises were progressed when the participant was able to perform the current level easily and the next level safely. When safely able, participants also exercised on a stationary bicycle or treadmill. Participants attempted this exercise for a minimum of 5 minutes and progressed to a maximum of 15 minutes. The treadmill speed or bicycle resistance was set at the highest comfortable setting that was safe for the participant. A formal aerobic exercise training protocol was not performed. Exercise sessions lasted 45 to 90 minutes (with breaks), depending on the participant's ability and tolerance, which increased over the course of phase 1.

During the second exercise phase (phase 2), progressive resistance training was added. One-repetition maximum (1-RM) voluntary strength was measured on each of 6 different exercises (knee extension, knee flexion, seated bench press, seated row, leg press, and biceps curl), which were performed bilaterally on a Hoist weightlifting machine (Hoist Fitness Systems, San Diego, Calif). Initially, the participants performed 1 to 2 sets of 6 to 8 repetitions of each exercise at 65% of their 1-RM. By the end of the first month of weight training, they progressed to 3 sets of 8 to 12 repetitions performed at 85% to 100% of the initial 1-RM. The 1-RM measurements were repeated at 6 weeks and used to progressively increase each individual's exercise prescription. Participants continued to perform a shortened version of the phase 1 exercises and the treadmill or stationary bicycle warm-up exercise.

Participants were required to attend exercise sessions 3 times per week and to complete 36 sessions of each exercise phase before progression to the next phase of exercise training and program completion. Participants who missed exercise sessions because of illness or brief vacations were allowed to make up the sessions, up to a maximum of 9 sessions.

Control Condition

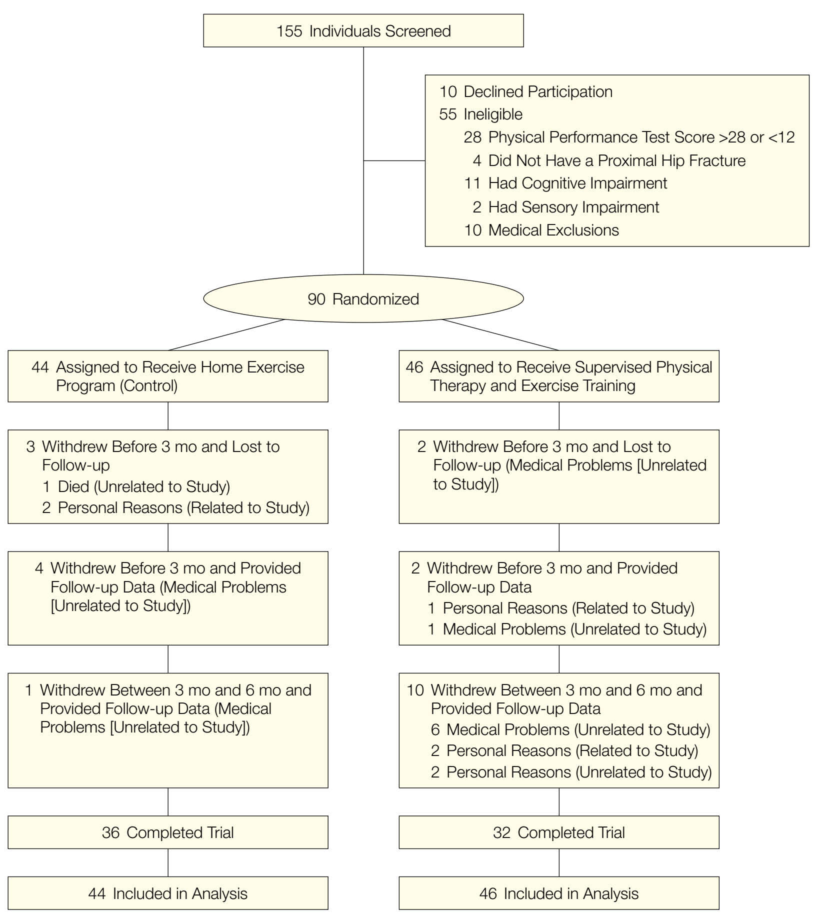
The rationale for the home exercise program was to provide the participants with a low-intensity exercise program that would mimic standard care after surgical repair and rehabilitation for a hip fracture. Commonly, such patients are prescribed a home exercise program at the conclusion of their course of physical therapy. The home exercise protocol included 9 of the 22 core exercises included in phase 1 of the supervised exercise program and focused primarily on flexibility. Control participants attended a 1-hour training session at our exercise facility. They were asked to perform the exercises at home 3 times per week but were not prohibited from performing them more often or from taking part in some other forms of exercise, such as walking or swimming. They were specifically prohibited from participating in a weight-training program. To enhance adherence, control participants attended a monthly 1-hour group session at our exercise facility during which the home exercise program was performed. Control exercises did not progress in difficulty beyond the first level for the physical therapy phase 1 program. In an effort to control for the increased social contact during physical therapy exercise sessions, weekly 10-minute telephone calls were made to control participants, during which research, health, and social issues were discussed. Control participants performed the assigned exercises for 2 consecutive 3-month intervals. Follow-up testing was performed at the end of each interval. Control participants recorded the number of exercise sessions performed on a calendar that was turned in monthly.

Statistical Analysis

The primary efficacy analysis used an intention-to-treat approach based on data from all randomized participants. This analysis included participants who completed the study and those who withdrew participation or completed less than the full dose of the supervised physical therapy program. Between-group comparisons of variables measured at a single time point were performed using unpaired *t* tests (for continuous variables) or χ^2 tests (for categorical variables), unless otherwise specified. Because of missing data, all longitudinal analyses for variables that were measured at more than 2 time points were carried out using mixed-model repeated-measures analysis of variance with the MIXED procedure in SAS, version 8.2 (SAS Institute Inc, Cary, NC). The focus of these analyses was on the significance of the interaction between group and time, which tested hypotheses regarding the equality of changes over time in the 2 groups. Within the framework of the mixed-model analysis, when interactions were significant ($P \leq .10$), the appropriate statistical contrasts were used in testing the null hypothesis that changes between 2 specific time points in one group were equal to corresponding changes in the other group. The mixed models were adjusted for the sample characteristic that was significantly different across groups (ie, number of days between baseline and final assessment). For participants who withdrew participation and did not provide any follow-up data (n=5), we used the last-observation-carried-forward method to impute missing data for their follow-up assessments. Analyses for variables that were measured at only 2 time points were carried out using analysis of covariance (ANCOVA), with the 6-month value as the dependent variable and the baseline value as covariate. All statistical tests were 2-tailed; $P < .05$ was considered to indicate statistical significance.

To address the issue of bias due to differential dropout rates between 3 and 6 months, we first performed a mixed-model repeated-measures analysis of variance using the Marcov Chain Monte Carlo method of imputation[26] for both primary and secondary outcome measures. Second, we compared the change in each primary outcome measure from baseline to 3 months for participants with and without 6-month follow-up data. For this analysis, we performed ANCOVA with the baseline value as a covariate and the 3-month value as the dependent variable. A separate ANCOVA was performed for each study group.

Figure 1. Flow of Participants Through the Trial



RESULTS

Study Population

One hundred fifty-five patients with hip fracture (46 men and 109 women) underwent the screening assessments (FIGURE 1). Fifty-five were excluded from participation. Of the 100 persons determined to be eligible, 10 (10%) declined participation. Eligible persons who declined to participate had less education than those who agreed to participate (10.7 [3.1] years vs 12.7 [2.7] years, respectively; $P = .03$) but otherwise did not differ significantly with respect to age, sex, modified PPT score, or ADL scores. Ninety individuals were randomized, 44 to the control group and 46 to physical therapy. A total of 22 individuals (24% of the sample) withdrew participation from the study. Five individuals withdrew participation within the first 3 months and did not provide any follow-up data. The 5 individuals who were lost to follow-up did not differ from the 85 participants who provided follow-up data with respect to age, sex, education, race (determined by self-report), fracture type, surgical repair type, baseline PPT, IADL, BADL, and FSQ, and number of days between hip fracture repair and enrollment ($P > .10$).

The baseline characteristics of participants included in the primary analysis did not differ between the 2 groups (TABLE 1). Seventeen participants (5 control and 12 physical therapy; 19% of sample) withdrew from the study and provided some follow-up data.

The 22 individuals who withdrew from the study did not differ from individuals who completed the study with respect to age, sex, education, fracture and surgical repair type, and baseline PPT and FSQ scores. Compared with participants who completed the study, participants who withdrew participation had significantly more days between surgical repair for the hip fracture and study enrollment (96 days vs 116 days, respectively; $P=.01$).

Adherence to the Protocol and Adverse Events

Among the physical therapy participants who provided follow-up data (n=44), adherence to the prescribed 72 exercise sessions was 87% (24%). Physical therapy participants exercised an average of 2.3 (0.2) exercise sessions per week. Among control participants who provided follow-up data (n=41), compliance with the exercise logs, measured as the percentage of completed logs out of a possible 6, was 67% (41%). Among control participants who provided exercise log data (n=32), exercise adherence, measured as the percentage of 72 sessions performed, was 131% (62%), indicating that many participants performed the exercises more than 3 times per week. Another informative measure that could be compared between groups was the time between baseline and the final follow-up assessments. There were group differences, with 248 (35) days for physical therapy and 231 (33) days for control ($P=.03$).

There were 3 adverse events directly related to the physical therapy protocol. One physical therapy participant fell during an exercise session and sustained a rib fracture; another physical therapy participant experienced a fractured metatarsal bone that was not symptomatic until a few days after an exercise session; and a third physical therapy participant sustained an ecchymosis to the ankle following a weight training session, without evidence of any other injury. All 3 individuals completed the physical therapy program. One physical therapy participant required continuous electrocardiographic monitoring during phase 2 because of a history of coronary artery disease and presence of frequent ventricular ectopy during an exercise treadmill test, but did not experience any adverse events. Four participants sustained fractures unrelated to exercise performance: 2 control participants fractured the contralateral hip; 1 physical therapy participant sustained a sacral fracture; another physical therapy participant sustained a fractured ulna. There were no other adverse events.

Primary Outcome Measures. Overall, physical therapy participants had improved physical performance and less self-reported disability than control participants at the final follow-up evaluation. The results of the mixed-models analyses for the change in the total modi-

Table 1. Baseline Characteristics of Participants Included in the Primary Analysis*

Characteristics	Control Group (n = 44)	Physical Therapy Group (n = 46)	*P* Value
Age, y	81 (8)	80 (7)	.46
Education, y	13 (3)	13 (3)	.92
Female, No. (%)	34 (77)	33 (72)	.55
White race, No. (%)	39 (89)	40 (87)	.81
Married, No. (%)	13 (30)	18 (39)	.34
Living alone, No. (%)	30 (68)	24 (52)	.12
Fracture type, No. (%)			
Subcapital	24 (55)	23 (50)	.45†
Intertrochanteric)	17 (39)	22 (48)	
Other	3 (7)	1 (2)	
Surgical repair type, No. (%)			
Hemiarthroplasty	20 (45)	17 (37)	.41
ORIF	24 (55)	29 (63)	
SBT score	2.7 (2)	2.0 (2)	.15†
GDS score	2.9 (3)	2.5 (2)	.83†
BMI	26 (4)	25 (5)	.27
Body weight, kg	64 (14)	64 (16)	.88
No. of routine medications	3.6 (2)	4.0 (2)	.36†
Charlson comorbidity index score	1.0 (2)	0.6 (1)	.21†
No. of falls in previous 12 mo	1.7 (1)	1.4 (1)	.36†
No. of assistive devices used for ADLs	2.7 (1)	3.1 (2)	.25
Prefracture IADL score	12.6 (1.8)	13.0 (1.5)	.33
Prefracture BADL score	13.5 (0.9)	13.4 (0.9)	.71
Use of assistive device to perform PPT, No. (%)	35 (80)	38 (83)	.71
Time from hip fracture to enrollment, d	103 (30)	99 (36)	.62
Medical history, No. (%)			
High blood pressure	23 (52)	25 (54)	.84
Arthritis	35 (80)	34 (74)	.53
Osteoporosis	13 (30)	16 (35)	.60
Diabetes	4 (9)	3 (7)	.71†
Atrial fibrillation	4 (9)	4 (9)	>.99†
Coronary artery bypass graft surgery	1 (2)	3 (7)	.62†
Congestive heart failure	2 (5)	1 (2)	.61†
Taking medication for osteoporosis ≥12 months prior to screening, No. (%)‡	11 (25)	10 (22)	.72
Using calcium supplements, No. (%)	16 (36)	18 (39)	.79
Serum 25-hydroxyvitamin D level, ng/dL	16.5 (7.2)	17.0 (8.7)	.80

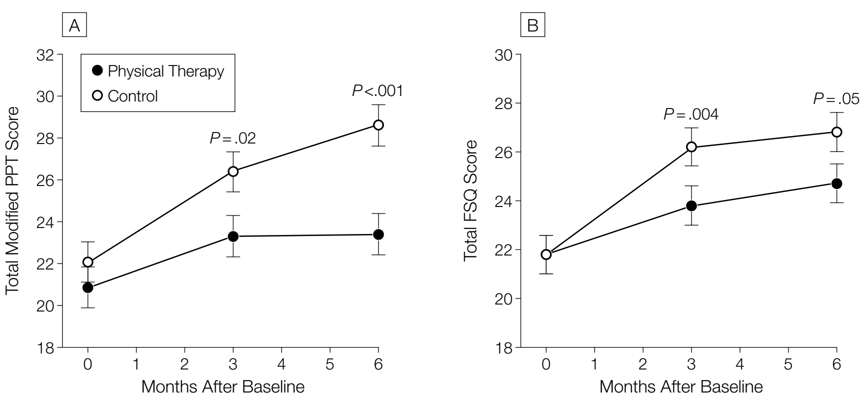
Abbreviations: ADLs, activities of daily living; BADLs, basic activities of daily living (eating, dressing, grooming, transferring, walking, bathing, and toileting); BMI, body mass index, calculated as weight in kilograms divided by the square of height in meters; GDS, Geriatric Depression Scale; IADL, instrumental activities of daily living (telephone use, shopping, transportation use, meal preparation, housework, medication use, and finances); ORIF, open reduction internal fixation; PPT, Physical Performance Test; SBT, Short Blessed Test of Orientation, Memory, and Concentration.
Conversion factor: To convert vitamin D level to nmol/L, multiply by 2.496.
*Data are expressed as mean (SD) unless otherwise noted.
†*P* values based on Wilcoxon rank-sum test or Fisher exact test.
‡Medications included bisphosphonates, estrogen, and calcitonin (no participant was taking raloxifene).

Table 2. Primary Outcome Measures

Outcome Measures	Control Group (n = 44) No.	Control Group (n = 44) Mean (SD)	Physical Therapy Group (n = 46) No.	Physical Therapy Group (n = 46) Mean (SD)	*P* Value	*P* Value for Change Over Time
PPT score (possible range, 0-36)						
Baseline	44	20.7 (6.2)	46	22.2 (5.9)	.25*	.02‡
3 mo	39	23.7 (8.2)	44	26.5 (6.3)		.02§
6 mo	43	23.3 (7.4)	37	29.0 (6.1)	.003†	<.001‖
FSQ score (possible range, 0-36)						
Baseline	44	21.8 (5.0)	46	21.8 (4.7)	.94*	.004‡
3 mo	41	24.2 (5.5)	45	26.3 (5.0)		.72§
6 mo	43	24.8 (5.6)	40	27.3 (5.7)	.01†	.05‖
IADL score (possible range, 0-14)						
Baseline	44	10.0 (2.6)	46	10.4 (2.2)	.42*	. . .
3 mo	41	11.0 (2.6)	45	11.7 (2.3)		. . .
6 mo	43	11.3 (2.5)	40	11.9 (2.6)	.58†	. . .
BADL score (possible range, 0-14)						
Baseline	44	12.3 (1.5)	46	12.4 (1.5)	.71*	. . .
3 mo	41	12.7 (1.3)	45	13.1 (1.1)		. . .
6 mo	43	12.8 (1.3)	41	13.2 (1.2)	.34†	. . .
Assistive device not used for gait, if required at baseline, No. (%)	35	11 (31)	33	19 (58)	.03	

Abbreviations: BADL, basic activities of daily living; ellipses, data not calculated for statistical contrasts between time points when the overall model for change was not significant; FSQ, Functional Status Questionnaire, IADL, instrumental activities of daily living; PPT, Physical Performance Test.
**P* value testing for baseline differences between groups.
†*P* value testing the group × time interaction.
‡*P* value for change from baseline to 3 months.
§*P* value for change from 3 months to 6 months.
‖*P* value for change from baseline to 6 months.

Figure 2. Changes in Total Modified PPT and Total FSQ Scores From Baseline to End of Study



PPT indicates Physical Performance Score; FSQ, Functional Status Questionnaire. Data are least square means (SEs). *P* values are for comparisons between physical therapy group vs control group and indicate significantly different values from baseline.

fied PPT score and the FSQ score favored the physical therapy group, indicating better physical performance and less difficulty with ADLs compared with controls (TABLE 2). These effects remained significant for the physical therapy group after controlling for age, sex, and the SF-36 Social Function subscale score (*P*=.001 for PPT model; *P*=.01 for FSQ model). Physical therapy participants had significantly greater increases than controls on the modified PPT score between baseline and 6 months (*P*<.001) (FIGURE 2A). The change in FSQ score between baseline and 6 months also favored the physical therapy group (*P*=.05) (Figure 2B). Mean change in the PPT score for physical therapy and control were 6.5 (5.5) points (95% confidence interval [CI], 4.6-8.3), and 2.5 (3.7) points (95% CI, 1.4-3.6 points), respectively. Mean change in FSQ score for physical therapy and control were 5.2 (5.4) points (95% CI, 3.5-6.9), and 2.9 (3.8) points (95% CI, 1.7-4.0 points), respectively. The group × time interactions for the changes in the BADL and IADL scores were not significant. However, among individuals who used an assistive device to perform the PPT at baseline, physical therapy participants were less likely to need a device at the time of final testing (Table 2; *P*=.03). In addition, comparisons between prefracture and 6-month ADL scores showed that among participants who provided follow-up data, the mean change on the IADL score was −1.1 (1.9) for controls and +0.04 (1.9) for physical therapy participants (*P*=.02); on the BADL score, the mean change was −0.6 (1.1) for controls and +0.04 (0.7) for physical therapy participants (*P*=.01), indicating an overall decline for controls and a return toward baseline in the physical therapy group.

Analyses of the change in each primary outcome measure between baseline and 3 months showed that for the control group, participants who withdrew participation between 3 and 6 months improved less on the FSQ and BADL scales at 3 months than individuals who completed the study (data not shown).

Secondary Outcome Measures. The effects of the exercise programs on selected secondary outcome measurements are shown in **TABLE 3** and **FIGURE 3**. Physical therapy participants had significantly greater improvements than controls in maximum voluntary knee extensor torque for both the fractured and unfractured legs, 1-RM strength measures, fast walking speed, Berg Balance score, single-limb stance time for the fractured leg, total Hip Rating Questionnaire score, and the Change in Health and Physical Function subscale scores of the SF-36. There were no significant group × time effects for the changes in body weight (data not shown), total fat-free mass, total body BMD, or total hip or femoral neck BMD (data not shown) of the contralateral femur.

Serum 25-hydroxyvitamin D levels increased in both groups without a between-group difference in the observed changes (6-month value, 27.4 [8.9] ng/dL for controls and 24.4 [8.0] ng/dL for physical therapy; $P=.13$). The proportion of participants in each group who received the bolus dose of vitamin D also was not significantly different.

COMMENT

This randomized clinical trial provides evidence that extended outpatient rehabilitation that includes whole-body progressive resistance training is effective at improving physical function and mobility among elderly community-dwelling hip fracture patients with physical frailty. Compared with a low-intensity home exercise program, the 6-month intensive rehabilitation program also led to clinically relevant reductions in self-reported disability and improved quality of life at approximately 9 to 12 months after the hip fracture. These changes were associated with improvements in skeletal muscle strength for a number of key muscle groups, gait speed, and balance.

Only a small number of controlled studies have been conducted of rehabilitation interventions after hip fracture. Most were performed in the acute hospital or immediate postdischarge setting and focused on short-term outcomes, with mixed results.[27-30] Tinnetti et al[31] conducted a randomized trial of a 12-month home-based rehabilitation program that included low-intensity strengthening exercises using resistive elastic bands. At 12 months after fracture, they did not observe group differences in measures of muscle strength, balance, gait, or ADL function, suggesting that a more intense resistance exercise stimulus might be required. In a small (n=24) randomized trial that included both elderly hip fracture and elective hip replacement patients, Hauer et al[32] recently found that 3 months of functional and progressive resistance training induced greater increases in measures of muscle strength, gait velocity, and balance but not self-reported disability compared with a control group that performed stretching exercises and memory tasks. Our study extends the evidence supporting the use of intensive exercise and progressive resistance training to improve physical function in this patient population.

Despite the advanced age and degree of physical frailty of the patients enrolled in this study, our supervised exercise protocol was generally well tolerated, with few adverse events directly related to exercise performance. The physical therapy intervention was designed with consecutive phases of exercise in an effort to minimize injury and prepare the participants for the weight training component of the program. It is easily adaptable to outpatient physical therapy settings, many of which now have facilities for progressive resistance training.

This study has implications for clinical practice, and potential implications for Medicare and insurance policy. Our findings suggest that elderly hip fracture patients who respond positively to home physical therapy but have persistent ADL and mobility impairments should be referred to outpatient rehabilitation facilities on discharge from their home program. It is unclear, however, whether Medicare and/or third-party insurance will reimburse for the 72 treatment sessions prescribed for our physical therapy group. Current Medicare guidelines for physical therapy include procedures for gait training and for the amelioration of losses or restrictions in mobility, strength, balance, or coordination. "Standard treatment" is considered to be 12 to 18 sessions within a 4- to 6-week period, although theoretically this can be extended pursuant to a written plan provided by a physician.[33,34] Therapy providers may face regional variability in payments for therapeutic procedures.[35] A change in Medicare policy may be necessary to implement this type of protocol for a treatment period of up to 6 months. Because we did not collect detailed information about the costs of our intervention, we are unable to evaluate potential costs in comparison with the clinical benefits derived. This type of analysis, as well as the long-term effects of this type of intervention on functional outcomes, should be a focus for future studies.

Our fracture rate is notable and is higher than in studies of exercise conducted in less frail or institutionalized elderly populations,[18,36-38] which did not report any fractures. The risk of sustaining a contralateral hip fracture has been estimated to be 6- to 20-fold that of the initial hip fracture,[8,39,40] a large percentage of which occur within the first year.[41] Our rate of 2 contralateral hip fractures may be slightly higher than that observed in a Danish study by Schroder et al,[40] in which the risk of a second hip fracture among 3898 individuals aged 40 years or older was 22 per 1000 women per year and 11 per 1000 men per year, although the advanced age and frailty of our participants make direct comparisons difficult. Our study was not powered to detect differences

Table 3. Selected Secondary Outcome Measures

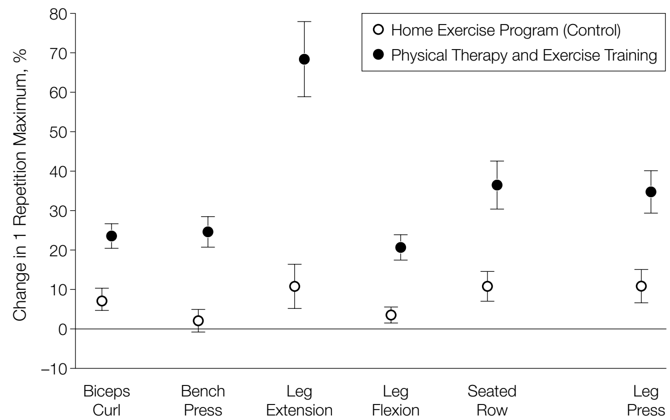
Outcome Measures	Control Group (n = 44)		Physical Therapy Group (n = 46)			
	No.	Mean (SD)	No.	Mean (SD)	*P* Value	*P* Value for Change Over Time*
Knee extension 60°/s, ft/lb						
Fractured side						
Baseline	42	32.9 (17.4)	43	35.6 (16.1)	.47†	.02¶
3 mo	37	40.6 (21.3)	42	47.1 (22.5)		.14#
6 mo	41	42.2 (19.8)	36	55.6 (25.1)	.01‡	.004**
Unfractured side						
Baseline	43	47.9 (18.4)	45	51.4 (23.4)	.44†	.35¶
3 mo	38	53.1 (18.7)	43	55.0 (22.3)		.02#
6 mo	42	51.9 (20.5)	37	62.4 (24.5)	.03‡	.01**
Fast walking speed, m/min						
Baseline	44	51.7 (17.0)	45	53.9 (16.3)	.55†	.002¶
3 mo	39	59.6 (22.6)	44	69.4 (22.0)		.69#
6 mo	43	59.4 (23.0)	36	72.9 (24.5)	.005‡	.008**
Single limb stance time, s						
Fractured side						
Baseline	33	1.9 (2.0)	42	1.6 (2.0)	.41†§	.006¶
3 mo	31	3.3 (6.1)	41	5.5 (8.4)		.89#
6 mo	34	2.8 (3.1)	38	6.8 (8.8)	.02‡‖	.04**
Unfractured side						
Baseline	36	3.7 (5.6)	42	5.0 (7.5)	.71†§	...
3 mo	33	3.6 (4.5)	40	5.7 (7.9)		...
6 mo	36	3.8 (5.0)	38	6.9 (7.1)	.22‡‖	...
Berg Balance Score (possible range, 0-56)						
Baseline	44	41 (8)	45	43 (7)	.26†	.01¶
3 mo	38	44 (10)	44	48 (7)		.37#
6 mo	42	43 (10)	39	49 (8)	.02‡	.009**
Total fat-free mass, kg						
Baseline	40	39.7 (7.5)	43	41.7 (10.2)	.32†	...
3 mo	37	41.0 (7.4)	41	42.6 (10.7)		...
6 mo	40	40.5 (7.7)	39	42.9 (11.4)	.35‡	...
Bone mineral density, g/cm^2						
Total body						
Baseline	40	1.00 (0.12)	44	1.02 (0.13)	.58†	...
3 mo	37	1.00 (0.12)	42	1.02 (0.14)		...
6 mo	40	1.00 (0.11)	39	1.03 (0.13)	.17‡	...
Total hip						
Baseline	39	0.68 (0.13)	44	0.63 (0.17)	.11†	...
3 mo	39	0.69 (0.12)	43	0.63 (0.16)		...
6 mo	40	0.69 (0.12)	38	0.64 (0.18)	.19‡	...
Short-Form 36 score						
Change in Health subscale (possible range, 0-100)						
Baseline	43	32 (16)	45	31 (16)	.78†	.21¶
3 mo	40	37 (19)	45	41 (19)		.05#
6 mo	42	41 (25)	41	58 (23)	.01‡	.004**
Physical Function subscale (possible range, 0-100)						
Baseline	43	49 (23)	45	51 (24)	.71†	.01¶
3 mo	40	60 (25)	45	68 (21)		.82#
6 mo	42	63 (27)	41	74 (22)	.04‡	.04**
Social Function subscale (possible range, 0-100)						
Baseline	43	76 (28)	45	70 (26)	.26†	.03¶
3 mo	40	87 (24)	45	89 (20)		.82#
6 mo	42	87 (24)	41	92 (16)	.07‡	.05**
Hip Rating Questionnaire total score (possible range, 0-100)						
Baseline	43	74 (12)	45	72 (10)	.45†	<.001¶
3 mo	40	79 (13)	45	82 (11)		.57#
6 mo	42	80 (11)	41	84 (11)	.002‡	.003**

*Ellipses indicate data not calculated for statistical contrasts between time points when the overall model for change was not significant.
†*P* value testing for baseline differences between groups.
‡*P* value testing the group × time interaction.
§Baseline comparisons using Wilcoxon rank-sum test.
‖Mixed-model analysis performed using ranks.
¶*P* value for change from baseline to 3 months.
#*P* value for change from 3 months to 6 months.
***P* value for change from baseline to 6 months.

in the rate of fracture between the intervention groups, as this would require a sample size of several hundred patients.

We did not observe between-group differences in the changes in total or regional BMD or fat-free mass. It is notable, however, that declines in our measures of body composition were not observed over the study period. Prospective studies of BMD following a hip fracture have consistently documented a loss of approximately 4% at the femoral neck and 2% in the intertrochanteric region at 12 months after fracture.[42-44] Fox et al[42] also documented a 6% decline in lean body mass at 12 months after fracture in a sample of elderly female hip fracture patients. Because we provided calcium and vitamin D supplements and nutritional counseling, we cannot distinguish between the effects of exercise and nutritional supplementation in preventing a decline in BMD and fat-free mass. Some may question the inclusion of calcium and vitamin D supplements in this study. Because of the high incidence of osteoporosis in elderly hip fracture patients[43,45,46] and the evidence supporting the use of these supplements for osteoporosis[47] and because body composition measures were secondary outcomes, we did not think it was ethical to prohibit participants from taking supplements, and we implemented a protocol to control for their use. Results from our study suggest that calcium and multivitamin supplements combined with low-intensity home-based exercise may protect against bone loss after hip fracture. Further study is needed to confirm this and to determine the independent effects of micronutrient supplementation and exercise in this patient population.

Figure 3. Change in 1-Repetition Maximum Voluntary Strength Values Between Month 3 and Month 6



Data are means (SEs). All group differences were significant ($P<.001$) after adjusting for the 3-month value.

Our findings have some limitations. One issue is the generalizability of our findings. Because we included community-dwelling ambulatory hip fracture patients with mobility and ADL impairments, our findings may not apply to individuals who are more fit or those with more severe physical or cognitive impairments, including nursing home residents. Our intent was to specifically target individuals in the community at risk of decline and nursing home placement. Based on our experience screening individuals for this study, we estimate that approximately 20% to 30% of hip fracture patients aged 65 years or older may be appropriate for this type of intervention. To maximize study adherence, we provided transportation, which may not be practical in many clinical settings. Our study sample may not reflect the percentage of eligible individuals who would be able to participate in this type of rehabilitation program without such support. Our rate of dropout of 24% is comparable with other studies of exercise in elderly patients.[18,48] Individuals who dropped out of the control group between 3 and 6 months improved less on the FSQ at 3 months than individuals who continued. This may have biased our estimates of the magnitude of the group difference in the FSQ score at 6 months.

The lack of a nonexercising control group limits our ability to determine the effect of different intensities of exercise on the functional outcomes and may have reduced the magnitude of the effect size of the physical therapy intervention. Physical therapy participants may have had greater social contact than controls, and it is possible that an increased level of socialization enhanced their motivation more than in controls and may account for some of the improvements observed, particularly the SF-36 measures. However, the high compliance rate and lower dropout rate among control participants appear to reflect a high level of motivation. It is unlikely that differences in socialization account for the changes observed in the modified PPT and strength measures, and this is supported by analyses of covariance that included the changes in SF-36 Social Functioning subscale scores. Our study was not designed to answer questions about the optimal timing of intensive physical therapy or weight training, and further study is needed to address this issue. Most patients who had a hemiarthroplasty repair procedure were prescribed range-of-motion restrictions that prohibited them from performing some of the exercises, including lower-extremity weight training, until 10 to 12 weeks after their fracture.

In summary, the present study demonstrates that extended supervised outpatient rehabilitation in elderly hip fracture patients with physical frailty results in improved physical performance and mobility, reduced disability, and improved quality of life. Our findings raise a question about whether the current practice of discontinuing physical therapy at the conclusion of home treatment is sufficient for this high-risk population. Further research is needed to determine whether the effects obtained in this study can be replicated in outpatient rehabilitation facilities, and the long-term effects of this type of intervention. Although these issues and questions regarding the optimal training protocol remain unanswered, the present findings have important implications for rehabilitation of patients with persistent mobility and ADL impairments after a hip fracture.

Author Contributions: Dr Binder had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Binder, Brown, Sinacore, Yarasheski, Schechtman.
Acquisition of data: Binder, Brown, Sinacore.
Analysis and interpretation of data: Binder, Sinacore, Steger-May, Yarasheski, Schechtman.
Drafting of the manuscript: Binder, Steger-May, Yarasheski.
Critical revision of the manuscript for important intellectual content: Brown, Sinacore, Yarasheski, Schechtman.
Statistical analysis: Binder, Steger-May, Schechtman.
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Study supervision: Binder, Sinacore.

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