

## Original Investigation

# Effect of a Home-Based Exercise Program on Functional Recovery Following Rehabilitation After Hip Fracture

## A Randomized Clinical Trial

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**IMPORTANCE** For many older people, long-term functional limitations persist after a hip fracture. The efficacy of a home exercise program with minimal supervision after formal hip fracture rehabilitation ends has not been established.

**OBJECTIVE** To determine whether a home exercise program with minimal contact with a physical therapist improved function after formal hip fracture rehabilitation ended.

**DESIGN, SETTING, AND PARTICIPANTS** Randomized clinical trial conducted from September 2008 to October 2012 in the homes of 232 functionally limited older adults who had completed traditional rehabilitation after a hip fracture.

**INTERVENTIONS** The intervention group (n = 120) received functionally oriented exercises (such as standing from a chair, climbing a step) taught by a physical therapist and performed independently by the participants in their homes for 6 months. The attention control group (n = 112) received in-home and telephone-based cardiovascular nutrition education.

**MAIN OUTCOMES AND MEASURES** Physical function assessed at baseline, 6 months (ie, at completion of the intervention), and 9 months by blinded assessors. The primary outcome was change in function at 6 months measured by the Short Physical Performance Battery (SPPB; range 0-12, higher score indicates better function) and the Activity Measure for Post-Acute Care (AM-PAC) mobility and daily activity (range, 23-85 and 9-101, higher score indicates better function).

**RESULTS** Among the 232 randomized patients, 195 were followed up at 6 months and included in the primary analysis. The intervention group (n=100) showed significant improvement relative to the control group (n=95) in functional mobility (mean SPPB scores for intervention group: 6.2 [SD, 2.7] at baseline, 7.2 [SD, 3] at 6 months; control group: 6.0 [SD, 2.8] at baseline, 6.2 [SD, 3] at 6 months; and between-group differences: 0.8 [95% CI, 0.4 to 1.2],  $P < .001$ ; mean AM-PAC mobility scores for intervention group: 56.2 [SD, 7.3] at baseline, 58.1 [SD, 7.9] at 6 months; control group: 56 [SD, 7.1] at baseline, 56.6 [SD, 8.1] at 6 months; and between-group difference, 1.3 [95% CI, 0.2 to 2.4],  $P = .03$ ; and mean AM-PAC daily activity scores for intervention group: 57.4 [SD, 13.7] at baseline, 61.3 [SD, 15.7] at 6 months; control group: 58.2 [SD, 15.2] at baseline, 58.6 [SD, 15.3] at 6 months; and between-group difference, 3.5 [95% CI, 0.9 to 6.0],  $P = .03$ ). In multiple imputation analyses, between-group differences remained significant for SPPB and AM-PAC daily activity, but not for mobility. Significant between-group differences persisted at 9 months for all functional measures with and without imputation.

**CONCLUSIONS AND RELEVANCE** Among patients who had completed standard rehabilitation after hip fracture, the use of a home-based functionally oriented exercise program resulted in modest improvement in physical function at 6 months after randomization. The clinical importance of these findings remains to be determined.

**TRIAL REGISTRATION** clinicaltrials.gov Identifier: NCT00592813

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**M**ore than 250 000 people in the United States fracture their hip each year, with many experiencing severe long-term consequences.<sup>1-3</sup> Two years after a hip fracture, more than half of men and 39% of women are dead or living in a long-term care facility.<sup>4</sup> Many of these patients are no longer able to independently complete basic functional tasks that they could perform prior to the fracture, such as walking 1 block (>80% unable) or climbing 5 steps (90% unable) 2 years after a fracture.<sup>5</sup> In 2003, the lifetime attributable cost of a hip fracture was estimated to be \$81 300, with nearly half (44%) of these costs the result of long-term care expenses.<sup>6</sup>

A 2004 study<sup>7</sup> found that a 6-month intensive extended rehabilitation program conducted in an outpatient setting resulted in significant improvements in function, mobility, and other outcomes. Since this study, systematic reviews have concluded that intensive, supervised exercise programs can result in additional functional gain following hip fracture.<sup>8,9</sup> Although these studies demonstrate the potential for patients with hip fracture to improve their function, most efficacious programs are in essence a continuation of standard rehabilitation with close supervision and frequent visits. Given the increase in postacute care costs for hip fracture, it would be difficult to add a large amount of extended therapy to hip fracture treatment.<sup>10,11</sup>

The aim of this study was to determine the efficacy of a 6-month, functionally oriented, home exercise hip rehabilitation program with modest in-person contact with a physical therapist intended to extend the benefits of the initial hip fracture rehabilitation. Our primary objectives were to determine whether an extended hip rehabilitation intervention improved overall function at 6 months and to determine if the effects of the program persisted 9 months after randomization.

## Methods

This study was a randomized clinical trial with 2 parallel groups and blinded outcome assessment. Outcomes were assessed at baseline and at the primary end point of 6 months after randomization. A follow-up assessment occurred at 9 months after randomization. The study was approved by each site's institutional review board. A data and safety monitoring board met annually to monitor the study. The first patient was enrolled in September 2008 and the final outcome assessment was completed in October 2012.

### Participants

Potential participants were identified at acute care and rehabilitation hospitals, skilled nursing facilities, home care agencies, and through advertisements in the greater Boston, Massachusetts, region. Verbal consent was obtained to record each patient's contact information and enable contact via telephone. Patients were tracked until they had completed all traditional rehabilitation related to their hip fracture, at which time participants provided written informed consent to enroll in the study. Approval for participation

was obtained from the patient's primary care physician or orthopedic surgeon. Race and ethnicity was self-reported by study participants.

To be eligible for enrollment, participants had to have a primary diagnosis of hip fracture, be 60 years or older, and have been discharged from rehabilitation services within 20 months of the baseline assessment. Participants had to be able to understand and communicate in English and be able to safely and independently move from the sitting to the standing position with or without the aid of a mobility device. All participants had to have a functional limitation, which was defined as a limitation in at least 1 of the tasks listed in the Short Form 36 physical function scale.

Potential participants were excluded based on following criteria: significant cognitive deficits (ie, a Mini-Mental State Examination score of <20), severe depression (ie, a score of  $\geq 10$  on the short form of the Geriatric Depression Scale), a terminal illness (survival expected to be <1 year), significant pulmonary or cardiovascular contraindications or preexisting conditions that precluded participation in an exercise program, legally blind, currently receiving rehabilitation therapy, lived outside of the study's catchment area in New England, had a bilateral hip fracture, hip fracture was the result of a malignancy, it had been more than 24 months since the hip fracture at enrollment in the study, or had a rapidly progressive neurological disease.

### Outcome Measures

A blinded outcome assessor evaluated the participants at each time point in the patient's current place of residence. The primary outcome was physical function at 6 months after randomization. Function was measured using the Short Physical Performance Battery (SPPB)<sup>12</sup> (a physical performance measure) and the Activity Measure for Post-Acute Care (AM-PAC)<sup>13,14</sup> (a patient-reported measure). The 3 components of the SPPB are standing balance, gait speed, and chair rise; total scores range from 0 to 12 (with 0 indicating poor function and 12 indicating excellent function). The AM-PAC was developed to examine basic mobility and daily activity functional activities important to adults.<sup>13,14</sup> The range of possible scale scores for the AM-PAC is 23 to 85 for mobility and 9 to 101 for daily activity (higher scores indicate better function). The minimum clinically important difference is 0.3 to 0.8 points for the SPPB,<sup>15</sup> 4.3 points for the AM-PAC mobility, and 3.7 points for AM-PAC daily activity.<sup>14</sup>

The secondary outcomes included lower extremity isometric muscle strength, balance, self-efficacy, adverse events, and exercise adherence. Lower extremity isometric muscle strength was measured using a strain gauge dynamometer attached to a standardized chair. Following the protocol of Lord et al,<sup>16</sup> this measured bilateral knee extension force in pounds. Balance was assessed using the Berg Balance Test.<sup>17-19</sup> Falls self-efficacy was assessed using the Modified Falls Self-Efficacy Scale, which was initially developed by Tinetti et al<sup>20</sup> and later modified by Hill et al<sup>21</sup> to include community mobility tasks. The Self-Efficacy for Exercise Scale<sup>22</sup> and the Outcomes Expectations for Exercise Scale<sup>23</sup> were used to assess those concepts. Each scale was developed by Resnick et al,<sup>22,23</sup> had 9

items, and had been validated in older adults. Adverse events were monitored via telephone contact every 4 weeks by an adverse event monitor, as well as reported by study staff. Exercise adherence was recorded by participants on exercise calendars that were provided along with stamped, self-addressed envelopes. Participants received a \$1 bill as an incentive for returning the calendar every 2 weeks. The study physical therapists reminded participants to fill out the calendars, and obtained additional exercise data with each visit or telephone call.

### Stratification and Randomization

Participants were allocated to the intervention exercise program or attention control groups using a computerized central randomization scheme generated by the study biostatistician. A stratified block randomization technique was used to ensure that the number of patients in the treatment groups was balanced by sex, functional level, and most recent site of rehabilitation. Block size randomly varied between 6 and 8 to minimize the possibility of breaking the randomization scheme. After the research assistants enrolled participants, obtained consent, and completed all baseline assessments, the study manager ran the computer randomization program to assign patients to the treatment group.

### Intervention

The intervention group was instructed to perform the home exercise program 3 times per week for 6 months. This program was taught in 3 home visits conducted by a physical therapist, which lasted approximately 1 hour. A fourth training session was provided if health or other problems required additional modifications to the program. The physical therapists also provided monthly telephone calls. Participants were provided with a DVD version of the program and, if necessary, a DVD player.

The content of the intervention focused on repeating simple functional tasks based on the Strong for Life<sup>24</sup> program using Thera-Bands for resistance (eTable 1 in Supplement). The intervention also included standing exercises using steps of varying height, with weighted vests used to provide overload. These exercises were based on the INVEST<sup>25</sup> and Sherrington and Lord<sup>26</sup> hip fracture programs. The therapists also used cognitive and behavioral strategies to positively enhance the attitudes and beliefs of each study participant related to exercise, including viewing a DVD about the benefits of exercise and overcoming fear of falling, setting specific goals, and self-monitoring progress using an exercise calendar.<sup>24</sup>

### Attention Control Group

Registered dietitians provided the control group with nutrition education for cardiovascular health based on the Dietary Guidelines for Americans<sup>27</sup> during a single home visit of approximately 1 hour, followed by a series of telephone calls of approximately 30 minutes' duration and mailings. The frequency of contact with dietitians was matched to the contact with physical therapists in the intervention group. All participants received an illustrated nutrition manual designed specifically for this population.

### Statistical Analyses

The study was powered to detect a moderate effect size of 0.4 using the SPPB and the AM-PAC. This effect is equivalent to a change from 6 to 7 (SD, 2.5) on the SPPB or a change from 50 to 54 (SD, 10) on the AM-PAC. These differences would exceed the minimum clinically important difference for the SPPB<sup>15</sup> and for the AM-PAC daily activity domain.<sup>14</sup> Assuming an alpha level of .05, a 2-sided effect, and a loss to follow-up of 15% at 6 months, 230 participants would provide 80% power to detect an effect.

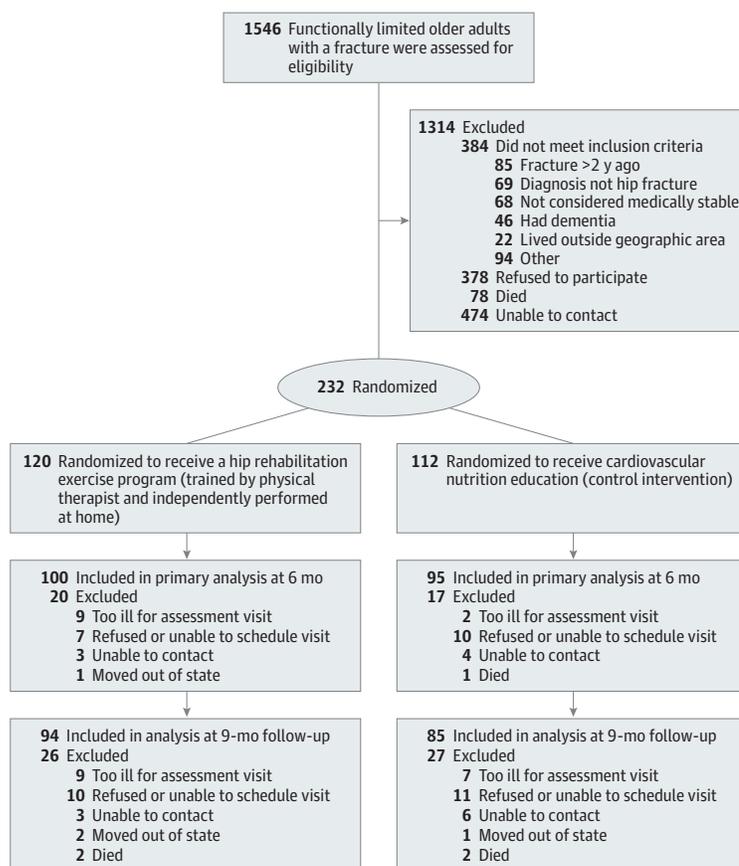
As a check on randomization, baseline characteristics of the intervention and control groups were compared using the independent sample *t* test (for continuous measures) and the  $\chi^2$  test (for categorical characteristics). Baseline characteristics were compared for those followed up vs those lost to follow-up at 6 months. The primary analyses for this trial were conducted on an intention-to-treat basis, in that participants were analyzed according to their randomized assignment, regardless of whether they complied with the study protocol. Mixed-effects linear regression models for longitudinal, repeated-measures data were used to examine changes in outcomes from baseline to 6 months and to 9 months. These models included interaction terms between study group (intervention vs control) and time (0, 6, or 9 months) that modeled differential changes from baseline to 6 months and baseline to 9 months for those in the intervention vs control groups (ie, the intervention effect). In addition to the unadjusted models, we also controlled for the potential confounding variables of age and sex, which were identified a priori.

The primary analyses included a complete case analysis (ie, the data without imputation or other adjustment for missing data). To account for possible bias introduced by the participants without 6-month and 9-month data, multiple imputation analyses were performed. The Markov Chain Monte Carlo approach, which is based on multivariate normality and appropriate for the measurement outcomes in this study, was used to generate 5 imputed data sets based on age, sex, and prior observations of the outcome variables. Data were imputed and analyzed using the SAS MI and MIANALYZE procedures (SAS Institute Inc). For all analyses, we used the 2-sided level of .05 for significance and SAS version 9.3 (SAS Institute Inc) statistical software.

## Results

We identified 1546 potentially eligible older adults (Figure 1). However, 1314 individuals were not randomized because they did not meet the criteria, refused to participate, had died, or were unable to be contacted. A total of 232 patients were randomized (120 to the intervention group and 112 to the control group). A total of 37 participants (20 in the intervention group and 17 in the control group), which amounted to 15.9% of the randomized sample, were lost to follow-up at 6 months (the primary end point). There were no significant differences based on age, baseline function, or sex between participants who were lost to follow-up and those who completed the study. Fifty-three participants (26 in the intervention group and 27

Figure 1. Patient Recruitment, Attrition, and Retention



Individuals who missed the 6-month assessment were still eligible to attend the 9-month assessment. There were 172 individuals who completed both the 6- and 9-month assessments, 20 completed only the 6-month assessment, and 7 completed only the 9-month assessment.

in the control group), which amounted to 21.6% of the randomized sample, were lost to follow-up at 9 months.

At enrollment, the mean age of participants was 78.0 years (SD, 9.9 years); 69% were female (Table 1). Almost half (46.6%) lived alone at study enrollment and most lived in their own home. Many of the participants had mobility limitations prior to their fracture; 35% regularly used a cane or other mobility device when walking outside in the month prior to their fracture. After their fracture, 32.3% of patients had a full or hemiarthroplasty, and the rest received a variety of other treatments including plates, nails, or rods. All study participants received some physical therapy after their fracture. After patients were discharged from inpatient care, 92.2% received home care therapy services and 42.4% received outpatient therapy. The mean (SD) SPPB score of 5.9 (2.8) at enrollment was consistent with severe functional limitations.<sup>15,28</sup>

The intervention group had a 70% rate of adherence to the exercise program across the 26 weeks (ie, they exercised an average of 2.1 times/week of the 3 times/week prescribed). The intervention group showed significant improvement relative to the control group for the primary outcomes for both the adjusted and unadjusted analyses (Table 2). The between-group differences for the mean change in functional scores at 6 months were 0.8 (95% CI, 0.4 to 1.2;  $P < .001$ ) for SPPB, 1.3 (95% CI, 0.2 to 2.4;  $P = .03$ )

for AM-PAC mobility, and 3.5 (95% CI, 0.9 to 6.0;  $P = .03$ ) for AM-PAC daily activity. When missing data were taken into account (multiple imputation analyses), effects continued to be statistically significant for the between-group difference in the change scores for SPPB (0.9 [95% CI, 0.5 to 1.3],  $P < .001$ ) and AM-PAC daily activity (3.4 [95% CI, 0.7 to 6.0],  $P = .01$ ); however, the effect for AM-PAC mobility was no longer statistically significant (1.0 [95% CI, -0.1 to 2.1],  $P = .06$ ) (eTable 2 in Supplement). The differences exceeded the minimal clinically important difference for the SPPB, but not for the AM-PAC measures.

Both the adjusted and unadjusted analyses indicated that a significant difference in function between the 2 groups persisted at the 9-month follow-up assessment and when the trend for the change over time was modeled across the 3 time points (Table 2). The between-group differences in the change scores at 9 months increased slightly compared with 6 months for the SPPB (1.0; 95% CI, 0.6-1.4) and AM-PAC mobility (1.7; 95% CI, 0.5-2.8), and declined slightly for AM-PAC daily activity (2.8; 95% CI, 0.3-5.4). However, there were no significant differences between the 6- and 9-month scores for these outcomes (Figure 2). When missing data were taken into account (multiple imputation analyses), the measured effects continued to be statistically significant at 9 months for all 3 measures (eTable 2 in Supplement).

Table 1. Baseline Demographic and Clinical Characteristics

|   | No. (%) of Participants <sup>a</sup> |                      |
|---|--------------------------------------|----------------------|
|   | Intervention<br>(n = 120)            | Control<br>(n = 112) |
| Age, mean (SD), y   | 77.2 (10.2)                          | 78.9 (9.4)           |
| Female sex  | 83 (69.2)                            | 77 (68.8)            |
| White race  | 109 (90.8)                           | 97 (86.6)            |
| Earned a bachelor's degree or higher                                  | 41 (42.5)                            | 48 (42.8)            |
| Currently living alone  | 41 (42.5)                            | 48 (42.8)            |
| Place of residence in month prior to fracture                         |                                      |                      |
| Own home  | 103 (85.8)                           | 95 (84.8)            |
| With family or a friend   | 5 (4.2)                              | 3 (2.7)              |
| Assisted living   | 9 (7.5)                              | 10 (8.9)             |
| Other <sup>b</sup>  | 2 (1.7)                              | 5 (4.5)              |
| Use of cane or other mobility device prior to fracture                | 43 (35.8)                            | 35 (31.2)            |
| Most recent therapy site  |                                      |                      |
| Outpatient  | 57 (47.5)                            | 42 (42.9)            |
| Inpatient   | 1 (0.8)                              | 2 (1.8)              |
| Home  | 62 (51.7)                            | 62 (55.4)            |
| Time since fracture, mean (SD), mo                                    | 9.5 (5.2)                            | 8.6 (4.8)            |
| Treatment of fracture   |                                      |                      |
| Total hip joint replacement   | 27 (22.5)                            | 20 (17.9)            |
| Hemiarthroplasty  | 16 (13.3)                            | 12 (10.7)            |
| Pin, plate, nail, or other device                                     | 77 (64.2)                            | 80 (71.4)            |
| Mini-Mental State Examination score, mean (SD) <sup>c</sup>           | 28.8 (1.7)                           | 28.7 (2.0)           |
| Geriatric Depression Scale Short Form score, mean (SD) <sup>d</sup>   | 2.6 (2.0)                            | 2.4 (1.9)            |
| Type of comorbidity   |                                      |                      |
| Heart disease   | 42 (35.6)                            | 38 (34.2)            |
| Diabetes  | 14 (11.9)                            | 16 (14.4)            |
| Cancer  | 36 (30.5)                            | 33 (29.7)            |
| Osteoarthritis  | 64 (54.2)                            | 71 (64.0)            |
| Depression  | 22 (18.6)                            | 17 (15.3)            |
| Lung disease  | 15 (12.7)                            | 18 (16.2)            |
| Short Physical Performance Battery score, mean (SD) <sup>e</sup>      | 5.9 (2.8)                            | 5.9 (2.8)            |
| Activity Measure for Post-Acute Care score, mean (SD)                 |                                      |                      |
| Mobility <sup>f</sup>   | 56.1 (7.3)                           | 55.7 (7.1)           |
| Daily activity <sup>g</sup>   | 57.2 (13.8)                          | 58.0 (15.0)          |
| Berg Balance Test score, mean (SD) <sup>h</sup>                       | 40.8 (11.8)                          | 40.2 (10.8)          |
| Leg strength score, mean (SD), lb                                     |                                      |                      |
| Fractured leg   | 25.5 (11.4)                          | 25.6 (13.3)          |
| Nonfractured leg  | 29.0 (12.1)                          | 29.0 (12.1)          |
| Self-Efficacy for Exercise Scale score, mean (SD) <sup>i</sup>        | 62.2 (19.4)                          | 64.4 (16.9)          |
| Outcome Expectations for Exercise Scale score, mean (SD) <sup>j</sup> | 16.2 (4.9)                           | 15.5 (4.3)           |
| Modified Falls Self-Efficacy Scale score, mean (SD) <sup>k</sup>      | 104.6 (31.8)                         | 102.7 (34.9)         |

<sup>a</sup> Values are expressed as No. (%) unless otherwise indicated. Means and SDs are based on the entire baseline sample. However, the baseline means reported in the text relating to changes in outcomes from baseline to 6 months are based on those participants followed up at 6 months.

<sup>b</sup> Included senior housing, a church facility, and public housing.

<sup>c</sup> The score range is 0 to 30, with a higher score indicating better memory.

<sup>d</sup> The score range is 0 to 15, with a higher score indicating worse depression.

<sup>e</sup> The score range is 0 to 12, with a higher score indicating better function.

<sup>f</sup> The score range is 23 to 85, with a higher score indicating better function.

<sup>g</sup> The score range is 9 to 101, with a higher score indicating better function.

<sup>h</sup> The score range is 0 to 56, with a higher score indicating better balance.

<sup>i</sup> The score range is 0 to 90, with a higher score indicating better self-efficacy.

<sup>j</sup> The score range is 9 to 45, with a higher score indicating worse outcome expectations.

<sup>k</sup> The score range is 0 to 140, with a higher score indicating better efficacy.

With respect to secondary outcomes, balance significantly improved in the intervention group compared with the control group at 6 months (2.3 [95% CI, 1.1-3.5],  $P < .001$ ). There were no statistically significant between-group differences in the change in muscle strength in either leg (fractured or nonfractured) at 6 months. However, a significant improvement in strength was found at 9 months in the nonfractured leg, but not in the fractured leg (Table 2). The change over time in exercise self-efficacy was better in the intervention group (adjusted  $P = .03$ ), but the change in falls self-efficacy and out-

comes expectancy for exercise was not significantly different between groups.

No serious adverse events occurred that were related to the intervention. One adverse event that was possibly related to the intervention was mild to moderate pain. Pain was considered to be an adverse event if it persisted for more than 48 hours and if the pain caused participants to modify their daily activities or take medication. Mild to moderate pain was experienced by 23 patients in the intervention group. Both groups had a high number of health events that were not related to

Table 2. Primary Outcomes for Both Adjusted and Unadjusted Analyses and Between-Group Differences

|  | Mean (SD) Score |              | Score Change From Baseline, Mean (95% CI) |                      | P Values for Exercise Intervention vs Control |                       |
|--|-----------------|--------------|---|----------------------|---|-----------------------|
|  | At 6 mo         | At 9 mo      | At 6 mo                                   | At 9 mo              | Unadjusted <sup>a</sup>                       | Adjusted <sup>b</sup> |
| <b>SPPB<sup>c</sup></b>                                    |                 |              |   |                      |   |                       |
| Exercise intervention <sup>d</sup>                         | 7.2 (3.0)       | 7.6 (2.9)    | 1.0 (0.8 to 1.3)                          | 1.3 (1.0 to 1.5)     |   |                       |
| Control <sup>e</sup>                                       | 6.2 (3.0)       | 6.3 (2.9)    | 0.2 (0 to 0.5)                            | 0.3 (0 to 0.6)       |   |                       |
| Exercise vs control  |                 |              | 0.8 (0.4 to 1.2)                          | 1.0 (0.6 to 1.4)     | <.001   | <.001                 |
| <b>AM-PAC mobility<sup>f</sup></b>                         |                 |              |   |                      |   |                       |
| Exercise intervention                                      | 58.1 (7.9)      | 59.5 (9.3)   | 1.9 (1.1 to 2.7)                          | 2.6 (1.9 to 3.4)     |   |                       |
| Control  | 56.6 (8.1)      | 56.7 (7.6)   | 0.6 (-0.2 to 1.4)                         | 1.0 (0.2 to 1.8)     |   |                       |
| Exercise vs control  |                 |              | 1.3 (0.2 to 2.4)                          | 1.7 (0.5 to 2.8)     | .01   | .01                   |
| <b>AM-PAC daily activity<sup>g</sup></b>                   |                 |              |   |                      |   |                       |
| Exercise intervention                                      | 61.3 (15.7)     | 63.0 (15.9)  | 3.9 (2.2 to 5.7)                          | 4.2 (2.5 to 6.0)     |   |                       |
| Control  | 58.6 (15.3)     | 59.0 (14.9)  | 0.5 (-1.3 to 2.2)                         | 1.4 (-0.4 to 3.3)    |   |                       |
| Exercise vs control  |                 |              | 3.5 (0.9 to 6.0)                          | 2.8 (0.3 to 5.4)     | .02   | .01                   |
| <b>Berg Balance Test<sup>h</sup></b>                       |                 |              |   |                      |   |                       |
| Exercise intervention                                      | 44.4 (10.7)     | 45.6 (10.0)  | 2.4 (1.6 to 3.2)                          | 2.7 (1.9 to 3.6)     |   |                       |
| Control  | 41.1 (10.7)     | 40.4 (11.4)  | 0.1 (-0.7 to 1.0)                         | 0.1 (-0.8 to 1.0)    |   |                       |
| Exercise vs control  |                 |              | 2.3 (1.1 to 3.5)                          | 2.7 (1.4 to 3.9)     | <.001   | <.001                 |
| <b>Leg strength in fractured leg, lb</b>                   |                 |              |   |                      |   |                       |
| Exercise intervention                                      | 27.7 (12.8)     | 29.9 (12.9)  | 1.9 (0.3 to 3.5)                          | 2.3 (0.6 to 4.0)     |   |                       |
| Control  | 26.7 (14.3)     | 25.6 (14.2)  | 0.3 (-1.5 to 2.2)                         | 0 (-1.9 to 3.5)      |   |                       |
| Exercise vs control  |                 |              | 1.5 (-0.9 to 4.0)                         | 2.3 (-0.3 to 4.8)    | .19   | .16                   |
| <b>Leg strength in nonfractured leg, lb</b>                |                 |              |   |                      |   |                       |
| Exercise intervention                                      | 29.4 (13.3)     | 30.8 (13.7)  | 0 (-1.6 to 1.7)                           | 0.4 (-1.3 to 2.1)    |   |                       |
| Control  | 28.8 (13.9)     | 25.8 (13.6)  | -0.8 (-2.5 to 0.8)                        | -3.1 (-4.8 to -1.3)  |   |                       |
| Exercise vs control  |                 |              | 0.9 (-1.5 to 3.2)                         | 3.5 (1.0 to 5.9)     | .02   | .02                   |
| <b>Self-Efficacy for Exercise Scale<sup>i</sup></b>        |                 |              |   |                      |   |                       |
| Exercise intervention                                      | 59.6 (19.4)     | 63.2 (18.3)  | -3.0 (-6.3 to 0.4)                        | -0.5 (-3.9 to 2.9)   |   |                       |
| Control  | 58.7 (21.5)     | 58.1 (20.2)  | -6.4 (-9.8 to -3.0)                       | -7.1 (-10.6 to -3.6) |   |                       |
| Exercise vs control  |                 |              | 3.4 (-1.4 to 8.2)                         | 6.6 (1.7 to 11.5)    | .03   | .03                   |
| <b>Modified Falls Self-Efficacy Scale<sup>j</sup></b>      |                 |              |   |                      |   |                       |
| Exercise intervention                                      | 110.5 (31.6)    | 113.6 (30.6) | 4.2 (0.1 to 8.3)                          | 5.7 (1.5 to 9.8)     |   |                       |
| Control  | 103.7 (36.2)    | 107.8 (34.1) | 0.8 (-3.3 to 5.0)                         | 4.6 (0.3 to 9.0)     |   |                       |
| Exercise vs control  |                 |              | 3.4 (-2.5 to 9.2)                         | 1.0 (-5.0 to 7.0)    | .52   | .53                   |
| <b>Outcome Expectations for Exercise Scale<sup>k</sup></b> |                 |              |   |                      |   |                       |
| Exercise intervention                                      | 16.0 (5.6)      | 16.0 (5.7)   | 0 (-0.8 to 0.8)                           | 0 (-0.9 to 0.8)      |   |                       |
| Control  | 16.3 (5.3)      | 16.3 (5.5)   | 1.0 (0.2 to 1.8)                          | 1.1 (0.2 to 1.9)     |   |                       |
| Exercise vs control  |                 |              | -1.0 (-2.1 to 0.2)                        | -1.1 (-2.3 to 0.1)   | .12   | .13                   |

Abbreviations: AM-PAC, Activity Measure for Post-Acute Care; SPPB, Short Physical Performance Battery.

<sup>a</sup> Compares trend over time.

<sup>b</sup> Compares trend over time, controlling for age and sex.

<sup>c</sup> The score range is 0 to 12, with a higher score indicating better function.

<sup>d</sup> There were 120 participants at baseline, 100 at 6 months, and 94 at 9 months.

<sup>e</sup> There were 112 participants at baseline, 95 at 6 months, and 85 at 9 months.

<sup>f</sup> The score range is 23 to 85, with a higher score indicating better function.

<sup>g</sup> The score range is 9 to 101, with a higher score indicating better function.

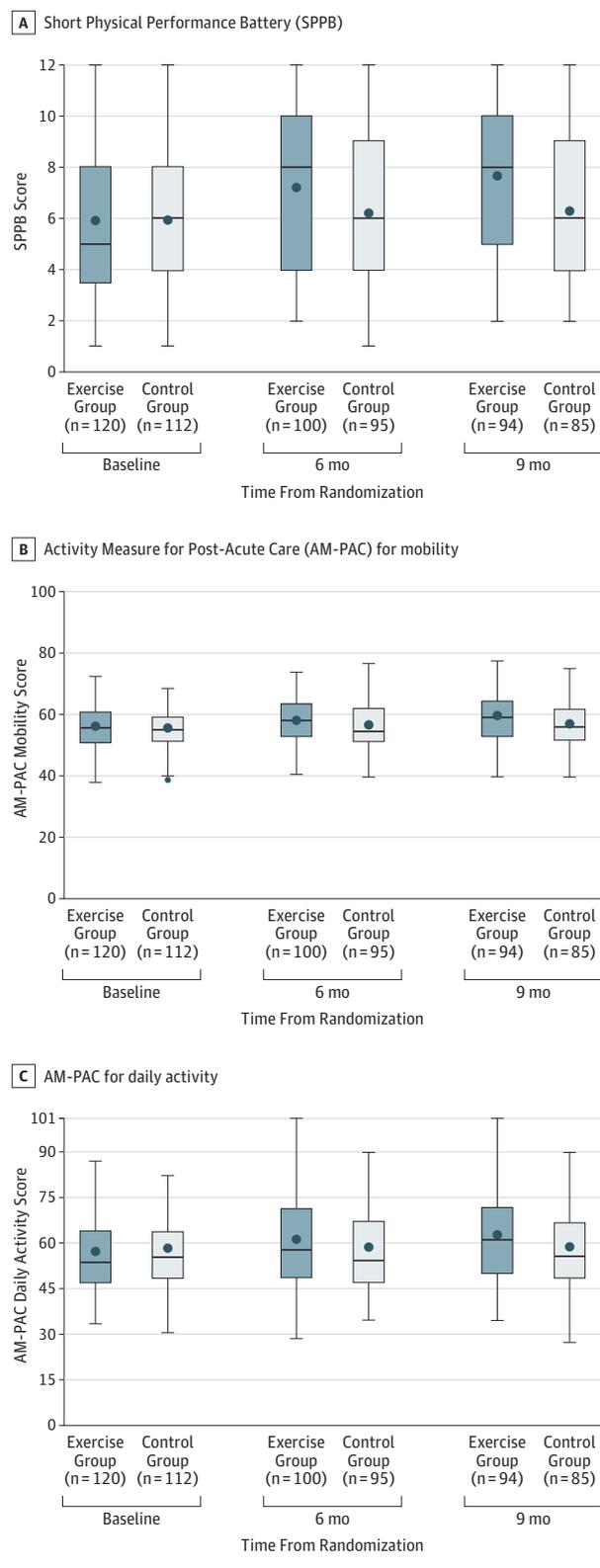
<sup>h</sup> The score range is 0 to 56, with a higher score indicating better balance.

<sup>i</sup> The score range is 0 to 90, with a higher score indicating better self-efficacy.

<sup>j</sup> The score range is 0 to 140, with a higher score indicating better efficacy.

<sup>k</sup> The score range is 9 to 45, with a higher score indicating worse outcome expectations.

Figure 2. Changes in Functional Measures Over Time



The top whisker indicates the maximum value; the bottom whisker, the minimum value; the top of the box, 75th percentile; the bottom of the box, 25th percentile; horizontal line inside the box, median; and circle, mean.

the study procedures, which is consistent with the high level of comorbidity in this population.

## Discussion

This randomized clinical trial found that compared with controls, the home exercise program resulted in improvement in function after formal hip fracture rehabilitation ended. Improvements in mobility function at 6 months as measured by the SPPB were clinically important, whereas improvements in the AM-PAC mobility and AM-PAC activity were statistically significant but did not exceed the prespecified minimal clinically important difference. The effects of the exercise program on function as measured by the SPPB persisted for 3 months after the 6 months of the active intervention ended (ie, 9 months).

Previous exercise studies using intensive professional supervision and equipment have found a significant capacity for adults with hip fracture to improve after usual rehabilitation has ended.<sup>7-9</sup> In contrast, the exercise intervention in this study was performed at home and was implemented with minimal contact (maximum of 4 visits) from a physical therapist, and has the potential to be incorporated into current rehabilitation protocols. With this intervention, there was no need for participants to travel outside their home or to use expensive exercise equipment. The home exercise program did not require a team of people, but was delivered by 1 physical therapist and the level of contact with the physical therapist was modest. Despite their substantial functional and balance limitations at baseline, participants were able to perform the exercise program effectively and safely in their home.

In addition to the lower frequency and intensity of supervision, the intervention in this study differed from other studies in several ways. This program included a well-developed cognitive-behavioral component, which previous studies indicated was necessary to achieve adherence in a home-based program with limited supervision.<sup>24,29</sup> The rehabilitation program contained functionally oriented exercises, rather than exercises that focused on basic strength impairments. The stepping exercises were developed based on studies that had found some effect on function in adults with hip fracture and in frail older adults.<sup>25,30</sup> The activities focused on tasks that have been found to be limited for many people 2 years after hip fracture, such as standing up from a chair or climbing steps.<sup>5</sup> The principle of the specificity of training suggests that more directly training functional tasks might lead to better functional outcomes. This training approach might be one reason for the outcomes observed for function and balance, whereas the changes in strength were more modest, and only statistically significant in the nonfractured leg.

Function was measured in a comprehensive way, using both patient-reported and physical performance measures, and examined relevant basic mobility and complex daily activity functions important to the lives of older adults. It has been established that self-report and performance-based functional outcomes measure similar but distinct aspects of function.<sup>31</sup> Finding significant changes in both approaches to measuring

function provides consistent evidence that a change in overall function took place in the exercise rehabilitation group. The high level of comorbidity and functional limitation at baseline are consistent with the general population of patients with hip fracture.

Our study has several limitations. Despite rigorous efforts to obtain data from all study participants, some loss to follow-up did occur. However, significant between-group differences persisted when missing data were accounted for in the analyses. Loss to follow-up in this study, however, is low for a trial of patients with hip fracture, who due to their frequent comorbid illnesses, rehospitalizations, and transitions in their home environments are a challenging population to maintain.<sup>32</sup> Another limitation of this trial is that we do not have detailed information about the physical therapy interventions that patients received before enrolling in the trial, or details about new medical or rehabilitation services they might have received during the trial. In addition, the overall effect was modest and exceeded the minimum clinically important difference for only part of the prespecified primary outcome. The intervention group achieved greater levels of improvement relative to the control group in performance-based measures of mobility than in the patient-reported measures of function. This finding suggests that it may be easier to improve a person's capacity to function than to change their actual level of functioning in daily life in the face of significant comorbidities.

The traditional approach to rehabilitation for hip fracture leaves many patients with long-term functional limitations that could be reduced with extended rehabilitation. However, it is unlikely that additional months of highly supervised rehabilitation can be provided to patients with hip fracture. Medicare spending on postacute care for hip fracture doubled from 1994 to 2009, with postacute care accounting for 73% of the increase in Medicare expenditures for hip fracture.<sup>10</sup> Outpa-

tient therapy services cost Medicare over \$5.7 billion in 2011, with 70% of those payments going to physical therapy outpatient services.<sup>11</sup> These outpatient therapy costs have increased by an average of 4% per year in the past decade,<sup>11</sup> despite various attempts to contain costs.<sup>33</sup>

The increasing costs of postacute care combined with evidence that patients would benefit from additional therapeutic exercise suggest that alternative strategies are needed. Outpatient physical therapy services are typically delivered in discrete short-term episodes and include a limited number of visits.<sup>34</sup> After an episode is completed, the patient is discharged with a written home exercise program and instructions to carry out this program independently on an ongoing basis. Exercise programs are challenging for people to perform on their own without clear feedback about whether they are performing the exercises accurately and safely and without guidance as to how to change the exercises over time. The findings from our study suggest that this approach could be introduced to patients after completion of traditional physical therapy following hip fracture and may provide a more effective way for these patients to continue to exercise in their own homes. However, future research is needed to explore whether the interventions in this trial can be disseminated in a cost-effective manner in real clinical environments.

## Conclusions

Among patients who had completed standard rehabilitation after hip fracture, the use of home-based functionally oriented exercises compared with an attention control group resulted in improved physical function at 6 months and 9 months after randomization. The clinical importance of these findings remains to be determined.

### ARTICLE INFORMATION

**Author Contributions:** Dr Latham 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:** Latham, Harris, Bean, Zawacki, Giorgetti, Jette.

**Acquisition of data:** Bean, Goodyear, Heislein, Mustafa, Pardasaney, Giorgetti, Holt, Goehring.  
**Analysis and interpretation of data:** Latham, Harris, Bean, Heeren, Jette.

**Drafting of the manuscript:** Latham, Goodyear, Pardasaney, Goehring, Jette.

**Critical revision of the manuscript for important intellectual content:** Latham, Harris, Bean, Heeren, Zawacki, Heislein, Mustafa, Giorgetti, Holt, Jette.

**Statistical analysis:** Latham, Harris, Heeren.

**Obtained funding:** Latham, Harris, Jette.

**Administrative, technical, or material support:** Latham, Harris, Bean, Goodyear, Heislein, Mustafa, Giorgetti, Holt, Goehring.

**Study supervision:** Latham, Harris, Bean, Goodyear, Giorgetti, Jette.

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National Institutes of Health and travel reimbursement from the American Geriatrics Society. Ms Giorgetti reported receiving consulting fees, travel reimbursement, and fees for participating in review activities from MGH Institute of Health Professions and being employed by Metrowest Homecare and Hospice. Dr Jette reported holding stock in CREcare LLC, which is a small business he started that distributes outcome instruments including the AM-PAC; and receiving royalties from Boston University for instrument licenses. No other disclosures were reported.

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**Data and Safety Monitoring Board:** Jay Magaziner, MSHyg, PhD (University of Maryland), Roger Fielding, PhD (Tufts University), Clarissa Valim, MD, ScD (Harvard School

of Public Health), and Ilona Kopits, MD, MPH (Boston University School of Medicine).

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## REFERENCES

1. Stevens JA, Rudd RA. The impact of decreasing US hip fracture rates on future hip fracture estimates. *Osteoporos Int*. 2013;24(10):2725-2728.
2. Brauer CA, Coca-Perrillon M, Cutler DM, Rosen AB. Incidence and mortality of hip fractures in the United States. *JAMA*. 2009;302(14):1573-1579.
3. Kammerlander C, Gosch M, Kammerlander-Knauer U, Luger TJ, Blauth M, Roth T. Long-term functional outcome in geriatric hip fracture patients. *Arch Orthop Trauma Surg*. 2011;131(10):1435-1444.
4. Fransen M, Woodward M, Norton R, Robinson E, Butler M, Campbell AJ. Excess mortality or institutionalization after hip fracture: men are at greater risk than women. *J Am Geriatr Soc*. 2002;50(4):685-690.
5. Magaziner J, Hawkes W, Hebel JR, et al. Recovery from hip fracture in eight areas of function. *J Gerontol A Biol Sci Med Sci*. 2000;55(9):M498-M507.
6. Braithwaite RS, Col NF, Wong JB. Estimating hip fracture morbidity, mortality and costs. *J Am Geriatr Soc*. 2003;51(3):364-370.
7. Binder EF, Brown M, Sinacore DR, Steger-May K, Yarasheski KE, Schechtman KB. Effects of extended outpatient rehabilitation after hip fracture: a randomized controlled trial. *JAMA*. 2004;292(7):837-846.
8. Auais MA, Eilayyan O, Mayo NE. Extended exercise rehabilitation after hip fracture improves patients' physical function: a systematic review and meta-analysis. *Phys Ther*. 2012;92(11):1437-1451.
9. Handoll HH, Sherrington C, Mak JCS. Interventions for improving mobility after hip fracture surgery in adults. *Cochrane Database Syst Rev*. 2011;(3):CD001704.
10. Chandra A, Dalton MA, Holmes J. Large increases in spending on postacute care in Medicare point to the potential for cost savings in these settings. *Health Aff (Millwood)*. 2013;32(5):864-872.
11. Akamigbo A, Winter A. *Mandated Report: Improving Medicare's Payment System for Outpatient Therapy Services*. Washington, DC: MEDPAC; 2012.
12. Guralnik JM, Simonsick EM, Ferrucci L, et al. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. *J Gerontol*. 1994;49(2):M85-M94.
13. Haley SM, Coster WJ, Andres PL, et al. Activity outcome measurement for postacute care. *Med Care*. 2004;42(1)(suppl):149-161.
14. Jette AM, Haley SM, Tao W, et al. Prospective evaluation of the AM-PAC-CAT in outpatient rehabilitation settings. *Phys Ther*. 2007;87(4):385-398.
15. Kwon S, Perera S, Pahor M, et al. What is a meaningful change in physical performance? findings from a clinical trial in older adults (the LIFE-P study). *J Nutr Health Aging*. 2009;13(6):538-544.
16. Lord SR, Menz HB, Tiedemann A. A physiological profile approach to falls risk assessment and prevention. *Phys Ther*. 2003;83(3):237-252.
17. Berg K, Wood-Dauphinee S, Williams JI. The Balance Scale: reliability assessment with elderly residents and patients with an acute stroke. *Scand J Rehabil Med*. 1995;27(1):27-36.
18. Berg KO, Maki BE, Williams JI, Holliday PJ, Wood-Dauphinee SL. Clinical and laboratory measures of postural balance in an elderly population. *Arch Phys Med Rehabil*. 1992;73(11):1073-1080.
19. Berg KO, Wood-Dauphinee SL, Williams JI, Maki B. Measuring balance in the elderly: validation of an instrument. *Can J Public Health*. 1992;83(suppl 2):S7-S11.
20. Tinetti ME, Richman D, Powell L. Falls efficacy as a measure of fear of falling. *J Gerontol*. 1990;45(6):P239-P243.
21. Hill KD, Schwarz JA, Kalogeropoulos AJ, Gibson SJ. Fear of falling revisited. *Arch Phys Med Rehabil*. 1996;77(10):1025-1029.
22. Resnick B, Jenkins LS. Testing the reliability and validity of the Self-Efficacy for Exercise Scale. *Nurs Res*. 2000;49(3):154-159.
23. Resnick B, Zimmerman SI, Orwig D, Furstenberg AL, Magaziner J. Outcome Expectations for Exercise Scale: utility and psychometrics. *J Gerontol B Psychol Sci Soc Sci*. 2000;55(6):S352-S356.
24. Jette AM, Lachman M, Giorgetti MM, et al. Exercise—it's never too late: the strong-for-life program. *Am J Public Health*. 1999;89(1):66-72.
25. Bean JF, Herman S, Kiely DK, et al. Increased Velocity Exercise Specific to Task (InVEST) training: a pilot study exploring effects on leg power, balance, and mobility in community-dwelling older women. *J Am Geriatr Soc*. 2004;52(5):799-804.
26. Sherrington C, Lord SR. Home exercise to improve strength and walking velocity after hip fracture: a randomized controlled trial. *Arch Phys Med Rehabil*. 1997;78(2):208-212.
27. US Department of Health and Human Services; US Department of Agriculture. *Dietary Guidelines for Americans*. 6th ed. Washington, DC: US Government Printing Office; 2005.
28. Guralnik JM, Ferrucci L, Simonsick EM, Salive ME, Wallace RB. Lower-extremity function in persons over the age of 70 years as a predictor of subsequent disability. *N Engl J Med*. 1995;332(9):556-561.
29. Jette AM, Harris BA, Sleeper L, et al. A home-based exercise program for nondisabled older adults. *J Am Geriatr Soc*. 1996;44(6):644-649.
30. Sherrington C, Lord SR, Herbert RD. A randomized controlled trial of weight-bearing versus non-weight-bearing exercise for improving physical ability after usual care for hip fracture. *Arch Phys Med Rehabil*. 2004;85(5):710-716.
31. Latham NK, Mehta V, Nguyen AM, et al. Performance-based or self-report measures of physical function: which should be used in clinical trials of hip fracture patients? *Arch Phys Med Rehabil*. 2008;89(11):2146-2155.
32. Orwig DL, Hochberg M, Yu-Yahiro J, et al. Delivery and outcomes of a yearlong home exercise program after hip fracture: a randomized controlled trial. *Arch Intern Med*. 2011;171(4):323-331.
33. Latham NK, Jette AM, Ngo LH, Soukup J, lezzoni LI. Did the 1997 balanced budget act reduce use of physical and occupational therapy services? *Arch Phys Med Rehabil*. 2008;89(5):807-814.
34. Fritz JM, Hunter SJ, Tracy DM, Brennan GP. Utilization and clinical outcomes of outpatient physical therapy for medicare beneficiaries with musculoskeletal conditions. *Phys Ther*. 2011;91(3):330-345.