

ARTICLES

A Prehabilitation Program for the Prevention of Functional Decline: Effect on Higher-Level Physical Function

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ABSTRACT. Gill TM, Baker DI, Gottschalk M, Peduzzi PN, Allore H, Van Ness PH. A prehabilitation program for the prevention of functional decline: effect on higher-level physical function. *Arch Phys Med Rehabil* 2004;85:1043-9.

Objective: To determine whether a home-based physical therapy (PT) program prevented decline in several higher-level measures of physical function among physically frail, community-living older persons.

Design: Randomized controlled trial.

Setting: General community.

Participants: Persons (N=188) who were physically frail and aged 75 years or older.

Intervention: A home-based PT program (ie, prehabilitation) that focused primarily on improving underlying impairments in physical capabilities.

Main Outcome Measures: Self-reported instrumental activities of daily living (IADLs); mobility, as determined by a modified version of the Performance Oriented Mobility Assessment; timed rapid gait and timed chair stands; and integrated physical performance, as determined by a modified version of the Physical Performance Test, were assessed at baseline, 7 months, and 12 months.

Results: As compared with participants in the educational control group, participants in the intervention group had reductions in IADL disability of 17.7% at 7 months ($P=.036$) and 12.0% at 12 months ($P=.143$) and had gains, ranging from 7.2% to 15.6%, in mobility and integrated physical performance at 7 and 12 months.

Conclusions: Our home-based prehabilitation program offered modest but consistent benefits for the prevention of decline in several higher-level measures of physical function.

Key Words: Frail elderly; Home care services; Physical therapy; Preventive health services; Randomized controlled trials; Rehabilitation.

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PHYSICALLY FRAIL, community-living older people have high rates of functional decline and disability.^{1,2} Because disability is associated with considerable morbidity and mortality,³⁻⁶ interventions to prevent functional decline in this population are desperately needed.

In a recently published randomized trial,⁷ we showed that a home-based physical therapy (PT) program, targeting underlying impairments in physical capabilities, prevented the progression of decline in basic activities of daily living (ADLs) among physically frail, community-living older persons. The reduction in ADL disability was accompanied by nonsignificant reductions in fall-related fractures and nursing home utilization during the 12-month follow-up period. The program, referred to as prehabilitation, was found to be safe and to cost about \$2000 per participant.

To evaluate more completely the effectiveness of our program, we set out in our study to determine whether the intervention prevented decline in several higher-level measures of physical function, including instrumental activities of daily living (IADLs), mobility, and integrated physical performance.

METHODS

Study Population

Complete details of our recruitment procedures have been reported elsewhere.⁸ Physically frail, community-living people aged 75 years or older were identified from busy primary care practices in southern Connecticut using 2 strategies. In the first, potential participants were screened for physical frailty during routine office visits; in the second, potential participants were identified from a patient roster and were screened for physical frailty in their homes. Physical frailty was defined on the basis of 2 tests of physical capability that are highly predictive of functional decline and disability.^{1,9} People were considered physically frail if they scored greater than 10 seconds on the rapid gait test (ie, walk back and forth over a 10-ft [3-m] course as quickly as possible) or could not stand from a hard-back chair with their arms folded. People meeting only 1 of these criteria were classified as moderately frail; those meeting both criteria were classified as severely frail.⁹ Persons were ineligible for the study if they were nonambulatory, were receiving PT or participating in an exercise program, did not speak English, had a diagnosis of dementia or scored less than 20 on the Mini-Mental State Examination¹⁰ (MMSE), had a life expectancy of less than 12 months, or had had a stroke, hip fracture, hip or knee replacement, or myocardial infarction within the past 6 months.

Of the 216 people found to be eligible, 188 (87.3%) agreed to participate. Eligible people who declined to participate did not differ significantly from those who were enrolled in terms of age, sex, level of physical frailty, or recruitment strategy. Participants were randomized within strata, defined on the basis of recruitment strategy and level of physical frailty, using a computer-generated algorithm. Informed consent was ob-

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tained during the initial home visit according to procedures approved by the Yale Human Investigation Committee.

Assessments

Home-based assessments were completed at baseline and at 7 and 12 months by a team of 4 research nurses who had no role in the intervention and were unaware of the exact nature of the study and of the participants' group assignments. These nurses underwent intensive training and followed standard procedures outlined in a detailed manual. All data were collected on standardized, precoded forms, were entered twice in a computerized database, and underwent extensive checks of error and validity.

In addition to physical frailty and cognitive status,¹⁰ self-reported information was collected at baseline on age, sex, race, living situation, education, and 10 physician-diagnosed chronic conditions: hypertension, myocardial infarction, congestive heart failure, stroke, diabetes, arthritis, hip fracture, chronic lung disease, cirrhosis or liver disease, and cancer (other than minor skin cancers).

Outcomes. At baseline, 7 months, and 12 months, data were collected on 5 self-reported IADLs, including shopping for groceries, meal preparation, housework, laundry, and getting to places beyond walking distance^{11,12}; on mobility; and on integrated physical performance. Based on prior research,¹³ each IADL task was scored as 0 for did without human help during the last month, 1 for did with human help, and 2 for did not do; a summary IADL disability score was created with a range of 0 to 10. The mobility assessment^{1,2,8,14} included timed rapid gait (walking back and forth over a 10-ft course as quickly and safely as possible), timed chair stands (standing and sitting from a standard chair 3 times as quickly and safely as possible), and a modified version of the Performance Oriented Mobility Assessment (POMA), which included 5 gait items—step continuity and symmetry, path deviation, turning, and missed steps—and the 3 standard tasks of standing balance from the Established Population for Epidemiologic Studies of the Elderly battery. Possible scores for the modified POMA ranged from 0 to 12 (best score). Integrated physical performance was assessed with a modified version of the Physical Performance Test (PPT), which included 3 items of primarily upper-extremity function—putting on and removing a jacket, lifting a book and putting it on a shelf, and picking up a pencil from the ground—and was scored from 0 to 12 (best score).^{8,15}

Telephone interviews, instead of home-based assessments, were completed for 5 participants in the intervention group and 6 in the control group at 7 months and for 1 participant in the intervention group and 5 in the control group at 12 months. Follow-up data were otherwise 100% complete, except for 1 control group participant who missed the 7-month assessment because of an administrative error and another who refused the timed chair stands and modified POMA at the 12-month assessment (fig 1).

Intervention Group

Participants who were randomized to the intervention group received a 6-month, home-based training program, which has been described in detail elsewhere.^{7,16} In brief, each participant was assessed by a physical therapist for impairments in joint range of motion (ROM), bed mobility, transfers, balance, indoor gait, foot care, sensation and tone, and outdoor mobility, and each had an environmental assessment of the home. Detailed algorithms and decision rules were developed to link the results of the assessment with the recommended interventions. These rules were subsequently automated on notebook computers for use by the therapist in participants' homes.¹⁷ Inter-

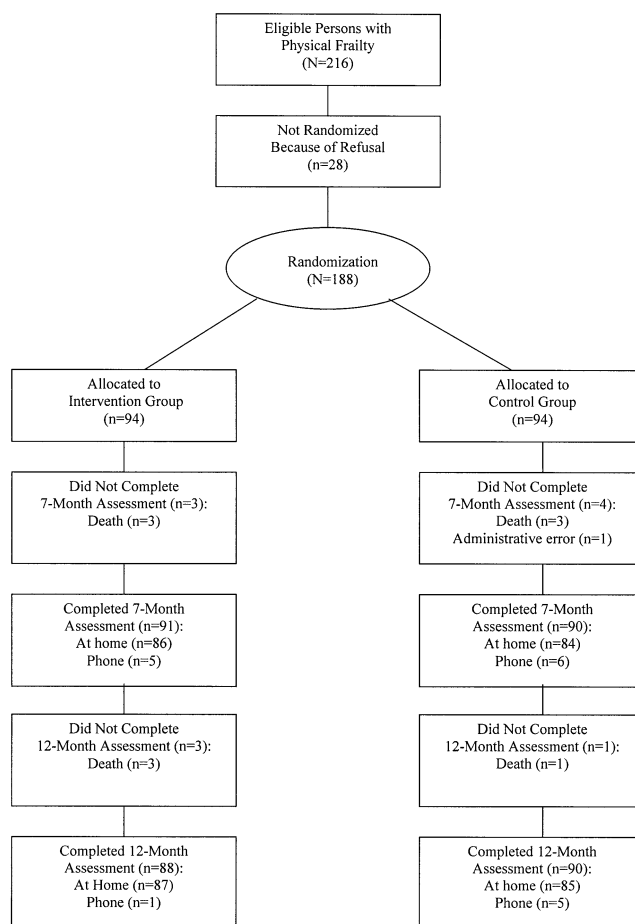


Fig 1. Flow of participants through the trial.

ventions for bed mobility, transfers, indoor gait, and outdoor mobility involved instruction in safer, more effective techniques, training in the proper use of assistive devices, and recommendations for environmental modifications. Progressive, competency-based exercises were developed for joint ROM, balance, and muscle conditioning and strengthening (with Thera-Band^a elastic bands). Exercises were performed only under supervision until the therapist determined that the participant was able to perform the exercises safely and effectively. Subsequently, participants were instructed to perform their balance exercises once each day and their conditioning exercises 3 days a week. Although the program was designed to include an average of 16 visits during a 6-month period, the actual number of visits was determined by the number and severity of the underlying impairments and by each participant's progress. On completion of the visits, the therapist called the participants monthly for 6 additional months to answer questions and provide encouragement.

As reported elsewhere,⁷ among the 94 participants randomized to the intervention group, 61 (64.9%) completed the program, and 20 (21.3%) ended the program prematurely, after an average \pm standard deviation (SD) of 9.5 ± 4.1 home visits. The remaining participants (13.8%) did not receive the intervention, primarily for reasons of worsening personal or family health. On average, participants who completed the program had 14.9 ± 2.4 visits (range, 7–19). Overall, adherence to the training program was high, with completion of 73.4%, 78.4%,

Table 1: Baseline Characteristics of Participants According to Treatment Group

Characteristic	Intervention Group (n=94)	Control Group (n=94)
Age (y)	82.8±5.0	83.5±5.2
Women	80 (85)	70 (74)
Non-Hispanic white	85 (90)	86 (91)
Living alone	41 (44)	47 (50)
Education (y)	11.3±3.1	11.3±2.3
Chronic conditions	2.1±1.1	2.0±1.3
MMSE score	26.7±2.6	26.3±2.4
Moderate physical frailty	60 (64)	56 (60)

NOTE. Values are mean ± SD or n (%). There were no significant differences in any of these characteristics between the intervention and control groups. Chi-square and *t* tests were used, respectively, for categorical and continuous variables.

and 78.7% of the assigned exercises for balance, lower-extremity conditioning, and upper-extremity conditioning, respectively.

Control Group

Participants who were randomized to the control group received 6 monthly home visits from a trained health educator. During these sessions, which lasted between 45 and 60 minutes, the health educator and participant reviewed several content areas in general health practices and health promotion, including proper nutrition, management of medications, phys-

ical activity, sleep hygiene, immunizations, and other areas noted in the *Healthy People 2000* recommendations.¹⁸ Sessions were tailored to participants' specific needs based on their responses to a brief health survey. On completion of the visits, the health educator called the participants monthly for 6 additional months to answer questions and to provide encouragement.

Among the 94 participants randomized to the control group, 78 (83.0%) completed the program, 7 (7.4%) discontinued the program after a mean of 1.3±1.5 visits because of death or a move after an acute illness or injury, and 9 (9.6%) refused to continue the program after a mean of 1.8±1.1 visits.

Statistical Analysis

All analyses were according to intention-to-treat and were performed using SAS, version 9.0.^b Scores for IADL disability, the modified POMA, and the modified PPT were analyzed separately at 7 and 12 months by generalized linear models (GLM) with a negative binomial error distribution, which provided the best fit to the data.^{19,20} Treatment effects were adjusted for the study design (recruitment strategy and level of physical frailty) and the baseline score of the respective measure. The exponential of the adjusted regression coefficient for the treatment effect was calculated for each outcome at 7 and 12 months, and the results are presented as the percentage reduction in scores for IADL disability and the percentage increase in scores for the modified POMA and PPT in the intervention group relative to the control group. To account for the correlation among the repeated measurements within each participant, we also analyzed these data using generalized

Table 2: Mean Scores by Treatment Group at Baseline, 7 Months, and 12 Months for IADL Disability, Mobility, and Integrated Physical Performance*

Outcome [†]	Baseline		7 Months				12 Months			
	n	Score	n	Score	% Difference [‡]	<i>P</i> Value	n	Score	% Difference [‡]	<i>P</i> Value
IADL disability (0–10)										
Intervention group	94	3.2	91	3.2	17.7	.036	88	3.7	12.0	.143
Control group	94	3.7	91	4.5	—	—	90	4.8	—	—
Mobility										
Timed rapid gait [§] (0–60s)										
Intervention group	94	15.7	85	15.1	13.6	.036	87	18.1	11.3	.143
Control group	94	16.0	84	18.9	—	—	85	22.0	—	—
Timed chair stands (0–30s)										
Intervention group	94	18.2	85	14.7	11.1	.101	87	15.1	13.2	.046
Control group	94	18.4	84	16.9	—	—	84	17.2	—	—
Modified POMA (0–12)										
Intervention group	94	8.2	85	8.1	12.2	.036	87	7.7	7.2	.183
Control group	94	7.7	84	7.1	—	—	84	6.9	—	—
Integrated physical performance										
Modified PPT (0–12)										
Intervention group	94	5.2	85	6.4	10.3	.112	87	6.5	15.6	.036
Control group	94	5.3	84	5.8	—	—	85	5.5	—	—

*Six participants in the intervention group and 4 in the control group died during the 12-month follow-up period. One participant in the control group missed the 7-month assessment because of an administrative error, and another refused the timed chair stands and modified POMA at the 12-month assessment. As described in the Methods, a small number of follow-up assessments were completed over the telephone, leading to some diminution in sample size for the mobility and integrated physical performance outcomes.

[†]The possible range of scores is provided within parentheses. As described in the Methods, high scores represent poor physical function for IADL disability, timed rapid gait, and timed chair stands and good physical function for the modified POMA and modified PPT.

[‡]For comparisons of the intervention group and the control group. Differences represent relative reductions in scores for IADL disability, timed rapid gait, and timed chair stands and relative increases in scores for the modified POMA and PPT. For each comparison, the results are adjusted for baseline score, recruitment strategy, and level of physical frailty, as described in the Methods.

[§]In the intervention group, 3 participants were unable to complete the test at 12 months. In the control group, 3 and 8 participants were unable to complete the test at 7 and 12 months, respectively.

^{||}In the intervention group, 17, 7, and 8 participants were unable to complete the test at baseline, 7 months, and 12 months, respectively. In the control group, 20, 16, and 13 participants were unable to complete the test at baseline, 7 months, and 12 months, respectively.

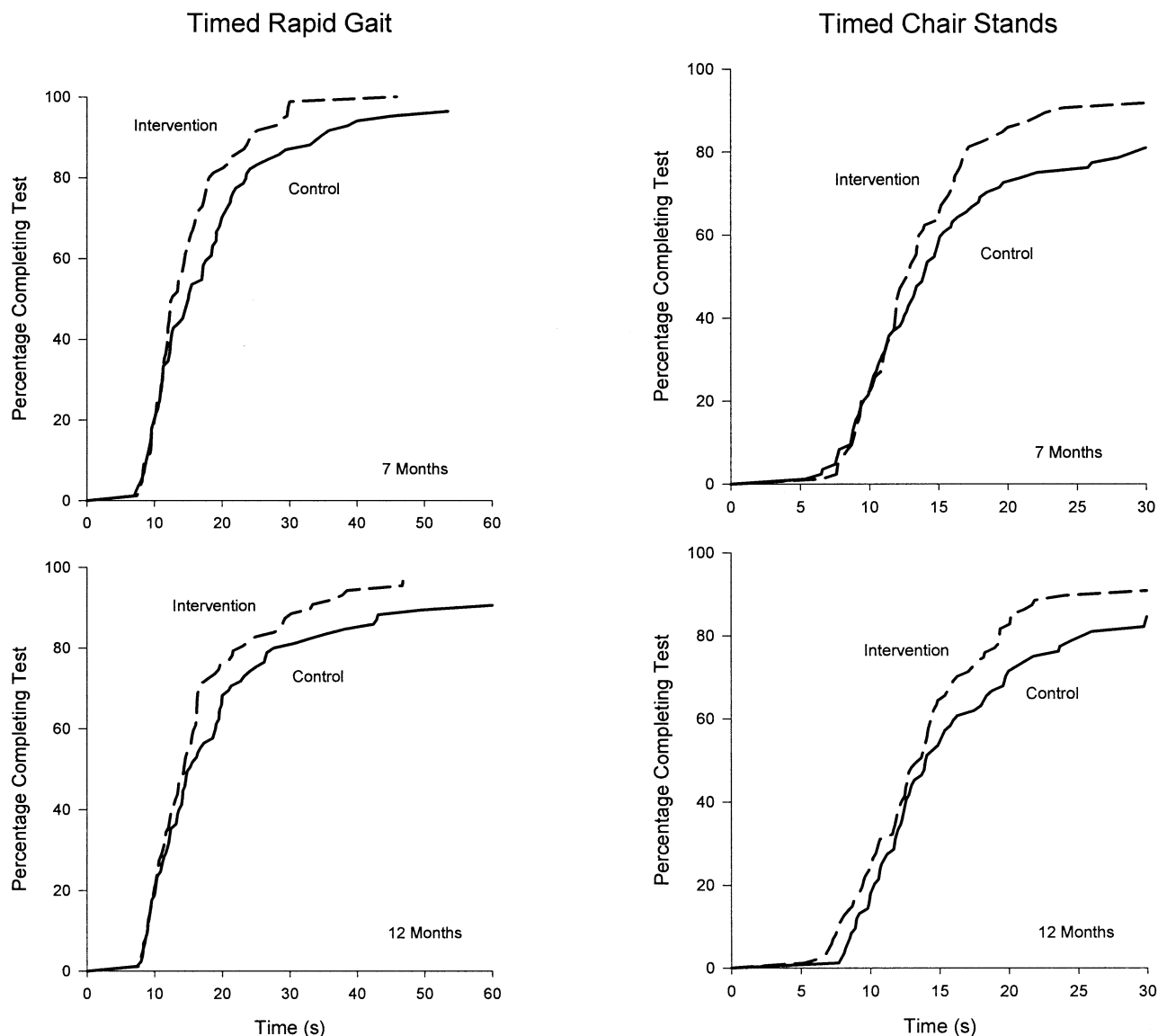


Fig 2. Percentage of participants completing the rapid gait and chair stand tests at 7 and 12 months, by treatment group, according to the time to completion (in seconds). Six participants in the intervention group and 4 in the control group died during the 12-month follow-up period. At 7 months, 3 participants (3.6%) in the control group were unable to complete the rapid gait test, whereas 7 participants (8.2%) in the intervention group and 16 (19.0%) in the control group were unable to complete the chair stand test. At 12 months, 3 participants (3.4%) in the intervention group and 8 (9.4%) in the control group were unable to complete the rapid gait test, whereas 8 participants (9.2%) in the intervention group and 13 (15.5%) in the control group were unable to complete the chair stand test.

estimating equations.^{7,21} The results were similar and are not presented.

For the rapid gait and chair stand tests, an accelerated failure time regression model was used based on the logarithm of the timed scores.²² Participants who were unable to complete the tests within the allotted time (60s for rapid gait, 30s for chair stands) were right-censored, that is, treated as having scores greater than the highest recorded time.²³ Adjusted treatment effects were calculated as described for the GLM analysis.

To account for type I statistical error (ie, false-positive results) in the context of multiple comparisons, *P* values for all between-group differences were adjusted according to the method recommended by Benjamini and Hochberg,²⁴ which is specifically designed to control for the expected proportion of

erroneously rejected null hypotheses among the total number of rejected null hypotheses. In a final set of analyses, the percentage change in scores was calculated for each of the 5 outcomes between baseline and the 7- and 12-month follow-up assessments for the intervention and control groups, respectively. Because these analyses were not designed to evaluate between-group differences, results were not adjusted for recruitment strategy or for level of physical frailty.

All statistical tests were 2-tailed, and a *P* value less than .05 was considered statistically significant.

RESULTS

The baseline characteristics of participants in the intervention and control groups are shown in table 1. The mean age was

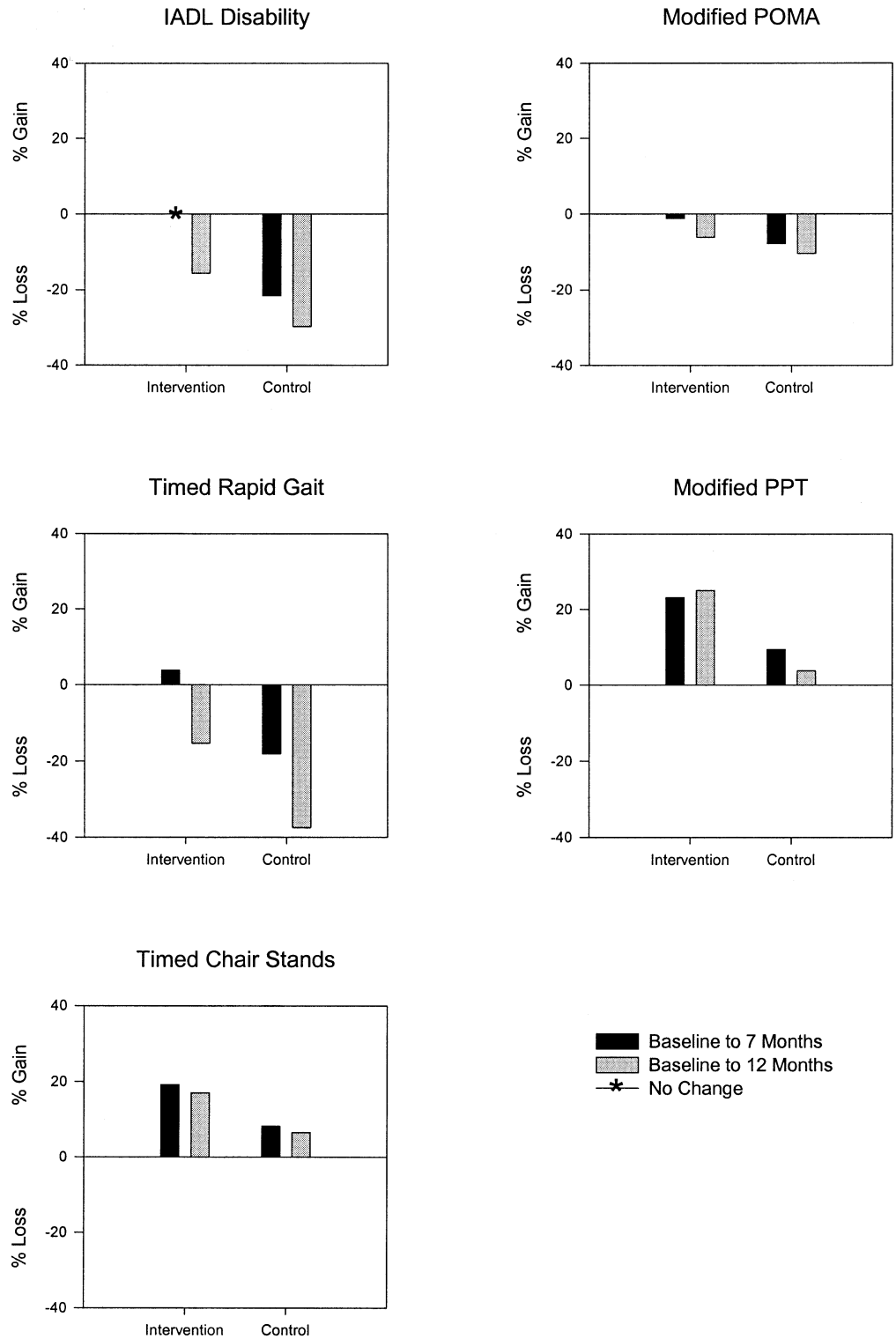


Fig 3. Percentage change in scores for the 5 outcomes between baseline and the 7- and 12-month follow-up assessments for the intervention and control groups, respectively. Gains (losses) represent reductions (increases) in scores for IADL disability, timed rapid gait, and timed chair stands and increases (reductions) in scores for the modified POMA and PPT. Results are not adjusted for recruitment strategy or for level of physical frailty.

83 years. The majority of participants were women, white, and had moderate physical frailty. On average, participants had a grade 11 education, 2 chronic conditions, and an MMSE score of 26.5. The characteristics of the 2 groups were comparable, although a slightly higher proportion of participants in the intervention group were women ($P=.07$). Six participants in

the intervention group (6.3%) and 4 in the control group (4.5%) died during the 12-month follow-up period (fig 1).

Table 2 provides the mean scores by treatment group at baseline, 7 months, and 12 months for IADL disability, the 3 tests of mobility, and integrated physical performance. For each outcome, participants in the intervention group did better

than those in the control group at 7 and 12 months, with percentage differences ranging from 7.2% at 12 months for the modified POMA to 17.7% at 7 months for IADL disability. At 7 months, the differences between treatment groups were statistically significant for IADL disability, timed rapid gait, and the modified POMA. Statistically significant differences were observed at 12 months for timed chair stands and for the modified PPT but not for the other 3 outcomes. Figure 2 provides a graphic display of the timed scores by treatment group at 7 and 12 months for the rapid gait and chair stand tests. Overall, participants in the intervention group completed the 2 tests more quickly than those in the control group, although the scores did not differ among participants within the fastest 25th to 40th percentiles, with the exception of timed chair stands at 12 months.

Figure 3 shows the percentage change in scores for the 5 outcomes between baseline and the 7- and 12-month follow-up assessments for the intervention and control groups, respectively. For participants in the intervention group, scores improved or remained unchanged at 7 months for all the outcomes other than the modified POMA but subsequently worsened at 12 months for 4 of the 5 outcomes: IADL disability, timed rapid gait, timed chair stands, and the modified POMA. For participants in the control group, scores worsened at 7 months and again at 12 months for all the outcomes, with the exception of timed chair stands and the modified PPT, both of which improved at 7 months.

DISCUSSION

We have previously shown that our home-based prehabilitation program led to reductions in ADL disability scores of 45% and 37%, respectively, at 7 and 12 months, relative to our educational control program.⁷ The results of the current study indicate that our prehabilitation program was also effective in preventing decline in several higher-level measures of physical function, including IADLs, mobility, and integrated physical performance. Together, these results provide strong evidence that functional decline among physically frail, community-living older persons can be slowed, if not prevented, by a prehabilitation program that targets underlying impairments in physical capabilities.

In contrast to our earlier report,⁷ the effect size in the current study was modest, whether interpreted as absolute or relative differences in scores between the intervention and control groups. What is most impressive about our results, however, is the consistency of the treatment benefit across several different outcomes. The persistence of a beneficial effect 6 months after completion of the last home visit, with statistically significant differences for 2 of the 5 outcomes despite adjustment for multiple comparisons, suggests that older persons can maintain their treatment gains in the absence of ongoing "hands-on" training. Because follow-up data were not collected beyond 1 year, we cannot comment on the long-term benefit of the prehabilitation program.

Our results should be widely applicable to other physically frail, nondemented, community-living older persons. We recruited participants from busy community-based, primary care practices. There were relatively few exclusion criteria, and the participation rate was high. We have previously shown that our target population of older persons with physical frailty can be readily identified in the context of routine primary care.⁸ The 2 "screening" tests—rapid gait and a single chair stand—can be completed in less than a minute by a nonclinician. Poor performance on these tests, which may be considered "geriatric" vital signs,²⁵ generally signifies impairments in lower-extrem-

ity strength and balance,^{26,27} the 2 domains with the strongest epidemiologic link to functional decline and disability.¹⁻³

Our prehabilitation program was designed to address impairments, not only in lower-extremity strength and balance, but also in joint ROM, bed mobility, transfer skills, indoor gait, foot care, sensation and tone, upper-extremity strength, and outdoor mobility. The intervention modalities included instruction in safer, more effective techniques, training in the proper use of assistive devices, balance and muscle conditioning exercises, and recommendations for environmental modifications. Determining the mechanisms by which this multimodal program exerted its beneficial effects, although of great interest, is beyond the scope of our report. Although our prehabilitation program could conceivably be incorporated into the array of services offered by home care agencies, there is currently no mechanism to pay for such a program. Reimbursement for home-based, rehabilitation services through Medicare, for example, is currently restricted to enrollees who are home bound,²⁸ usually after an acute hospital admission. A formal cost-effectiveness analysis would likely be necessary before our prehabilitation program could be considered for inclusion as a "covered" benefit.

About a third of the participants ended the prehabilitation program prematurely or did not receive the assessment or intervention. Given the high-risk status of our participants, attrition should not be surprising. By virtue of their physical frailty, our participants had high predicted rates of functional decline, hospitalization, nursing home placement, and death.^{1,2,9,29} Indeed, the most common reason why participants did not complete the program was a new or worsening personal illness. We have previously shown that intervening events increase with age and physical frailty.³⁰ Nonetheless, as noted,⁷ participants in the intervention group did not experience a higher rate of adverse events than participants in the control group, indicating that the prehabilitation program can be implemented safely in this population.

We recognize potential limits to the validity of our findings. The impracticality of masking participants to the treatment assignment may have biased the self-reports of IADL disability. Bias alone, however, is unlikely to explain fully the differences between the 2 groups, because similar results were observed for the objectively measured tests of mobility and integrated physical performance. The possibility that our findings are attributable to the attention received rather than the training program itself is diminished by our use of an active control intervention, which had a high completion rate and included up to 12 personal contacts.⁷ The validity of our findings is further strengthened by the random assignment of participants, by keeping the nurse assessors masked to the treatment assignments and the participants unaware of the study hypotheses, and by minimizing losses to follow-up.

CONCLUSIONS

Our home-based, prehabilitation program offered modest but consistent benefits for the prevention of decline in several higher-level measures of physical function. These results, combined with our earlier findings,⁷ offer hope to frail older persons and their families that functional decline and disability can be slowed, if not prevented.

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Suppliers

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