

A PROGRAM TO PREVENT FUNCTIONAL DECLINE IN PHYSICALLY FRAIL, ELDERLY PERSONS WHO LIVE AT HOME

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ABSTRACT

Background Functional decline in physically frail, elderly persons is associated with substantial morbidity. It is uncertain whether such functional decline can be prevented.

Methods We randomly assigned 188 persons 75 years of age or older who were physically frail and living at home to undergo a six-month, home-based intervention program that included physical therapy and that focused primarily on improving underlying impairments in physical abilities, including balance, muscle strength, ability to transfer from one position to another, and mobility, or to undergo an educational program (as a control). The primary outcome was the change between base line and 3, 7, and 12 months in the score on a disability scale based on eight activities of daily living: walking, bathing, upper- and lower-body dressing, transferring from a chair, using the toilet, eating, and grooming. Scores on the scale ranged from 0 to 16, with higher scores indicating more severe disability.

Results Participants in the intervention group had less functional decline over time, according to their disability scores, than participants in the control group. The disability scores in the intervention and control groups were 2.3 and 2.8, respectively, at base line; 2.0 and 3.6 at 7 months ($P=0.008$ for the comparison between the groups in the change from base line); and 2.7 and 4.2 at 12 months ($P=0.02$). The benefit of the intervention was observed among participants with moderate frailty but not those with severe frailty. The frequency of admission to a nursing home did not differ significantly between the intervention group and the control group (14 percent and 19 percent, respectively; $P=0.37$).

Conclusions A home-based program targeting underlying impairments in physical abilities can reduce the progression of functional decline among physically frail, elderly persons who live at home. (N Engl J Med 2002;347:1068-74.)

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THE ability to perform activities of daily living, such as bathing, dressing, and walking, is essential to living independently. Despite recent reductions in the prevalence of disability, the number of chronically disabled Americans 65 years of age or older currently exceeds 7 million.¹ Because disability is associated with increased mortality² and leads to increased rates of adverse outcomes,

such as hospitalization, admission to a nursing home, and use of formal and informal home services,³⁻⁶ it places a substantial burden on elderly persons, informal caregivers, and health care resources.^{7,8} Therefore, interventions designed to prevent functional decline have the potential not only to generate large health care savings⁹ but also to lead to important reductions in the physical, emotional, social, and financial problems attributable to disability.

Previously studied interventions have focused largely on the restoration of function in disabled elderly persons undergoing rehabilitation after an acute medical event, such as a stroke or hip fracture. There have been relatively few attempts to evaluate strategies aimed at the prevention of functional decline in frail, elderly persons who have not had an acute illness or injury (strategies known as “prehabilitation”). Because elderly persons with impairments in physical abilities are at high risk for the development of functional decline,¹⁰⁻¹² they may be particularly good candidates for preventive interventions.

We conducted a randomized clinical trial of a home-based program designed to prevent functional decline in a high-risk group of physically frail, elderly persons who lived at home. Our primary aim was to determine whether the intervention improved the ability of these elderly persons, relative to those in a control group, to perform essential activities of daily living. Our secondary aim was to identify the subgroups of this elderly population that benefited most from the intervention.

METHODS

Study Population

Complete details of our recruitment procedures have been described elsewhere.¹³ We used two strategies to identify physically frail, elderly persons 75 years of age or older from busy primary care practices in southern Connecticut. In the first, potential participants were screened for physical frailty during routine office visits; in the second, potential participants were identified from a roster of patients and were screened for physical frailty in their homes. Physical frailty was defined according to the results of two tests of physical

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abilities that are strongly associated with the development and progression of disability.^{11,12,14} Persons were considered physically frail if they required more than 10 seconds to perform a rapid-gait test (i.e., to walk along a 10-ft [3.0-m] course and back as quickly as possible) or if they could not stand up from a seated position in a hardback chair with their arms folded. Persons meeting one of these criteria were considered moderately frail, and those meeting both criteria were considered severely frail.¹²

Persons were ineligible for the study if they were unable to walk, were undergoing physical therapy 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 Examination (on which possible scores range from 0 to 30, with lower scores indicating worse cognitive status),¹⁵ had a life expectancy of less than 12 months, or had had a stroke, hip fracture, or myocardial infarction or had undergone hip- or knee-replacement surgery within the previous 6 months.

Of the 216 persons determined to be eligible, 188 (87 percent) agreed to participate. Eligible persons who declined to participate did not differ significantly from those who did agree to participate in terms of age, sex, level of physical frailty (moderate or severe), or recruitment strategy (during an office visit or from a roster). Random assignment to the intervention group or the control group was performed within strata, defined according to the level of physical frailty and the recruitment strategy, with the use of a computer-generated algorithm. Oral informed consent was obtained from all the participants according to procedures approved by the Yale Human Investigation Committee.

Assessments

Base-line and follow-up assessments were completed by a team of four research nurses who had no role in the intervention and who were unaware of the study hypothesis and of the participants' group assignments. The nurses underwent intensive training and followed standardized procedures, which were outlined in a detailed manual. All the data were collected on standardized forms.

In addition to data on physical frailty and cognitive status,¹⁵ self-reported information was collected at base line with regard to 10

physician-diagnosed chronic conditions¹³ and eight activities of daily living: walking, bathing, upper- and lower-body dressing, transferring from a chair to a standing position, using the toilet, eating, and grooming.¹³ On the basis of previous research,¹⁶ performance on each task was scored as follows: 0, if the participant had not needed help with the task and had not had difficulty with it during the preceding month; 1, if he or she had had difficulty but had not needed help; and 2, if he or she had needed help, regardless of the difficulty of the task. A summary disability score, with a range of 0 to 16, accounted for all eight activities.¹³ An increase of two points on this scale could represent a transition from independence without difficulty to dependence with respect to a single activity of daily living or from independence with difficulty to dependence with respect to two activities. These transitions are associated with an increased risk of admission to a nursing home or death.¹⁶

Self-reported data on activities of daily living, along with information on nursing home admissions, were again collected at 3 months (during a telephone interview) and at 7 and 12 months (during face-to-face interviews). All nursing home admissions were confirmed by review of the medical records. Data on potential adverse events were also collected at 3, 7, and 12 months.

Intervention Group

Table 1 summarizes the features of our home-based intervention program, which has been described in detail elsewhere.¹⁷ A physical therapist assessed each participant for potential impairments in physical abilities and assessed the participant's home environment. Detailed algorithms and decision rules were developed to link the results of the assessment with the recommended interventions. The program was designed to include an average of 16 visits over a six-month period, although the actual number of visits was determined by the number and severity of the underlying impairments and by the participant's progress. To monitor adherence to the program, participants were asked to complete a daily exercise calendar, which was reviewed by the physical therapist during each visit.¹⁸ On completion of the visits, the physical therapist called the participants monthly for six additional months to answer questions and to provide encouragement.

TABLE 1. FEATURES OF THE HOME-BASED INTERVENTION PROGRAM.*

FOCUS OF ASSESSMENT	RECOMMENDED INTERVENTION†
Impaired ability to move in bed or outdoors; impaired ability to transfer from one position to another; or impairment in indoor gait	Instruction in safe, effective techniques to facilitate activity Training in proper use of assistive devices Removal of environmental hazards
Impairment in balance or range of motion	Progressive, competency-based exercises‡
Presence of environmental hazards	Removal of loose rugs, cords, and clutter in walking paths Placement of nonskid mats in bathroom and at kitchen sink Improvement in lighting Repair of walking surfaces, stairways, and railings Installation of adaptive equipment in bathroom

*A complete description of the program is available elsewhere.¹⁷

†Unless such activity was medically contraindicated, all participants performed progressive, competency-based conditioning exercises of the arms and legs with resistant elastic bands. The exercises were performed only under supervision until a physical therapist determined that the participant was able to perform them safely and effectively without supervision. Subsequently, the participant was instructed to perform the conditioning exercises three days per week.

‡These exercises were performed once per day without supervision after the physical therapist determined that the participant was able to perform them safely and effectively without supervision.

Control Group

An educational program designed to provide attention and health education was used in the control group. During six monthly home visits, a health educator and the participant reviewed general practices promoting good health, such as proper nutrition, management of medications, physical activity, sleep hygiene, and other health-related areas.¹⁹ Sessions were tailored to the participant's specific needs according to his or her responses on a brief health-related questionnaire. On completion of the visits, the health educator called the participants monthly for six additional months to answer questions and to provide encouragement.

Outcomes

The primary outcome was the change in the summary disability score between the base-line assessment and the follow-up assessments at 3, 7, and 12 months. Follow-up data on function in terms of activities of daily living were available for all the participants who did not die during the study, with the exception of one participant in the intervention group, who refused to complete the assessment at three months, and one participant in the control group, who missed the assessments at three and seven months because of an administrative error. In a subgroup of 18 participants who were interviewed twice on consecutive days, the reliability of our summary disability scale was found to be excellent (intraclass correlation coefficient, 0.86).²⁰ Secondary outcomes were admission to a nursing home and the number of days spent in a nursing home. "Permanent" admissions to a nursing home were not distinguished from shorter admissions, since this distinction is difficult to make during a 12-month period.

Statistical Analysis

All analyses were performed according to the intention-to-treat principle. The primary outcome was analyzed with the use of generalized estimating equations with a negative binomial error distribution, which provided the best fit to the data.²¹ Treatment effects were adjusted for recruitment strategy (recruitment during an office visit or from a roster), level of physical frailty (moderate or severe), and disability score at base line. The exponential of the regression coefficients for the effects of treatment at 3, 7, and 12 months was calculated, and the results are presented as the percent change in the mean disability score at each time point in the intervention group relative to the control group. These analyses were repeated separately for participants with moderate frailty and those with severe frailty. We also evaluated the effect of the intervention within pre-specified subgroups. Differences in treatment effects according to subgroup were evaluated by tests of interaction, and the statistical significance of the results was determined by Hochberg's variation of the Bonferroni procedure.²²

A two-part model, adjusted for recruitment strategy and level of physical frailty, was used for the assessment of secondary outcomes.²³ First, logistic regression was used, with admission or no admission to a nursing home as a binary outcome. Second, data from participants who were admitted to a nursing home were analyzed by ordinary least-squares regression, with the number of days spent in the nursing home as the outcome.

All the statistical tests were two-tailed, and a P value of less than 0.05 was considered to indicate statistical significance.

RESULTS

The base-line characteristics were similar in the two groups, although there was a slightly higher proportion of women in the intervention group ($P=0.07$) (Table 2). Six participants in the intervention group (6 percent) and four in the control group (4 percent) died during the 12-month follow-up period.

Among the participants randomly assigned to the intervention group, 61 (65 percent) completed the program, and 20 (21 percent) withdrew from the program prematurely, after a mean (\pm SD) of 9.5 ± 4.1 home visits; the remaining 13 participants in this group (14 percent) did not receive the intervention at all, primarily because of worsening personal health or illness in a family member. On average, participants who completed the program had 14.9 ± 2.4 visits (range, 7 to 19). Overall, adherence to the exercise program was high, with completion of 73 percent of the assigned exercises for balance, 78 percent of the leg-conditioning exercises, and 79 percent of the arm-conditioning exercises. Among the participants randomly assigned to the control group, 78 (83 percent) completed the program; 7 (7 percent) discontinued the program, after a mean of 1.3 ± 1.5 visits, because

TABLE 2. BASE-LINE CHARACTERISTICS OF THE PARTICIPANTS.*

CHARACTERISTIC	INTERVENTION GROUP (N=94)	CONTROL GROUP (N=94)
Age — yr	82.8 \pm 5.0	83.5 \pm 5.2
Age \geq 85 yr — no. (%)	35 (37)	41 (44)
Female sex — no. (%)	80 (85)	70 (74)
White race — no. (%)	85 (90)	86 (91)
Living alone — no. (%)	41 (44)	47 (50)
Education — yr	11.3 \pm 3.1	11.3 \pm 2.3
No. of chronic conditions†	2.1 \pm 1.1	2.0 \pm 1.3
Mini-Mental State Examination		
Mean score	26.7 \pm 2.6	26.3 \pm 2.4
Score — no. (%)		
\geq 28	39 (41)	32 (34)
24–27	42 (45)	48 (51)
<24	13 (14)	14 (15)
Recruitment strategy — no. (%)		
Assessment in office	51 (54)	50 (53)
Identification from roster	43 (46)	44 (47)
Level of physical frailty — no. (%)		
Moderate	60 (64)	56 (60)
Severe	34 (36)	38 (40)
Summary disability score‡		
Mean score	2.3 \pm 2.2	2.8 \pm 2.8
Score — no. (%)		
0	22 (23)	28 (30)
1	20 (21)	10 (11)
2	15 (16)	15 (16)
3	12 (13)	12 (13)
4	12 (13)	7 (7)
\geq 5	13 (14)	22 (23)

*Plus-minus values are means \pm SD. There were no significant differences in any of these characteristics between the intervention and control groups. Chi-square tests were used for categorical variables, and t-tests were used for continuous variables.

†Chronic conditions included congestive heart failure, diabetes, and arthritis.¹⁷

‡Possible scores, based on an assessment of performance of eight activities of daily living, ranged from 0 (no disability) to 16 (total disability); the highest score in each group was 11.

of death or a move after an acute illness or injury; and 9 (10 percent) withdrew from the program after a mean of 1.8 ± 1.1 visits.

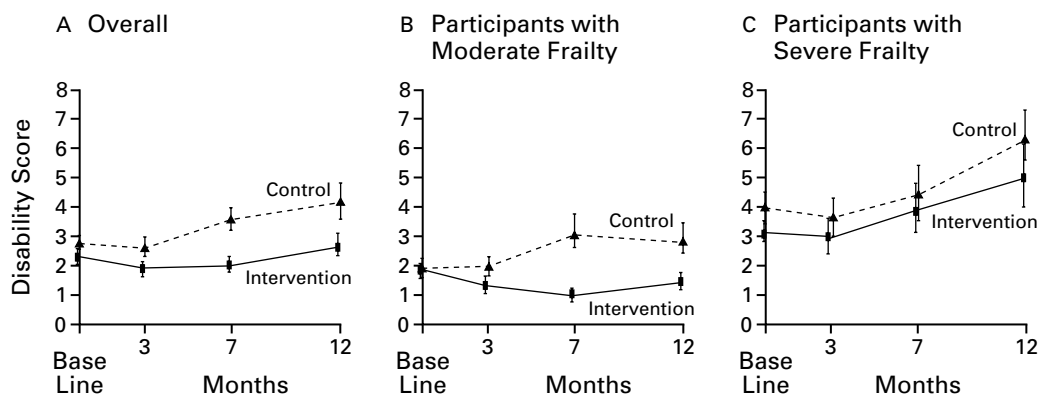
Overall, participants in the intervention group had less disability than participants in the control group at 3, 7, and 12 months (Fig. 1A). The disability scores were significantly different between the two groups at 7 and 12 months. In a separate analysis of participants with moderate frailty, those in the intervention group had significantly lower disability scores at 7 and 12 months than those in the control group (Fig. 1B). In contrast, in an analysis of participants with severe frailty, the disability scores at 7 and 12 months were not significantly different between the two groups (Fig. 1C).

Whereas the participants who lived alone benefited from the intervention, those who lived with others did not (Fig. 2); this difference, however, did not achieve statistical significance at 7 months (corrected $P=0.10$) or at 12 months (corrected $P=0.05$). There were no differences between subgroups defined ac-

cording to age (less than 85 years old or at least 85 years old), sex, or score on the Mini-Mental State Examination (28 or higher, 24 to 27, or less than 24).

Thirteen participants in the intervention group (14 percent) and 18 in the control group (19 percent) were admitted to a nursing home during the 12-month follow-up period ($P=0.37$). Among these participants, the mean number of days spent in a nursing home was 58.5 (median, 16) in the intervention group and 75.2 (median, 34.5) in the control group ($P=0.22$).

With only one exception (the rate of angina diagnosed by a physician, which was more common in the control group), the rates of possible adverse events of the intervention, such as falls or musculoskeletal problems, did not differ significantly between the two groups (Table 3). The total cost of the intervention, including the cost of staff time spent in intervention activities, the cost of equipment and supplies, and consultant fees, was \$187,808, or an average of \$1,998 per participant in the intervention group.



	A Overall				B Participants with Moderate Frailty				C Participants with Severe Frailty			
	Base Line	3	7	12	Base Line	3	7	12	Base Line	3	7	12
No. of participants												
Intervention group	94	91	91	88	60	58	58	58	34	33	33	30
Control group	94	91	90	90	56	55	54	54	38	36	36	36
Disability score												
Intervention group	2.3	1.9	2.0	2.7	1.9	1.3	1.0	1.4	3.1	3.0	3.9	5.0
Control group	2.8	2.6	3.6	4.2	1.9	2.0	3.0	2.8	4.0	3.6	4.4	6.3
Change (%)	—	15	45	37	—	25	66	53	—	1.7	5.1	16s
P value	—	0.48	0.008	0.02	—	0.40	<0.001	0.005	—	0.95	0.87	0.50

Figure 1. Mean (\pm SE) Disability Scores at Base Line and at 3, 7, and 12 Months in All Participants (Panel A), Participants with Moderate Frailty (Panel B), and Participants with Severe Frailty (Panel C).

Physical frailty was defined according to the results of two tests of physical ability (one involving rapid walking and one involving transferring from a chair to a standing position) that are strongly associated with the development and progression of disability¹¹⁻¹³; persons meeting one of these criteria were considered moderately frail, and those meeting both criteria were considered severely frail. Ten participants died during the 12-month follow-up period. Results are reported as the percent reductions in the mean disability scores of the intervention group relative to the control group, as calculated from negative binomial models, which included adjustments for recruitment strategy (recruitment during an office visit or from a roster), level of physical frailty (in Panel A only), and disability score at base line. P values are for the comparison between the disability scores in the two groups at each time point, after adjustments.

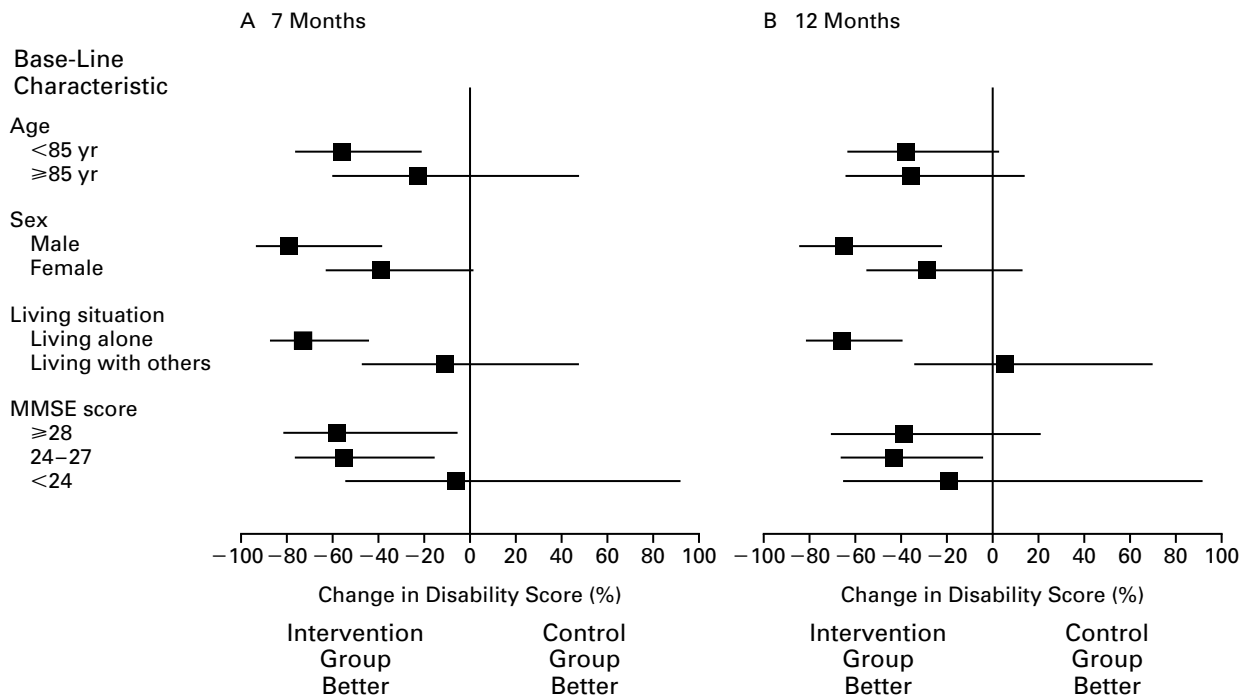


Figure 2. Mean Changes in Disability Scores at 7 Months (Panel A) and 12 Months (Panel B) in the Intervention Group Relative to the Control Group, According to Base-Line Characteristics.

The results were adjusted for recruitment strategy (recruitment during an office visit or from a roster), level of physical frailty (moderate or severe), and disability score at base line. None of the differences between the subgroups were statistically significant, although the corrected P value for the comparison between participants living alone and those living with others at 12 months was 0.05. Scores for the Mini-Mental State Examination (MMSE) can range from 0 to 30, with lower scores indicating worse cognitive status.¹⁵ Results are given as means and 95 percent confidence intervals.

DISCUSSION

This randomized clinical trial provides evidence that a home-based “prehabilitation” program is effective in preventing functional decline among physically frail, elderly persons who live at home. As compared with an educational program, the 6-month intervention program led to clinically relevant reductions in self-reported disability at 7 and 12 months. The benefits of the intervention were observed largely among persons with moderate (as opposed to severe) frailty. Despite the intervention, persons with severe frailty had worsening disability over time.

The extent to which our results can be generalized is enhanced by our inclusion criteria for entry and by the high participation rate. More stringent exclusion criteria or the use of a run-in phase might have resulted in a higher rate of completion of the training program, possibly leading to a finding of greater efficacy, but would have diminished the applicability of the program. Our criteria for physical frailty identified elderly persons with substantial impairments in physical abilities¹³ and hence with high projected rates of disability and functional decline,^{10,11,14} as were observed

among participants in the control group, in whom disability worsened over time. In contrast, the disability scores among participants in the intervention group were relatively stable. These findings support the conclusion that our program has preventive value.

It is not clear why the participants with severe physical frailty did not benefit from the intervention. The cause of disability in elderly persons is highly complex²⁴ and is increasingly thought to involve an interplay among specific risk factors, including impairments in physical ability and cognitive status, and subsequent illnesses, injuries, or other problems.²⁵⁻²⁷ Because our intervention was designed primarily to improve underlying impairments in physical abilities, it would not be expected to prevent some of the most common disabling events, such as strokes or worsening heart failure, or to reduce the progression of cognitive decline. This might explain in part why participants in our study who had cognitive impairment, as indicated by a score of less than 24 on the Mini-Mental State Examination, appeared to benefit less from the intervention than participants whose cognition was intact. The finding that participants who lived alone benefited

TABLE 3. ADVERSE EVENTS.*

ADVERSE EVENT	INTERVENTION GROUP	CONTROL GROUP	P VALUE
	(N=92)	(N=92)	
	no. (%)		
One or more falls	51 (55)	53 (58)	0.77
Fall-related fracture†	1 (1)	5 (5)	0.21
Chest pain	23 (25)	32 (35)	0.15
Physician-diagnosed angina	6 (7)	16 (17)	0.02
Musculoskeletal problems leading to restriction in usual activities	30 (33)	28 (30)	0.75

*Two participants in each group died before the first follow-up assessment, at three months.

†There were six fractures (four of the hip, one of the coccyx, and one of the shoulder) in the control group and one fracture (of the hand) in the intervention group.

from the intervention, whereas those who lived with others did not, may be attributable to the lower rates of severe frailty and cognitive impairment and the higher rate of program completion among those who lived alone (data not shown).

Adverse events were not more common in the intervention group than in the control group, indicating that this home-based intervention program is safe for frail, elderly persons. Our program also does not rely on expensive equipment, so it is feasible in the home setting. The number of physical-therapy visits, however, far exceeded the number that is currently reimbursed by Medicare for home-based rehabilitation. The absence of a benefit at three months suggests that a shorter training program, with fewer home visits, would not be effective. Furthermore, the program's estimated cost of \$2,000 per person is moderate when compared with the costs of other treatments, which may be of uncertain benefit in frail, elderly persons.²⁸ Although the benefit of our training program was maintained for 12 months, we cannot comment on its benefit over longer periods.

In a recent meta-analysis, Stuck et al.²⁹ found that preventive home visits are effective when they target persons with relatively good functional status and when they include a systematic evaluation of multiple domains (i.e., medical, functional, psychosocial, and environmental) and frequent follow-up home visits. With only one exception,³⁰ however, these interventions were designed to address unmet medical or social needs, often in the context of comprehensive geriatric assessment, rather than to improve underlying impairments in physical abilities. In contrast to a home-based intervention consisting of resistance training, as assessed in a previous study that included sedentary per-

sons 60 years of age or older,³¹ our home-based intervention targeted a diverse group of physically frail persons whose mean age was 83 years.

Our study has some limitations. Most important, the impracticality of masking group assignments may have biased the participants' reports of disability. Bias alone, however, is unlikely to explain fully the differences between the intervention and control groups. Similar trends, although not statistically significant, were observed both with respect to nursing home use and the number of fall-related fractures — outcomes that are less susceptible to reporting bias than are participants' assessments of disability. The possibility that our findings are attributable to the attention received rather than to the training program itself is diminished by our use of an active control, which consisted of an educational program that included up to 12 personal visits or telephone calls and that had a high completion rate. The validity of our findings is further strengthened by the random assignment of participants, the use of a validated measure of disability with high reliability, the blinding of the research nurses with respect to the group assignments and of the participants with respect to the study hypothesis, and the minimal rate of loss to follow-up.

Our study was not designed to detect significant differences between the groups in the rate of admission to a nursing home or the number of days spent in a nursing home, both of which were assessed as secondary outcomes. Possible explanations for the absence of significant differences between the groups in nursing home use, despite differences in disability scores, include an inadequate sample size and insufficient length of follow-up. We were not able to distinguish nursing home admissions that were potentially preventable from those that were not, since we did not collect data on reasons for these admissions.

In summary, the results of our study indicate that functional decline among physically frail, elderly persons who live at home can be slowed, if not prevented. Further evaluation is needed to determine the cost effectiveness of this program and to identify means by which it exerts a beneficial effect.

Supported by grants from the National Institute on Aging (P60AG10469, to the Claude D. Pepper Older Americans Independence Center at Yale University) and from the Gaylord Rehabilitation Research Institute (to Dr. Gill). Dr. Gill is the recipient of an academic award (K23AG00759) from the National Institute on Aging, and he was a Paul Beeson Physician Faculty Scholar in Aging Research and a Robert Wood Johnson Foundation Generalist Physician Faculty Scholar during the course of this study.

We are indebted to Evelyn Gabbauer, M.D., M.P.H., and Daphna Pollack, M.P.H., for data management and programming; to Peter Charpentier, M.P.H., for development of the computerized assessment and intervention software used in the intervention program; to Denise Shepard, B.S.N., Paula Clark, R.N., Shirley Hannan, R.N., and Martha Oravetz, R.N., for assistance with data collection; to Paul DeRegt, P.T., M.S., Sarah Wallace, P.T., M.S., and Luann Bianco

for refinements and implementation of the intervention; to Geraldine Hawthorne and Wanda Carr for assistance with data entry and management; to Joanne McGloin, M.Div., M.B.A., for leadership and advice as the project director; to Mary Tinetti, M.D., director of the Yale Program on Aging, for guidance and oversight; and to the following people for facilitation of our recruitment efforts: David Chess, M.D., Nicholas Bertini, M.D., and the other participating physicians and staff of PriMed; Bruce Wainer, M.D., Peter Yannopoulos, M.D., and the staff of Connecticut Medical Associates; Nicholas Dainiak, M.D., and Robert Bernasek, M.D., of Bridgeport Hospital; and Bashi Chaddha, M.D., of Southwest Community Health Center.

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