

# A Randomized, Controlled Pilot Study of a Home-Based Exercise Program for Individuals With Mild and Moderate Stroke

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**Background and Purpose**—Many stroke survivors have minimal to moderate neurological deficits but are physically deconditioned and have a high prevalence of cardiovascular problems; all of these are potentially modifiable with exercise. The purposes of this randomized, controlled pilot study were (1) to develop a home-based balance, strength, and endurance program; (2) to evaluate the ability to recruit and retain stroke subjects; and (3) to assess the effects of the interventions used.

**Methods**—Twenty minimally and moderately impaired stroke patients who had completed inpatient rehabilitation and who were 30 to 90 days after stroke onset were randomized to a control group or to an experimental group that received a therapist-supervised, 8-week, 3-times-per-week, home-based exercise program. The control group received usual care as prescribed by the patients' physicians. Baseline and postintervention assessments included the Fugl-Meyer Motor Assessment, the Barthel Index of Activities of Daily Living (ADL), the Lawton Scale of Instrumental ADL, and the Medical Outcomes Study-36 Health Status Measurement. Functional assessments of balance and gait included a 10-m walk, 6-Minute Walk, and the Berg Balance Scale. Upper extremity function was evaluated by the Jebsen Test of Hand Function.

**Results**—Of 22 patients who met study criteria, 20 completed the study and 2 refused to participate. The experimental group tended to improve more than the control group in motor function (Fugl-Meyer Upper Extremity: mean change in score, 8.4 versus 2.2; Fugl-Meyer Lower Extremity: 4.7 versus -0.9; gait velocity: median change, 0.25 versus .09 m/s; 6-Minute Walk: 195 versus 114 ft; Berg Balance Score: 7.8 versus 5; and Medical Outcomes Study-36 Health Status Measurement of Physical Function: 15.5 versus 9). There were no trends in differences in change scores by the Jebsen Test of Hand Function, Barthel Index, and Lawton Instrumental ADL Scale.

**Conclusions**—This study demonstrated that a randomized, controlled clinical trial of a poststroke exercise program is feasible. Measures of neurological impairments and lower extremity function showed the most benefit. Effects of the intervention on upper extremity dexterity and functional health status were equivocal. The lasting effects of the intervention were not assessed. (*Stroke*. 1998;29:2055-2060.)

**Key Words:** exercise ■ rehabilitation ■ stroke management

Stroke disability may persist for life and limits independence and quality of life, even in those deemed recovered on the basis of independence in self-care.<sup>1</sup> The incidence of stroke has remained constant over the last 3 decades, but mortality and stroke severity have declined.<sup>2</sup> The majority of individuals who survive a stroke have minimal to moderate neurological deficits,<sup>3,4</sup> and >50% of them are expected to be alive in 5 years.<sup>5</sup> The increasing number of persons surviving with less severe stroke results in increased need for programs to enhance their recovery, improve functional status, and optimize quality of life.

Individuals with mild strokes may have significant impairments in postural control and gait velocity.<sup>6-9</sup> The 6-month incidence of falls among individuals with mild to moderate stroke has been reported to be 73%. Forty-seven percent of this cohort fell more than once, and 24% could not get up after they fell.<sup>10</sup> Many stroke survivors are physically deconditioned and have a high prevalence of cardiovascular risk factors and problems that are potentially modifiable with exercise.<sup>11,12</sup>

Current approaches to stroke rehabilitation are characterized by multiple, conflicting, and unsubstantiated treatment

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philosophies and a tendency to invest efforts in those with severe stroke and in goals limited to self-care.<sup>13-15</sup> For the most part, physical interventions for stroke are targeted to functional training such as dressing, transfers, and gait. A recent review of the literature through 1994 found limited evidence to support recommendations for specific exercise interventions for stroke survivors.<sup>16</sup> Emerging evidence suggests that intensive remedial therapy may be beneficial for stroke survivors.<sup>17</sup> Two recent trials have explored the benefits of aerobic training in chronic stroke patients.<sup>12,18</sup> These studies suggest that individuals with stroke experience improved cardiovascular function and some demonstrated improved motor recovery with aerobic conditioning interventions. While some proportion of stroke disability may be permanent, optimal therapy might further reduce disability.

To our knowledge, no study has combined all 3 components (strength, balance, and endurance) into 1 intervention for individuals with stroke. We developed an intensive home-based exercise program based on evidence from prior exercise interventions for elderly individuals and stroke survivors. Our intervention targeted individuals who had experienced mild and moderate strokes because they often retain significant deficits that may not have received specific interventions and they are likely to have secondary deconditioning. The purposes of this pilot study were to (1) develop an exercise intervention based on principles of exercise physiology and motor learning and to deliver it in the home to individuals with mild or moderate strokes, (2) evaluate the feasibility of the intervention and the ability to recruit and retain stroke subjects, and (3) assess the effects of the interventions.

## Subjects and Methods

### Research Design

In this randomized controlled pilot study, 20 individuals with mild to moderate strokes who had completed acute rehabilitation and who were 30 to 90 days after onset were randomized to a 12-week (8-week therapist-supervised program and 4-week independent program) home-based intervention (experimental group) to improve strength, balance, and endurance or to usual care (control group).

### Subjects

Subjects were recruited from local participating hospitals and the registry of the Kansas City Stroke Study. The Kansas City Stroke Study is an ongoing prospective cohort study of individuals with stroke who were admitted to 12 participating hospitals in the greater Kansas City area. Individuals enrolled in the Kansas City Stroke Study were evaluated within 14 days after stroke and reassessed at 1 month, 3 months, and 6 months after stroke to characterize recovery of neurological impairments, functional abilities, and health status. For the purpose of the Kansas City Stroke Study, a stroke is defined as "symptoms of rapid onset and of presumed vascular origin reflecting a focal disturbance of cerebral function, excluding isolated impairment of higher function."<sup>19</sup> Subjects selected from the Kansas City Stroke Study Registry were screened for eligibility, and informed consent was obtained from each participant as well as from each participant's physician. Specific inclusion criteria for participation in this pilot study were (1) 30 to 90 days after stroke; (2) minimal or moderately impaired sensorimotor function (Fugl-Meyer Motor Score 40 to 90,<sup>20</sup> Orpington Prognostic Scale score 2.0 to 5.2<sup>21</sup>); (3) ambulatory with supervision and/or assistive device; (4) living at home; and (5) living within 50 miles of the University of Kansas Medical Center.

Exclusion criteria were (1) a medical condition that interfered with outcome assessments or limited participation in submaximal exercise program, (2) a Mini-Mental State score <18,<sup>22</sup> or (3) receptive aphasia that interfered with the ability to follow a 3-step command. As part of the enrollment, medical records from the Kansas City Stroke Study Registry were reviewed to determine each subject's demographics, stroke onset, and stroke type.

### Procedures

Patients were evaluated by the therapist coordinator to determine stroke severity and study eligibility. After eligibility for this study was established and approval from the patient's primary physician was obtained, subjects were contacted by the study therapist to determine their willingness to participate. If subjects agreed to participate, they came to the University of Kansas Medical Center's Center on Aging Human Performance Laboratory for baseline assessments. Follow-up testing for postintervention results was performed 12 weeks after the baseline function assessment.

Stroke severity was assessed by the following scales:

#### *Orpington Prognostic Scale*

The Orpington Prognostic Scale<sup>21</sup> is a brief screen that includes assessment of motor function of the arm, upper extremity proprioception, balance, and 10 cognitive questions. The best possible Orpington score is 1.6.

#### *Fugl-Meyer Motor Score*

The Fugl-Meyer Motor Score<sup>20</sup> is probably the most widely known scale of motor recovery after stroke. The Fugl-Meyer includes items of upper and lower extremity function that require progressively more complex movements and hand grasps and measure speed and coordination. Each item is graded on a 3-point scale (0, cannot perform; 1, partially performs; 2, performs fully). The maximum score for upper extremity motor performance is 66 and for the lower extremity 34.

The following functional assessments were also performed:

#### *Barthel Index Activities of Daily Living*

The Barthel Index Activities of Daily Living (ADL)<sup>23</sup> is a weighted scale of 10 items of basic ADL including feeding, bathing, grooming, dressing, bladder and bowel control, chair/bed transfer, ambulation, and stair climbing. The highest possible score of the Barthel Index is 100.

#### *Lawton Instrumental Activities of Daily Living*

The Lawton Instrumental ADL<sup>24</sup> is a self-reported assessment of 9 activities: phone use, shopping, getting to places out of walking distance, meal preparation, housework, handyman work, laundry, medication management, and money management. All items are scored on a 3-point scale (3, can do without help; 2, can do with some help; and 1, completely unable to do). The maximum score on the Lawton IADL is 27.

#### *Medical Outcomes Study-36 Health Status Measurement*

The Medical Outcomes Study-36 Health Status Measurement (MOS-36)<sup>25</sup> is a self-report assessment that includes 8 domains (physical functioning, emotional role functioning, social role function, mental health, vitality, physical role, general health, and bodily pain.) Each domain is scored with a transformed scale of 100. Question 3 of the MOS-36 represents the physical functioning domain. It includes 10 items (vigorous activities; moderate activities; lifting or carrying groceries; climbing 1 flight of stairs; bending, kneeling, or stooping; walking several blocks; walking 1 block; and bathing or dressing).

Functional assessments of balance and gait included the following:

#### *10-Meter Walk*

The 10-meter walk is a measure of gait velocity. Individuals were given a 3-m warm-up distance. The time it took to traverse 10 m at the subject's usual pace was recorded. Two trials were averaged to determine gait velocity.

### 6-Minute Walk

The 6-Minute Walk<sup>26</sup> is a measure that was originally developed to assess cardiopulmonary function. In this test, subjects were given 6 minutes to walk as far as they could at their usual pace. The distance they covered in 6 minutes was recorded. Subjects were allowed to stop and rest as they deemed necessary.

### Berg Balance Scale

The Berg Balance Scale<sup>27</sup> consists of 14 items that require subjects to maintain positions of varying difficulty and perform specific tasks such as rising from a chair and timed stepping. Each item is graded from 0 to 4. The maximum possible score on the Berg Balance Scale is 56 points.

### Jebsen Test of Hand Function

Upper extremity function was evaluated with the Jebsen Test of Hand Function.<sup>28</sup> The Jebsen is a standardized assessment of the time it takes to perform hand activities. These include the following: writing a short sentence, turning over 3×5 cards, picking up small objects, stacking checkers, simulated eating, moving empty large cans, and moving weighted cans. Time of performance is recorded for each test. For the purposes of our analysis, we developed an ordinal scoring of change in time to do the activity between pretest and posttest (0, ≤2 seconds' difference between pretest and posttest; -1, decrease of >2 seconds between pretest and posttest; and 1, increase of >2 seconds between pretest and posttest). Ordinal scoring was used because some individuals could not perform some of the items. We assigned times of 120 seconds for the "unable to do" items. These scores skewed the data.

### Randomization

After baseline assessments, the subjects were randomly assigned to the experimental or control group. Randomization was done in blocks of 10. Before initiation of this study, a random list was generated by group assignments. Only a laboratory technician who had no input into subject selection or recruitment was aware of group assignment. After baseline assessment, the technician assigned the subject to the experimental or the control group.

### Intervention

The exercise program was designed to improve strength, balance, and endurance and to encourage more use of the affected extremity. The experimental group did not receive any physical or occupational therapy other than that provided by the study. If an experimental group subject required speech therapy, the subject was treated by usual care providers. The experimental exercise intervention was initiated within 5 days of baseline testing. It was a home-based exercise program provided by a physical therapist. The study principal investigator (a physical therapist) and coinvestigator (an occupational therapist) observed at least 1 therapy session for each subject to ensure standard application of interventions. The program included 3 visits a week for 8 weeks, and the patients were instructed to continue the exercise program on their own for 4 additional weeks. Each exercise session lasted ≈1.5 hours. Exercise sessions were divided into 4 blocks preceded by a 10-minute warm-up session of stretching and flexibility exercise. The first block included assistive and resistive exercises using Proprioceptive Neuromuscular Facilitation Patterns (PNF)<sup>29</sup> or Theraband exercise (see below) to the major muscle groups of the upper and lower extremities. PNF exercises include upper and lower extremity patterns. The movement patterns included (1) flexion, abduction, and external rotation of shoulder with the elbow extended and with wrist and finger extension; (2) extension, adduction, and internal rotation of shoulder with elbow extended and with finger and wrist flexion; (3) flexion, adduction, external rotation of hips with knee flexion, and ankle dorsiflexion; and (4) extension, abduction, internal rotation of hips with knee extension, and ankle plantar flexion.

Therabands are elastic bands of varying elasticity used as a means to provide resistance. Functional exercises in which body weight was used for resistance were also included. Assistive-resistive exercises that included PNF patterns were used only if the patient was too

**TABLE 1. Subject Characteristics by Group**

	Control Group (n=10)	Experimental Group (n=10)
Age, y	67.8 (±7.2)	67.3 (±9.6)
Stroke severity (Orpington Prognostic Scale)	2.8 (±0.5)	2.6 (±0.6)
Time since stroke, d	56	66
Type of stroke		
Ischemic	8	10
Hemorrhagic	2	0
Side of stroke		
5 Right CVA		6 Right CVA
4 Left CVA		4 Left CVA
1 Brain stem		0 Brain stem
Race		
8 White		6 White
2 Black		4 Black

weak to use the elastic bands. Resistance progression was based on a protocol in which when subjects could complete 2 sets of 10 repetitions through the available range of motion, resistance was increased by progression of Theraband elasticity (levels of resistance) or by increased manual resistance in PNF exercises. The second block included 15 minutes of balance exercises, which were progressively ordered by difficulty. In the third block, participants were encouraged to use the affected upper extremity in functional activities. The final session included a progressive walking program or progressive exercise on a bicycle ergometer. The detailed protocol of the intervention used is available from the authors.

Exercise stress testing was not included in baseline assessment; therefore, progression of the aerobic component of the program was conservative. Individuals were instructed to walk at their usual pace or bicycle at low revolutions per minute. The patients were then encouraged to increase their exercise time until they could exercise continuously for 20 minutes. Heart rate and blood pressure were monitored during the exercise sessions.

Subjects in the control group received usual care as prescribed by their physicians. Participants in this group were visited by a research assistant every 2 weeks to assess the patients' exercise and activity level. The clinicians providing therapeutic interventions to the usual care group were asked to complete an intervention log to capture type of exercises and frequency and duration of therapy visits during treatment or in a home exercise program. The study coordinator met with the treating therapists at least twice to discuss the therapy logs and intervention programs.

### Statistical Analysis

We used descriptive statistics to characterize demographics and performance for each group. We compared differences in change scores between groups using Wilcoxon rank sum tests.<sup>30</sup> The Cochran Mantel-Haenszel statistic<sup>31</sup> was used to compare differences in distributions of change scores for the Jebsen Test of Hand Function.

## Results

### Study Subjects

Twenty individuals with stroke were studied. Of 22 subjects recruited, 2 refused to participate. Table 1 characterizes the patients by control and experimental groups. Baseline scores on all assessments are presented in Table 2.

### Usual Care Therapy

The therapy programs received by the control group were variable in intensity, frequency, and duration. Six individuals

**TABLE 2. Baseline and 12-Week Follow-Up Scores for Subjects in Control and Experimental Groups**

	Control Group			Experimental Group			<i>P</i> for Test of Baseline Differences	<i>P</i> for Test of Differences in Change Score
	Pretest	Posttest	Mean Change	Pretest	Posttest	Mean Change		
Fugl-Meyer Upper Extremity	36.4	38.6	2.2	38.1	46.6	8.4	>0.2	0.2
Fugl-Meyer Lower Extremity	23.2	22.3	-0.9	21.7	26.3	4.77	>0.2	0.01<0.02
Gait velocity, m/s	0.57	0.65	0.09	0.42	0.67	0.25	>0.2	0.05<0.1
Berg Balance	40.8	45.8	5	38.3	46.1	7.8	>0.2	>0.2
6-Minute Walk, ft	556	671	114	491	686	195	>0.2	>0.2
Barthel ADL	82.5	95.6	13.3	82.5	95.5	13.0	>0.2	>0.2
Instrumental ADL	19.9	22.2	2.3	19.0	22.0	3.0	>0.2	>0.2
Physical function (MOS-36)	35.5	44.5	9	28.5	44.0	15.5	0.05-0.1	>0.2

Comparisons are by Wilcoxon rank sum tests.

received home health visits, and 4 received outpatient therapy. Types of exercises received by the usual care group were highly variable, but no one received endurance training. Table 3 provides a description of therapies received by the control group. All subjects in the control group complied with monitoring of therapies and were retested at 3 months.

### Experimental Therapy

Each member of the experimental group received 23 visits by a physical therapist for 90 minutes in duration. The experimental group was treated for 8 weeks and instructed to continue exercise interventions at home for an additional 4 weeks. All subjects completed the intervention program and were retested. One experimental group subject took 12 weeks to complete therapist-directed sessions. During the course of the intervention period, he had 2 surgeries (carotid endarterectomy and carpal tunnel release). Because of the intervening surgeries and the need for continuation of therapy for the upper extremity after carpal tunnel surgery, this patient received 17 additional therapy sessions.

**TABLE 3. Therapeutic Interventions for Control Group (n=0)**

Site of therapy	
Home health visit	6 (1 progressed to outpatient)
Outpatient	4
Therapy	
Physical therapy only	3
Occupational therapy only	0
Physical and occupational therapy	7
Average no. of visits (physical and occupational therapy)	39
Average duration of each visit, min	44
Type of exercise, %	
Endurance training	0
Balance training	60
Progressive resistive exercise	40
Bimanual activities	50
Facilitative exercise	30

Duration of surveillance was 12 weeks.

### Effect on Motor Recovery

The experimental group demonstrated more improvement in upper and lower extremity Fugl-Meyer scores than did the usual care group (Table 2). However, the differences in motor recovery were only significant for the lower extremity.

### Effect on Functional Performance

There were significant differences in changes in gait speed between the experimental group and the control group (Table 2). The direction of differences in changes in balance scores and the 6-Minute Walk favored the experimental group but was not significant (Table 2). Assessment of upper extremity functional performance by the Jebsen Test of Hand Function revealed no trends in changes in speed of upper extremity movements between the experimental and control groups (Table 4).

### Effect on Functional Status

No group differences were found in the changes on the Barthel Index ADL or the Lawton Instrumental ADL (Table 2). Assessment of the 8 domains of the MOS-36 did not reveal any direction of effect except for the Physical Function Scale. In the experimental group, the mean change on the MOS-36 Physical Function Scale was  $15.5 \pm 16.7$ , and the median change was 22.5. For the control group, the mean change was  $9 \pm 12.6$ , and median change was 5.

## Discussion

We demonstrated the feasibility of recruiting stroke survivors as subjects for a randomized clinical trial. Our target recruitment of 20 subjects for this 1-year pilot project was attained. Forty-nine percent of patients from the first 100 patients in the Kansas City Stroke Study were eligible to participate. Only 2 of 22 recruited subjects declined to participate. We provided transportation for baseline and postintervention assessments; only 3 of the 20 patients could have participated if transportation had not been provided. Compliance with the exercise intervention and retesting was excellent. All 20 subjects completed the study. We also learned that it is feasible to obtain records of usual care interventions and characterize rehabilitation services by types of exercises, intensity, duration, and frequency.

**TABLE 4. Distribution of Changes in Time to Perform Jebsen Test of Hand Function With Affected Upper Extremity**

Task	1 (Increased Time for Task >2 s)	0 (Difference in Time $\leq$ 2 s)	-1 (Decreased Time for Task >2 s)	P
Writing				0.42
Control	4	4	2	
Experimental	3	3	4	
Cards				0.82
Control	6	3	1	
Experimental	7	1	2	
Small objects				0.08
Control	7	2	1	
Experimental	3	4	3	
Checkers				0.42
Control	7	1	2	
Experimental	5	2	3	
Eating				0.10
Control	7	2	1	
Experimental	4	1	5	
Light objects				0.86
Control	6	3	1	
Experimental	6	2	2	
Heavy objects				0.86
Control	6	3	1	
Experimental	6	2	2	

This pilot study provided useful information about the feasibility of the experimental intervention. Our subjects tolerated the 1.5-hour intervention and were able to progress in intensity and duration of exercises. However, our experience suggests that our interventions were of insufficient duration and/or intensity to maximize aerobic capacity. Our original intent was to challenge endurance with a progressive walking program. Pragmatically, our experimental subjects did not have adequate space in their homes, nor were they community ambulators. After 7 subjects participated in the walking program, we switched from walking as a means to enhance cardiovascular endurance to cycle ergometers that were left in the patient's home. We believe that in future studies we need to stress the cardiovascular system with increased intensity and duration. However, increased intensity will require more extensive cardiac assessment and a stress test. Future studies will include a cardiovascular stress test.

Intervening comorbidities in 1 experimental subject prolonged his therapy program. We followed the "intent to treat" rule<sup>32</sup> in our analysis and did not exclude this subject from primary analysis. An analysis in which the subject with intervening comorbidities was excluded changed only 1 result. The change in Fugl-Meyer Upper Extremity scores with this subject excluded was significantly greater ( $0.025 < P < 0.05$ ) for the experimental group. Randomized clinical trials of stroke interventions may be complicated by intervening comorbidities, which may restrict therapies or

require additional therapies. The possibility of intervening comorbidities should be considered in the design of future studies.

This study demonstrated that a randomized, controlled clinical trial of a specific postdischarge rehabilitation intervention is feasible. Variability in usual care makes a usual care group appropriate for controls. The control group received a comparable number of treatment sessions and duration of treatment sessions if the individual occupational therapy and physical therapy sessions are counted as 1 session. The differences in programs were most evident in the types of interventions. For example, none of the members of the control group received endurance training. Larger differences in effect might have been expected if the experimental group was compared with a group that did not receive any intervention. However, a "no therapy" group is not an acceptable option to subjects or healthcare providers at the present time.

This pilot study demonstrated that individuals with stroke can make gains in function beyond that which occurs with usual care. The gains were apparent for lower extremity motor function and gait speed. There was a trend in effects for upper extremity motor function, improved balance, 6-minute walk time, and physical functioning (MOS-36). The lasting effects of these changes were not assessed. There were, however, no trends in effects for ADL, instrumental ADL, 7 domains of the MOS-36, or speed of upper extremity movement. The functional consequences of these gains are not known and will require a larger sample size in which interactions may be tested. Some important interacting factors may be size and location of lesion, depression, comorbidities, and self-efficacy.

Conclusions on the response to the interventions are complicated by sensitivity of measures to change. The Barthel Index has a well-known ceiling effect. The mean Barthel Index score at baseline for these individuals was 82.5, leaving little range for improvement. At follow-up, the mean Barthel Index scores for both groups were similar (95.5 and 95.6). However, the Jebsen Test of Hand Function demonstrated floor effects. The Jebsen Test of Hand Function assesses speed of primary movements of the affected extremity. Although qualitative improvements were apparent and individuals gained in their ability to use their upper extremity as a functional assist, these changes were not captured by the Jebsen Test of Hand Function.

There are several limitations of this study. First, this study is a pilot randomized, controlled trial with a small sample. A larger randomized, controlled clinical trial is needed to confirm the benefits of the intervention. Second, we did not have MRI results available to establish size and site of lesion. Characteristics of the lesion may explain the variability in responsiveness to the intervention. Third, we do not yet know the ideal timing of the intervention (early or late after stroke). We chose to initiate this study 30 to 90 days after stroke. Most spontaneous stroke recovery occurs in the first 30 days after stroke.<sup>33</sup> However, recovery continues for 6 months. We selected this period to decrease effects of spontaneous recovery on our results but still be in a period of some ongoing

recovery. Our results will not contribute to understanding the most appropriate timing for intervention.

## Conclusion

The results of this study guided us as we planned a more definitive trial. In the present trial, we modified our therapy program to include a more aggressive cardiovascular endurance component. The larger trial will provide more power to detect a change in health status and to evaluate interactions. In the ongoing trial, we will assess whether any gains are maintained beyond the immediate intervention period. The cost-effectiveness of the intervention will also be assessed in future studies.

There is increased pressure to discharge individuals with stroke to the community as soon as possible. The individuals may be discharged with significant residual deficits and limitations in function. In the past there has been no consensus about how to provide therapies to achieve the best outcomes. Effective home-based postacute rehabilitation interventions are extremely important since acute and postacute stays have been significantly decreased. Objective evidence of the benefits of therapeutic interventions for home-based programs is essential to ensure reimbursement from payors. Randomized clinical trials provide the most convincing evidence for the efficacy of interventions. This pilot study demonstrated that (1) a randomized clinical trial is possible in postdischarge stroke rehabilitation, (2) the intervention may be home based, and (3) a very structured intervention program to improve strength, balance, endurance, and bimanual activities may be effective.

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