

A Randomized Controlled Trial of Supervised Versus Unsupervised Exercise Programs for Ambulatory Stroke Survivors

Sandra J. Olney, PhD; Jennifer Nymark, MSc(A); Brenda Brouwer, PhD; Elsie Culham, PhD; Andrew Day, MSc; Joan Heard, BScPT; Margaret Henderson, MSc; Krishna Parvataneni, MSc

Background and Purpose—Little is known about the relative efficacy of supervised versus unsupervised community exercise programs for stroke survivors. This study compared the effectiveness of a 10-week supervised strengthening and conditioning program (supervised) with a 1-week supervised instruction program followed by a 9-week unsupervised home program (unsupervised) and evaluated retention of changes at 6 months and 1 year after program completion.

Methods—Seventy-two subjects retained at baseline (27 women, 45 men; mean \pm SD age, 64.6 ± 11.8 years) were randomly allocated to receive the supervised or unsupervised program. The primary outcome was walking speed over 6 minutes, and secondary outcome measures were Human Activity Profile, Medical Outcome Study 36-Item Short-Form survey (SF-36), Physiological Cost Index, and lower extremity muscle strength.

Results—The 6-minute walking speed increased significantly in both groups and remained significantly improved by 1 year. The Human Activity Profile demonstrated an increasing trend only in the supervised group that was significant by 1 year. The SF-36 Physical Component summary score increased significantly in the supervised group and remained improved by 1 year; the unsupervised group showed significant improvement at 1 year. Women made greater gains in supervised programs, but men made greater gains in unsupervised programs.

Conclusions—Supervised exercise programs and unsupervised programs after initial supervised instruction were both associated with physical benefits that were retained for 1 year, although supervised programs showed trends to greater improvements in self-reported gains. Gender differences require further research. (*Stroke*. 2006;37:476-481.)

Key Words: cerebrovascular accident ■ exercise ■ rehabilitation

Evaluations of the effectiveness of strengthening and physical conditioning programs for people who have sustained a stroke have shown evidence of increases in strength,¹ ambulation,² mobility,³ and function.⁴ Nevertheless, authors stress that it is an underresearched area that requires investigation into the efficacy and feasibility of training programs² and the retention of effects.¹ The American Heart Association recently published the recommendation⁵ that stroke survivors participate in regular physical activity, giving some urgency to the need for sound recommendations regarding effective and feasible programs.

It is generally well established that supervised programs administered over several weeks improve physical ability in the short term,^{6–8} although little is known about long-term effectiveness. Short supervised educational programs that teach people to continue their exercises unsupervised at home or in a fitness center are clearly more feasible and cost-

effective than supervised several-week programs, but their effectiveness has not been established in this population, and retention of effects is unknown. If these programs could be shown to be effective, it would be possible to provide the required education in the last week of formal rehabilitation, making them an attractive and cost-effective alternative to supervised, several-week programs.

The primary objectives of this study were to evaluate and compare the effectiveness of a 10-week supervised strengthening and conditioning program (supervised) and a 1-week supervised program followed by a 9-week home exercise program (unsupervised) at 10 weeks and at 6 months and 1 year after cessation of the programs.

Methods

Study Design and Randomization

Subjects were recruited through a local stroke club, newspaper advertisement, and local clinicians in Kingston and Ottawa, Ontario,

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From the Motor Performance Group, School of Rehabilitation Therapy, Queen's University, Kingston, Ontario, Canada (S.J.O., B.B., E.C., M.H., K.P.); Institute for Rehabilitation Research and Development, The Rehabilitation Centre, Ottawa, Ontario, Canada (J.N., J.H.); and Clinical Research Centre, Kingston General Hospital, Kingston, Ontario, Canada (A.D.).

Correspondence to Dr Sandra J. Olney, School of Rehabilitation Therapy, Queen's University, Kingston, Ontario, Canada K7L 3N6. E-mail olneys@post.queensu.ca

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Canada, for this randomized controlled study. The study statistician prepared a computer-generated randomization list stratified by walking speed (≥ 0.40 and < 0.40 m/s)^{9,10} and study center. The treatment assignments were concealed by the method of sealed envelopes. After informed consent was obtained and after the baseline assessment was performed, a research assistant opened the next sequential envelope and assigned the subjects to the supervised or unsupervised group accordingly. Seventy-four subjects were randomly allocated to either 1 of 2 programs offered at 2 treatment sites (Kingston or Ottawa): a supervised physical conditioning program 3 times a week for 10 weeks or an instructional physical conditioning program with supervision 3 times a week for the first week followed by an unsupervised home training program for 9 weeks. Measurements were collected at baseline and at 10 weeks, 6 months, and 1 year after cessation of the programs. Testers were not blinded to group allocation; standard procedures were used, and all tests were based on objective measures or were self-reported.

Subjects

Each potential participant was screened for eligibility, including the following: (1) age ≥ 20 years; (2) thromboembolic or hemorrhagic cerebrovascular disorder with many, but not all, confirmed by CT scan; (3) able to walk a total of 15 minutes with rests, with or without assistive devices (except a 4-point walker); (4) able to tolerate activity for 45 minutes with rests; (5) no coronary artery disease of sufficient severity that would limit involvement in an exercise program as judged by cardiologist and determined by the Dobutamine Stress Echocardiography criteria¹¹; and (6) no contraindications to exercise testing as specified by American College of Sports Medicine (1995) and as reported by the cardiologist. Written informed consent was obtained as approved by the Research Ethics Boards of Queen's University, Kingston, or The Rehabilitation Centre, Ottawa.

Sample Size

A sample size of 37 subjects per arm was chosen to provide 80% power to detect a difference of 0.2 m/s in 6-minute walking speed between treatment groups at 10 weeks.¹² This calculation is based on using an independent *t* test at a 2-sided 5% significance level and assumes a within-group SD of 0.3 m/s.

Interventions

Intervention consisted of supervised exercise sessions conducted in 1.5-hour sessions 3 days per week for 10 weeks (supervised) and 3 days per week for the first week followed by a home program for 9 weeks (unsupervised). Subjects joined the class of 3 or 4 participants as they were admitted. Each supervised session included the following: (1) a 5- to 10-minute warm-up consisting of leisurely walking, mild stretching, and range of motion exercises of lower limbs; (2) aerobic exercise consisting of a graded walking program and/or cycling, depending on subject preference and capability; (3) strength training; and (4) a cool-down period consisting of 5 to 10 minutes of leisurely walking and muscular relaxation exercises. Subjects were taught how to take their pulse and to maintain exercise within target range (between 50% and 70% of age-adjusted maximum and adjusted for β -blockers) and how to conduct their exercises and progress in them. With rests as indicated by the subjects, the program took subjects ≈ 1.5 hours to complete.

Aerobic conditioning used procedures modified from those recommended for healthy elderly adults.¹³ During the first 5 weeks of the program, walking intensity was increased from 50% to 70% aerobic working capacity, and walking duration per session was increased from 10 to 20 minutes. Exercise intensity and duration were kept constant between 50% and 70% of maximum and 20 minutes, respectively, during the second 5 weeks of the program. A Polar Heart Rate Monitor was worn, and perception of effort was monitored with the use of Borg's 15-point (scale of 6 to 20) psychometric scale.¹⁴ Strength training concentrated on hip flexors, extensors, and abductors; knee extensors and flexors; and ankle dorsiflexors and plantar flexors with particular attention to muscle

groups with obvious deficits. Theraband (Hygenic Corporation), simple weights, and functional exercises were used. Programs were tailored to each subject's needs and were adjusted weekly as indicated for supervised subjects. Subjects in the unsupervised group were given written and verbal instructions on advancing in their exercises.

Procedures

Baseline Measures

Baseline measures, including patient demographics and date and type of stroke and all outcomes (see below), were assessed and recorded before treatment assignment.

Outcome Measures

The primary outcome of this study was (1) the 6-minute walking speed. Secondary outcome measures were (2) Human Activity Profile (HAP) adjusted activity score; (3) Medical Outcome Study 36-Item Short-Form survey (SF-36) Physical Component summary score; (4) SF-36 Mental Component summary; (5) sum of the strength of lower limb muscles; and (6) Physiological Cost Index (PCI). Measures 1 to 4 reflect disability, and measures 5 and 6 reflect impairments.

Six-Minute Walk Test

A protocol for the 6-minute test used in standard practice was implemented.¹⁵

Human Activity Profile

The HAP is a survey of 94 activities listed in order of increasing metabolic cost equivalent.¹⁶ The activities include self-care, transportation, home maintenance, entertainment/social, and physical exercises, and subjects indicate whether they are still doing the activity, have stopped doing the activity, or have never done the activity. The activity with the highest metabolic equivalent still being performed is the maximum activity score, and the adjusted activity score subtracts the number of activities no longer performed from the maximum.

Medical Outcomes Study: The SF-36 Health Status Measurement

The SF-36 is a recommended measure of physical and mental health and quality of life for persons with stroke.¹⁷ We report the physical and mental health summary scales derived from this survey.¹⁸

Muscle Strength

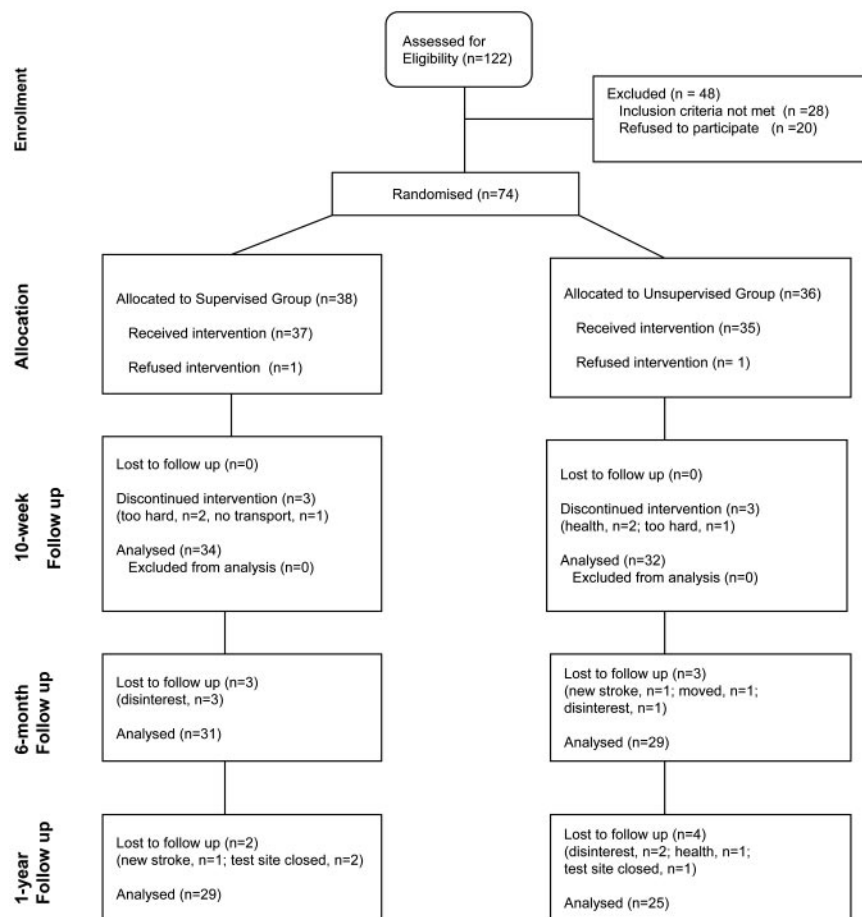
Muscle strength for the lower limb muscle groups primarily responsible for the work of walking, termed *generators* (hip flexors, extensors, ankle plantar flexors),¹⁹ was measured with the use of hand-held dynamometry.²⁰ Standardized phrases of encouragement were given, and the average of the highest 2 of 3 repetitions was used. Strength was calculated as the sum of hip flexor, hip extensor, and ankle plantar flexor strength on the affected side divided by the body mass (N/kg).

Physiological Cost Index

The PCI, calculated as the difference between the walking heart rate and the resting heart rate divided by the average walking speed, is expressed in beats per meter.^{21,22}

Statistical Analysis

The prespecified primary end point of this study was the change in 6-minute walking speed from baseline to week 10. Secondary end points included changes from baseline to 6 months and to 1 year. All comparisons were made within the framework of a single repeated-measures linear mixed-effects model with a random subject effect. All parameters were estimated by restricted maximum likelihood as implemented in the MIXED procedure of the statistical analysis package SAS V8.2.²³ Changes in walking speed from baseline to 10 weeks, 6 months, and 1 year were modeled as outcomes with baseline walking speed and treatment by period as fixed predictor variables. We added the baseline value as a covariate in the model



Flow of participants through trial.

because it explained much of the between-subject variance in the follow-up scores and therefore improved the statistical efficiency of our between-group comparisons. This model provided estimates of the average expected within-subject change by each group at each time point after adjustment for baseline walking speed. Contrasts were constructed to compare treatment groups at each time. The aforementioned linear mixed-effects model simply extends the classic ANCOVA (or linear regression) to appropriately account for the dependence induced by having repeated measures on subjects. A similar approach was used to examine the interaction between treatment and gender at 10 weeks. Secondary outcomes were analyzed similarly. All tests were 2 sided, and a nominal significance level of 0.05 was used. All subjects were analyzed as randomized according to the intent-to-treat principle, although no imputation was made for missing data.

Results

Seventy-four subjects were randomized to this study from Kingston (n=33) and Ottawa (n=41) between January 2000 and January 2003. One subject from Kingston randomized to the supervised program and 1 subject from Ottawa randomized to the unsupervised program refused the programs, leaving 72 subjects in the study (see details in the Figure).

The subjects in both groups had similar characteristics (Table 1). However, the self-assessed quality of life outcomes (HAP and SF-36) were somewhat higher in the supervised arm at baseline (Table 2). Because the baseline assessment was collected before randomization, imbalances are attributable to chance alone.

Table 2 presents descriptive statistics of the raw outcome scores for each testing visit. Table 3 presents the expected change from baseline to each follow-up visit based on the repeated-measures model with adjustment for the baseline values. This model presents the expected average change by group if each group had the same baseline average. The 6-minute walking speed increased significantly in both groups (0.09 ± 0.02 m/s in unsupervised group, 0.06 ± 0.02 m/min in supervised group) and remained significantly improved by 1 year with no significant differences between groups. The HAP demonstrated a continued increasing trend in the supervised group that reached statistical significance by 1 year, whereas the unsupervised group experienced a similar initial nonsig-

TABLE 1. Subject Characteristics by Group at Baseline (n=72)

Variable	Supervised	Unsupervised
Location Kingston/Ottawa	16/21 (43.2%/56.8%)	16/19 (45.7%/54.3%)
Sex, F/M	14/23 (37.6%/62.2%)	13/22 (37.1%/62.9%)
Side of paresis, left/right	20/17 (54.1%/45.9%)	20/15 (57.1%/42.9%)
Age, y	63.5 \pm 12.0	65.8 \pm 11.6
Height, m	1.69 \pm 0.09	1.68 \pm 0.10
Mass, kg	77.2 \pm 13.2	81.8 \pm 12.1
Onset, y	4.1 \pm 4.4	3.4 \pm 3.9
Gait speed, m/s	0.73 \pm 0.36	0.76 \pm 0.33

Values are number (%) or mean \pm SD.

TABLE 2. Raw Scores for Outcome Variables at Each Visit

Variable	Baseline	10 Weeks	6 Months	1 Year
	Supervised (n=37); Unsupervised (n=35)	Supervised (n=34); Unsupervised (n=32)	Supervised (n=31); Unsupervised (n=29)	Supervised (n=29); Unsupervised (n=25)
Six-minute walking speed, m/s	0.73±0.36	0.82±0.38	0.81±0.39	0.78±0.37
	0.76±0.34	0.87±0.37	0.89±0.35	0.91±0.36
HAP (maximum=94)	53.0±13.1	56.0±14.3	56.5±13.6	56.5±14.7
	48.3±15.3	51.7±14.3	51.5±17.0	51.0±19.2
SF-36 Physical Component	41.3±8.8	44.6±8.8	44.1±9.1	44.5±7.2
	36.1±9.6	37.6±8.6	38.0±9.0	39.3±10.5
SF-36 Mental Component	55.0±8.8	57.5±7.4	57.4±7.7	56.9±7.7
	50.8±11.8	50.6±11.7	50.6±12.1	52.0±11.5
Strength sum, N · m/kg	1.5±0.0.7	1.7±0.7	1.7±0.7	1.6±0.7
	1.4±0.5	1.6±0.7	1.6±0.7	1.6±0.8
PCI, beats/m	0.74±0.64	0.71±0.59	0.80±0.80	0.78±0.74
	0.82±0.73	0.72±0.4	0.61±0.36	0.53±0.28

Values are mean±SD.

nificant improvement at 10 weeks but declined thereafter (Table 3). The SF-36 Physical Component summary scale increased significantly in the supervised group and remained significantly improved by 1 year, but the unsupervised group did not see any significant improvements until the final assessment; differences between groups never reached statis-

tical significance. The Mental Component scale followed a similar trend, although the improvement in the supervised arm was smaller than that in the physical scale and reached statistical significance only at the 10-week assessment. Strength did not change significantly over time in either group, and PCI was significantly improved only at 1 year for the unsupervised group.

TABLE 3. Adjusted Expected Change From Baseline

Variable	Intervention	10 Weeks After	6 Months After	1 Year After
Six-minute walking speed, m/s	Supervised program	0.06±0.02†	0.07±0.02†	0.09±0.02‡
	Unsupervised program	0.09±0.02‡	0.06±0.02*	0.05±0.02*
	Difference	-0.03±0.03	0.01±0.03	0.03±0.03
HAP	Supervised program	2.7±1.8	3.3±1.9	4.6±1.9*
	Unsupervised program	2.7±1.9	0.5±1.9	-1.6±2.0
	Difference	0.0±2.6	2.8±2.7	6.1±2.8*
SF-36 Physical Component	Supervised program	4.2±1.3†	4.0±1.4†	3.9±1.4†
	Unsupervised program	0.5±1.3	0.8±1.4	2.9±1.5*
	Difference	3.7±1.9	3.2±2.0	1.0±2.1
SF-36 Mental Component	Supervised program	3.7±1.5*	2.9±1.5	2.5±1.6
	Unsupervised program	-1.3±1.5	-0.3±1.6	1.7±1.6
	Difference	5.0±2.1*	3.2±2.2	0.9±2.3
Strength sum, N · m/kg	Supervised program	0.104±0.081	0.073±0.084	-0.007±0.085
	Unsupervised program	0.118±0.084	0.108±0.089	0.077±0.094
	Difference	-0.015±0.117	-0.035±0.122	-0.084±0.128
PCI, beats/m	Supervised program	-0.017±0.045	0.043±0.047	0.010±0.049
	Unsupervised program	-0.084±0.048	-0.053±0.051	-0.111±0.053*
	Difference	0.068±0.066	0.096±0.069	0.121±0.073

Values are expected change±SE.

*P<0.05; †P<0.01; ‡P<0.001.

TABLE 4. Adjusted Expected 10-Week Change by Gender

Variable	Intervention	Female (n=25)	Male (n=41)	Gender by Treatment Interaction (P)
Six-minute walking speed, m/s				
	Supervised	0.11±0.03‡	0.03±0.02	
	Unsupervised	0.04±0.03	0.12±0.03‡	0.01
HAP				
	Supervised	4.1±2.3	2.0±1.8	
	Unsupervised	4.2±2.4	2.2±1.8	0.99
SF-36 Physical Component				
	Supervised	6.5±1.9‡	2.3±1.6	
	Unsupervised	1.8±2.0	0.1±1.5	0.47
SF-36 Mental Component				
	Supervised	1.6±2.2	4.8±1.8*	
	Unsupervised	-0.8±2.3	-1.8±1.8	0.33
Strength sum, N · m/kg				
	Supervised	0.32±0.13*	-0.04±0.10	
	Unsupervised	0.06±0.13	0.17±0.10	0.040
PCI, beats/min				
	Supervised	-0.128±0.063*	0.028±0.050	
	Unsupervised	-0.146±0.066*	-0.049±0.052	0.62

Values are expected change±SE.

* $P<0.05$; † $P<0.01$; ‡ $P<0.001$.

There were some interactions between treatment effects and gender at 10 weeks. A significant interaction was present for the change in walking speed ($P=0.010$), with women making greater gains in supervised programs but men making greater gains in unsupervised programs (Table 4). The strength changes showed a similar trend, with women benefiting from supervised programs and men benefiting from unsupervised programs. Women from both groups experienced significant improvement in PCI, but PCI in men did not change (Table 4).

Discussion

Gains in physical outcome variables were modest compared with the few similar studies.^{24,25} Walking speed gains during the 6-minute walk were 3.6 and 5.4 m/min, respectively, for supervised and unsupervised groups compared with average gains of 12.6 m/min²⁴ and 9.6 m/min²⁵ in somewhat similar studies. The longer time since stroke in our study may explain some differences from the report of Duncan and colleagues²⁵ because their subjects entered the study 30 to 90 days after stroke and would be expected to make rapid gains. Gains on the HAP in this study averaged ≈3 points for both groups, whereas gains in another study²⁴ averaged 17 points. In addition, measures of strength of lower limb muscles were significantly higher in the latter study but not in the present study. It is possible that the programs of the present study were less rigorous.

We demonstrated that it is possible for community-living stroke survivors to make significant gains in physical ability, indicated primarily by the speed of walking, that were evident 1 year later through taking part in a 10-week supervised or unsupervised strengthening and conditioning program. Although the speed at which a person chooses to walk is a single measure, it provides an overall measure of his/her walking ability, reflects functional health,²⁶ and indicates physical

incapacity.²⁷ The fact that gains in walking speed were retained is very positive because numerous studies report that physical measures return to baseline values within a few months of program cessation.^{28,29} To our knowledge, the retention of effects for either type of program for stroke survivors has not been reported previously.

The fact that the unsupervised group made significant physical gains is important and may have been assisted by 3 factors. First, all exercise apparatus was usable at home, and subjects had been trained to progress in their program independently. Second, subjects initially attended sessions for a 1-week period, which generally required that a caregiver drive the subject to classes, which suggests the presence of the high level of social support that is known to relate to adherence.³⁰ Third, the subjects knew that they were going to be tested after the program, which may have offered some incentive to adhere to the program.

There were some notable differences between supervised and unsupervised groups. The Physical Component of the SF-36 of the supervised group showed significant improvements throughout the follow-up period, whereas the results for the unsupervised group were not statistically significant until the 1-year follow-up. The more positive finding for the supervised group may reflect the social aspect of the program and the positive environment associated with it. The HAP was significantly higher only for the supervised group at 1-year follow-up. These results suggest that there may be a supportive role played by supervision or by the inclusion in a social group that does not occur with home exercise. Exploration of these factors warrants further investigation.

This study supports home-based programs as a means of improving physical performance. Economical, home-based programs have received little attention for stroke survivors, how-

ever. This study has clearly demonstrated that a brief period of exercise instruction followed by home exercise produces changes in physical function that are retained over 1 year. The program is feasible and can be included in standard rehabilitation practice. No financial incentives were offered, and no transportation was provided to subjects except for testing.

There were some limitations to the study. It was not possible to blind participants to group membership. Because of fiscal constraints, testers were not blinded, but the use of standard and objective measures and self-reports would reduce possibilities of bias. The absence of a nonintervention control group does not preclude the possibility of natural maturation, but the long average time since stroke makes this unlikely.

Some findings that could influence the delivery of similar programs require further investigation. The fact that women made greater gains in walking speed and in strength in supervised programs while the reverse was true of men is intriguing. This finding may have a social basis and warrants further research. Exploration of supplementary data may help to determine what factors relate to the retention of program effects. These factors all have implications for program delivery.

The generalizability of the findings must be limited to volunteers who wish to take part in exercise, who agree to return periodically for testing, who can ambulate for 15 minutes and tolerate 45 minutes of activity with rests, and who have no severe coronary artery disease. With these restrictions, the substantial range in function of the subjects of this study suggests that a fairly wide range of subjects may profit from similar programs.

Conclusion

This study demonstrated the following: (1) significant gains in measures reflecting physical ability can be made through taking part in a 10-week strengthening and conditioning program, either supervised or unsupervised; (2) supervised programs show trends to greater improvements in self-reported gains; and (3) gender differences are present and require further research.

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