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Getting on with the rest of your life following stroke: A randomized trial of a complex intervention aimed at enhancing life participation post stroke

Nancy E Mayo[1], Sharon Anderson[2], Ruth Barclay[3], Jill I Cameron[4], Johanne Desrosiers[5], Janice J Eng[6], Maria Huijbregts[7], Aura Kagan[8], Marilyn Mackay Lyons[9], Carolina Moriello[10], Carol L Richards[11], Nancy M Salbach[7], Susan C Scott[1], Robert Teasell[12] and Mark Bayley[13]

Abstract

Objective: To enhance participation post stroke through a structured, community-based program.
Design: A controlled trial with random allocation to immediate or four-month delayed entry.
Setting: Eleven community sites in seven Canadian cities.
Subjects: Community dwelling persons within five years of stroke onset, cognitively intact, able to toilet independently.
Interventions: Evidence-based program delivered in three 12-week sessions including exercise and project-based activities, done as individuals and in groups.
Main measures: Hours spent per week in meaningful activities outside of the home and Reintegration to Normal Living Index; Stroke-Specific Geriatric Depression Scale, Apathy Scale, gait speed, EuroQuol EQ-5D, and Preference-Based Stroke Index. All measures were transformed to a scale from 0 to 100.

[1]Division of Clinical Epidemiology, McGill University, Montreal, QC, Canada
[2]Department of Human Ecology, University of Alberta, Alberta, Canada
[3]Department of Physical Therapy, University of Manitoba, Manitoba, Canada
[4]Department of Occupational Science and Occupational Therapy, University of Toronto, Toronto, ON, Canada
[5]School of Rehabilitation, Université de Sherbrooke, Sherbrooke, QC, Canada
[6]Department of Physical Therapy, University of British Columbia, Vancouver, BC, Canada
[7]Department of Physical Therapy, University of Toronto, Toronto, ON, Canada
[8]Education and Applied Research, Aphasia Institute – The Pat Arato Aphasia Centre, Toronto, ON, Canada
[9]School of Physiotherapy, Dalhousie University, Halifax, NS, Canada
[10]McGill University Health Center (MUHC), MUHC Research Institute, Montreal, QC, Canada
[11]Department of Rehabilitation and Center for Interdisciplinary Research in Rehabilitation and Social Integration, Laval University, Quebec, Canada
[12]Department of Physical Medicine and Rehabilitation, Western University, London, UK
[13]Brain and Spinal Cord Rehab Program, UHN-Toronto Rehabilitation Institute, Toronto, ON, Canada

Corresponding author:
Nancy E Mayo, McGill University, Division of Clinical Epidemiology, McGill University Health Center (MUHC), MUHC Research Institute, Royal Victoria Hospital Site, Montreal, QC, Canada.
Email: nancy.mayo@mcgill.ca

Assessments prior to randomization, after the first session at three months, six months, 12 months, and 15 months.

Results: A total of 186 persons were randomized. The between-group analysis showed no disadvantage to waiting and so groups were combined and a within-person analysis was carried out at three time points. There were statistically significant increases in all study outcomes on average over all persons. Over 45% of people met or exceeded the pre-specified target of a three hour per week increase in meaningful activity and this most often took a full year of intervention to achieve. Greatest gains were in satisfaction with community integration (mean 4.78; 95% CI: 2.01 to 7.55) and stroke-specific health-related quality of life (mean 4.14; 95% CI: 2.31 to 5.97).

Conclusions: Community-based programs targeting participation are feasible and effective, but stroke survivors require time to achieve meaningful gains.

Keywords

Stroke, rehabilitation interventions, randomized controlled trial, participation (WHO ICF)

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Introduction

Over half of all persons living at home six months after stroke report that their life is lacking some aspect of social, recreational, or purposeful activity.[1,2] Limited mobility, depressive symptomatology, apathy, cognitive impairment, fatigue, lack of social connection, and lack of self-efficacy for engagement all act to restrict participation.[3–5]

A model for participation for people with stroke has been developed on a cohort of 454 persons followed over a one-year period post stroke.[6] A structural equation model supported by qualitative evidence identified three components: "accomplishment" (defined by ability to carry out social functions and roles, recreational activities, work, driving, and usual activities); "restricted roles" (attributed to mental and physical impairments and limitations) and "health efficacy" (defined by perception of health and recovery post stroke). This model provides additional guidance for how to promote participation and also measure its effects.

The importance of the development and evaluation of effective and sustainable programs targeting the life-long needs of community-dwelling individuals with stroke and their partners was the first of five research priorities arising from a Canadian consensus conference.[7] Participation in this context refers to a person's involvement in a life situation and represents the societal perspective of functioning[8] (essentially contributing to family life and society) although individuals would define the particular ways in which these contributions are made. Within the World Health Organization's (WHO) framework, these roles include, but are not limited to, domestic life, interpersonal interactions and relationships, education, work and employment, economic life, community, social and civic life, recreation and leisure, religion and spirituality, human rights and political life, and citizenship.[8]

At the time of the development of this intervention, evidence for the benefits of community-based or community-adaptable exercise programs existed.[1,9,10] Additional evidence included how to develop competence in leisure[11] and how to support conversation for people with aphasia.[12] There was no evidence for how to provide social support for persons with stroke in the community, but there was evidence that interventions that promote active social contact, have defined goals, encourage creativity, and use mentoring, are most likely to positively affect health and well-being.[13] In people with depression, a problem-solving intervention was found to be more effective in alleviating symptoms of depression and increasing function than an education-based intervention or no intervention at all.[14]

Equipped with sufficient evidence for the effective components of a program targeting participation, and recognizing that there was a gap in how to package the evidence and deliver it in the community, we designed this study to be embedded in the community. The aim was to estimate the extent to which participation in personal, family, social, and community life be enhanced, over a one-year period, through the provision of a community-based structured program providing the opportunity for exercise, leisure enhancement, life-long learning, and social interaction. A secondary objective is to estimate the extent to which health-related quality of life (HRQL) was impacted on by the program. Explanatory questions related to the extent to which internal barriers to participation (mobility, symptoms of depression, and apathy) were impacted upon positively by the structured program.

Methods

A site-stratified, assessor blinded, randomly allocated, wait-list controlled, trial was carried out at 11 sites in seven cities across Canada starting in 2009. The trial was registered at ClinicalTrials.gov (NCT01085240) and was approved by the research ethics boards of each participating center. The wait-list process created two groups, one that entered the program immediately after randomization and one that waited three to four months before entering. This design provided the opportunity for a between-group comparison after 3 months, and a within-person comparison at the end of the program (~12 months) and at follow-up three months later (at 15 months).

The target population was persons living in the community who have completed all formal rehabilitative interventions. Persons within five years of stroke onset were targeted. Excluded were persons: (i) who were already enrolled in existing community-based programs; (ii) with cognitive impairment, as reflected by a score of less than 14/18 on the Brief Mini-Mental State Examination (MMSE) score[15] (delete 23); (iii) unable to toilet independently. Recruitment was through referral, advertising, stroke recovery associations, community programs, rehabilitation centers, and word of mouth.

These persons were allocated to the two groups, with a 1:1 ratio, using a random allocation sequence based on odd or even birth date (sum of month and day). The sites sent the birth dates of each person to the central site and an independent person made the allocation. This method was preferred over simple randomization as the participants were randomized after the number of potential participants was sufficiently large for two group to be formed and the process needed to be transparent.

Intervention

The intervention was developed based on a series of focus groups of stroke survivors who expressed their preferences for a program that was offered in one setting, provided opportunities for exercise and physical activities, speech and language development, learning, creativity, music, games, celebration of special events, and planned outings. Emotionally, people expressed that an optimal environment would foster a sense of belonging where someone could just be him or herself, develop self-confidence, and have fun, in an environment of mutual encouragement, empathy, and respect. A program with lectures from "experts" was not endorsed as a useful format. Persons expressed the need to have somewhere to go at least three times per week, but also stated that barriers such as transportation and fees limited accessibility to programs.

The Getting on with the Rest of Your Life: Mission Possible© program was a group-based intervention that included exercise and project-based activities promoting learning, leisure, and social activities, done as individuals and in groups. The groups met in a community-based setting twice a week for approximately three hours each time for three blocks, each lasting three months. The total duration of the program was 12 months. Group leaders were recreation therapists, educators, exercise therapists, or other personnel with experience in healthcare and with stroke; all participated in a two-day training program. Each site tailored the program to the clientele, respecting the overall philosophy of intervention rather than specific elements that would be influenced by the participants, the leader, and the setting.

Mission Possible©. This was the name given to the leisure/learning/social component as the person with stroke was put on a "Mission": to formulate life goals that are then staged into a series of realistic projects that the person can meet by developing internal resources and existing community-based resources. Leisure/learning/social component was based on a study of a leisure intervention in the home setting.[11,16] The program was also inspired by educational theory of project-based learning[17] and by cognitive-behavioral theory.[18,19] A method of making "Mission Possible©" accessible to people with aphasia was developed by the group led by Kagan.[12]

Exercise component. This was based on the interventions tested by Salbach[20] and by Eng[10] in the FAME program. Five key elements were incorporated: aerobic exercise, strength of peripheral and core musculature, balance, flexibility, and rapidity of movements. An instruction package was developed with specific examples of exercises depending on the ratio of participants to instructors. The particular structure of the exercise component differed from site-to-site depending on the characteristics of the group and their interests. Examples were: group exercise, circuit with different stations, and dance. The exercise component was 45 minutes of continuous exercise with rests when needed, twice a week for the duration of the session (~3 months).

Training

All investigators and group leaders participated in a two-day training session in which they experienced all the components of the program through expert-facilitated group activities simulating Mission Possible© sessions. The study co-ordinator monitored the intervention through site visits and/or email communications with group leaders. She provided help for structuring the program and there was also a website for sharing project and activity ideas.

Duration

The program was designed to run through three sessions termed "semesters" and were labeled "Lift-off", "Gaining Altitude", and "Full Flight". The activities and progression within the Mission Possible© program are outlined in Table 1, available online. Progression was from within-house activities (Lift-off), to exploration of resources and opportunities available in their communities (Gaining Altitude), to meet goals as well as to continue the exercise program, group projects, and individual leisure or self-development projects identified (e.g. volunteering, driving, playing musical instrument, photography, cooking). The Full Flight session encouraged engagement in community-based activities to meet leisure and life-goals; at this stage, the Mission Possible© group had more of a social orientation as people were more engaged in the community. Many of the activities were now group, rather than leader, initiated.

Measurement. The measurement strategy was designed to provide data on outcome and also on variables known to play an explanatory role in achieving outcomes.

The main outcome was hours spent in meaningful activity and stroke survivors expressed the desire to have about nine hours of meaningful activity per week during the focus groups conducted as part of the pilot work. The measure to be used was the Community Healthy Activities Model Program for Seniors (CHAMPS) questionnaire[21] and for this study we considered time spent in meaningful activity outside of the home excluding activities directly provided by the program. The reliability across two measures taken six months apart in a group not expected to change was 0.66 for all activities measured; the ICCs (intraclass correlation coefficients) for two week recall was 0.62 for all activities.

A related participation outcome was the Reintegration to Normal Living (RNL) Index, which queries the extent to which an individual was able to accomplish common activities in and outside of the house.[22] The RNL Index comprises 11 questions scored on a 4-point scale, from 0 to 3, with higher scores (maximum 33) indicating better reintegration.

The variables considered as internal barriers to participation were gait speed[23] and symptoms of

depression: Stroke-Specific Geriatric Depression Scale;[24] and apathy measured using the Apathy Scale.[25] Secondary outcomes were generic and stroke-specific HRQL as measured by the EuroQuol EQ-5D[26] and the Preference-Based Stroke Index (PBSI).[27] All secondary outcomes have excellent psychometric properties for use in stroke populations.

Clinically meaningful differences in outcomes were obtained from the literature when available or using distribution methods.[28,29] Changes of 5% or more are considered clinically meaningful for visual analogue scales (VASs), such as the health rating scale of the EQ-5D™;[30] for a quality adjusted life-year, clinically meaningful difference has been estimated at around 3%.[31] The clinically meaningful difference for gait speed has been estimated at 0.1 m s^{-1}.[32] For the distribution methods we used 10% of the range[28] of 90% of the sample (excluding the two tails or <5% or >95%). Using this criteria, the clinically meaningful difference for apathy was 5%; depression 8%; RNL Index 7%; and the PBSI 6%.

Statistical analysis. For the parallel group comparison, the analysis was carried out after the intervention group had completed the first three-month session and the wait-list control had not yet started. For the main outcome, hours of meaningful activity, missing data were excluded; for all other variables, missing data was replaced using the last value carried forward for missing at follow-up and last value carried backward for missing data at baseline and intention-to-treat analysis was carried out.

In order to account for clustering within groups and sites, models comparing outcomes between groups and within persons over time were estimated with generalized estimating equations (GEE) using SAS proc genmod.

Change over time was analyzed comparing time post-intervention to study entry. The differences in scores were modeled using GEE to adjust for clustering. Variables were added to identify any differences in change by group status.

We also calculated the proportion of people who made a clinically meaningful change in the number of hours spent, per week, in meaningful activity outside the home, and the number of sessions needed to reach the target change.

Sample size

The sample size for this study was based on 80% power, with a risk of a Type I error of 5%, to detect a between-group difference at the first evaluation of three hours per week of meaningful activity with a standard deviation (SD) of four hours. Our pilot data indicated that people with stroke found outside activities for about six hours per week (SD 4). This would require a minimum of 30 subjects per group (total 60),[33] but as there were multiple sites and there would be a need to consider the effect of site, the sample size was inflated by a factor of four reflecting the maximum inflation factor for testing interaction,[34] yielding a maximum recruitment target of 240.

Results

Figure 1 presents the CONSORT diagram. In all, 250 people agreed to be randomized, but 21 were deemed not eligible and 64 could not be randomized owing to timing of the intervention. Thus, only 186 were finally randomized. There were drop-outs throughout the study for reasons that are typical when people have to travel to attend for intervention. Table 2 presents information on the participants in the two intervention groups. On average participants were in their 60s and most had sustained a stroke approximately two years in the past.

Table 3 compares the two groups on study outcomes at study entry and after three months, during which the immediate entry group had completed the first session of intervention and the delayed entry group had not received any intervention. There were no differences between the two groups at three months. Data on number of hours of outside activity are presented without including the scheduled program hours ($n = 6$ per week) given to the immediate entry group as part of the design. The slight decline in hours is compensated by the six hours of intervention programming. The delayed group increased their engagement by an average amount of 2.9 hours without any intervention. None of these between-group differences on the health-related outcomes were statistically significant. Means and medians were closely similar.

Table 4 presents the results of the analyses estimating within-person change at each key time point

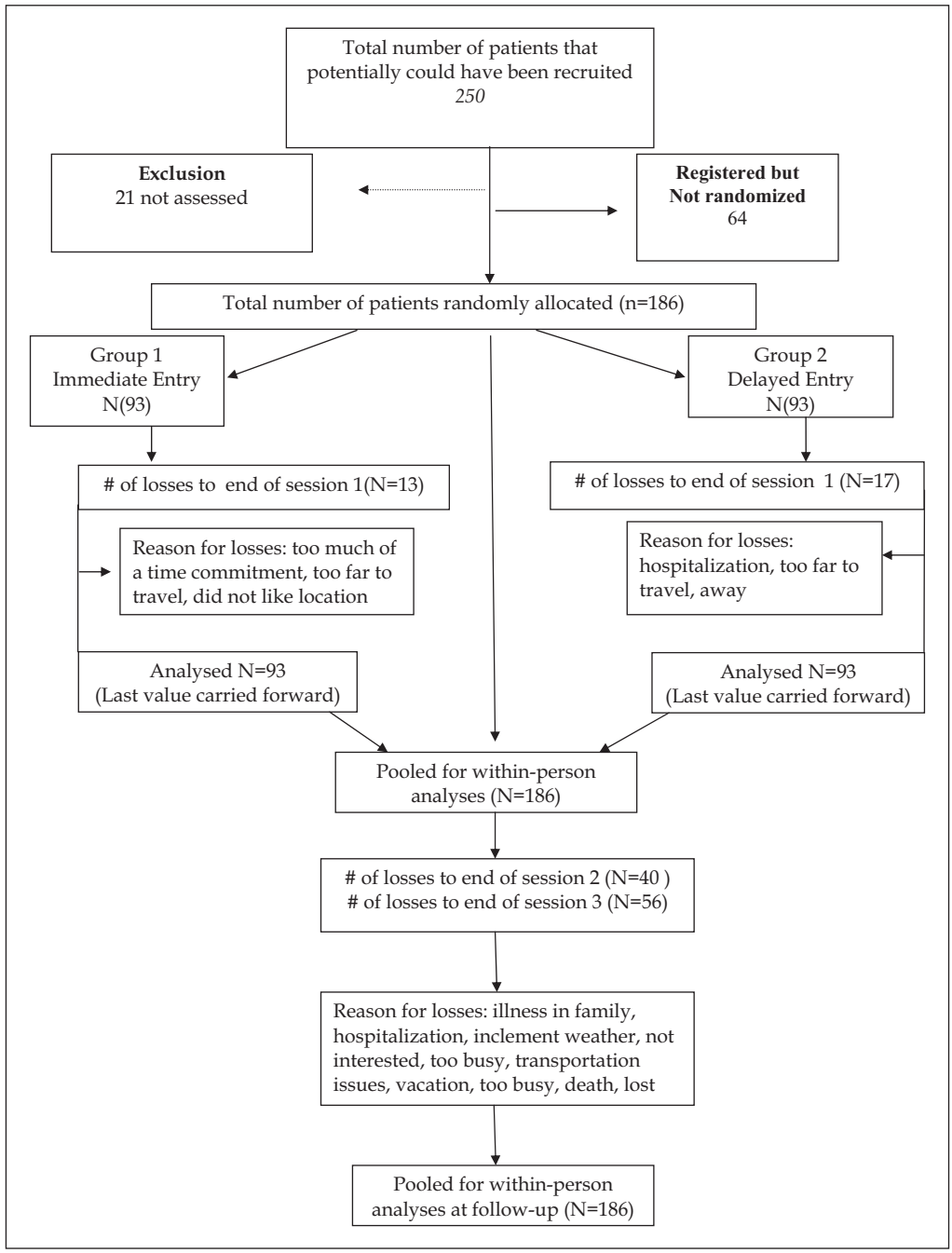

Figure 1. Consort diagram.

over the course of the intervention. The first time period presented is baseline to six months to provide time for all persons to have had some intervention. Presented are estimated change values (adjusted for clustering within site); for the patient-reported outcomes, the units have been transformed

Table 2. No statistically significant differences between the immediate and delayed entry groups on key personal and environmental factors at randomization.

Variable	Immediate entry ($n=93$)	Delayed entry ($n=93$)
	N (%)	*N* (%)
Age: mean years (SD)	61 (12)	65 (11)
Men	57 (61%)	56 (60%)
Years since stroke: mean (SD)	2.5 (2.2)	3.1 (3.1)
Inpatient rehabilitation	74 (91%)	72 (89%)
Attended college	54 (58%)	55 (60%)
Current smoker	11 (12%)`	8 (9%)
Born in Canada	66 (79%)	53 (68%)
Co-morbidity	41 (44%)	36 (39%)
Hours of activity[a] outside of home in past week [*n*]	11.2 (8.3) [92]	10.4 (8.2) [86]

[a]Hours of activity (measured by CHAMPS) includes physical and social activities occurring outside of the home.

Table 3. No statistically significant differences between immediate and delayed entry groups on health and stroke related outcomes at three months from trial entry.

Outcome	Immediate ($n=93$)		Delayed ($n=93$)	
Scoring range: 0 (worst) to 100 (best) except when indicated	Mean (SD)		Mean (SD)	
Primary outcome on those with complete data only				
Hours of activity[a] outside of house in past week				
Study entry[*n*]	10.5	(8.2) [77]	10.2	(7.7) [75]
Three months [*n*]	7.2	(6.1) [78]	13.1	(10.2) [75]
Difference [*n*]	−3.3	(6.5) [77]	2.9	(8.2) [75]
Program hours in past weeks	6		0	
Net change	2.7			2.9
Secondary participation outcome with LVCF[b] for missing data				
Participation (RNL)				
Study entry	72.5	(21.0)	75.7	(19.2)
Three months	76.4	(19.5)	77.0	(20.2)
Difference	3.7	(16.1)	1.2	(12.8)
Explanatory outcomes with LVCF[b] for missing data				
Apathy Scale (higher=worse)				
Study entry	29.4	(14.1)	31.2	(15.3)
Three months	30.5	(15.2)	29.8	(13.4)
Difference	0.6	(10.1)	−1.5	(8.9)
Depression (S-GDS) (higher = worse)				
Study entry	28.8	(27.6)	29.2	(25.0)
Three months	26.1	(26.9)	27.4	(21.0)
Difference	−2.6	(20.7)	−1.6	(22.5)
Gait speed comfortable ($m\,s^{-1}$)				
Study entry	0.82	(0.33)	0.76	(0.42)
Three months	0.87	(0.41)	0.79	(0.45)
Difference	0.05	(0.17)	0.04	(0.17)

(Continued)

Table 3. (Continued)

Outcome	Immediate ($n=93$)		Delayed ($n=93$)	
Scoring range: 0 (worst) to 100 (best) except when indicated	Mean (SD)		Mean (SD)	
Gait speed maximum ($m\,s^{-1}$)				
Study entry	1.15	(0.59)	1.03	(0.58)
Three months	1.22	(0.62)	1.08	(0.61)
Difference	0.06	(0.23)	0.05	(0.21)
Distal health outomes				
Health rating (EQ-VAS)				
Study entry	64.5	(19.4)	66.8	(19.4)
Three months	66.4	(19.4)	66.6	(20.8)
Difference	1.9	(16.1)	−0.2	(17.3)
Health-related quality of life (EQ-5D)				
Study entry	60.1	(19.3)	61.4	(18.8)
Three months	62.8	(19.8)	62.3	(18.8)
Difference	2.7	(16.7)	1.2	(14.9)
Stroke-specific HRQL (PBSI)				
Study entry	65.1	(15.4)	65.5	(17.6)
Three months	68.0	(16.1)	67.3	(17.8)
Difference	2.9	(11.5)	1.7	(9.6)

[a]Includes physical and social.
[b]LVCF was used for all secondary outcomes to replace data missing at 3 months (15 to 25 persons across groups).
LVCF: last value carried forward; RNL: Reintegration to Normal Living; S-GDS: Stroke Specific Geriatric Depression Scale; EQ-VAS: Visual Analogue Scale; EQ-5D™: ; HRQL: health-related quality of life; PBSI: Preference-Based Stroke Index.

to be on a 0 to 100 scale. Also presented are the 95% confidence interval (CI); CI which exclude the null value of 0 are considered statistically significant, these are shown in bold. The main outcomes are presented first, those that reflect participation; the second set of outcomes are those hypothesized to be prognostic or explanatory for participation; the last set of outcomes are those distal from participation, related to HRQL. The aim of the intervention was to increase hours of meaningful activity by three or more per week; increases of approximately two hours, on average, were achieved by 12 months, when the intervention ended, and maintained until 15 months, when the follow-up period ended. The change on the RNL was significant at all time points, showing a linear increase with time. All explanatory variables showed changes in a favorable direction. There was a significant increase on the PBSI, a measure of stroke-specific HRQL. Measures of generic HRQL also increased, but health perception not until after 12 months, and health utility, a measure used to calculate quality-adjusted life years (QALY) increased. By the end of the program and into follow-up clinically meaningful differences were observed for RNL, PBSI, EQ-VAS (health rating) and EQ-5D™ utility value. Significant changes were also observed for apathy, depression, and gait speed, but these did not meet the threshold of clinically meaningful differences. No adverse events occurred during the intervention. There were no adverse events reported during the intervention.

Table 5 shows that 45% of the study subjects increased the number of hours spent per week in meaningful activity outside the home by the targeted amount of three hours. Also shown are the proportions making two, four, and five hours, 52%, 40%, and 37%, respectively. Also shown is that only a small proportion of people were able to reach this target, with fewer than the three sessions of the

Table 4. Estimates[a] (95% CI) of within-person absolute change (out of 100) from baseline to all later time points.

Outcome (scale worst to best)	Change B to session 2 (~6 months)	Change B to last session 3 (~12 months)	Change B to follow-up (~15 months)
Hours of activity[b] outside home per week	−1.84 (−2.88 to −0.79)	**1.84 (0.22 to 3.46)**	1.88 (0.59 to 3.17)
Reintegration to Normal Living (0 to 100)	**2.77 (0.38 to 5.17)**	**3.68 (0.81 to 6.55)**	**4.78 (2.01 to 7.55)**
Depression (100 to 0)	−0.39 (–0.84 to 0.05)	**–0.99 (−1.41 to −0.565)**	**–1.13 (−1.63 to −0.63)**
Apathy (100 to 0)	−0.40 (–2.20 to 1.39)	−1.74 (–3.51 to 0.03)	**–3.52 (−4.41 to −0.63)**
Gait speed – comfortable ($m\,s^{-1}$)	**0.05 (0.02 to 0.08)**	**0.06 (0.03 to 0.09)**	**0.06 (0.02 to 0.09)**
Gait speed fast ($m\,s^{-1}$)	**0.07 (0.01 to 0.12)**	**0.06 (0.02 to 0.10)**	**0.07 (0.02 to 0.11)**
Stroke Specific HRQL (PBSI)	**3.15 (1.41 to 4.88)**	**4.27 (2.09 to 6.44)**	**4.14 (2.31 to 5.97)**
Health rating (EQ-5D)	1.64 (–1.21 to 4.50)	**3.73 (0.65 to 6.80)**	**3.46 (1.02 to 5.90)**
HRQL (EQ-5D index value)	0.79 (–1.90 to 3.48)	**2.71 (0.32 to 5.10)**	**2.85 (0.70 to 5.00)**

Bolding indicates changes that are statistically significant as 95% CI excludes null value of 0 change.
Missing data was replaced with last value was carried forward.
[a]Adjusted for clustering within site.
[b]Includes physical and social activities occurring outside of the home but excluding program hours.
HRQL: health-related quality of life; PBSI: Preference-Based Stroke Index; EQ-5D: index value.

Table 5. Distribution of Change in number of hours of meaningful activity over time in the whole sample randomized ($n = 186$).

Change in number of hours	*N* (%)	Sessions to change ≥3 hours	*N* (%)
≥2	97 (52)	1	11 (6)
≥3	42 (23)	2	20 (11)
≥4	37 (20)	3	80 (43)
≥5	34 (18)	Follow-up	45 (24)
Missing	16 (9)	Missing	32 (17)

program: 6% after one session and 11% after two sessions. For 42% of the sample, all three sessions were needed to reach an increase of three hours, and for 24%, this was not reached until the end of follow-up. A total of 31 people (17%) did not have two evaluations and are labeled as missing.

Discussion

This study showed that a novel and complex intervention aimed at increasing social participation after stroke increased the number of hours of activity occurring outside the house, and improved a range of other outcomes when delivered in community settings across Canada to long-term survivors of stroke. The intervention was based on evidence and also on the preferences and needs of stroke survivors facing participation challenges. Evidence also suggests that the number of hours of activity occurring outside the house was of particular importance to most people.

The average change in the number of hours spent in meaningful activity over the duration of the study period was estimated at 1.88 hours, carrying the last value forward for people who did not go on to the next assessment. The mean also fell below our targeted change of three hours. On closer inspection of the distribution of change, 45% of the participants met the targeted change value of three hours per week and an additional 39% exceeded this target increasing by four and five hours (see Table 5). Thus, over a third of people made substantial changes, something that is masked with analyses of averages. To put this in context, almost one in every two participants increased a meaningful amount (three hours), and over one in three increased four to five hours.

The increases in the number of hours the person spent in meaningful activity was

accompanied by reports of a higher degree of satisfaction with meaningful roles and also by hypothesized improvements in mobility, as measured by gait speed, and by decreasing apathy and symptoms of depressed mood. Positive changes were also observed for more distal outcomes related to stroke specific HRQL and overall HRQL. The eventual outcome is that the change was equivalent to an improvement of almost 0.03 QALYs, a value that is considered clinically meaningful.

Our intervention was based on the evidence of the time. Since, there have been a number of new studies of community-based interventions targeting participation.[35–43] The interventions varied, including self- or lifestyle management, behavioral, goal attainment, education, occupational therapy, physical therapy, physical activity, exercise, general rehabilitation, or inspiring stories, some in combination and some alone. Results were mixed with either no effect on participation outcomes,[37,38,40,43] or within-group effects only.[35,41,42] The only between-group effects were observed for two studies with a no intervention control group,[36,39] with one study using a concurrent control group for comparison.[39] There were many other sources of variation, including time since stroke, duration of the intervention, and the control situation. None of these studies could be considered to have offered a comprehensive program.

A recent systematic review[44] summarized the evidence of multidisciplinary care provided to people with stroke living in the community. This review indicated that the types of services for this population at this stage of recovery are very heterogeneous and there is no overarching outcome that is being targeted. We suggest that participation is that outcome.

The importance of this topic is further emphasized by the number of studies that are ongoing with published protocols.[45–49] However, again there is a lot of variation in what is being tested: self-management, problem solving, telemonitoring, music, therapeutic riding, and goal attainment as examples. Thus, our study is unique in its approach of offering a theory-based comprehensive program targeting participation.

We chose a wait-list control, rather than a non-intervention control group, as we had on hand evidence that, when left to their own devices, more than 50% of community dwelling people six months post stroke did not have enough meaningful activity to fill their day.[1] We chose the randomized controlled trial framework in recognition that strong evidence to support the benefits of these programs could attract sustainable infrastructure from the community, government, private, and charitable sources.

This decision was not without drawbacks. With a wait-list control group, eventually people need to have access to the intervention and we felt we could not delay this for more than three months. This did not leave a lot of time for changes to be made, particularly as we targeted people many months or years post stroke (mean ~2.5 years; see Table 1, available online). As the first analysis involved outcomes measured after only three months of intervention, and as people had been living with the sequelae of stroke for several years, the intervention did not result in any between-group differences, nor in any within-group changes of any clinical relevance. The wait-list group did increase their hours of activity spontaneously (mean 2.9); this is often the effect of the evaluation process, which queries this outcome and may result in people seeking to do more activity or reporting more, regardless of what was actually done.

As waiting did not seem to incur any harm (or benefit) we combined groups and estimated changes overtime for all persons who participated in the intervention. We recognize that pre–post change could have occurred as a result of changes outside of the program, but given long-term survivors were recruited, the potential for change without stimulus is small.

The within-person effects emerged over time, with the strongest effects being seen at 12 and 15 months from study entry (see Table 4), supporting our hypothesis that gains in participation outcomes take time. The effects seen were also, for the most part, clinically relevant. Most impressively, gains were associated with a change in HRQL, equivalent to almost a gain of 0.03

QALY (change in EQ-5D index value of 2.85%; 95% CI: 0.7 to 5.0).

The program was not designed with a therapeutic intent for stroke impairments, such as walking speed, depression, or speech. It was designed to enhance participation given existing impairments and that the activities would have reciprocal effects on these outcomes as well as on downstream outcomes such as HRQL. For example, the program did not deliver a therapeutic dose of exercise, but included exercise as a component; the exercise component was different across sites and included such activities as dance and aqua exercise, as well as more traditional exercise formats.

Taking a rehabilitation framework outside of a clinical setting and into the community is methodologically challenging as this study demonstrated. If programs are to be ecologically valid, risks need to be taken and using a randomized controlled trial design is such a risk. All randomized controlled trials need one primary outcome measure. The complex construct of participation is difficult to measure and includes difficulties, limitations, and satisfaction with specified activities, but our earlier work[1] indicated that over 50% of the community stroke population lacked meaningful activity that went beyond activities of daily living and maintaining a dwelling. Meaningful activities are difficult to assess and we felt the CHAMPS was closest to getting at this construct because it asks the respondent to specify time spent in activities. We modified it to focus on the activities the respondent usually did and enjoyed, and then asked about frequency. We specifically counted only social or recreational activities done outside the home, as this was the outcome identified by our focus group sample who defined the program elements. While not without its drawbacks, this method was superior to using patient-reported outcomes that focus on difficulty and/or satisfaction, as these could be affected by response shift.[50]

The program had to be adapted to meeting the variable needs of study subjects, in different sites and settings, and with different program leaders. Given this background of variability, the strength of the signal is encouraging.

The next challenge in stroke recovery is to ensure that these types of programs are available to the stroke population. This will require concerted action between policy makers responsible for health programs and local community organizations who would host this type of program. We never envisioned that people with stroke would need to have access to this type of program for life, as the aim was to provide stroke survivors with enough internal resources to access existing community programs designed for all citizens. In fact, this transition away from "specialized" programs to generic community programs was observed after the two sessions of the Mission Possible© program, with many participants continuing into the third session because they enjoyed the social contacts and often arranged them on their own.

The observation that it took the full three sessions to achieve the targeted change of three hours (see Table 5), may be because our sample was almost three years post stroke, on average, when intervention was initiated. Evidence shows[5] that patterns of participation are set and unchanging from three months post stroke. Clearly, interventions targeting participation need to be put into place earlier post stroke; if started earlier, perhaps 12 months of intervention may not be needed.

Even if available, it is a challenge to motivate people with stroke to engage. An investigation of component causes of participation in a similar population identified walking capacity, mood, social support,[5] and apathy[51] as contributors; of these only normal walking capacity could be considered a sufficient cause of good participation. A conclusion we reached after conducting an exercise-only intervention post stroke[52] and identifying difficulties with study entry and completion, was that there was a need for an integrated community-based group program that could include gender-specific and mood-sensitive activities to improve all aspects of survivorship. In this study, we have demonstrated that this type of intervention can induce positive change in these aspects of survivorship. Now these programs need to be built.

Clinical messages

- Engagement in an evidence-, needs-, and preference-based community rehabilitation program was associated with an increase in the hours spent in meaningful activity.
- Gains in meaningful activity took one year to achieve and were accompanied by changes in satisfaction and health-related quality of life.
- The program was also associated with a reduction in many of the barriers to participation, such as mood, apathy, and mobility.

Conflict of interest

The authors declare that there is no conflict of interest.

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