

New South Wales
Health Promotion Demonstration
Research Grants Scheme

EXERCISE INTERVENTION
TO PREVENT FALLS
AFTER STROKE



EXERCISE INTERVENTION TO PREVENT FALLS, ENHANCE
MOBILITY AND INCREASE PHYSICAL ACTIVITY IN
COMMUNITY DWELLERS AFTER STROKE: A RANDOMISED
CONTROLLED TRIAL



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Abbreviations and acronyms

AAP	Adelaide Activities Profile
CI	Confidence Interval
GP	General Practitioner
IRR	Incidence risk ratio
MAS	Motor Assessment Scale
PPA	Physiological Profile Assessment
RCT	Randomised Controlled Trial
RR	Relative risk
SSWAHS	Sydney South West Area Health Service
WEBB	Weight-bearing Exercise for Better Balance

Executive summary

Background

Stroke is the most common disabling neurological condition in adults. Falls and poor mobility are major contributors to stroke-related disability. Falls are more frequent and more likely to result in injury among stroke survivors than among the general older population. Currently there is good evidence that exercise can enhance mobility after stroke, yet ongoing exercise programs for community-based stroke survivors are not routinely available. In partnership with the NSW Stroke Recovery Association, this project established and evaluated a community-based sustainable exercise intervention program for people who have suffered a stroke. We hypothesised that a lower limb weight-bearing exercise program would prevent falls, enhance mobility and increase habitual physical activity levels among community dwelling stroke survivors.

The Intervention

Both the experimental and control groups participated in 40 weekly group-based physiotherapist-led exercise classes delivered at NSW Stroke Recovery Association stroke clubs, a home program and received verbal advice delivered in the exercise classes over a 12 month period. The duration of each exercise class and home program session was 45-60 minutes. The intervention received by the experimental group aimed to prevent falls, enhance mobility and increase physical activity using the Weight-bearing Exercise for Better Balance program which involves weight bearing exercise that challenges balance and promotes strength. The intervention received by the control group aimed to improve upper limb and cognitive function. This included exercises aimed at managing and improving the function of the affected arm and cognition, carried out in the seated or lying positions.

Methods

The design of this project was a prospective randomised controlled trial. Participants were recruited to the study between November 2006 and January 2009. After

completion of the pre-test assessment, participants were randomly allocated to the experimental or control groups. The primary outcome measures were falls, walking capacity and walking speed. Secondary outcome measures were risk of falling, physical activity levels, community participation, health-related quality of life, health service utilisation, arm function and cognition.

Results

Exercise classes were established in 11 stroke clubs and delivered by eight physiotherapists. One hundred and fifty-one participants (73 female, 78 male), with an average age of 67 (SD 12) years and on average 5.9 (SD 6.1) years since stroke were recruited to the study. Seventy-six participants were randomly allocated to the experimental group and 75 to the control group.

After 12 months, the experimental group walked 34m further in six minutes (95%CI 19 to 50, $p<0.001$) and 0.07m per second faster over 10m (95%CI 0.01 to 0.14, $p=0.03$) than the control group after controlling for baseline performance.

Over the 12 month period, 129 falls were reported by the experimental group and 133 falls were reported by the control group. There was no difference in the rate of falls between groups (incidence risk ratio 0.96; 95%CI 0.59 to 1.51, $p=0.88$) or proportion of fallers (relative risk 1.22; 95%CI 0.91 to 1.62, $p=0.19$).

On exploratory analysis, we found a significant differential effect of the experimental intervention on falls based on initial walking speed (significant interaction term, walking speed x group, $p=0.03$). This significant interaction means that the experimental intervention was more likely to prevent falls for those with faster walking speeds.

There were significant between-group differences favouring the experimental group in choice stepping reaction time, strength of the intact knee extensor muscle and the 'service to others' domain of the Adelaide Activities Profile. There

were also trends favouring the experimental intervention in increased physical activity and single leg stance time on the affected leg. However, there were no significant between-group differences in falls risk, health-related quality of life or health service utilisation.

Sustainability of the exercise program after the research phase was poor with an exercise class continuing at only one stroke club and poor uptake of referrals to Heartmoves (a community-based exercise program suitable for stroke survivors).

Conclusion

The major findings of this project were that a 12 month program of the lower limb Weight-bearing Exercise for Better Balance intervention delivered via weekly exercise classes for long term stroke survivors at stroke clubs, a home program and advice to increase walking was more effective than an upper limb and cognitive exercise program in improving walking capacity and walking speed in community dwelling stroke survivors.

While there was no overall effect on falls, exploratory analysis found a significant differential effect of the intervention according to baseline walking speed. The intervention as delivered was more likely to prevent falls in faster walkers.

Recommendations

We recommend:

- further research is undertaken, which is sufficiently powered to explore the interaction between walking speed and the effect of lower limb weight bearing exercise on falls prevention after stroke
- weekly exercise classes, home program and advice to increase walking be implemented for community dwelling stroke survivors whose walking is not markedly slowed
- further research is undertaken on effects of falls prevention programs for stroke survivors with markedly slowed walking
- the national registry of stroke (Australian Stroke Clinical Registry) currently in development be fully funded and maintained so that researchers can utilise the registry to identify potential participants
- further research is undertaken to establish strategies to facilitate and support stroke survivors to participate in community exercise programs which are not necessarily stroke-specific.

Introduction

Background

Falls and poor mobility are major contributors to stroke-related disability. Despite good evidence that exercise can enhance mobility, ongoing exercise programs for stroke survivors are not routinely available.

This project, the 'Exercise after Stroke' project, consists of exercise interventions developed and implemented through the NSW Stroke Recovery Association Stroke Club network, and evaluated using a randomised controlled trial (RCT). The RCT investigated whether these exercise interventions can reduce fall rates and increase mobility and physical activity levels in stroke survivors.

The Exercise after Stroke project was conducted by the University of Sydney, Stroke Recovery Association of NSW and the Health Promotion Service of Sydney South West Area Health Service (SSWAHS) from 2006 to 2010. It was funded by the NSW Health Promotion Demonstration Research Grant Scheme, with additional funds from the SSWAHS Health Promotion Service and the Faculty of Health Sciences, The University of Sydney.

Rationale

Stroke is the most common disabling neurological condition in adults and is estimated to cost \$1.3 billion per year in Australia.¹ Some 48,000 Australians suffer a stroke each year,² and in the developed world 25 per cent of men and 20 per cent of women will suffer a stroke if they live to 85 years.³ The major burden of stroke is chronic disability rather than death.⁴ In Australia there are an estimated 346,700 stroke survivors, of whom 90 per cent live at home and 282,000 (80%) live with permanent disability.² In NSW, there were approximately 6,382 people admitted with stroke to NSW public hospitals in the 12 month period from July 2005 to June 2006 and 4,169 of these were within the Sydney metropolitan area.⁵ The burden of stroke-related disability has increased over the last decade as more people are surviving stroke. It is also projected that stroke-related disability will increase dramatically over the next two decades as the population ages.⁶ Development and implementation of effective strategies to minimise stroke-related disability is essential to minimise spiralling future health costs.

Falls are a major problem for older people and society

Falls and poor mobility are major contributors to stroke-related disability. Preventing falls in older people is a major priority for NSW Health (as indicated by the release and implementation of the NSW Health Management Policy to Reduce Fall Injury Among Older People).⁷ It has been estimated that in NSW by 2051, over 440 000 public hospital bed days per year will be required to care for older people with fall injuries (the equivalent of four new 200 bed acute care facilities and 1,200 new nursing home places), and the cost to the health system will be over \$640 million, more than three times the current cost of falls to the health system.⁸ Falls also adversely affect the quality of life of older people.

Falls are more common and serious after stroke

Stroke is a major risk factor for falls.⁹ Over 70 per cent of stroke survivors fall within six months of discharge from hospital¹⁰ and nearly 50 per cent of community-dwelling female stroke survivors will continue to fall each year.¹¹ Stroke survivors are up to four times more likely to suffer a hip fracture than other community-dwellers.¹² Gait and balance problems have been found to be important risk factors for falls in stroke survivors.^{11,13} Falls prevention strategies implemented to date in NSW, have not been targeted to stroke survivors.

Poor mobility is also a major problem after stroke

Although on completion of post-stroke rehabilitation most individuals can walk independently, over 90 per cent of these people are unable to walk with sufficient speed or endurance to function effectively in the community.¹⁴ Specifically, many stroke survivors cannot walk fast enough to cross a road safely or far enough to do the shopping.¹⁴ Walking speed and walking capacity among community dwelling stroke survivors is markedly lower than age-matched controls,^{15,16} which results in major limitations in community participation. Poor mobility can reduce quality of life and contribute to social isolation. People fear

dependency more than anything else after a stroke and the ability to walk independently has been found to provide the greatest protection against dependency.¹⁷

Falls and poor mobility increase the risk of further health and social problems

The consequences of falls and poor mobility are extensive and include low physical activity levels, fear of falling, reduced quality of life, limited participation in activities outside the home and social isolation. This reduction in physical activity and community participation increases the risk of further morbidity, falls and hospitalisation.

Exercise can improve functional abilities even if started many years after stroke

There is now good evidence that well-designed exercise programs can enhance functional abilities after stroke.¹⁸ Our own previous work has shown the efficacy of small-group 'circuit-style' exercise programs among people following stroke¹⁵ or other disabling conditions¹⁹ for improving mobility. It is commonly thought that recovery following stroke occurs within the first three months and is complete by 12 months.²⁰ However there is growing evidence that functional abilities can improve with exercise provided many years after stroke.^{15,16,21,22} In these studies exercises are typically withdrawn at the end of the research period and functional gains are not maintained.

Exercise can prevent falls among general community dwellers

It is clear that well-designed exercise programs can prevent falls in older people^{23,24} but it is not yet known whether exercise can prevent falls among people following stroke. We hypothesised that provision of regular exercise intervention for community-dwelling stroke survivors will prevent falls. We proposed to tailor the program to address each individual's need by using the Physiological Profile Assessment (PPA) falls risk assessment tool²⁵ and functional evaluations to assist in exercise prescription.

There are few ongoing exercise opportunities for stroke survivors

In NSW, stroke rehabilitation services are provided by both the public and private healthcare sectors. Typically services are provided for three to six months after stroke onset and cease permanently at or before 12 months. It is widely accepted that to maintain health, physical activity is essential. Currently in NSW, routine provision of long term ongoing physical activity/exercise programs for stroke survivors residing in the community is virtually non-existent. There are a range of community-based physical activity programs for healthy older people. However, the chronic disability often associated with stroke means that these programs are not usually accessible to this population.

Partnership with local stroke clubs

The Exercise after Stroke project was designed in partnership with the Stroke Recovery Association. After the cessation of rehabilitation services, stroke survivors are often encouraged to join their local community support group. The Stroke Recovery Association coordinates many of these support groups into a network of stroke clubs throughout urban and rural areas of NSW. These stroke clubs typically meet weekly in community facilities such as Returned Services League, Workers' and Catholic clubs and senior citizen's centres. There were 23 stroke clubs operating in metropolitan Sydney. We hypothesised that working with the Stroke Recovery Association's Stroke Club network would ensure that this community based exercise program was sustainable and that the exercise intervention would be effective in preventing falls, enhancing mobility and physical activity levels.

Broader implications

While people following stroke already have cardiovascular disease and frequently other chronic conditions (diabetes and obesity) we postulated that with enhanced physical activity and mobility, worsening of disease and onset of other chronic conditions could be prevented or delayed.

If this community-based exercise intervention is effective, the collaborative approach to enhancing exercise opportunities may also have wide applications for other chronic diseases which are worsened by inactivity (for example, Parkinson's Disease).

SECTION 2

Aims and objectives

Aims

The Exercise after Stroke project aimed to establish and evaluate a community-based sustainable exercise program for people who have suffered a stroke. We hypothesised that the lower limb exercise program would prevent falls, enhance mobility and increase habitual physical activity levels among community dwelling stroke survivors.

Objectives

Primary research question

To determine the effects on falls, walking capacity and walking speed of a lower limb weight bearing exercise program among stroke survivors who reside in the community.

Secondary research questions

- To determine the effects of the lower limb weight-bearing exercise program on falls risk, physical activity levels, community participation, health-related quality of life and health service utilisation.
- To assess sustainability of the exercise program established in the extensive network of the NSW Stroke Recovery Association's stroke clubs.

Additional research question

The design also allowed us to examine the effect of the control intervention. Therefore we had the following additional research question: to determine the effects of the upper limb and cognitive exercise program on upper limb function and cognition.

The intervention

Recruitment and implementation plans

We aimed to recruit 350 stroke survivors through 12 stroke clubs with an average of 30 participants from each club. This figure was based on sample size power calculations, presented in Section 4: Sample size. The recruitment target appeared feasible, as in 2005 there were 23 stroke clubs operating in Metropolitan Sydney and an additional three accessible clubs located on the Central Coast and the Illawarra. In 2005, the NSW Stroke Recovery Association had over 1,500 members with 800 regularly attending Club meetings. Moreover, most of the stroke survivors who regularly attended stroke club meetings were able to walk independently and therefore were likely to be eligible for this study.

We also aimed to recruit people who had recently suffered strokes, through hospital stroke units and rehabilitation units. The NSW Stroke Recovery Association and the Exercise after Stroke project investigators had close links with many NSW hospitals. Hospital staff routinely distributed written information about the NSW Stroke Recovery Association's stroke club network to stroke survivors at discharge from hospital and this material would include information about this project. The NSW Stroke Recovery Association was confident that the provision of an exercise intervention through its club network would enhance membership (particularly among those who recently suffered a stroke) and increase attendance at meetings.

We anticipated that community participation would be integral to the success of this project. We invited the metropolitan Sydney stroke clubs and those on the Central Coast and the Illawarra to participate in the project through the NSW Stroke Recovery Association's newsletter and follow-up phone calls via the association. Members of each stroke club considered the project and collectively decided if the project was initiated at their club. To facilitate uptake of the project we allowed stroke clubs to negotiate with the project coordinator on pragmatic aspects of implementation of the project. Such aspects included the timing of the weekly classes with respect to the other activities held at club meetings and where in the venue the classes were set

up. Each stroke club liaised with the project coordinator to ensure that members reliant on community transport were able to participate in the project.

Problems with recruitment were identified early and continued throughout the project. Low recruitment, specifically the low numbers of potential participants identified to be screened for eligibility, was the major issue addressed during both project team and Advisory Committee meetings. Since the intervention period was 12 months, we needed to recruit 350 participants over two years to complete the project within a three year period. Early recruitment data suggested we would not reach the target unless screening of potential participants improved. Each stroke club had capacity for a maximum of 24 participants; however participant numbers at the clubs recruited early in the project ranged from only four to 12 participants. On the recommendation of the Advisory Committee, a range of recruitment strategies outlined in Table 1 were implemented as well as offering the project in rural areas. Following implementation of these strategies the project team was confident that knowledge of the project by NSW Health professionals involved in the care of stroke survivors was achieved. One strategy developed by the SSWAHS Health Promotion Service was a print media campaign with advertisements (Appendix B) and a press release (Appendix C) being distributed to five local newspapers in areas of participating stroke clubs. The press releases and print advertisements were approved by SSWAHS Public Affairs and Marketing. The effectiveness of this campaign was poor, the advertisements generated 30 enquiries but only eight participants were recruited to the project. Unfortunately the press release was not used concurrently by any of the five newspapers publishing the advertisement.

We also investigated other recruitment strategies which were unable to be implemented as we could not obtain the necessary ethical approvals in the time period. One strategy included establishment of a database of stroke survivors discharged from hospital with a plan to mail a project flyer (Appendix D) to those on the database three months after discharge. The other strategy investigated was joining with another stroke trial being conducted in the acute setting. Discussions with the lead investigator were positive,

Table 1: Recruitment strategies implemented and details of distribution or target audience

Strategy	Distribution or target audience
Verbal Presentation	<ul style="list-style-type: none"> ■ NSW Stroke Recovery Association stroke club executive committee members' training workshop ■ NSW Stroke Recovery Association stroke clubs ■ SSWAHS, SESIAHS forums ■ Smartstrokes Conference ■ NSW Rehabilitation Hospital in-services ■ NSW Health stroke units ■ Aged Care Assessment Teams ■ Transitional Care teams ■ Retirement villages ■ NSW Health Stroke Services Research day
Bright yellow flyer and information pack	<ul style="list-style-type: none"> ■ NSW Stroke Recovery Association's newsletter ■ Division of general practice mail out ■ NSW Hospital rehabilitation departments ■ Australian Physiotherapy association Neurology and Gerontology Group members ■ NSW stroke service group ■ NSW Health Acute Stroke units ■ Community services ■ Local councils ■ Senior networks ■ Religious and welfare providers of community services
Information posted on websites	<ul style="list-style-type: none"> ■ NSW Stroke Recovery Association website ■ The University of Sydney Neurological Rehabilitation Research group website ■ Australian New Zealand Clinical Trials Registry website
Radio Interview	Regional Community radio station
Print advertisements	Five local newspapers in vicinity of established classes
Media release	Five Local newspapers in vicinity of established classes
Media stories	Published in four newspapers

Note: SESIAHS = South East Sydney Illawarra Area Health Service; SSWAHS = South West Area Health Service

however the acute stroke trial investigators were not prepared to undertake the necessary ethics modification.

The major issue affecting the implementation of this project was the difficulty in recruiting stroke clubs and stroke survivors to the project. Gaining support from the stroke clubs was more time challenging than envisaged. Many stroke clubs did not meet on a weekly basis and those that did frequently had other regular activities or outings planned. Some stroke clubs did not want these activities interrupted, which caused time pressure for classes and the

need to extend use of the venue. Extension of the stroke club time caused problems for participants reliant on community transport to access the Club.

Intervention overview

Both the experimental and control groups participated in weekly exercise classes and were given an individually prescribed home exercise program. Each class and home program session was designed to take between 45-60 minutes. A physiotherapist delivered classes and designed

individual home programs. Physiotherapists were trained in delivering both interventions and were provided copies of the Weight-Bearing Exercise for Better Balance (WEBB) program²⁶ and 'Drive your own recovery' upper limb program which outlined guidelines for training and progression. Refer to Appendix A for further information on the exercises used in both the experimental and control groups' classes.

Classes were conducted over 40 weeks (aligned with school terms) and were held in the venues used by the stroke club, prior to or after meeting times. Where possible, the experimental and control classes were held in different rooms and/or at different times to minimise cross-group contamination. Both programs were progressed as performance improved to ensure the intervention remained challenging. Home programs consisted of at least three sessions a week and were reviewed and modified monthly.

The experimental group intervention

The experimental group received an exercise intervention designed to prevent falls, enhance mobility and increase physical activity. The intervention involved a weekly circuit-style group exercise class, a home exercise program completed at least three times a week and verbal advice, delivered at the weekly exercise class, to increase their walking.

The experimental group exercises used in the classes and home program had an emphasis on functionally-relevant lower limb weight-bearing exercise designed to reduce falls by enhancing balance, improving strength and functional abilities. The specific exercises were taken from the Weight-Bearing Exercise for Better Balance (WEBB) program. This program was written by the Exercise after Stroke project leaders Dr Catherine Sherrington and Dr Catherine Dean and other colleagues, and is available on the internet.²⁶ Interventions were tailored to an individual's functional ability and the nature and difficulty of exercises were progressed regularly.

The exercise class and home program were a minimum of 45 minutes in duration (maximum 60 minutes) and consisted of warm-up, progressive balance, lower limb strengthening exercises, walking and cool down. The lower limb extensor muscle groups, which act to prevent collapse of the lower limb (hip and knee extensors and ankle plantar flexors), were targeted with exercises designed to challenge balance and increase muscle strength. The balance exercises included standing with a decreased base of support,

forwards and sideways stepping/walking, and graded reaching activities in standing. The use of upper limbs for support while exercising was discouraged except where necessary to ensure safety. Strengthening exercises included sit-to-stand, forward or lateral step-ups onto a small block, semi squats and heel raises in standing. Resistance for strengthening exercises were applied using weighted vests in a similar protocol to one which has been successfully used by people with multiple sclerosis in a home-based program.²⁷ The amount of resistance applied was determined by the physiotherapist running the classes and was based on the American College of Sports Medicine guidelines²⁸ and the American Heart Association Science Advisory regarding the use of resistance training.²⁹ Standard principles governing frequency, volume, duration, intensity and progression of exercise were applied.³⁰ This intervention was based on available evidence^{15,16,18,19,23} and consistent with the NSW Health Management Policy to Reduce Fall Injury Among Older People.⁷

The control group intervention

The control group exercise class was designed to improve upper limb function, manage upper limb contracture and improve cognition. The upper limb exercise component was based on a program Drive Your Own Recovery developed by Dr Ruth Barker (Exercise after Stroke project advisor) from James Cook University.³¹ The cognitive component of the exercise class was based on the program designed by Dr Catherine Dean (and used in a previous RCT in chronic stroke with good effect).²¹ The cognitive component involved sorting, matching and sequencing tasks. The control group was also prescribed a home program aimed at self-management of the affected upper limb and improving upper limb function and cognition. It also included verbal advice provided at the weekly exercise class to use their affected arm and keep their mind active with cognitive leisure tasks such as word puzzles and Sudoku. Similar to the experimental group the duration of the control group exercise class and home program was between 45-60 minutes.

We postulated that the control program would enhance upper limb function and cognition, thus control participants would also be receiving a beneficial intervention. The exercises during the class and home program for the control group were carried out in either the seated or lying position to minimise the challenge to balance.

We postulated that the control circuit class and home program was unlikely to affect change in walking capacity

or falls risk. This study design enabled assessment of additional benefits of the trial intervention over and above likely benefits of social aspects of exercise classes.

Safety

Maintaining safety for both experimental and control participants while completing the exercise classes and home program was a prime consideration when level of difficulty of exercises was prescribed. Each individual's home program was reviewed monthly by the physiotherapist delivering the interventions. A home exercise folder was developed which contained information on safety precautions, clear pictures and descriptions of exercises prescribed (many obtained from Physiotherapy exercises for people with spinal cord injuries and other neurological conditions³²) and participants were asked to keep an exercise log. Family members and/or carers were encouraged to assist with the supervision and performance of the home program, where appropriate. Participants were provided with a shoulder bag to facilitate carrying the exercise folder.

Sustainability evaluation plan

This project was designed to not only answer the specific research questions described in section 2, but also to deliver ongoing community-based exercise opportunities for community dwelling stroke survivors. The research project needed to run over three years to recruit, intervene and measure a sufficient number of participants. However, individual participants were only required to participate over a 12 month period. On completion of the 12 month research project, we planned to encourage participants to continue the weekly exercise classes. They could also complete additional exercises from the other group's intervention if deemed appropriate by the study physiotherapist.

We anticipated that both the experimental (lower limb exercise) and control (upper limb and cognitive exercises) classes would be delivered by a physiotherapist employed on a casual basis at each stroke club. This would incur a cost of between \$40-\$60 per session, which would be covered by charging participants \$4 per class during the research phase and beyond. Charging this fee was considered essential to sustain classes. We were confident that participants would be prepared to pay the fee as there was a history of stroke club members paying fees for similar services such as speech therapy and hydrotherapy. The fee we proposed was also similar to fees charged in a previous Tai Chi project run in SSWAHS.³³ The venue and liability

insurance was covered by the NSW Stroke Recovery Association.

We planned to collect data about attendance and fee collection for participants recruited in the first two years (estimated 240 participants) of the project for 12 months after completion of the research phase. We factored the expected amount of money that would be generated through fees into the project budget.

Project plan modifications

The SSWAHS Ethics committee did not approve our plan to collect fees for exercise classes during the 12 month research phase, requiring the classes to be provided free and recommending we assess what level of fees would be sustainable after the research phase. This decision affected our ability to employ casual physiotherapists to deliver the intervention and the project plan was amended.

The absence of class fees during the research phase contributed to the budget overrun and necessitated reassigning duties to complete the project. The project coordinator, whose original duties were to coordinate the project, recruit stroke clubs and participants, train casual physiotherapists and complete all the pre- and post-assessments was also required to deliver the intervention at some stroke clubs. With the project coordinator delivering the intervention, casual research assistants were required to complete post-assessments to ensure blinding.

After the 12 month research phase, participants were encouraged to continue attending weekly exercise classes, and complete any additional exercises which were deemed appropriate by the study physiotherapist. A fee was charged to enable the classes to be self-funding. Participating stroke clubs were to be randomised into three groups to ascertain a sustainable level of fees: one group would charge \$4 per class; the second group \$6 per class and the third group \$8 per class. We planned to analyse data about ongoing attendance and fee collection for participants recruited in the first two years (estimated 240 participants) for a 12 month period.

We were unable to continue delivering classes after the 12 month research phase in the majority of our clubs due to insufficient funds. A \$6 fee per class was charged for ongoing participation in the four clubs which offered classes after the 12 month research phase, rather than the proposed differential fee structure. Fee collection and

attendance was monitored for participants who continued after the 12 month research phase. Participants at clubs which did not have ongoing classes were offered a referral to Heartmoves.³⁴ At the end of the Exercise after Stroke project participants at the clubs offering ongoing exercise classes were also referred to Heartmoves. Heartmoves was developed by the National Heart Foundation to provide ongoing low- to moderate-intensity exercise opportunities in the community for Australians living with chronic health conditions.³⁴ It is one of the few programs that encourage the attendance of stroke survivors. It is a sustainable exercise option delivered in fitness and community centres that importantly is not time limited.

As the participants completed the project, they were sent a letter thanking them for participation and given information on their individual results. Participants were advised to share the information with their general practitioner (GP). The letter also described the general benefits of exercise for health and offered a referral to a local Heartmoves class. Written permission from participants to generate the referral was required, so we developed a permission form that they could return to the project coordinator. We then sought permission from those who agreed to the referral to a telephone interview after three months, to evaluate how many attended a Heartmoves class.

The SSWAHS Ethics Committee was informed annually on the progress of the project and modifications to our project protocol were approved by the SSWAHS ethics committee in September 2008.

Research methods

Design

A prospective, multicentre, single-blind RCT was undertaken. Participants were randomly allocated into either an experimental group (lower limb exercise program) or a control group (upper limb and cognitive exercise program). Randomisation was stratified by stroke club using random permuted blocks of four to eight participants. Stratification by stroke club was undertaken to minimise the impact of differences between socio-economic status between clubs. The allocation sequence was computer-generated before the study commenced and a set of consecutively-numbered sealed opaque envelopes containing the allocation was generated for each stroke club. This approach ensured randomisation was concealed and secure.

The participants and therapists delivering the intervention could not be blinded to the intervention. Blinding in the collection of all outcome measures other than falls was ensured using several strategies: the assessor was blinded to group allocation, participants were asked not to reveal details of the intervention to the assessors; and assessments were collected outside the exercise class times.

The study protocol was approved by SSWAHS Ethics Committee (Clearance No: X06-0039) and The University of Sydney Human Research Ethics Committee (HREC Number 07/2006/9031), and written informed consent was obtained from all participants. The protocol for this study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12606000479505) and published.³⁵

Sample size

We undertook an 'a priori' power calculation to determine sample size. As we planned to compare fall rates between groups using incidence rate ratios (IRR) from negative binomial regression models³⁶ we conducted an analysis of statistical power using the 'nbpower' command in the Stata software package.³⁷ A sample size of 350 participants (175 per group) was needed for the trial to have 80 per cent power to detect a 34 per cent reduction in the rate of falling in the 12 month follow-up period (at 5 per cent significance), that is, an IRR of 0.66 using negative binomial

regression analysis. This sample size would allow for a 15 per cent loss to follow-up due to death or withdrawal from the study. Experience from our previous work indicated that this sample size would exceed what is necessary to have sufficient power to detect meaningful between-group differences for the other primary outcome measures.^{15,16,19} For example, data from a previous trial indicated that 63 participants per group would be needed to detect a 50m between-group difference in walking with 80 per cent power at a two-tailed significance level of 0.05.¹⁶

Participants, therapists, stroke clubs

Participants were primarily recruited at meetings of stroke clubs which had agreed to participate in the project. Other interested stroke survivors who contacted the project team were advised of the location of the nearest participating stroke club. For individual participants, there was no restriction on the type of stroke and time since stroke. Participants were invited to participate if they: had suffered one or more strokes; were able to walk 10m independently with or without a mobility aid; were able to gain medical clearance from their local GP to participate; were willing to join the NSW Stroke Recovery Association; were willing to undertake a weekly exercise class and home program for 12 months; and were able to give informed consent.

Participants were excluded if they: had a cognitive impairment defined by a Folstein Mini-Mental State Examination³⁸ score of less than 20; had insufficient communication/English skills to participate in assessment and intervention; had a medical condition precluding exercise such as unstable cardiovascular disease; suffered from other uncontrolled chronic conditions²⁸ that would interfere with the safety and conduct of the training and testing protocol.

Potential participants were screened for eligibility by a physiotherapist. Medical clearance was required from each participant's usual GP to certify him/her able to participate in moderate-intensity semi-supervised exercise before being accepted into the trial. After obtaining medical clearance and completing the initial assessment, eligible participants were formally entered into the trial.

Therapists were included if they were: registered physiotherapists; willing and able to deliver both the experimental and control interventions, available to deliver classes on the day and times specified by the stroke club; and prepared to undertake specific training to follow the trial protocol. Years since graduation, highest qualification and previous research experience were recorded.

Stroke clubs were included if club members and the individual club's committee agreed to participate in the trial and if exercise classes were able to be delivered at the club or a nearby venue on a weekly basis. The number of participants recruited at each stroke club was recorded.

Outcome measures

The primary outcome measures were falls and mobility. A fall was defined according to the Kellogg International Work Group definition "as an incident in which the body unintentionally comes to rest on the ground or other lower level which is not as a result of a violent blow, loss of consciousness, sudden onset of paralysis as in a stroke or an epileptic seizure." (Gibson et al, 1987:1)³⁹ Falls were monitored for one year with monthly fall calendars. All participants received monthly calendars on entry to the study, with instructions to record the following events: number of falls, visits to or by nursing and allied health personnel, GP or specialists appointments and hospitalisations. Participants were asked to return the completed calendar monthly at their weekly exercise class. If calendars were not returned, after therapist reminders, further contact was made by telephone. Details of any falls (including how and where the fall occurred, injuries suffered, medical intervention required and limitations to activity as a result of a fall) were verified. Falls were assessed by comparing the falls rate between experimental and control groups.

Two aspects of mobility, walking speed and capacity were assessed. Walking speed (m/s) was measured using the 10m walk test. Participants were timed as they walked at their comfortable speed and fastest speed over the middle 10m of a level 14m walk track. Walking capacity was measured by quantifying the distance walked (m) from a Six-minute Walk Test.⁴⁰ The test was conducted over a 25-30m level corridor. The instructions for the test were standardised according to Lipkin and colleagues.⁴⁰ Participants were instructed to "walk as far as possible in six minutes, you can slow down and rest if necessary but at the end of the six minutes you should aim to not have been able to have

walked any further in the time period." No encouragement was given but the measurer informed participants at the half-way point (three minutes) and when there was one minute to go. Participants were allowed to wear shoes and use walking aids if necessary. Rests were permitted and recorded but the time kept going. While administering this test the assessor walked slightly behind the participant to ensure safety, but to avoid influencing the participant's self selected walking pace.

Secondary outcomes were falls risk, habitual physical activity, quality of life, community participation and health service utilisation. Falls risk score was assessed using the Short-form PPA, the falls risk assessment tool developed by Professor Stephen Lord which includes five tests.²⁵ Falls risk is measured by the composite score which is calculated by summing standardised canonical correlation coefficients for five tests from the PPA short form. The five tests are:

- contrast sensitivity using the Melbourne Edge Test – a test that measures edge contrast sensitivity
- quadriceps strength (knee extension), measured for each leg isometrically with the subject seated in a standard dining room chair, with the knee and hip flexed at 90 degrees
- postural sway using a sway meter that measures displacements of the body at the level of the pelvis. Testing was performed with participants standing with eyes open on the floor and on a foam rubber mat (40cm by 40cm by 7.5cm thick)
- proprioception, measured using a lower limb-matching task. Errors were recorded using a protractor inscribed on a vertical clear acrylic sheet (60cm x 60cm x 1cm) placed between the legs
- hand reaction time in m/s measured using a light as the stimulus and a finger-press as the response.

Physical activity (steps per day) was measured by recording the number of steps taken each day for seven consecutive days using a Digimax pedometer. Health-related quality of life was measured using the SF12TM Version 2.⁴¹ This commonly used health-related quality of life scale is a shortened version of the SF36. The physical composite and mental composite scores (0-100) were reported for this study.⁴² Community participation was measured using the Adelaide Activities Profile (AAP) which has been shown to be a valid measure of the lifestyle activities of elderly people in Australia.⁴³ Each activity is rated with four possible responses from zero to three, where a higher score reflects more participation. The questions reflect performance on

activities in four domains: domestic chores (0-24 points), household maintenance (0-21 points), service to others (0-15 points), and social activities (0-12 points) over the last three months. Community participation was reported in the four domains separately for the purposes of this study and in line with recommendations.⁴⁴

Health service utilisation was recorded on the falls calendars. Participants were required to indicate when they had seen a doctor or health worker and if they were hospitalised. We did not follow up on missing health utilisation data.

Several other additional impairment and activity measures were collected and analysed. Also some individual items of the PPA were analysed. These measures may provide insight into the mechanisms underlying any of the changes in the primary and secondary outcomes. Scores on these measures at the initial assessment were also used by the therapists to guide the original individual exercise prescription.

The impairment of dexterity was evaluated by measuring choice stepping reaction time.⁴⁵ Choice stepping reaction time measured as the time (s) to complete a standardised stepping routine. Choice stepping reaction time has been found to be a composite measure of risk of falling when assessed with an electronic device.⁴⁵ We measured choice stepping reaction time in a modified manner with a portable mat. A mat with four white squares were placed in front of the standing participant, and the participant was asked to make a standard number of steps with either foot to a particular square and back again, using a standardised script.

The impairment of strength was evaluated by measuring knee extensor strength in both legs. This test is part of the short form PPA and has been described earlier. Strength (kg) was recorded as the best score from three attempts for each leg.

The impairment of balance was measured by four tests: maximal sway range,⁴⁶ coordinated stability,⁴⁶ and single leg stance time for both intact and affected legs.⁴⁷ The maximal balance range (mm) measures the maximal forward- and backward-leaning capacity of the participant. Subjects were asked to lean forward as far as possible from the ankles without moving the feet, then back as far as possible. Maximal anterior-posterior distance moved was measured with the swaymeter, which extended in the anterior plane. The participants had three attempts at the test, with the best trial used in the analysis. The coordinated stability test

(total error score) measures participants' ability to adjust balance in a steady and coordinated manner while placing them near or at the limits of their base of support. In this test, the swaymeter was again attached to the waist with the rod extending anteriorly. The participant was asked to adjust balance by bending or rotating the body without moving the feet so that the pen on the end of the rod followed and remained within a convoluted track that was marked on a piece of paper attached to the top of an adjustable-height table. Subjects had to remain within the track, which was 1.5cm wide, and be capable of adjusting the position of the pen 29cm laterally and 18cm in the anterior-posterior plane. The total error score was calculated combining the sum of the number of occasions the pen on the swaymeter failed to stay within the path and measuring the magnitude of each error in mm. Subjects attempted the test twice, with the better trial result used in the analysis. Single leg stance time (s) was measured for both affected and intact legs. The best trial from three was analysed.

Activity limitation was measured by four additional tests:

- Sit-to-stand ability was measured by recording the time (s) to complete five stands from a 45cm chair.⁴⁸
- Mobility was measured as the time (s) taken to stand up, walk 3m at usual pace, turn around, return, and sit down again, that is, the Timed Up and Go Test.⁴⁹
- Stepping ability was measured for both affected and intact legs using the Hill step test, that is, the number of steps onto a 7.5cm block in 15s.⁵⁰

Measures of upper limb function and cognition were also collected to evaluate the effect of the upper limb and cognitive exercise program undertaken by the control group. Upper limb function was assessed using three items of the Motor Assessment Scale (MAS) for stroke⁵¹ and the nine hole peg test.⁵² Upper arm function (MAS item 6), hand function (MAS item 7) and advanced hand activities (MAS item 8) were all scored on a scale from 0-6 for the affected arm. The time taken (in s) to complete the nine hole peg test was also measured for the affected hand and intact hands. Cognition was measured using the Montreal Cognitive Assessment and the letter cancellation test. The Montreal Cognitive Assessment assesses different cognitive domains: attention and concentration; executive functions; memory; language; visuoconstructional skills; conceptual thinking; calculations; and orientation.⁵³ The Montreal Cognitive Assessment is scored from 0-30 points. Accuracy (%) and speed (time/letter in s) on the letter cancellation test⁵⁴ was also measured.

Data on sustainability of the exercise program was not completed as originally planned. Insights into sustainability of the exercise programs after the research phase was gleaned from assessing attendance records of exercise classes held after the research phase, to determine the number of participants offered ongoing exercise classes. The uptake of referrals to Heartmoves was also evaluated.

Compliance with trial method

To assess compliance with the trial method therapists kept attendance records for each exercise class and collected participant's self completed record sheets of home programs.

Therapists estimated the number of prescribed home sessions per week and rated the intensity of the home program and compliance at 3, 6 and 12 months. Intensity of exercise was rated for balance and strength components on a scale of 0-3 with 0= none, 1=low, 2=moderate, 3=high. Compliance was rated at 3, 6, 13 months on a scale from 0-3 with 0=nil, 1=low, 2=moderate and 3=high.

Statistical analysis

All primary analyses were by 'intention to treat'. Analyses were conducted using the SPSS Version 17.0.¹⁵⁵ and Stata version 10³⁷ software packages. Missing data for individual variables were imputed using regression, where possible. Overall missing data was less than 10 per cent. The number of falls per person-year was compared between groups using incidence rate ratios from negative binomial regression to estimate the difference in fall rates. The proportion of fallers in each group was compared using the relative risk and its 95% confidence interval (CI). Between-group comparisons for the post intervention evaluation for the continuously-scored outcome measures were made using General Linear Models (ANCOVA) controlled for baseline values. When distributions were highly skewed, change scores were compared using linear regressions. Categorical data were dichotomised and between-group differences were compared using logistic regression models. The level of significance was set as $p < 0.05$ and the mean difference between the groups using a CI calculation were undertaken for all the outcome measures. A 'per protocol' analysis on the primary outcome measures was also undertaken. Participants who had attended more than 20 per cent of classes were included in the per protocol analyses.

A post hoc exploratory analysis was undertaken to assess whether there was a differential effect of the intervention on the primary outcomes and on physical activity levels based on baseline walking speed. Statistically, this effect was quantified using interaction terms (group allocation and initial fast walking speed) in linear regression models. However, for ease of interpretation and presentation of these analyses, we divided the sample into two sub-groups, participants with a baseline fast walking speed greater than 0.8m/s were classified as faster walkers and those less than or equal to 0.8m/s slower walkers. This cut-off was the criterion used by Perry and colleagues for those classified as full community ambulators.⁵⁶ Moreover, others have reported improving walking speed above this cut-off was associated with better function and quality of life.⁵⁷

Table 2: Characteristics of participants in experimental and control groups on entry to study and those lost to follow-up

Characteristic	Randomised		Lost to follow-up	
	Experimental (n=76)	Control (n=75)	Experimental (n=11)	Control (n=7)
Age (yr) mean (SD; range)	66.7(14.3; 31-91)	67.5 (10.2; 40-85)	65.6 (21.5;37-91)	72.3(8.3;60-81)
Years since stroke at enrolment mean (SD; range)	6.7(6.7;0.1-24.8)	5.2 (5.4;0.2-25.1)	5.2(7.0;0.9-23.4)	5.4 (3.9; 1.4-10.6)
Mini-mental score (0-30) mean (SD; range)	27 (3;20-30)	27 (3;20-30)	26 (4;20-29)	27 (3;22-30)
Gender, males n (%)	38 (50)	40 (53)	5 (46)	5 (71)
Hemiplegia right side n (%)	34 (45)	28 (37)	4 (36)	2 (28)
Recurrent falls n (%)	19 (25)	19 (25)	4 (36)	2 (28)
Fear of falling n (%)	34 (45)	31(41)	5 (46)	0 (0)
Visual Impairment n (%)	61 (80)	56 (75)	7 (64)	6 (86)
Hearing Impairment n (%)	26 (34)	26 (35)	4 (37)	3 (43)
Parkinson's Disease n (%)	1 (1)	1 (1)	0 (0)	0 (0)
PVD/Leg ulcers n (%)	4 (5)	5 (7)	0 (0)	1 (14)
Diabetes n (%)	16 (21)	14 (19)	4 (36)	2 (29)
Heart condition n (%)	26 (34)	28 (37)	3 (27)	2 (29)
Hypertension n (%)	44 (58)	44 (59)	4 (36)	3 (43)
Asthma/COPD n (%)	16 (21)	11 (15)	0 (0)	2 (29)
Incontinence n (%)	20 (26)	19 (25)	2 (18)	2 (29)
Epilepsy n (%)	14 (18)	11 (15)	0 (0)	1 (14)
Osteoporosis n (%)	16 (21)	8 (11)	2 (18)	1 (14)
Arthritis n (%)	34 (45)	28 (37)	3 (27)	2 (29)
Hip Fracture n (%)	5 (7)	2 (3)	0 (0)	0 (0)
Vertigo/Dizziness n (%)	29 (38)	26 (35)	5 (46)	2 (29)
Pain n (%)	47 (62)	52 (69)	8 (73)	2 (29)

Table 3: Number and percentage of experimental and control participants recruited to each stroke club and those lost to follow up

Stroke club	Randomised		Lost to follow-up	
	Experimental (n=76) n (%)	Control (n=75) n (%)	Experimental (n=11) n (%)	Control (n=7) n (%)
A	13 (17)	11 (15)	3 (27)	0 (0)
B	2 (3)	3 (4)	1 (9)	1 (14)
C	6 (8)	7 (9)	2 (18)	1 (14)*
D	13 (17)	14 (19)	0 (0)	4 (57)*
E	3 (4)	3 (4)	1 (9)	0 (0)
F	7 (9)	8 (11)	0 (0)	0 (0)
G	7 (9)	7 (9)	2 (18)	1 (14)*
H	5 (7)	4 (5)	0 (0)	0 (0)
I	7 (9)	5 (7)	0 (0)	0 (0)
J	5 (7)	4 (5)	1 (9)	0 (0)
K	8 (11)	9 (12)	1 (9)	0 (0)

Note: *denotes a participant died during research period.

unable to provide a suitable exercise class at an appropriate location and/or time to enable these individuals to participate.

One hundred and fifty-one participants (73 female, 78 male), with an average age of 67 (SD 12) and average time since stroke of 5.9 (SD 6.1) years were recruited to the study

between November 2006 and January 2009. Seventy-six participants were allocated to the experimental group and 75 to the control group. Three participants died (experimental=0, control=3) and another 15 did not complete the 12 month follow-up assessment (experimental=11, control=4). At baseline the groups were similar in terms of age, sex, time since stroke to admission

Table 4: Characteristics of project implementation of participating stroke clubs

Stroke club	Class Frequency	Duration of classes(months)	Venue for classes	Venue Cost	Sustainability option implemented
A	weekly	36	Stroke club venue	Free	Ongoing classes at club then referral to Heartmoves
B	weekly	1	Stroke club venue	Free	referral to Heartmoves
C	weekly	22	Stroke club venue	Free	Ongoing classes at club then referral to Heartmoves
D	weekly	30	Stroke club venue	Free	Ongoing classes at club then referral to Heartmoves
E	weekly	12	Stroke club venue	Free	referral to Heartmoves
F	weekly	12	Stroke club venue	Free	referral to Heartmoves
G	weekly	15	Stroke club venue	Free	referral to Heartmoves
H	weekly	12	Alternate venue	Free	referral to Heartmoves
I	weekly	12	Alternate venue	\$25/week	referral to Heartmoves
J	fortnightly	12	Stroke club venue	Free	referral to Heartmoves
K	weekly	24	Alternate venue	\$25/week	Ongoing classes at club then referral to Heartmoves

to the study, side of hemiparesis, history of recurrent falls, fear of falling and other co-morbidities (Table 2).

Exercise classes were established at 11 stroke clubs. The number of participants recruited at each club varied ranging from six (club E) to 27 (club D) however, the number of participants in each group was similar at each club (Table 3).

Eight physiotherapists, on average 28 (SD 13) years since graduating, provided the intervention. Six had relevant post graduate qualifications and seven had research experience. All therapists provided both experimental and control intervention at the nominated stroke club. One therapist delivered the intervention at four clubs whereas the other seven delivered the intervention at only one stroke club each.

The characteristics of the project implementation for each of the participating stroke clubs are presented in Table 4. All but one club (club J) established weekly classes. The majority of classes were held at the same venue as regular stroke club meetings, however we were required to pay a modest fee to hire a venue for two of the three clubs who required an alternative venue. One club (club B) withdrew involvement after one month for a variety of reasons including: difficulty encountered with venue; opposition from club volunteers; clashes with club activities; and transport deadlines. As alternative community exercise classes could not be sourced, participants from this club who wished to continue in the project were offered monthly home visits to review their exercise programs and regular phone encouragement. Exercise classes at the majority of clubs (club E, F, H, I, J) were held only for the 12

month intervention period. Clubs A, C, D and K held classes over a longer period up to three years. This allowed for progressive recruitment of new participants into the trial and created an opportunity for ongoing exercise classes for completing participants.

Compliance with trial method

The participants' record keeping of home programs was generally poor and was abandoned early in the trial to focus participants' attention on recording a primary outcome (falls) and returning their monthly falls calendars.

Class attendance records indicated most participants received the intervention as allocated. Aside from the 18 withdrawals, only six participants (experimental=1; control=5) did not attend a single class. Although 40 classes was the recommended dose, on average the experimental group had access to 32 (SD 8) classes and the control group 31 (SD 9) classes. The class attendance was similar between the groups. On average the experimental group attended 20 (SD 10) classes and the control group 19 (SD 12). The experimental group's attendance level was 63 per cent (SD 27) of available classes and 51 per cent (SD 26; range 0-90) of the intended number of classes. The control group's attendance level was 62 per cent (SD 32) of available classes and 49 per cent (SD 29; range 0-95) of the intended number of classes.

Therapist ratings indicating compliance and adherence of the experimental participants to their home program were available for 61 (94%) experimental participants who completed the trial. The mean intensity for balance component was 2.3 (SD 0.5) and strength 1.9 (SD 0.6),

Table 5: Falls data for experimental and control groups and between group differences

Falls	Group		Difference between groups RR/IRR* (95% CI, p value)
	Experimental n=76	Control n=75	
Overall			
Total number of falls	129	133	
Fallers n (%)	47 (62)	38 (51)	RR 1.22 (0.91 to 1.62, 0.19)
Fall rates (falls/person) mean (SD; Range)	1.7 (2.5; 0-15)	1.8 (3.6; 0-22)	IRR 0.96 (0.59 to 1.51, 0.88)
Slower walkers (falls/person) mean (SD)	2.4 (3.2)	1.6 (2.9)	IRR 1.46† (0.77 to 2.80, 0.27)
Faster walkers (falls/person) mean (SD)	1.1 (1.3)	1.9 (4.2)	IRR 0.57† (0.28 to 1.17, 0.13)
Fall rates by location and activity			
Inside (falls/person) mean (SD; Range)	1.2 (1.9; 0-9)	1.1 (2.1; 0-9)	
Outside (falls/person) mean (SD; Range)	0.5 (1.1; 0-6)	0.7 (1.9; 0-14)	
Fall rates by activity			
Walking (falls/person) mean (SD; Range)	0.7 (1.2; 0-5)	0.9 (2.1; 0-10)	
Transferring bed/chair (falls/person) mean (SD; Range)	0.2 (0.9;0-7)	0.1 (0.3; 0-1)	
Sit-to-stand (falls/person) mean (SD; Range)	0.3 (1.2;0-5)	0.2 (0.7;0-4)	

Notes: *RR= relative risk; IRR= incidence rate ratio; †There was a significant differential effect of the experimental intervention based on baseline fast walking speed as evidenced by a significant interaction term (walking speed x group) IRR=0.36 (0.14 to 0.92, p=0.03). The sample has been stratified into slower (walking speed ≤0.8m/s) and faster walkers (baseline fast speed >0.8m/s) for ease of interpretation and presentation.

Table 6: Number and proportion of falls, resulting injuries, falls location and activities resulting in falls

Falls	Experimental (n=129) n (%)	Control (n=133) n (%)
Injurious falls		
Fractures	10 (8)	5 (4)
Neck of femur	2	1
Arm	2	3
Finger	1	0
Ribs	3	1
Spine	2	0
Minor injuries*	62 (48)	46 (35)
Falls by location		
Inside falls	88 (68)	82(62)
Outside falls	41 (32)	51 (38)
Falls by activity		
Walking falls	50 (39)	63 (47)
Transferring bed/chair falls	13 (10)	5 (4)
Sit-to-stand falls	21 (16)	17 (13)

Note: *minor injuries were defined as abrasions, bruising and sprains

which means the balance intensity was between moderate and high and the strength component close to moderate. The mean number of sessions prescribed a week was 3.4 (SD 1.2). The estimated compliance drop over the 12 month period being rated 2.1 (SD 0.9) or moderate at three months; 1.6 (SD 0.9) or low/moderate at six months and 1.1 (SD 1.0) or low at 12 months.

No falls occurred during the exercise classes, home program or assessments and there were few adverse events in either group. Of the 18 withdrawals only one was related to the intervention. One participant withdrew as the experimental exercise exacerbated an incontinence problem. Ten withdrawals were due to ill health related to co-morbidities or ill health of family members or carers. Two participants moved away and could not be contacted for reassessment. Two participants refused to participate in classes or reassessment and another was unavailable for reassessment. Three participants died during the study period, two of these deaths appeared related to falls: one died several months after a fall at home; and one had a stroke, fractured his shoulder and died in hospital.

Effect of experimental group intervention

Results for the primary outcomes are presented in Tables 5-8, the secondary outcomes in Table 9. Health service utilisation data are presented in Table 10. Additional measures of impairment and activity limitation which may help explain changes in primary and secondary measures are presented in Table 11.

Primary outcomes

Falls

Falls data were available from all 151 participants, for an average of 339 days (SD 80) for the experimental group

Table 7: Walking speed and capacity of experimental and control group participants and the differences within and between groups

Mobility	Groups				Difference within groups:		Difference between groups:
	Month 0		Month 12		Month 12 minus Month 0		Month 12 adjusted for Month 0
Primary outcomes	Experimental (n=76) Mean (SD)	Control (n=75) Mean (SD)	Experimental (n=65) Mean (SD)	Control (n=68) Mean (SD)	Experimental (n=65) Mean (SD)	Control (n=68) Mean (SD)	Experimental minus Control Mean (95%CI, p value)
Comfortable walking speed (m/s)	0.72 (0.36)	0.67 (0.38)	0.74 (0.39)	0.67 (0.37)	0.01 (0.17)	-0.01 (0.15)	0.03 (-0.03 to 0.08, p=0.35)
Fast walk speed (m/s)	0.87 (0.46)	0.84 (0.52)	0.89 (0.49)	0.80 (0.48)	0.01 (0.20)	-0.06 (0.18)	0.07 (0.01 to 0.14, p=0.03)
Walking capacity (m)	233 (124)	220 (131)	273 (133)	224 (135)	32 (37)	-2 (50)	34 (19 to 50, p<0.001)

and 351 days (SD 54) for the control group. During the 12 month follow up period, 129 falls were reported by participants in the experimental group and 133 falls were reported by participants in the control group (Table 5). The number of falls per person ranged from zero to 22. Forty-seven (62%) experimental and 38 (51%) control participants fell during the 12 month period. Most falls occurred inside and walking was the activity most frequently reported to be associated with falls for both groups (Table 6). The majority of falls resulted in either no injury or minor injury (cuts, abrasion, bruising). Fifteen falls resulted in fractures, 10 in the experimental group and five in the control group. This difference between groups in fracture rate was not significant (IRR 2.03, 95% CI 0.69 to 6.02, p=0.20). There were no differences in the proportion of fallers or the rate of falls between groups. However there was a significant differential effect of the experimental intervention on fall rates based on initial fast walking speed as evidenced by a significant interaction term (initial walking speed x group, IRR=0.36, 95% CI 0.14 to 0.92, p=0.03). The experimental intervention was therefore more likely to prevent falls for those with faster walking speeds. When the sample was stratified by walking speed, the faster walkers in the experimental group had on average 43 per cent fewer falls (95% CI 72% fewer falls to 17% more falls) than the faster walkers in the control group. In contrast the experimental slower walkers had on average 46 per cent more falls (95% CI 23% fewer falls to 180% more falls) than control slower walkers.

Walking

After 12 months, the experimental group walked significantly further in six minutes and significantly faster over 10m (when trying to walk quickly) than the control

group after controlling for baseline performance (Table 7). There was no significant difference between the groups for walking at a comfortable speed.

There was a trend to a greater effect of the intervention on both walking distance and walking speed in those with faster baseline walking, but this did not reach statistical significance (interaction term fast walking speed p=0.10; walking capacity p=0.11). In the subgroups, the experimental faster walkers walked significantly further in six minutes and significantly faster over 10m than the control faster walkers after controlling for baseline performance (Table 8).

Secondary outcomes

Falls risk score

Before the intervention both groups had a PPA falls risk score of approximately three indicating a very high risk of falling (Table 9). After the 12 month intervention there was no difference in falls risk between the groups.

Physical activity

Before the intervention the mean physical activity was 3,417 and 3,284 steps/day for the experimental and control groups respectively (Table 9). After the 12 month intervention, on average the experimental group increased their physical activity by 622 steps/day more than the control group, however this difference did not meet statistical significance.

There was a trend to larger effects of the intervention on physical activity based on walking speed (walking speed x group interaction, p=0.30). In the subgroups, the experimental faster walkers increased their physical activity

Table 8: Slower and faster walkers' fast walking speed, walking capacity and physical activity and the differences within and between experimental and control groups

Subgroup analyses	Groups				Difference within groups:		Difference between groups:
	Month 0		Month 12		Month 12 minus Month 0		Month 12 adjusted for Month 0
	Experimental Mean (SD) n	Control Mean (SD) n	Experimental Mean (SD) n	Control Mean (SD) n	Experimental Mean (SD) n	Control Mean (SD) n	Experimental minus Control Mean (95% CI, p value)
Fast walking-10m speed							
Slower walkers* (m/s) mean (SD)	0.46 (0.22) n=35	0.42 (0.21) n=38	0.50 (0.30) n=30	0.42 (0.25) n=32	0.02 (0.21) n=30	0.01 (0.12) n=32	0.01 (-0.07 to 0.1, p=0.75)
Faster walkers [†] (m/s) mean (SD)	1.21 (0.30) n=41	1.27 (0.37) n=37	1.23 (0.35) n=35	1.1 (0.36) n=36	0.01 (0.21) n=35	-0.11 (0.21) n=36	0.12 (0.02 to 0.21, p=0.02)
Walking capacity-6 min distance							
Slower walkers* (m) mean (SD)	128 (79) n=35	121 (60) n=38	158 (81) n=30	124 (79) n=32	25 (35) n=30	6 (37) n=32	17 (-1 to 36, p=0.07)
Faster walkers [†] (m) mean (SD)	324 (74) n=41	321 (105) n=37	372 (74) n=35	312 (111) n=36	38 (39) n=35	-10 (59) n=36	49 (25 to 72, p<0.001)
Physical activity-7 day pedometer							
Slower walkers* (steps/day) mean (SD)	2,039 (1,639) n=35	1,694 (1,881) n=38	2,578 (1,996) n=29	1,948 (1,929) n=29	383 (1,933) n=29	119 (1,608) n=29	413 (-440 to 1,265, p=0.34)
Faster walkers [†] (steps/day) mean (SD)	4,594 (2,885) n=41	4,916 (3,699) n=37	5,844 (3,540) n=35	4,594 (3,685) n=33	1,033 (2,135) n=29	174 (2,254) n=29	873 (-199 to 1,945, p=0.11)

Notes: *slower walkers are those with a baseline fast speed of ≤ 0.8 m/s; [†] faster walkers are those with a baseline fast speed of >0.8 m/s

by 873 steps/day more than the control faster walkers however this difference did not meet statistical significance (Table 8).

Participation and health-related quality of life

There were significant between-group differences in participation in two of the four domains of the AAP (Table 9). After the 12 month intervention the experimental group scored 0.9 points higher than the control group in the 'service to others' domain. Interestingly over the same period, in the 'social activities' domain the control group scored 0.8 points higher than the experimental group. There were no between group differences in 'domestic chores' or 'household maintenance' domains. Similarly, there was no difference between the groups in the health-related quality of life measures.

Health service utilisation

Descriptive information on the utilisation of health services is presented in Table 10. This data was recorded on the monthly falls calendars. The health utilisation data should

be interpreted cautiously as there was no data for 25 per cent of the experimental group participants and 15 per cent of the control group participants. In addition much of the data presented in Table 10 is incomplete as monthly calendars documenting health service utilisation were often not returned. There was no significant difference between the groups in proportion of those hospitalised [relative risk (RR) 1.29; 95% CI 0.67 to 2.48, p=0.51] nor the number of days hospitalised (IRR 1.76, 95% CI 0.45 to 6.91; p=0.42).

Additional measures

Measures of impairment and activity limitation are presented in Table 11. The only significant between group differences were in choice stepping reaction time and intact knee extensor strength. After the 12 month intervention, the experimental group completed the choice stepping task 10s faster than the control group after controlling for baseline performance. Similarly, the experimental group had increased their intact knee extensor strength by 3kg compared to the control group.

Table 9: Secondary outcomes and the difference within and between experimental and control groups

Secondary outcomes	Groups				Difference within groups:		Difference between groups:
	Month 0		Month 12		Month 12 minus Month 0		Month 12 adjusted for Month 0
	Experimental (n=76) Mean (SD)	Control (n=75) Mean (SD)	Experimental (n=65) Mean (SD)	Control (n=68) Mean (SD)	Experimental (n=65) Mean (SD)	Control (n=68) Mean (SD)	Experimental minus Control Mean (95% CI, p value)
Falls Risk							
Physiological Profile Assessment (Score)	3.1 (1.3)	2.8 (1.2)	3.0 (1.6)	2.9 (1.4)	0.0 (1.1)	0.1 (1.2)	-0.02 (-0.4 to 0.4, p=0.93)
Physical Activity							
7 day Pedometer count (steps/day)	3,417 (2,702)	3,284 (3,325)	4,365 (3,350)	3,357 (3,256)	738 (2056) n=64	148 (1963) n=62	622 (-88 to 1332, p=0.09)
Quality of Life							
SF12v2 Physical Composite (0-100)	37 (10)	33 (9)	37 (9)	35 (10)	0 (9)	2 (9)	0 (-3 to 3, p=0.98)
SF12v2 Mental Composite (0-100)	50 (11)	50 (12)	50 (10)	50 (11)	0 (11)	0 (12)	0 (-3 to 3, p=0.96)
Participation: Adelaide Activities Profile (AAP) Domains*							
AAP Domestic Chores (0-24)	12.0 (6.9) n=70	10.8 (7.3) n=68	12.7 (7.8) n=62	10.4 (7.3) n=67	-0.1 (4.3) n=58	-0.4 (4.1) n=61	0.4 (-1.1 to 1.9, p=0.63)
AAP Household Maintenance (0-21)	7.5 (5.1) n=69	7.7 (5.1) n=69	8.3 (5.1) n=61	7.1 (5.1) n=65	0.4 (3.6) n=56	-0.8 (4.3) n=60	1.2 (-0.2 to 2.5, p=0.09)
AAP Service to Others (0-15)	4.5 (2.9) n=69	4.7 (3.3) n=68	5.5 (3.1) n=62	4.5 (2.5) n=64	0.5 (2.7) n=57	-0.4 (2.6) n=59	0.9 (0 to 1.7, p=0.04)
AAP Social Activities (0-12)	5.1 (1.6) n=67	4.8 (2.0) n=69	5.0 (2.1) n=62	5.5 (2.2) n=66	-0.3 (2.2) n=55	0.6 (2.4) n=61	-0.8 (-1.6 to -0.1, p=0.04)

Note: *AAP questionnaire data missing relevant, n are noted for each group and domain

Table 10: Number of participants in experimental and control groups who consulted health professionals or were admitted to hospital, and the average number of consultations and days in hospital over the 12 month research phase

Health utilisation outcomes	Group	
	Experimental (n=57)	Control (n=64)
Visited doctor n (%)	51 (89)	54 (84)
Number of doctor visits mean (SD; range)	8 (15; 0-99)	9 (9; 0-45)
Visited to and/or by health worker n (%)	23 (40)	37 (58)
Number of health worker visits mean (SD; range)	7 (22;0-136)	17 (53; 0-304)
Number of participants hospitalised n (%)	15 (26)	13 (20)
Hospital days mean (SD; range)	4.4 (10.6; 0-48)	2.5 (7.6; 0-39)

Note: Health utilisation data should be interpreted with caution as there was no data for 25% of experimental group participants and 15% of control group participants.

Table 11: Impairment and activity outcomes and the differences within and between experimental and control groups

Impairment and activity outcomes	Groups				Difference within groups:		Difference between groups:
	Month 0		Month 12		Month 12 minus Month 0		Month 12 adjusted for mMonth 0
	Experimental (n=76) Mean (SD)	Control (n=75) Mean (SD)	Experimental (n=65) Mean (SD)	Control (n=68) Mean (SD)	Experimental (n=65) Mean (SD)	Control (n=68) Mean (SD)	Experimental minus Control Mean (95% CI)
Impairment: Dexterity							
Choice Stepping Reaction Time (s)	63.5 (30.8)	61.0 (29.4)	58.7 (31.4)	67.7 (34.6)	-4.4 (28.9)	6.6 (33.5)	-10.3 (-20.0 to -0.5, p=0.04)
Impairment: Strength							
Affected Knee Strength (kg)*	19.9 (10.2)	18.3 (8.7)	20.5 (8.4)	18.6 (8.4)	0.4 (7.7)	0.1 (6.9)	0.95 (-1.2 to 3.1, p=0.38)
Intact Knee Strength (kg)*	25.0 (10.7)	23.9 (10.1)	26.6 (8.5)	23.0 (10.6)	1.2 (7.3)	-1.3 (9.5)	3.0 (0.4 to 5.5, p=0.03)
Impairment: Balance							
Maximum Sway Range (mm)	114 (57)	117 (61)	123 (70)	118 (67)	9.3 (60.7)	2.7 (61.0)	6 (-13 to 26, p=0.53)
Coordinated stability (error)	211 (197)	201 (193)	194 (208)	233 (223)	-12 (12)	26 (151)	-38 (-91 to 15, p=0.16)
Single Leg Stance-Intact (s)	5.0 (8.0)	5.5 (8.6)	6.2 (8.9)	6.5 (13.5)	1.2 (10.0)	0.9 (8.4)	0.1 (-3.0 to 3.3, p=0.93)
Single Leg Stance-Affected (s)	1.5 (2.4)	1.8 (4.5)	3.1 (6.6)	2.2 (6.2)	1.5 (5.5)	0.3 (2.8)	1.3 (-0.1 to 2.8, p=0.08)
Activities							
Timed 5 STS (s)	23.7 (14.3)	24.2 (13.9)	20.4 (12.6)	23.4 (15.9)	-1.9 (6.0)	-1.2 (12.9)	-1.1 (-4.5 to 2.4, p=0.54)
Timed Up and Go (s)	25.0 (28.3)	30.2 (32.9)	26.3 (34.7)	28.6 (28.3)	4.2 (27.1)	-1.2 (18.3)	5.1 (-2.9 to 13.1, p=0.21)
Step test Intact (#)	5.7 (4.5)	5.9 (4.4)	6.3 (5.1)	6.0 (6.0)	0.6 (2.9)	0.1 (3.5)	0.5 (-0.6 to 1.6, p=0.37)
Step Test Affected (#)	5.4 (4.0)	5.2 (4.1)	5.8 (4.5)	5.4 (5.3)	0.4 (2.8)	0.2 (3.2)	0.3 (-0.8 to 1.3, p=0.60)

Note: *Month 12 and within group comparisons experimental (n=64) and control (n=66).

Per protocol analysis

The results for the primary outcomes were similar when a per protocol analysis was undertaken. Participants had to have attended more than eight (20%) of the recommended 40 exercise classes to be included in these analyses. One hundred and fourteen participants met this criterion. The experimental participants walked 33m (95% CI 18 to 49 p<0.001) further in six minutes and 0.08m/s (95% CI 0.01 to 0.15, p=0.03) faster over 10m than control participants. There was no difference in the rate of falls between the groups (IRR 1.15, 95% CI 0.69 to 1.93, p=0.574). The per

protocol results were therefore very similar to the intention to treat results.

Sustainability evaluation

The sustainability evaluation data is presented in Tables 12 and 13. Four of the 11 stroke clubs were able to provide ongoing exercise classes after the research phase. Overall, 69 participants were offered ongoing exercise classes at their stroke club, with only 26 (38%) participating in at least one class and only 18 (26%) participating regularly. Participants were charged a fee of \$6 for these classes and

Table 12: Ongoing exercise participation in stroke clubs offering classes after the research phase

Stroke club	Participants offered ongoing exercise classes	Participants who completed ≥ 1 classes after research phase	Participants who undertook exerciseclassesonongoingbasis
	n (%) [*]	n (%) [†]	n (%) [‡]
A	20 (95)	14 (70)	7(50)
C	12 (92)	0 (0)	0 (0)
D	22 (92)	7 (32)	6 (88)
K	15 (94)	5 (33)	5 (100)

Notes: ^{*}proportion of participants completing trial at each club; [†]proportion of participants offered ongoing exercise classes at the club; [‡]proportion of those who attended at least one class in the club

Table 13: Ongoing exercise participation through referral and participation in Heartmoves

Stroke club	ParticipantsreferredtoHeart-moves	Participantswhoattendeda Heartmoves class	Participants who continued Heartmoves at 3 months
	n (%) [*]	n (%) [†]	n(%) [‡]
A	11 (46)	6 (55)	6 (100)
B	1 (20)	0 (0)	0 (0)
C	4 (40)	0 (0)	0 (0)
D	10 (43)	1 (10)	1 (100)
E	1 (20)	0 (0)	0 (0)
F	8 (53)	0 (0)	0 (0)
G	4 (36)	0 (0)	0 (0)
H	2 (22)	0 (0)	0 (0)
I	12 (100)	2 (17)	2 (17)
J	3 (38)	0 (0)	0 (0)
K	8 (44)	0 (0)	0 (0)

Notes: ^{*}proportion of participants completing trial at each club; [†]proportion of participants referred from club; [‡]proportion of those who attended one Heartmoves class from club

across the four clubs we collected \$1,272 which was equivalent to 212 class fees.

Seventy participants returned the permission form for generating a Heartmoves referral, 64 (91%) of which gave permission to be referred to Heartmoves³⁴ and agreed to be telephoned three months later. At the three month follow-up only nine (14%) participants had taken up the referral to Heartmoves. The Heartmoves class undertaken by six participants was run at one stroke club (Club A) during the meeting time. The project coordinator had negotiated with the Heartmoves provider to take over classes prior to finishing the project at the stroke club. Only three (5% of referrals) participants had managed to participate in Heartmoves classes at a venue not involved in the project.

At the stroke club's request the research team endeavoured to source a local exercise professional to take over classes on a self-funding basis at the completion of the project. Five stroke clubs (Clubs A, D, F, I and K) were interested in pursuing this option; however we were only able to find an

exercise professional for Club A, a local Heartmoves provider who provided an exercise class on a weekly basis. As of 19 August 2010, the Heartmoves class continues to run at the stroke club with the six participants exercising on a regular basis. There were two main barriers to sourcing an exercise professional to take over classes at the stroke clubs. The first was identifying a person able to deliver the class on the scheduled day and time, and the second, when a professional was identified, the proposed fee structure was deemed unaffordable by the stroke survivors.

Effect of the control intervention

Results of measures of upper limb function and cognition which allow for the examination of the efficacy of the upper limb cognitive program are presented in Table 14. There were no significant between group differences in any measures of upper limb and hand function nor cognition.

Table 14: Upper limb function and cognitive outcomes and the differences within and between experimental and control groups

Upper limb and cognitive outcome	Groups				Difference within groups		Difference between groups
	Month 0		Month 12		Month 12 minus Month 0		Month 12 adjusted for Month 0
	Experimental (n=76) Mean (SD)	Control (n=75) Mean (SD)	Experimental (n=65) Mean (SD)	Control (n=68) Mean (SD)	Experimental (n=65) Mean (SD)	Control (n=68) Mean (SD)	Experimental minus Control Mean (95% CI)
Upper limb function							
Affected Upper Arm Function MAS item 6 (0-6)	4.3 (2.2)	3.7 (2.6) n=74	4.2 (2.3) n=64	3.7 (2.5) n=67	-0.1 (1.0) n=64	0.1 (1.1) n=66	-0.1 (-0.4 to 0.3, p=0.64)
Affected Hand Movements MAS Item 7 (0-6)	4.0 (2.6)	3.5 (2.7) n=74	4 (2.6) n=64	3.3 (2.7) n=67	0(0.6) n=64	-0.1(0.8) n=66	0.1 (-0.1 to 0.4, p=0.28)
Affected Advanced Hand Activities MAS Item 8 (0-6)	3.8 (2.8)	3.2 (2.9) n=74	3.6 (2.8) n=64	3.0 (2.9)	0 (1.5) n=64	-0.2 (1.1) n=67	0.2 (-0.3 to 0.7, p=0.37)
Affected Hand 9 peg hole test (s)	160.0 (157.7) n=75	195.3(159.0) n=73	165.0 (159.4) n=62	203.4 (161.5) n=66	0 (6.3) n=61	-1.4 (9.5) n=64	1.5 (-0.5 to 3.4, p=0.13)
Intact Hand 9 peg hole test (s)	28.4 (8.3)	27.5 (8.1)	29.0 (9.0) n=64	26.9 (6.3) n=67	0.9 (4.9) n=64	-0.3 (7.4) n=67	1.5 (-0.5 to 3.4, p=0.13)
Cognition							
Montreal Cognitive Assessment (0-30)	22.0 (6.5)	22.1 (5.9)	23.3 (5.6) n=64	22.3 (6.5)	0.9 (4.1) n=64	0.3 (3.2)	0.7 (-0.5 to 1.9, p=0.27)
Letter cancellation task Accuracy (%)	89.4 (15.2)	91.7 (11.3)	94.1 (7.4)	92.3 (14.0)	4.9 (13.4) n=62	0.6 (13.6)	2.7 (-0.8 to 6.3, p=0.13)
Letter cancellation task Time/letter (s)	4.1 (2.0)	4.2 (2.0)	4.1 (1.7) n=62	6.2 (17.5)	0.1 (1.1) n=62	2.2 (16.8)	-2.0 (-6.2 to 2.1, p=0.34)

SECTION 6

Discussion

The major findings of this study were that a 12 month program of the lower limb WEBB intervention delivered via weekly exercise classes at stroke clubs and a home program was more effective than an upper limb and cognitive exercise program in improving walking capacity and fast walking speed in community dwelling stroke survivors. While there was no overall effect on preventing falls, exploratory analysis revealed a significant differential effect of the intervention according to baseline walking speed. The intervention as delivered appears to be more likely to prevent falls in faster walkers, and this differential effect warrants further investigation.

The baseline data collected in this project confirmed our sample had poor mobility and low levels of physical activity. Our sample of community dwelling stroke survivors were on average: over five years post stroke; walked at three quarters the speed and covered half the distance in six minutes of healthy older people;^{58, 59} and took approximately 30 per cent of the recommended 10,000 steps/day.⁶⁰ The 34m improvement in walking capacity achieved in this project was similar to other studies in community dwelling stroke survivors.^{15,16,61} However, the magnitude of the improvement in fast walking speed was small and of questionable clinical benefit. The mean improvement of 0.07m/s was above the 0.05m/s cut off for small meaningful changes proposed by Perera and colleagues⁶² but considerably smaller than the 0.16m/s suggested by Tilson and colleagues⁶³ as the smallest meaningful clinical improvement for individuals within two months of stroke. The improvements in walking capacity and speed were larger for faster walkers compared to slower walkers.

There were also significant between group differences in effects of the intervention favouring the experimental group in choice stepping reaction time, strength of the intact knee extensor muscle and the 'service to others' domain of the AAP. There were also trends favouring the experimental intervention in increasing physical activity and single leg stance time on the affected leg. However there was no effect of the lower limb weight-bearing exercise intervention on falls risk, health-related quality of life or health service utilisation. In general, the significant between group differences were mediated by small improvements by the experimental group and small deteriorations in performance

by the control group. This finding highlights the importance of lower limb weight bearing exercise in maintaining mobility and physical activity in community dwelling stroke survivors.

The positive findings reported in this project were achieved with a modest dose of exercise and advice to increase walking. Advice to increase walking was a controversial component of our program as in the general older population walking programs have been associated with increased falls.^{23,24} Advice to increase walking, was provided verbally at the weekly exercise class, and was included as we aimed to improve mobility, increase physical activity and prevent falls. The intended dose of the program was 40 exercise classes and a home program completed at least three times a week over 12 months. The average class adherence was only 50 per cent of the recommended 40 classes and concordance with the home program deteriorated progressively over the 12 month period. The low adherence rates and decreased concordance with the home program was not surprising given the presence of a large number of co-morbidities and also the reliance of many participants on family members and carers to access classes and assist with home programs.

The results of this project confirm that falls continue to be a common problem in community dwelling stroke survivors. In total, participants recorded 262 falls over the 12 month period. While there are no stroke-specific falls prevention trials to compare our findings, the significant differential effect of the intervention based on baseline walking speed has implications for delivery of ongoing exercise programs for community dwelling stroke survivors. Based on our results, we would recommend the lower limb WEBB program (or a similar program) and advice to increase walking as delivered in this project for stroke survivors without markedly slowed walking.

Further research is required to establish effects of exercise on fall rates among stroke survivors with greater mobility impairments as measured by slower walking speed. Lower limb weight-bearing exercise which challenges strength and balance may still be an effective intervention for slower walkers but issues around dosage and amount and nature of supervision are worthy avenues for further research. Alternatively other falls prevention strategies such as home

modifications, education and carer training may be more beneficial.

Determination of the cut-off walking speed to separate stroke survivors into slower and faster walkers requires further research. Until such research is completed, from our data a speed above 0.8m/s cut-off appears reasonable, it matches the full community ambulator classification devised by Perry and colleagues.⁵⁶ In addition achievements of speeds above 0.8m/s have been associated with improvements in function and quality of life.⁵⁷ However because of the uncertainty regarding the cut-off speed we also recommend closer monitoring and supervision of stroke survivors undertaking lower-limb weight-bearing exercise whose walking speed approximates 0.8m/s.

This project, in partnership with the NSW Stroke Recovery Association, sought to utilise the Association's stroke club network as a means of establishing sustainable ongoing exercise opportunities for stroke survivors. Recruitment of stroke clubs to the project was more difficult than anticipated. The most common barriers to stroke club participation were irregular meetings, insufficient members to make the project viable, transport issues, and an unwillingness to disrupt or change the current meeting program. However exercise classes were established in 11 stroke clubs with only one club (Club B) withdrawing from the project. One club (Club A) continues to provide ongoing exercise classes on a self-funded basis.

Referral to Heartmoves, a community exercise program initiated by the National Heart Foundation, was the other strategy to achieve sustainable ongoing exercise opportunities for stroke survivors. The poor uptake was disappointing but perhaps not surprising given the findings of a recent study. Boysen and colleagues completed a multi-national trial and found repeated encouragement and verbal instruction to increase physical activity after stroke was not effective.⁶⁴ While Heartmoves seems an appropriate ongoing community exercise program for stroke survivors, it seems further work to facilitate stroke survivors' uptake of Heartmoves is required.

An additional aim of this project was to assess the effectiveness of the control intervention on improving upper limb function and cognition by comparing the control group's performance on the upper limb and cognitive measures with the experimental group. This comparison demonstrated that the upper limb and cognitive program as delivered was not effective. There may be several reasons for this result. First,

the intervention may not have been delivered in the most appropriate way. This reason is very plausible as the training was delivered only in sitting and lying because it was the control intervention for the experimental intervention and we needed to minimise any threats to balance. In practice, however, upper limb training would occur in a range of body postures and activities. Second, the measurement tools selected may not have been sensitive enough to detect changes. Finally, as our sample was on average over five years post stroke, many had significant musculoskeletal changes in their affected arm including contracture and shoulder subluxation which may have rendered improvements in upper limb function unrealistic.

The major issue in delivering the Exercise after Stroke project was the difficulty in recruiting sufficient participants into the trial. Specifically, the main problem was the identification of sufficient potential participants to screen as we recruited 49 per cent of those we screened. Despite the high prevalence of stroke and large numbers of stroke survivors living in the community, it is evident that the recruitment strategies employed in this study did not reach sufficient potential participants to meet the recruitment target. Another study with community dwelling stroke survivors also reported difficulty in identifying potential participants to screen.⁶⁵ They used similar recruitment strategies to this study and found personal referral from a health professional was the most effective. Similarly, Lloyd and colleagues found that a print media campaign was costly and ineffective.⁶⁵

One solution to the problem of identifying potential participants is to develop a National Stroke Registry.⁶⁶ Development of the Australian Stroke Clinical Registry is underway. At this stage the purpose of the registry is to ensure equitable and quality stroke services. There is scope that in future the function of the registry could be expanded to assist stroke researchers with recruitment in a similar way to the Australian Cancer Registry that is maintained by the Cancer Council for the Australian Government.⁶⁷

There are several limitations to our study. First, our failure to meet our recruitment target of 350 resulted in the study being underpowered for falls. Second, as in most clinical trials of complex interventions, therapists and participants cannot be blinded and are therefore potential sources of bias. Third, the high levels of disability and co-morbidities resulted in variable adherence to class schedules, deteriorating concordance with the home program and incomplete datasets. We implemented rigorous statistical methods to minimise the impact of missing data.

Conclusions & recommendations

This project showed that the lower limb WEBB program delivered via weekly exercise classes at stroke clubs, a home program and advice to increase walking improved walking capacity and speed in community dwelling stroke survivors. While there was no overall effect on preventing falls, exploratory analysis revealed a significant differential effect of the intervention according to baseline walking speed. The intervention as delivered appeared to be more likely to prevent falls in faster walkers. The NSW Stroke Recovery Association stroke club network is a potential avenue to sustain exercise classes. However, sourcing an exercise professional to deliver the classes and finding sufficient stroke survivors to undertake the classes at the same location and time are known challenges which may limit viability of exercise classes at stroke clubs.

Recommendations

We recommend:

- further research is undertaken, which is sufficiently powered to explore the interaction between walking speed and the effect of lower limb weight bearing exercise on falls prevention
- weekly exercise classes, home program and advice to increase walking be implemented for community dwelling stroke survivors whose walking is not markedly slowed
- further research is undertaken on the effects of falls prevention programs for stroke survivors with markedly slowed walking
- the Australian Stroke Clinical Registry, currently in development, be fully funded and maintained so that researchers can utilise the registry to identify potential participants
- further research is undertaken to establish strategies to facilitate and support stroke survivors' participation in general community-based exercise programs as delivery of stroke only groups is unlikely to be sustainable.

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Appendix A: Published papers, abstracts and websites related to this project and contact details for further information

Papers

Tiedemann A, Sherrington C, Dean CM, Rissel C, Lord SR, Kirkham C et al. Predictors of adherence to a structured exercise program and physical activity participation in community dwellers after stroke. *Stroke Research and Treatment* Volume 2012, Article ID 136525, 8 pages, doi:10.1155/2012/136525.

Dean CM, Rissel C, Sharkey M, Sherrington C, Cumming RG, Lord SR et al. (under review) Exercise intervention to prevent falls, enhance mobility and increase physical activity in community dwellers after stroke: The stroke club randomised controlled trial. Submitted to *Neurorehabilitation and Neural repair*.

Dean CM, Rissel C, Sharkey M, Sherrington C, Cumming RG, Barker RN et al. Exercise intervention to prevent falls and enhance mobility in community dwellers after stroke: a protocol for a randomised controlled trial. *BMC Neurol*. 2009 Jul 22;9:38.

Conference presentations

- Dean CM, Sherrington C, Rissel C, Sharkey M, Cumming R, Lord S et al. Exercise intervention to prevent falls, enhance mobility and increase physical activity in community dwellers after stroke: the stroke club trial. *World Congress of Physical Therapy*; Amsterdam, Netherlands: June 2011.
- Sherrington C, Dean CM, Rissel C, Sharkey M, Cumming R, Lord S. Predicting falls in long term stroke survivors. *Australia and New Zealand Falls Prevention Society Conference*; Dunedin, NZ: November 2010.
- Dean CM, Sherrington C, Rissel C, Sharkey M, Cumming R, Lord S et al. Mobility enhancement and falls prevention after stroke: the Stroke Club trial Australia and New Zealand Falls Prevention Society Conference; Dunedin, NZ: November 2010.

- Dean CM, Rissel C, Sharkey M, Sherrington C, Cumming R, Lord S, Barker R & Kirkham C. Ongoing exercise opportunities to prevent falls and enhance mobility in community dwellers after stroke: The stroke club trial. *Stroke Society of Australasia Conference*; Melbourne: September 2010. *International Journal of Stroke* vol 5: Supplement 1 p.12
- Kirkham C, Sherrington C, Dean CM, O'Rourke S, Sharkey M, Rissel C. High prevalence of mobility-related predictors of falling in stroke club Members. *Australian Physiotherapy Association National Neurology Group Conference*; Sydney: October 2009. *The e-AJP* Vol 55:4, Supplement:12.
- Dean CM, Rissel C, Sharkey M, Sherrington C, Cumming R, Lord S et al. Ongoing exercise opportunities to prevent falls and enhance mobility in community dwellers after stroke. *Smart Strokes, 3rd Australasian Nursing & Allied Health Stroke Conference*; Sydney: August 2007.

Websites

The WEBB program is available at www.webb.org.au²⁶

Details, pictures and descriptions of many of the exercises used in both the programs are available on www.physiotherapyexercises.com³²

Contact details

Further information on project or the WEBB Program is available from Dr Catherine Dean, email: catherine.dean@mq.edu.au.

Information on the Upper Limb Program Drive Your Own Recovery is available from Dr Ruth Barker, email: ruth.barker@jcu.edu.au.

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STROKE RECOVERY ASSOCIATION NSW

Appendix C: Media release

Exercise after stroke

New free exercise classes for people who have suffered a stroke are being run as part of a unique research study aimed at improving mobility and reducing the risk of falls.

The study being run by the University of Sydney, Sydney South West Area Health Service and the Stroke Recovery Association NSW, tests an exercise program designed specifically for people who have had a stroke.

Cath Dean, chief investigator of the research trial and senior lecturer in physiotherapy from the faculty of health sciences, University of Sydney said there are very few options for people to continue exercise after stroke.

“We know that regular exercise reduces risk of falling in the general population of older adults, but we need to find out what works for people who have had a stroke and put some programs in place.

“Those who have suffered a stroke often have problems with balance and walking, and four out of five people fall within six months of being discharged from hospital,” she said.

Walter Watts who suffered a stroke four years ago is helping recruit people into the program and spread the word about the benefits of exercise.

“I started attending the exercise classes early this year.

“I’ve always believed that it’s important to be physically active and after having had more than one fall last year I knew I had to do something to avoid being seriously injured”, said Mr Watts who is in his eighties.

The study involves weekly exercise classes conducted by physiotherapists in Stroke Clubs.

Participants attend for 12 months and are also given a home exercise program.

The program is open to any adult who has experienced a stroke, walks either independently or with a walking aid, regardless of whether or not they’ve had a fall.

“I was tickled pink when I heard about the exercise classes and knew they would be good for me. My balance and confidence have improved, and it’s good to be out and about meeting new people.

“The physiotherapist who runs the program is excellent, and gives us lots of encouragement and individual attention.

“I’d encourage anyone who has had a stroke to join”, he said.

Classes are held at Cronulla, Blacktown, Hornsby, Liverpool and Woy Woy, and people can join at any time.

To join the program or for more information phone Cath Kirkham at the University of Sydney on 9351 9482.

ENDS

Issued by Sydney South West Area Health Service, Health Promotion Service. For more information contact Gai Stackpool on 9515 9074.

Have You Had A Stroke ?

Improve your
walking and arm movement.

Reduce your risk of a fall.

Join an exciting new research program.

**Get FREE exercise classes
for 12 months**

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