The feasibility of a short duration, intensive, multidisciplinary, self-managed approach to improve mobility for community stroke survivors.

A Multidisciplinary Intensive Stroke Rehabilitation Program

Research Protocol Version 1.0
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Contents

Title

The feasibility of a short duration, intensive, multidisciplinary, self-managed approach to improve mobility for community stroke survivors.

1 Study Management

1.1 Project Team Roles and Responsibilities

Principle Investigator:

1. Dr Kate Scrivener, Senior Lecturer, Macquarie University

   Dr Scrivener will supervise the design and implementation of the research project and provide advice on data analysis and manuscript preparation.

Associate Investigators:

2. Avanthi Elisha Ball (nee Rajaratnam), Master of Research Candidate, Macquarie University

   Ms Ball will complete the project as part of her MRes degree. She has conceptualised, designed, and will implement the project under the supervision of Dr Scrivener and A/Prof Glinsky.

3. Dr Joanne Glinsky, Associate Professor, Macquarie University

   Dr Glinsky will mentor and support the research team in the implementation of evidence-based practice, and provide advice on research methods, implementation, and data analysis.

1.2 Research Sites

1. Concentric Rehabilitation Centre, Suite 4, 1-17 Elsie Street, Burwood, NSW, 2134
2. Concentric Rehabilitation Centre, Suite 205/10 Norbrik Drive, Bella Vista, NSW, 2153

2 Background and Aims

2.1 Background

Stroke survivors are not routinely offered structured, intensive, and multidisciplinary rehabilitative programs in the community (1-3). Rarely are they also offered support to improve self-management skills alongside intensive rehabilitative training (2,4-5). This may be due to the lack of knowledge about the amount of therapy they should participate in (6-8). Or in part due to the 'clear and impressive void' in current literature on the development of programs for community dwelling stroke survivors to improve their physical function, mobility, and quality of life beyond acute and subacute rehabilitative settings (1). The Australian Stroke Guidelines have not yet indicated the recommended amount of practice in community-based rehabilitation, perpetuating the difficulty for community rehabilitation to deliver appropriate care in the chronic stages of recovery (1,9). The lack of research into ideal practice in the chronic phase may also result from a previously held belief that functional recovery after stroke

plateaus after 12 months, despite the evidence suggesting that improvement is possible later than this (1). In the community, increasing amounts of practice is typically through the provision of group programs as they are feasible to implement, cost efficient and can be replicated multiple times per week (1,10-12). Circuit and group classes do improve physical activity, however, do not routinely result in ongoing changes in mobility, independence, or quality of life in community dwelling stroke survivors in long term follow up (10-12).

At the study site, an intensive program is already offered, however there are numerous limitations including noting that it is an option rarely selected by clients, not structured, and simply includes more frequent appointments. The current program offering has recently been revised to include more structured support and include multidisciplinary and self-management interventions. It is important that new programs be evaluated to determine acceptability in this population and whether this type of training results in positive mobility outcomes. New programs which offer this level of training warrant further investigation and ultimately must offer stroke survivors in the community an option of training which is aspirational towards goals and pragmatic in application (13).

2.2 Rationale for Study

There was recent success of a single group study which was able to deliver an 'intensive' bout of therapy, offering 90 hours of upper limb therapy over three weeks using a multidisciplinary team (13). They observed improvement in upper limb function in a proportion of stroke survivors, these improvements were sustained at the six months follow up and were hypothesized to also be the result of building self-efficacy and education into the program (4, 13). This study suggests the feasibility of intensive and multidisciplinary models of therapy which improve upper limb activities may be suitable for community dwelling stroke survivors. Rehabilitation centres in the community, may be uniquely primed to offer the intensity of practice and the support to improve mobility for stroke survivors in the long term (1,13). Thus, there is a need for further investigation into intensive programs offered by these settings to determine what is an accepted model of training and what parameters are required to improve mobility.

The complex nature of stroke means that survivors experience multifaceted barriers to physical activity and adequate rehabilitation post stroke, including lack of motivation, external support, and stroke related impairments (14). New models of therapy in the community must address these barriers to physical activity in more wholistic methods, possibly using the breadth of the multidisciplinary team to better deliver long term care (14, 15). Currently the Australian Clinical Guidelines for Stroke makes no recommendation on the explicit need for ongoing multidisciplinary intervention throughout the rehabilitation process, including community-based rehabilitation (9,15). This is possibly due to the limited number and low quality of previous studies evaluating their efficacy and utility beyond primary care (16). Thus, the justification for an ongoing multidisciplinary intervention may be drawn from application of the International Classification of Functioning, Disability and Health (ICF) model (17). Chronic conditions and disabilities such as stroke have several characteristics which impact all domains of the ICF (17). There is an apparent need for community interventions which better address the diverse barriers to prolonged inactivity experienced by stroke survivors and resist the tendency to silo disciplines into addressing only certain aspects of the ICF domain (14,17).

Self-management is the process by which an individual is enabled to manage all the aspects of their health condition through building new health behaviours and supporting skills. Research into the utility

of self-management programs to enable ongoing self-management in stroke populations lags other chronic conditions such COPD or arthritis (19,20). Only half the number of stroke survivors in Australia were provided information about self-management programs when discharged from formal rehabilitation (21). This is despite most health professionals acknowledging that the level of structured support post discharge significantly declines (20-21). The Taking Charge After Stroke (TACAs) trial showed that self-efficacy and independence after stroke matters to stroke survivors in the community (19). A study by Marsden and colleagues (2010) showed integrating self-management and task specific training delivered by a multidisciplinary team for rural community dwelling stroke survivors improves physical performance and quality of life (2).

It is hypothesised that with the support of a self-management program delivered with the benefits of access to a multidisciplinary team and intensive training, stroke survivors living in the community may build the self-efficacy and skills required to better manage their condition. It is hoped this novel method offers an alternative to improve mobility and function and provide better tailored goal directed training.

2.3 Research aims

The primary aim of this study is to determine the feasibility of a short duration, intensive multidisciplinary therapy mobility program, delivered using a self-management approach for stroke survivors living in the community.

2.4 Research questions

1.Is it feasible to deliver a multidisciplinary, short duration, intensive program for people after stroke using a self-management approach (in terms of adherence, acceptability, cost, and safety) in a community setting?
2. Does this approach warrant further investigation, indicated by an improvement of more than 10% in the main secondary measure of the study, mobility pre and post intervention?

2.5 Hypothesis

We hypothesise that it will be feasible to implement a multidisciplinary, intensive, short duration therapy program and that this program will have a high adherence rate and acceptability. It is likely to offer an alternative option to regular therapy programs currently provided in community rehabilitation (typically either non-existent or longer duration, less frequent and not intense). In addition, community-dwelling stroke survivors may prefer this mode of therapy delivery because it offers a different structure of multidisciplinary and self-management support alongside intensity of practice. We anticipate that there will be no significant safety issues or adverse events associated with this type of program.

3 Study Design

3.1 Type of Study

A prospective single group pre and post intervention study will be conducted with participants recruited from Concentric Rehabilitation Centre at two Sydney sites (Burwood and Bella Vista) who have decided to participate in an intensive program run by the rehabilitation centre.

3.2 Study Design

The study will look at the feasibility of providing this type of training offered to clients attending the program at the study sites. As part of the intensive program, participants will undertake 45 hours (three hours for five consecutive days over three weeks) of intensive, multidisciplinary practice both in the clinic and at home. At-home therapy will be delivered by video-guided exercise programs or individualised exercise programs. The primary outcome measure for this study will be feasibility, measured by adherence, acceptability, cost and safety. The secondary outcome measures for this study will be mobility, quality of life, self-efficacy skills and goal attainment. Outcome measures will be collected just prior commencement (week 0) (T1), midpoint (second week) (T2), upon completion of the intensive program (third week) (T3) and three weeks post intensive program (T4).

3.2.1 Risks and Benefits associated with the study

Participation in this research study is considered low risk. It may be inconvenient for participants, due to the extra time required to fill out consent forms and surveys. This time will be allocated outside therapy and program time.

The potential benefits associated with this study include gains in knowledge about the feasibility of this type of training for community populations who have survived stroke. This includes a better understanding of the amount of acceptable training and potential clinical benefits in mobility, building self-efficacy and quality of life into therapy approaches and as drivers of outcomes. This study has the potential to inform future studies, programs and research.

3.3 Study Duration

The study will run for approximately 12 months including study design, recruitment, enrolment, screening, consent, intervention, follow up period, data collection and analysis. The total data collection period is 7 weeks from (T1) to (T4) including the initial assessment (T1) through to follow up three weeks after intervention with participants at (T4).

3.4 Flow of Study

An allied health clinician from the study site will collect demographic information such as age, gender, side of hemiparesis and time post stroke by asking the participant in an initial assessment and using the study demographic form (T1). In the same assessment (T1), the abilities of the participant using the Motor Assessment Scale for Stroke (MAS), Short Physical Performance Battery (SPPB), 2 Minute Walk Test (2MWT), Exercise Self Efficacy Scale (ESES) and the 12-Item Short Form Survey (SF-12) will be taken and recorded in the participant rehabilitation centre files (22-26). The clinician with the participant will then identify an 'area of difficulty' based on an individual activity limitation or participation. The clinician with the participant will establish one primary physical goal for the intervention and up to two secondary goals and score them based on the Goal Attainment Scale (GAS) (27). These outcomes and goals will be recorded the participant's rehabilitation centre files, handed over to treating therapists for the program and recorded in the participant's paper workbook.

Participants will then undergo the intervention and clinicians will record in their practice sheets the exercises completed and participant's perceived rating of exertion for each exercise for the duration

of the intensive program (via the Borg Rating of Perceived Exertion (RPE scale)) (28). After two weeks of the intensive program (T2), a summary of performance outcomes (SPPB and 2MWT) will be taken as an indicator of progress by an allied health clinician (23,24). These two outcome measures will be recorded in the participant's rehabilitation centre files and in a participant's paper workbook.

After the three-week intervention period (T3), an allied health clinician blinded to the pre-intervention outcome measures of the program will reassess the initial assessment measures (MAS, SPPB, 2MWT and SF-12, ESES) and rescore the goals (using the GAS) (22-27). These outcomes, along with the Borg perceived exertion ratings will be recorded in the participant's rehabilitation centre files (28). Participants will also be given a post intervention survey by the allied health clinician to determine the intervention's feasibility and effect on self-management and quality of life (this survey is detailed below). This survey will be completed in allocated time outside the intervention either at home or in the clinic and if needed an allied health clinician or carer will be available to support filling out the survey and collecting the surveys from participant. Completed surveys will be filed in the participant's rehabilitation centre file and in a participant's paper workbook. Participants will be followed up in three weeks (T4) by the same allied health clinician, who will complete a follow up assessment to obtain follow up outcome measures (MAS, SPPB, 2MWT, ESES SF-12) and participants will be asked to complete the same survey again under the same conditions and provisional support as the first survey (22-26). The results from the survey and the outcome measures will be filed in the participant's rehabilitation centre file.

3.5 Outcome Measures

Outcome measures will be extracted from the participant's rehabilitation centre file by the associated research investigator for this study at timepoints T1, T2, T3, T4 and are listed here below:

3.5.1 Primary Outcome Measures

Feasibility of delivering the intervention will be in assessed using measures of adherence, acceptability, cost and safety. This will be collected by an allied health clinician at timepoints (T2), (T3) and (T4).

Adherence

Adherence will be measured by each participant in a workbook. The two measures of adherence will be percentage of sessions attended and number of repetitions completed per session will recorded in the participant's rehabilitation centre files. Attaining a personal best is encouraged in each session.

Acceptability

Acceptability will be determined via two methods, extracting perceived exertion (via the Borg Rating of Perceived Exertion (RPE scale)) from the practice sheets of participants at the study site at timepoints (T2), (T3) and (T4) and via purpose-built paper survey post intervention at timepoints (T3) and (T4) (28). The practice sheets will be stored on the participant's rehabilitation centre files. The paper survey will be provided in person by an allied health clinician from the study site. A paper survey was selected as in previous research at the study site there was a poor response to an electronic survey with participants requesting a paper-based survey. We expect the survey to take approximately 10 minutes to complete, participants will be given support to complete the study in clinic or may take the survey home to complete in time allocated outside the intervention. The

participant may receive support from a family member or carer. If requested, the allied health clinician may allocate time to assist in completion of the survey. Using a Likert scale, the survey will ask four questions:

i) Were you satisfied with the program?
ii) How easy was it to participate in the program?
iii) Did the program give you adequate support?
iv) Would you recommend the program?

They will also be given free text to input an answer to the following questions:

i) What did you like or dislike about the multidisciplinary aspect of the program?
ii) What did you like or dislike about the inclusion of Take Charge and participant workbook in the program?
iii) What did you like or dislike about the amount of practice that was required?

Cost
Cost will be reported by calculating the cost of the program per individual participant based on standard clinic fees. Participants will be charged for the therapeutic program as per usual care at the study site. Participants will not be charged for any research activities include assessments, surveys or research related follow up.

Safety
Safety will be monitored during training sessions by a member of the rehabilitation team and participants will be asked to log any events occurring at home in their participant workbook. All incidents will be recorded in the rehabilitation centre files and reported by the research team.

3.5.2 Secondary Outcome Measures

Clinical outcomes
Clinical outcome will include mobility and lower limb function as well as quality of life, self-efficacy skills and goal attainment. This will be collected by an allied health clinician at timepoints (T1), (T2), and an allied health clinician blinded to the previous measures at timepoints (T3) and (T4). The secondary outcome measures and the description of how they will be used is described in Table 1 below:

Table 1: Secondary clinical outcome measures and details of their use in the study

Outcomes with Outcome Measures being used	***Description of outcome measure used***	***How and where will outcomes be measured***	***Timepoints when the outcome will be measured***
General Mobility - *Motor Assessment Scale (MAS)* (22)	The Motor Assessment Scale for stroke is a widely used performance-based scale used to measure 8 different	The MAS will be assessed using the standardised assessment protocol developed by Carr and Shepherd (1985) in	(T1) (T3) (T4)

	domains and 1 item related to muscle tone of everyday motor function in people with stroke. It has a high test-retest reliability and inter and intra-rater reliability (22).	clinic by the specified allied health clinician of the study at the noted timepoints (22).	
Mobility: Lower Limb Function and Disability - *Short Physical Performance Battery (SPPB)* (23)	The Short Physical Performance Battery is typically used to assess lower limb function in elderly community welling persons. It assesses balance, gait speed and ability to stand from sitting five times. It has been shown to be a predictor of short-term mortality, hospital admission and strongly associated with self-reported disability (23).	The SPPB will be measured using the standardised assessment protocol developed by Guralnik and colleagues (1994) in clinic by the specified allied health clinician at the noted timepoints (23).	(T1) - (T4)
Mobility: Walking Capacity - *2 Minute Walk Test (2MWT)* (24)	The Two Minute Walk Test is a shortened form of the 12- and 6-minute walk tests and is a measure of self-paced walking capacity (24).	The 2MWT will be measured using the standardised assessment protocol developed by Butland and colleagues (1982) in clinic by the specified allied health clinician at the noted timepoints (24).	(T1) - (T4)
Quality of Life- 12-Item *Short Form Survey (SF-12*) (25)	The 12- Item Short Form Survey is a self-reported measure of the impact of an	The SF-12 will be provided to participants by the specified allied health clinician at	(T1) (T3) (T4)

	individual's health on their daily life (25).	the timepoints noted in the form it was developed and no changed made to the content (25).	
Self-Efficacy- *Exercise Self Efficacy Scale (ESES)* (26)	The Exercise Self Efficacy Scale is a self-reported measure of exercise related self-efficacy and was originally used in people with spinal cord injury (26).	The ESES will be provided to participants by the specified allied health clinician at the timepoints noted and in the form it was developed with no changes made to the content (26).	(T1) (T3) (T4)
Goal Attainment- *Goal Attainment Scale (GAS)* (27)	The Goal Attainment Scale is a method of scoring the level of achievement of a participant's pre-determined goal over the course of an intervention (27).	The GAS will be provided to participants by the specified allied health clinician at the timepoints noted. It will be administered in the form it was developed and no changes made to the content, but some formatting changes made to scoring table which will be noted in more detail in the intervention manual (27).	(T1) (T3) (T4)

4 Study Treatments

4.1 Intervention

The participants will undergo the intensive program that was developed by the rehabilitation centre. The intervention is an intensive (45 hour over three weeks) therapy program delivered to a single group across two centres and provided on an 'intention to treat' basis and is described detail in the intervention manual. The intervention will be delivered by three disciplines (physiotherapy, exercise physiology and occupational therapy) working collaboratively to deliver the self-management program 'Take Charge', provide support in goal setting and deliver the strength, cardiorespiratory,

mobility and task specific therapy practice (19).

4.2 Resources

Minimal resources are required to conduct this project. All resources related to the delivery of the intervention will be provided by the research sites. Participants will be self-funding their attendance in the program as part of usual practice at the site.

5 Participant Enrollment

5.1 Recruitment

The recruitment of participants will occur over 6-month period from study commencement. As part of usual practice at the study site, clients elect to participate in an intensive multidisciplinary therapy program. The program is offered routinely in the clinic as an alternative to regular scheduled therapy and clients elect to participate in a 3-week intensive therapy program with the consent to the potential risks, costs and perceived benefit of the program. In the discussion with their elected therapist regarding the program, clients will be asked if they consent to be contacted by a member of the research team the understanding that any research conducted is additional to the program offered by the rehabilitation centre. Participants will be given 4-6 weeks to consider participation in the study.

5.2 Eligibility

The inclusion and exclusion criteria for the study are outlined below. Clients can participate in the program if:

- They are over 18 years of age
- Physical or Medical readiness to participate using the Physical Activity Readiness Questionnaire (PARQ) (29)
- They have sufficient mobility: They achieve 3 or more in the sitting component and 2 or more in the sitting to standing component of the Motor Assessment Scale for Stroke (MAS) (22).

5.3 Inclusion criteria

Participants will be included in the research study if:

- They have nominated to participate in an intensive mobility program at the study site and meet the sites criteria as listed above
- Have a primary diagnosis of stroke

5.4 Exclusion Criteria

Participants will be excluded from the research study:

- They cannot read or understand verbal or written English
- Do not have sufficient cognition to participate in a video guided or semi-supervised exercise program (as determined by their score on a Mini Mental State Examination (MMSE) > 24/30) (30).

5.5 Proposed Sample Size

An approximate sample size of fifteen people will be recruited to participate in this study. This is likely to be reflective of the size of population recruited from the intervention run by the two sites.

5.6 Informed Consent

If clients consent to being contacted to participate in the research, a rehabilitation staff member will provide a list of interested clients to the primary research investigator to be contacted via email, phone or in person. It will be made clear to the client that the decision to participate in the research is voluntary and will in no way affect their relationship or ongoing therapy with the rehabilitation centre. Investigators will provide the information and consent forms (PICF) to the clients who are interested and be available to contact should they have any questions regarding participation in the investigation. Clients who consent to participating in the research will be informed that data on their demographics, performance in the intensive program and responses to two surveys will be extracted from their client files and de-identified for group data analysis only. They will be informed that a follow up period of 3 weeks will be required after attending the intensive program as part of the research and they will need to be available for this extra time (a total of 7 weeks).

5.7 Withdrawal from the Study

Clients will be informed that they may choose to withdraw from the research at any time and it will in no way affect the intervention they continue to receive or their relationship with the rehabilitation center, and the result of their intervention will still be used to support their clinical care but will not be included in the data set. Screened participants who meet the research inclusion criteria and have consented to the collection of their data will be admitted for research data collection.

6 Data Management and Analysis

6.1 Data Collection and Management

Data collected at each time point (T1) - (T4) will be extracted from participants rehabilitation centre files with names replaced by individual participants study identification number to organise and collect the data. This data will be stored, in a locked filing cabinet at the study site in paper form.

After the intervention the consenting participants' paper data will be collected by the associate research investigator and converted to electronic files. These electronic files will be uploaded to Excel in a password protected file for storing and analysis. The database housing this information will be stored on a secure Macquarie University server and Cloudstor and will be password protected. Only the named research team will have access to the files. Any paper data will be de-identified and stored in a secured archive onsite at Macquarie University for a period of 7 years post study completion. The electronic data files will be kept on the secure Macquarie University server and Cloudstor indefinitely.

6.2 Data Analysis

De-identified data analysis will be conducted using SPSS Version 25. Demographic data will be

reported via descriptive statistics. Adherence data will be calculated from each week and from week 0 (T1) to week 3 (T2) and will be reported as mean repetitions per hour, session, and week and then as a percentage of overall sessions attended. Acceptability and self-management data will be taken from the surveys and will be reported as frequencies comparing time points week 3 (T3) and week 6 (T4). Acceptability data from the practice sheets use will be calculated from each week and from week 0 (T1) to week 3 (T3) and will be reported as mean values per week and then as a percentage overall. Paired t-tests will be used to analyse within group change over time for the clinical outcomes between week 0 (T1) to week 3 (T3) and between week 0 (T1) to week 6 (T4). Differences will be reported as a mean and 95% confidence interval.

7 Research Outcomes and Future Plans

Participants will have the opportunity to review their initial (T1) and post intervention (T3, T4) results with their treating allied health clinician (as per usual care at the study site). A publication and conference presentation are expected from this project to satisfy the requirement of the Master by Research candidature. Participants who have consented to participation in the research will be informed that only de-identified group data will be presented.

7.1 COVID impact

This project would ideally be implemented via in person therapy but can be adjusted to account for any social distancing or lockdown measures implemented because of COVID-19. In doing so the emphasis of the program may shift to more self-directed practice via remote methods, either via telehealth or via delivery of exercise programs using home-based programs and equipment or videos. If so, the program would emphasise the need for increased efficacy towards self-directed practice and could potentially identify any pragmatic determinants of implementing self-directed training. If this is the case, participants and relevant ethics committees will be notified before any changes are made to the investigation.

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