

Implementing “Stepping On after Stroke Program”: Feasibility Study Protocol

Study Title

Piloting the “Stepping On after Stroke” falls prevention program for community stroke survivors in Singapore: A feasibility study.

Abstract

This feasibility study is part of the research project in developing Stepping On after Stroke (SOS) falls prevention program for community stroke survivors in Singapore, which aims to reduce their fall rate and increase community participation. Prior to this study, systematic review was conducted to identify the fall risk factors in community stroke survivors, followed by a series of qualitative studies to seek input from various stakeholders to determine the key elements of the SOS program. Thereafter, this new program will be piloted in two day rehabilitation centers (DRC).

Pre-post design and prospective observational method will be used in this study, where 12-16 stroke clients, 12-16 family members and 12-16 domestic helpers will be recruited from **two DRCs**. This program will consist of 2-hour weekly session led by a trained Stepping On after Stroke program leader for 7 weeks; two educational sessions for family members and helpers; supervised community mobility practices in a small group; a post-intervention home visit and 3-month booster session. Stroke participants will be followed up for 6 months after week 7.

Monthly fall calendar will be used to collect fall incidents during the study. Findings from pre-post outcome measures on stroke participants’ physical mobility, fall related self-efficacy, fall risk behavior, and community participation will be collected. The caregiver’s self-assessment of health and quality of life will be collected from the family and helpers before and after the program.

Data will be analyzed to determine if the proposed measurement tools are culturally applicable and sensitive in detecting the changes in respective functions among participants. **Program evaluation survey** will be conducted with the participants and program leaders to find out their perspective of the usefulness and applicability of the program. All findings from the feasibility study will assist in further refining the program for a larger effectiveness trial.

Study period

September 2016 (KIV) – May 2017

- Subject recruitment will start only when IRB approves.
- Intervention will be from October to November 2016.
- Follow up period will be from December 2016 to May 2017.

Principle Investigator:

- Xu Tianma, Lecturer, Health & Social Sciences Cluster, Singapore Institute of Technology;
Ph.D student, The University of Sydney, Australia

Co-Principle Investigators

- Professor Lindy Clemson, Faculty of Health Sciences, The University of Sydney, Australia
- Associate Professor Koh Choon Huat Gerald, Saw Swee Hock School of Public Health, National University of Singapore
- Associate Professor Natasha Lannin, School of Allied Health, La Trobe University, Australia
- Professor Catherine Dean, Faculty of Medicine and Health Sciences, Macquarie University, Australia
- Associate Professor Kate O’Loughlin, Faculty of Health Sciences, The University of Sydney, Australia

Clinic sites for conducting this study

1. Kwong Wai Shiu Hospital Day Rehabilitation Centre
2. SPD@Toa Payoh Day Rehabilitation Center

Background

Stroke is the fourth leading cause of death and the largest cause of long-term disabilities in Singapore (Singapore Ministry of Health, 2015). In comparison with the general ageing population, stroke survivors are more likely to fall (Weerdesteyn, de Niet, van Duijnhoven, & Geurts, 2008). Falls after stroke can lead to further restriction of activities and increased dependence in mobility and self-care. At the same time, it increases the burden on family members and caregivers. Hence, an effective falls prevention program for community-dwelling stroke survivors is needed. Currently, many healthcare and community centres in Singapore are focusing on fall risk screening, however, there's a lack of evidence-based falls prevention programs for community stroke survivors at this stage.

Our research project is adapting the "Stepping On" program (Clemson et al., 2004), an evidence-based falls prevention program for community-dwelling older adults, to community stroke survivors in Singapore. This program (Clemson et al., 2012) was proven effective in a randomized trial published in the British Medical Journal reducing falls by 31% (RR=0.69) and is supported as an effective intervention in the Cochrane Systematic Review of Community Fall Prevention Interventions (Gillespie et al., 2012).

Our research study aims to design an adapted Stepping On program for community stroke survivors in Singapore so as to reduce their risk of fall and at the same time increase their community participation. The novelty of this research project is that 1. this program will be adapted for people with stroke and 2. there is currently no known effective intervention for preventing falls in people post stroke. Before it can be adopted across the community sectors in Singapore, a feasibility study using an outcomes-based approach is needed to assess whether the adapted "Stepping On after Stroke" program is culturally relevant and acceptable among stroke survivors living in the community as well as their family members and domestic helpers.

Study objectives

1. To assess the feasibility of implementing the evidence-based Australian "Stepping On" program, a group-based program that aims to reduce fall rate and increase community participation for community stroke survivors in Singapore.
2. To assess the applicability and effectiveness of such a program by examining important social and cultural parameters that are needed to design a larger-scale study, such as willingness of participants to join the group based sessions, number of eligible participants in the community settings, compliance rates, follow-up rates, response rates to fall calendar and characteristics of the proposed outcome measures.
3. To investigate the effectiveness of additional educational sessions on stroke and falls prevention in empowering and increasing the coping strategies of caregivers through the learned knowledge, handling skills and community resources.

Preliminary Studies

Prior to this study, a series of preliminary studies and preparation works were completed:

- ☑ The results of the Stepping On trial with older people led by Co-PI Clemson was published as: Clemson, L., et al. (2004). "The effectiveness of a community-based program for reducing the incidence of falls among the elderly: A randomized trial." Journal of American Geriatrics Society 52(9): 1487-1494.

- ☑ Principle Investigator (PI) has completed training in the Stepping On program in Australia with the program developers Clemson and Swann.
- ☑ PI has undertaken a systematic review that is registered with PROSPERO 2015 (CRD42015023389) <http://www.crd.york.ac.uk/PROSPERO/>.
- ☑ PI presented the systematic review protocol poster at *Singapore Health & Biomedical Congress* on 3rd October 2015.
- ☑ PI did oral presentation on the preliminary findings of systematic review of fall risk factors for community stroke survivors at *National Occupational Therapy Conference* on 10th October 2015.
- ☑ PI completed the 2-day SG-GCP workshop organized by SingHealth group in October 2015.
- ☑ The phase II qualitative studies have been approved by the Human Research Ethics Committee, University of Sydney.
- ☑ PI has completed the interviews with stroke clients, family members and domestic helpers as part of the qualitative studies in phase II.
- ☑ PI successfully organized two Stepping On facilitator training workshops in Singapore in February and April 2016.
- ☑ PI conducted 4 focus groups with the trained Stepping On facilitators as part of the qualitative studies in phase II.

The adapted Stepping On after Stroke program key elements based on the inputs from various stakeholders will be further brainstormed by the experts within the research team before it is sent to local and international experts in falls prevention and stroke rehabilitation for review as part of the modified Delphi study in phase II. Thereafter, the first version of the Stepping On after Stroke program will be developed and ready for piloting in the community settings in Singapore.

Methodology

Pre-post design and prospective observational method will be used in this study. A group of stroke survivors, their family members and domestic helpers who meet the inclusion and exclusion criteria will be recruited from purposive sampling in the 2 day rehabilitation centers. Pre-screening using a series of standardized outcome measures will be conducted at baseline. Post-evaluation will be conducted after the home visits. Program evaluation survey will be conducted after the post-intervention home visit and 3-month booster session. Fall data will be collected using monthly fall calendar throughout the 8 months study period.

The researcher will be physically available and taking field notes for some sessions. The fidelity tools will be used to test the program leaders during the 7-week interventions (e.g. session 3, 4 & 5), aims to find out how the program leaders deliver the program and how the participant act in the group. Program leaders will be also asked to share the number of suitable stroke clients in the center, the acceptance rate, group dynamics, and the actual needs to address fall risks.

Sample size

	Center 1	Center 2	Total
Stroke participants	6-8	6-8	12-16
Family members	6-8	6-8	12-16
Domestic helpers	6-8	6-8	12-16
Total	18-24	18-24	36-48

Justification of sample size

Conducting 2 groups of Stepping On after Stroke program will be sufficient to test its workability and feasibility in the community rehabilitation settings in Singapore. The recommended number of elderly participants in each group for the original Stepping On program is 12. However, due to the complexity

and disability of people with stroke, literature suggest that the appropriate number of stroke participants in each group is 6-8, which was further confirmed by local therapists and experts in the previous studies.

Participant recruitment

- All participants will be referred by therapists in the day rehabilitation centers and screened for suitability based on the inclusion criteria one month prior to the study.
- The researcher will make an appointment with each eligible participant and explain the Participant Information Sheet that contains study details.
- Once the participants are agreeable to participate in the study voluntarily, they will be asked to sign the consent form.
- Family members and caregivers will be invited to attend the program briefing session after office hours or other preferred timing.
- Their family members and/or domestic helpers will be invited to join the program.
- Consent from family members and domestic helpers will be obtained before the program starts.
- All confirmed participants will be assessed using series of standardized assessment tools as baseline measures.
- The researcher will find out from the program leader the reasons for not taking part in the study among some eligible participants.

Inclusion criteria

Stroke participant:

- ✓ Age 50 and above
- ✓ Diagnosed with stroke (first or recurrent stroke) within two years
- ✓ Medically stable
- ✓ Able to walk minimum 10 meters unsupported with or without aid
- ✓ Has concerns about falling or had a history of fall
- ✓ Able to communicate verbally in conversational English or Mandarin
- ✓ Cognitively intact (Abbreviated Mental Test \geq 8)
- ✓ Able to make decision and give consent
- ✓ Stays with a caregiver (either family member or domestic helper)

Family member and domestic helper

- ✓ Family member and domestic helper of the enrolled stroke participant
- ✓ Able to understand and speak conversational English or Mandarin
- ✓ Give consent

Exclusion criteria

Stroke participants:

- Unable to express verbally or understand verbal instructions
- Cognitively impaired (AMT $<$ 8)
- Wheelchair bound or bed bound
- Medically unstable, e.g. unstable angina, untreated fits.

Recruitment process

This research project will be mainly conducted in community rehabilitation centers or day care centers in Singapore. Separate meetings have been arranged with the senior management of the participating

rehabilitation centers. Letters of support were obtained from the above two non-profit organizations to conduct this research project.

A pre-intervention briefing session will be organized in each rehabilitation center either after office hours or at their preferred timing. **Program recruitment flyers** will be issued to every audience. Recruitment poster will be displayed in the center. Any interested clients can contact the researcher for more details.

A therapist working in each day rehabilitation center will be assigned as an onsite clinical coordinator during the subject recruitment and intervention phase. Once there are suitable subjects for this study, the stroke clients will give a written consent to be contacted by the researcher. The researcher will then contact the stroke client to arrange for a first appointment. During the first appointment, the study aims, objectives and program details stated in the Participant Information Sheet will be explained to the stroke client. Once the stroke client agrees to participate and signs the consent form, he or she will be scheduled for the initial screening for suitability before being enrolled to the study.

Thereafter, an invitation letter together with study flyer will be passed to his or her family member and/or domestic helper (if available) by hand or mail. The family members and/or domestic helpers can contact the researchers directly or indicate their interests with the onsite clinical coordinator in each center. The interested family members and domestic helpers will be briefed by the researcher about the study details and their involvement. They will be enrolled in the study once the consent forms are signed.

Staff involved

Stepping On after Stroke program leaders

At least one occupational therapist and one physiotherapist from the participating rehabilitation center who have successfully completed the Stepping On facilitator training will be invited to join the half-day Stepping on after Stroke program leader training workshop. They will become ***Stepping On after Stroke*** program leaders in facilitating the program during the study.

Onsite clinical coordinators

There will be at least one therapist from each participating rehabilitation center to be appointed as onsite clinical coordinator to coordinate the participant recruitment and weekly sessions.

Program outline

Pre-intervention /baseline assessment

Pre-intervention evaluation will be conducted by the trained assessors at baseline using the series of standardized outcome measures.

*7 weeks intervention**

- Weekly session will be scheduled on weekdays at a comfortable time slot that suits the participants and the center.
- Each group session will be run in an enclosed environment.
- There will be one 2-hourly group session in each week for 7 weeks.
- Domestic helpers or caregivers are encouraged to join the weekly group session with the stroke participants.
- Two additional educational sessions will be conducted for family members and domestic helpers in the 1st week and 7th week.

- Each participant will receive at least one supervised community mobility practice session with a caregiver during the 7-week program.
- Each participant will be provided with program handouts in either English or Chinese and a communication booklet during the program.

Post-intervention home visit

- A home visit will be conducted by a therapist to each participant 4-6 weeks after the 7th session.
- Phone calls will be a backup option if home visits cannot be conducted to some participants.

Post-intervention reevaluation

- Same outcome measures will be conducted after the home visit to determine any improvements or changes in balance, behavior, safety strategies and community participation.
- All participants and program leaders will be invited to fill up the program evaluation survey form after the home visit.

Three months post-intervention booster session

- All participants will be invited to join the booster session at 3 months after the 7th session.
- Program evaluation survey will be issued to all participants again for their feedback after the booster session.

Six months follow-up

- All stroke participants will be followed up for a period of 6 months after the 7th session.
- Each participant will be asked to keep track of their fall incidents (if any) during the 7 weeks program and 6 months after the 7th session.
- Each participant will be asked to fill up the monthly fall calendar provided by the researcher and submit it to the onsite clinical coordinator or the researcher at the beginning of the following month. Family members and domestic helpers will be encouraged to assist the stroke participant in this activity. Researchers will remind them by phone call if the monthly fall calendar is not returned on time.

(Refer to Appendix A for the program schedule outline)

*Note: The details of the adapted program will be confirmed after consolidating the findings from the qualitative studies at phase II. **Stepping On After Stroke** program will be further refined based on the Pilot findings for larger trials.

Proposed outcome measures

Questionnaires for Stroke participants

- Falls Efficacy Scale (International) (FES-I) ★
- Falls Behavioural (FaB) Scale
- Life space assessment ★
- Modified Reintegration to Normal Living Index (mRNLI) ★

Evaluation tools used by the therapist

- Short physical performance battery (SPPB)
- Goal Attainment Scale (GAS)

Questionnaires for caregivers

- Modified Caregiver Strain Index ★
- SF-12 Health Survey ★

As majority of the outpatients in the community rehabilitation centers are Chinese-speaking, therefore, the validated Chinese version questionnaires will be used for participants in the Chinese-speaking group. The questionnaires with “★” are available in both English and Chinese version and have been validated in other studies.

Validating the Chinese translation version of Falls Behavioural (FaB) Scale

PI who is fluent in speaking both English and Mandarin will translate the FaB scale into Chinese, followed by back translation by another therapist who are fluent in both languages; Thereafter, the translated version will be reviewed by another independent reviewer with familiar background to confirm the translation. PI will pre-test the items with a small number of participants in the rehabilitation centers and validate the items with all stroke participants in the study.

Data analysis and interpretation

Pre-post evaluation

All assessors will be trained in using the following outcome measures by the researchers during the half-day Stepping On after Stroke program leader training workshop. The data collected from the pre-post outcome measures will be used for analysis. (*Refer to the Annex B for data collection schedule and Appendix C for data collection sheet template.*)

The data collected from the pre-post outcome measures will be used to determine if the selected outcome measures are culturally relevant and applicable to detect any improvements or changes in balance, behaviour, safety strategies and community participation. Analysis will be using graphs and descriptive statistics to visualize any trends. The acceptance and usefulness of the measures will be determined.

Program evaluation survey

Program evaluation survey forms for stroke participant and caregivers will be translated into Chinese with back translation method. All stroke participants, family members, domestic helpers, and program leaders will be invited to fill up the program evaluation survey form after the post-intervention home visit and 3-month booster session. General feedbacks on the program structure, outline, content, cultural relevancy, duration, timing, quality of program leaders, program location and challenges will be collected and analyzed.

Monthly fall calendar

All stroke participants will be asked to fill up the monthly fall calendar in bilingual languages (English and Chinese) throughout the 8 months study period. Each participant will submit their monthly fall calendar to the researcher or onsite clinical coordinator in the respective day rehabilitation center at the beginning of the following month. In the event of fall, the participant is asked to call the onsite clinical coordinator or the researcher. Details of the fall incidents (if any) including a number of falls, fall patterns, location and time of falls will be obtained and analyzed to calculate the fall rate and identify the common fall risk factors among the participants. The compliance rate, data accuracy, challenges faced and format of the monthly calendar will be analyzed for further improvement.

Potential benefits and risks to study participants

Potential benefits to stroke participants

We cannot guarantee that you will benefit from being in the study. However, the program will help you to better understand your potential fall risk factors and common strategies for falls prevention specifically for community stroke survivors. You would learn some simple strengthening and balance exercises specifically designed for stroke population, as well as some coping strategies in performing activities of daily living at home and in the community. The knowledge gained may benefit the public in the future.

Benefits to family members and domestic helpers

We cannot guarantee that they will benefit from being in the study. However, the program will help them to better understand the potential fall risk factors and common strategies for falls prevention specifically for community stroke survivors. They would learn some of the coping strategies and safe physical handling techniques in helping the stroke survivors to perform activities of daily living at home and in the community. They would also learn some commonly used community resources in Singapore as well as some common strategies of stress management.

Risk to stroke participants

Possible risks may include, but are not limited to:

- Feelings of distress due to the trigger of unhappy memories, conflicts with other group members or unable to cope or perform during the program.
- Muscle fatigue due to some strengthening exercises taught by the facilitator during the program
- Muscle or joint pain due to over doing of the learned exercises or activities in the rehabilitation center or at home
- Losing balance or falls during the group session or community outings due to unforeseen circumstances, such as unpredictable health conditions and road conditions.
- Inconvenience e.g. giving up time to participate in the research project.

Whenever they feel uncomfortable, distressed, muscle fatigue or pain, unsteady during the program, they can request to stop the session immediately. They can request to withdraw from the program completely if they wish to do so. The trained therapists working in the rehabilitation center will be available to provide a free consultation to address their concerns resulting from the program.

Risk to family members and domestic helpers

Possible risks may include, but are not limited to:

- Feelings of distress due to the trigger of unhappy memories, conflicts with other group members or unable to handle some questions during the educational session.
- Inconvenience e.g. giving up time to participate in the research project.

Whenever they feel uncomfortable and distressed during the session, they can request to quit the session immediately. They can request to withdraw from the program completely if they wish to do so. The trained therapists working in the rehabilitation center will be available to provide a free consultation to address their concerns resulting from the program.

Safety considerations

As this study involves stroke survivors in the day rehabilitation centers, the researcher and staff involved in the study will have to strictly follow the workplace safety practices. Orientation and fire

emergency protocols will be briefed to all participants by the center staff before starting the program. All stroke participants will be supervised by at least two center staff who are also program leaders during each intervention session. At least one family member or domestic helper will be invited to join the weekly group session, which will provide additional supervision.

Route planning and assessment will be conducted by the program leaders (center therapists) before the community mobility practice session being conducted in the neighborhood. First aid box and mobile phone will be brought along by the program leader (therapist). All participants will be supervised by the program leader as well as their caregivers to ensure safety during the community mobility practice session.

Data Safety Monitoring Plan

- All clinical data collected before, during and after the program, such as pre-post outcome measures, monthly fall calendars, and *program evaluation survey forms* will be kept confidentially in a locked cabinet in PI's office in Singapore Institute of Technology.
- All data will be coded without any personal information of each participant before entering into the computer software for quantitative analyses.
- The collected information will only be shared with other researchers in the group.
- All their personal information will be kept confidential.
- Participants may access their personal information from the study.
- The study results will be included in PI's PhD thesis, published in local or international journals, or shared in conference presentations.
- The electronic data will be saved to the password-protected hard disc. Both hard disc and hard copy data will be stored in a locked cupboard in researcher's office during and after the study.
- Only researchers involved in this project will have access to it.
- All these data will be retained for **10** years after the completion of the study. The electronic data will be deleted permanently from the hard disc at the end of the storage period. The hardcopy data will be destroyed in a paper shredder.

Potential difficulties and limitations

The potential difficulties and limitations that the research team might face will be:

- Not having enough stroke participants.
- High drop-out rate during the study
- Family members can't make it for the educational sessions
- Domestic helpers over-assist the stroke participants during and after the group session.

In order to address some of these potential challenges listed above, the research team has decided to:

- Widening the selection criteria and having a regular conversation with the therapists working in the two-day rehabilitation centers, so as to ensure a larger number of stroke clients being referred to the study.
- Highly competent program leaders are essential to make this program successful. PI who is the Stepping On master trainer will be available to offer onsite support at each center as when necessary.
- The researchers will get help from the center staff to seek input from different family members in regards to their available timing. The educational sessions can be scheduled based on their preferred timing if possible at each center.
- By involving the domestic helpers in the weekly group sessions, both stroke participants and the helpers will have a common understanding of the assistance level needed during exercises, functional mobility

and self-care activities. At the same time, the helper will learn the necessary skills and knowledge to become a better facilitator rather than just a helper.

- A special designed “Stepping On Singapore” website has been developed as a self-learning and communication platform for all participants and program leaders, in which falls prevention tips, community resources, and exercise videos are available for easy access during the program.

(Website address: <http://occupymytime.wix.com/SteppingonSingapore>)

Clinical significance of this study

The findings from this feasibility study will inform the design of a culturally relevant, client-centred, group-based falls prevention program that adopts the adult learning principles to promote positive behavioural changes and long-lasting treatment effect in local context.

The Stepping On after Stroke program will potentially reduce falls and increase community participation among stroke survivors that have been discharged to the community. This new program could offer an alternate solution in promoting community safety and ageing in place among stroke survivors, which directly or indirectly benefit the larger community, such as their family members, caregivers and service providers.

Once implemented, it will create more opportunities for local therapists to practice occupation-focused and goal oriented treatment interventions with their stroke clients in the community. The findings would contribute to the national best practice guide for community rehabilitation program in the community rehabilitation centers in the future. Furthermore, this is the first study in Singapore which will provide preliminary evidence of a customized and structured falls prevention program which targets both stroke survivors and caregivers through an exercise and a behavioural-modification approach.

Through this feasibility study, it will also create public awareness of evidence-based practice in local community settings. It also provides the opportunity to engage in research collaborations between community service providers, local academic institutions and international researchers who are leaders in falls prevention, stroke rehabilitation and ageing in place.

Financial Aspects/Conflicts of Interest

The PI (Xu Tianma) will be responsible for research related costs. The research related expenses will be covered under the Singapore Association of Occupational Therapists Research Grant. Subjects will not be expected to pay any fees or receive any financial payment or incentive for participation in this study.

Prepared by:

Xu Tianma
Lecturer, Health & Social Sciences Cluster, Singapore Institute of Technology/
Ph.D. student, The University of Sydney, Australia