PARTICIPANT INFORMATION SHEET (for stroke participant)

1. Project title

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

2. Principal Investigator and co-investigator(s), if any, with the contact number and organization:

PI: Mr Xu Tianma (Tim)
Lecturer, Health and Social Sciences Cluster,
Singapore Institute of Technology
PhD Student, Faculty of Health Sciences,
University of Sydney, Australia
Tel: 65928673
Email: tim.xu@singaporetech.edu.sg

Co-PI: Professor Lindy Clemson
Faculty of Health Sciences,
University of Sydney, Australia
Email: lindy.clemson@sydney.edu.au

Co-PI: Professor Catherine Dean
Faculty of Health Sciences and Medicine,
Macquarie University, Australia
Email: Catherine.dean@mq.edu.au

CO-PI: Associate Professor Gerald Koh
Saw Swee Hock School of Public Health,
National University of Singapore
Tel: 65164979
Email: gerald_koh@nuhs.edu.sg

Co-PI: Associate Professor Natasha Lannin
School of Allied Health,
La Trobe University, Australia
Email: N.Lannin@latrobe.edu.au

Co-PI: Associate Professor Kate O'Loughlin
Faculty of Health Sciences,
University of Sydney, Australia
Email: kate.oloughlin@sydney.edu.au

3. What is the purpose of this research?

You are invited to take part in research study in developing a falls prevention program for people with stroke in the community. The aim of this study is to test if it is feasible to run the adapted Stepping On after Stroke program for stroke clients in community rehabilitation centres in Singapore; We also would like to find out whether the format and content of the program address your physical and psychosocial needs in relation to falls prevention after stroke. The findings from this feasibility study will help the researchers to fine-tune the new falls prevention program for people with stroke in the community.

This information sheet provides you with information about the research. The Principal Investigator (the person in charge of this research) or his representative will also describe this research to you and answer all of your questions. Read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

4. Who can participate in the research? What is the expected duration of my participation? What is the duration of this research?

Any adult who meets the following criteria can take part in this study:

- 50 years old and above and experienced one or more than one falls after stroke
- currently attending community rehabilitation centre program
- able to walk short distance (estimated 10 metres) either indoors or outdoors
- has concerns about falls

- able to communicate in either conversational English or Mandarin
- able to give consent to participate in the study

However, you will not be suitable to participate in this study if you have the following:

- Unable to verbally express or understand verbal instructions
- Medically unstable, e.g. untreated fits, unstable angina
- Wheelchair or bed bound

The duration of this research will last for approximately 8 months, which includes:

- Group based interventions: 7 weeks
- Follow up period: 6 months

The expected duration:

- Pre-screening assessment will be 45 -60 minutes.
- Each group session will be 2 hours with a short tea break in between.
- The individual community outing session will be 30-45 minutes.
- The after-program evaluation will be 45-60 minutes.
- The home visit will be 30-45 minutes.
- The booster session will be 2 hours with a short tea break in between.

5. What is the approximate number of participants involved?

6-8 per group session

6. What will be done if I take part in this research?

- Your therapy record including therapy referral and initial therapy assessment will be accessed by the researcher to verify your clinical diagnosis.
- You will be assessed by the researcher or trained therapist using a set of standardized outcome measures upon referral. The areas of assessment are:
  - Cognitive function
  - Self-efficacy
  - Mobility & balance
  - Self-care activities
  - Fall risk behaviours
  - Community participation
  - Rehabilitation goals
- You will be given **monthly fall calendars** to record any falls during the whole study period (8 months). Your family member or helper can assist you if you have difficulty in filling up the fall calendar.
- You will need to call the center or researcher in the event of falling at home or in the community.
- You will join the seven-week group-based falls prevention program in the rehabilitation centre:
  - 2 hour per session every week facilitated by trained Stepping On after Stroke leaders
  - At least one community outing session based on your rehabilitation goals
- The therapist will visit your home to follow up with you few weeks after the 7 weeks program. Alternatively, the therapist can call you if you are not available.

- You will be invited back to the booster session 3 months after the 7 weeks program.
- You will be invited to fill up the **program evaluation survey form** after the post intervention home visit and upon the completion of the booster session,
- You will return the fall calendar to researcher or onsite clinical coordinator at the beginning of next month. Otherwise, you will be contacted by the researcher during the follow up period if the monthly fall calendar is not returned to the researcher.
- Your personal information will not be written in any paper documents.

7. How will my privacy and the confidentiality of my research records be protected?

Only the principal investigator has your identifiable information (e.g. names, contact information, IC nos.) and this will not be released to any other person, including members of the research team. Identifiable information will never be used in a publication or presentation. All your identifiable health information and research data will be coded (i.e. only identified with a code number) at the earliest possible stage of the research.

All data collected will be kept in accordance to the University's Research Data Management Policy. Research data used in publication will be kept for a minimum of 10 years before being discarded.

8. What are the possible discomforts and risks for participants?

It consists of mainly group-based interventions in this research study that are similar to your current rehabilitation program. Hence, the risk of injury is considered low. 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 centre or at home
- ✓ Loosing balance and fall during the group session or community outing due to unforeseen circumstances, such as unpredictable health conditions and road conditions.
- ✓ Inconvenience e.g. giving up time to participate in the research project.

9. What is the compensation for any injury?

If you follow the directions of the PI in charge of this research and you are physically injured in spite of the procedure given under the plan for this research, you will be covered under *NUS IRB's research insurance* to pay the medical expenses for the treatment of that injury. Payment for management of the normally expected consequences of your treatment will not be provided by the *NUS*. By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence. By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

10. Will there be reimbursement for participation?

No.

11. What are the possible benefits to me and to others?

We cannot guarantee that you will benefits 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.

12. Can I refuse to participate in this research?

Yes, you can. Your decision to participate in this research is voluntary and completely up to you. You can also withdraw from the research at any time without giving any reasons, by informing the principal investigator and all your *data* collected will be discarded. Refusal to participate or withdrawal from participation will not affect your rehabilitation program in this center or cause loss of benefits to which you are otherwise entitled.

13. Whom should I call if I have any questions or problems?

Please contact the Principal Investigator, Mr Xu Tianma (Tim), telephone 65928673 or email: tim.xu@singaporetech.edu.sg for all research-related matters and in the event of research-related injuries.

Alternatively, you can contact the onsite clinical coordinator below:

Name	(to be confirmed)
Designation	
Organization	
Telephone	
Email	

For an independent opinion regarding the research and the rights of research participants, you may contact a staff member of the National University of Singapore Institutional Review Board (Attn: Mr Chan Tuck Wai, at telephone (+65) 6516 1234 or email at irb@nus.edu.sg).

This information sheet is for you to keep!

Consent Form

Project title:

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

Principal Investigator with the contact number and organization:

Mr Xu Tianma (Tim)
Lecturer, Health and Social Sciences Cluster, Singapore Institute of Technology
PhD Student, Faculty of Health Sciences, University of Sydney, Australia
Tel: +65 65928673 Email: tim.xu@singaporetech.edu.sg

I hereby acknowledge that:

1. My signature is my acknowledgement that I have agreed to take part in the above research.

2. I have received a copy of this information sheet that explains the use of my *data* in this research. I understand its contents and agree to donate my *data* for the use of this research.

3. I can withdraw from the research at any point of time by informing the Principal Investigator and all *my data* will be discarded.

4. I will not have any financial benefits that result from the commercial development of this research.

5. I agree to the use of my medical / therapy records for this research.

6. I consent / do not consent* to have the coded data made available for future research.

7. I *agree / do not agree** to be re-contacted for future related studies. I understand that future studies will be subject to an Institutional Review Board's approval.

8. I *agree / do not agree** to the photo-taking/ audio-recording /video-recording of my participation in the research.

9. I *agree/do not agree** for the following personal identifiers to be disclosed in any publication or presentation relating to this research, if any.
   ☐ Surname ☐ First name ☐ Organisation Name ☐ Position/Designation
   ☐ Disagree (I wish to remain anonymous and only agree to be known as _____).

**please delete as appropriate*

** This research has been explained to me in _____ (state language), which I understand, by _____ (name of translator) on _____ (date).

_____ _____
Name and Signature (Participant) Date

_____ _____
Name and Signature (Consent Taker) Date

_____ _____
** Name and Signature (Translator) Date

***(Please include this section if the subject is unable to understand English and read any of the translated consent documents available.)*