1.1 Full Title of Study

Psychometric properties of the Balance Recovery Falls-Efficacy Scale (BRFES)

1.2. Abstract of the study

In no more than 300 words, describe concisely the specific aims, hypotheses, methodology and approach of the application, indicating where appropriate the application's importance to science or medicine. The abstract must be self-contained so that it can serve as a succinct and accurate description of the application when separated from it. Please use lay terms. If this not possible, the technical and medical terms should be explained in simple language.

This study is sequential to the project, "Incidence of near-falls and development of the Balance Recovery Falls-efficacy Scale (BRFES) for the community-dwelling older adults" approved by two institutions, Singapore Institute of Technology (SIT) (Project number: 2019129) and Queen Margaret University (QMU) (Project number: REP 0197). Under the approved project, a study evaluating the feasibility of studying near-falls in the community-dwelling older adults was completed in November 2019 and the second study to develop the BRFES is expected to be completed in June 2020. After completing the BRFES development, the new scale needs to be field-tested and be evaluated for its psychometric properties. This study aims to assess the measurement properties of the BRFES, which are the unidimensionality, internal structure, reliability and construct validity. The study targets to recruit 200 older adults aged 65 years and older living in the community to complete five self-reported instruments (BRFES, Activities-specific Balance Confidence Scale, Falls Efficacy Scale-International, Global Perceived Effect, and Late-Life Function and Disability Instrument-Function) and three performance measures (Hand strength dynamometer, 30-second Chair Stand, Mini BESTest). Two measurement testing theories, Classical Test Theory and Item Response Theory (Rasch Modeling) will be adopted for the analysis. This study will provide information on how well the scale and items can measure the latent construct and provide evidence that the novel BRFES can be usefully adopted into clinical and research practice.

1.3. Proposed duration date: from (mm/yyyy) to (mm/yyyy) : 08/2020 to 12/2021

1.8 Declaration of the Principal Investigator:

Section 5 Research Details

Organise details of the research protocol under the following headings (in no more than 7 pages).

5.1. Specific Aims:

5.1.1. State concisely and realistically what the research described in this application is intended to accomplish and/or what hypothesis is to be tested.

This study aims to investigate the psychometric properties of the BRFES with the community-dwelling older adults, using two measurement theories, Classical Test Theory (CTT) and Item Response Theory (Rasch Modeling) (RM).

The objectives are to determine:

1. The instrument BRFES is unidimensional.
2. There is adequate acceptability, scaling assumption, targeting and reliability of the BRFES.
3. There is sufficient construct validity of the BRFES to measure balance recovery confidence in the community-dwelling older adults.

5.2. Introduction:

5.2.1. Briefly describe the background to the current proposal.

Falls efficacy, a latent construct in community-dwelling older adults, is widely studied in research and clinical practice to maximise older adults' independence and promote maintenance of an active lifestyle to counter burdensome associations (1). Many self-reported instruments used include the Falls Efficacy Scale (FES) (2), modified Falls Efficacy Scale (mFES) (3), Activities-specific balance confidence scale (ABC) (4), CONFBal scale of balance confidence (CONFBal) (5), Falls Efficacy Scale-International (FES-I) (6) and Iconographical Falls Efficacy Scale (Icon FES) (7). These scales measure the perceived ability of the community-dwelling older adults performing activities without falling or losing balance (8). There has been no known instrument available to measure the perceived ability of older adults to recover their balance to prevent a fall.

A falls-efficacy instrument to measure balance recovery confidence is essential in falls-prevention rehabilitation. Essentially, recurrent falling in daily life have been attributed to the deterioration of physiological functioning (9). Pijnappels and colleagues (10) reported that the musculoskeletal performance , i.e. hand grip strength and lower limb strength have been found to be significantly lower for fallers compared to non-fallers. They identified that these ageing-related declines in muscle and tendon function can explain for the slower balance recovery reactions in older people. A greater understanding of balance recovery self-efficacy in older people will allow healthcare professionals to plan and deliver targeted falls-related rehabilitation interventions and strategies on tackling the threat of a fall.

The Balance Recovery Falls-Efficacy Scale (BRFES) has been developed for this purpose. A thorough methodology has been adopted to create the BRFES, involving a systematic review of the development and content validity of existing falls-efficacy instruments (8), concept validation with the community-dwelling older adults and use of consensus methods including Nominal Group Technique and Delphi technique involving relevant groups of experts, i.e. community-dwelling older adults and health professionals. After the BRFES has completed the pilot trial to evaluate the BRFES's face validity and content validity, the psychometric properties of the BRFES need a robust evaluation to provide evidence of its reliability and validity to measure the balance recovery confidence in the community-dwelling older adults. The purpose of this study will be to examine the measurement properties of the newly-developed instrument comprehensively using two traditional and modern measurement testing theories, Classical Test Theory (11) and Item Response Theory (Rasch Modelling) (12)

State concisely the importance of the research described in this application.

The psychometric properties of the BRFES are unknown. The newly developed BRFES must be validated to be usefully adopted into clinical and research practice. The BRFES is a novel self-reported instrument aiming to measure the balance recovery confidence in community-dwelling older adults. This instrument is instrumental to many nascent rehabilitation approaches adopting the use of perturbation-based types of training in falls prevention management. This research aims to provide the first psychometric validation of the BRFES guided by the internationally recognised Consensus-based Standards for the selection of health-status Measurement INstruments (COSMIN) criteria (13).

5.2.2. Relevant references.

1. Yoshikawa A, Smith ML. Mediating Role of Fall-Related Efficacy in a Fall Prevention Program. Am J Health Behav. 2019;43(2):393-405.
2. Tinetti M, Richman D, Powell L. Falls efficacy as a measure of fear of falling. Journal of Gerontology: Psychological Sciences. 1990;45(6):239-43.
3. Hill KD, Schwarz JA, Kalogeropoulos AJ, Gibson SJ. Fear of falling revisited. Arch Phys Med Rehabil. 1996;77(10):1025-9.
4. Powell LE, Myers AM. The Activities-Specific Balance Confidence (ABC) Scale. J Gerontol A Med Sci. 1995;50A:M28-M34.
5. Simpson JM, Worsfold C, Fisher KD, Valentine JD. The CONFbal Scale: A Measure of Balance Confidence - A Key Outcome of Rehabilitation. Physiother. 2009;95(2):103-9.
6. Yardley L, Beyer N, Hauer K, Kempen G, Piot-Ziegler C, Todd C. Development and Initial Validation of the Falls Efficacy Scale-International (FES-I). Age Ageing. 2005;34(6):614-9.

7. Delbaere K, Smith ST, Lord SR. Development and initial validation of the Iconographical Falls Efficacy Scale. Journals of Gerontology Series A: Biological Sciences & Medical Sciences. 2011;66A(6):674-80.

8. Soh SLH, Lane J, Xu TT, Gleeson N, Tan CW. Falls efficacy instruments for community-dwelling older adults: A COSMIN-based systematic review. In Review BMC Geriatrics (Preprint). 2020.

9. Novick MR. The axioms and principal results of classical test theory J Math Psychol. 1966;3:1-18.

10. Rasch G. Probabilistic Models for Some Intelligence and Attainment Tests. Chicago: University of Chicago Press; 1980.

11. Mokkink LB, Prinsen CA, Patrick DL, Alonso J, Bouter LM, Vet HCd, et al. COSMIN methodology for systematic reviews of Patient-Reported Outcome Measures (PROMs). 2018.

5.3. Preliminary Studies:

5.3.1. Provide an account of the Principal Investigator's preliminary/pilot studies (if any) pertinent to the application.

Study 1: Falls efficacy instruments for community-dwelling older adults: A COSMIN-based systematic review (8)

Our evaluation of content from the 18 self-reported instruments identified that the conceptual framework defining the construct of falls efficacy may include four domains of self-efficacy relating to a fall. The four domains have been expressed in a continuum of situational-specific phases of pre-fall, near-fall, fall-landing and a completed fall. Many existing self-reported instruments measure balance efficacy (or balance confidence) in pre-fall phase which is defined as the perceived abilities to undertake activities of daily living without losing balance. Other domains such as efficacy in balance recovery, fall-landing and post-fall management warrant further attention. While there is no all-purpose measure of perceived self-efficacy to reflect a range of circumstances surrounding falling adequately, specificity in various efficacy measures will facilitate greater understanding of the abilities of community-dwelling older adults to manage both falling and personal efficacy effectively.

Study 2: Near Falls in the Singapore Community-Dwelling Older Adults: A Feasibility Study (14)

This study provided the evidence that Singapore community-dwelling older adults understood the concept of near fall and the use of balance recovery manoeuvres to prevent a fall. In this feasibility study, the records of thirty-six incidents (5.7%) of near falls compared to one actual fall (0.16%) out of 630 responses, reflecting the importance of balance recovery manoeuvres. The use of reach-to-grasp strategy (36%), compensatory stepping (52.8%), and other body regions (11.2%) were balance recovery manoeuvres used to prevent the fall.

Study 3: Development of the BRFES (in process)

The process to develop the BRFES is currently under way. The first study to develop a preliminary list of items has been conducted through two focus group sessions with twelve community-dwelling older adults. The drafted instruments will be sent out to a group of experts to evaluate face validity and content validity. The study should be completed in July 2020.

5.4. Methodology:

5.4.1. Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the research.

This cross-sectional study will be conducted with Singapore community-dwelling older adults recruited using contact networks including Singapore Institute of Technology (SIT) Health and Social Sciences cluster's network of older adults, clinical partners, i.e. St Luke's Hospital as well as using the study team's contacts in the Singapore community, e.g. Residents' Networks (RN). Participants will be recruited through posters and participating centre staff. To be eligible, participants are aged 65-year and older, living in the community, functionally independent with or without the use of a walking aid and be able to read, write and communicate in English. Older adults who require any physical assistance from another person to walk within the home, presenting with clinical observable severe cognitive impairment or unable to provide written consent to participate in the study will be excluded.

All interested older adults will contact the study team, and a meeting will be arranged. All older adults will be provided study information (Appendix A) and asked to sign an informed consent form (Appendix B) if they meet the eligibility criteria and agree to participate. All participants will complete a standardised form (Appendix C), containing demographic variables administered by a researcher. The researcher will then use a measurement data form (Appendix D) to record the participants' results of four questionnaires: Balance recovery Falls Efficacy Scale (Appendix G), Activities-specific Balance Confidence Scale (Appendix H), Falls Efficacy Scale – International (Appendix J), and Late-Life Function and Disability Instrument-Function) (Appendix K) and three performance measures: Jamar hand strength dynamometer (Appendix M), 30-second chair stand test (Appendix N) and Mini BESTest (Appendix O). After seven days, participants will be asked to complete the BRFES. A Global Perceived Effect (GPE) scale (Appendix L) will be used to ensure participants' perception of their abilities remained unchanged during the seven days. The time interval of 7-day had been reported to be sufficient to minimize recall bias (15). Participants will also be asked if they had experienced a fall, near-fall, or any incident that might affect their balance recovery ability.

Measurements

Patient reported outcome measures

Balance recovery Falls Efficacy Scale (BRFES) (Appendix G)

The BRFES aims to measure the balance recovery confidence in community-dwelling older adults. A list of fall-related situations commonly experienced by older adults are presented to determine how certain the respondent can recover their balance to prevent a fall if the situation was to occur in the last month by recording a number from 0 to 10 with 10 indicating "Highly certain can do" and 0 refers to "Cannot do at all".

Activities-specific Balance Confidence Scale (ABC) (4) (Appendix H)

The ABC scale assesses older adults' confidence that they will not fall or lose their balance when performing several progressively challenging balance and mobility tasks. This scale provides a broad continuum of activity difficulty and contains situation-specific questions to determine the level of confidence in completing a task without falling or losing balance. The ABC Scale has 16 items, with answers ranging from 0% (no confidence) to 100% (complete confidence)

Falls Efficacy Scale – International (FES-I) (6) (Appendix J)

FES-I is a 16-item scale which measures fear of falling or "concerns about falling" relating to basic and more demanding activities both physical and social. Each question is answered with a four-graded scale (1-4); not at all concerned, somewhat concerned, fairly concerned and very concerned. A total score is calculated and ranges from 16 to 64, an ordinal scale (Yardley, 2005).

Late-Life Function and Disability Instrument-Function component (LLFDI) (16) (Appendix K)

The Late-Life Function and Disability Instrument assess function and disability in older adults. The Functional component of the instrument evaluates self-reported difficulty a person has in performing activities of daily living tasks. Factors that may influence the difficulty in task performance include pain, fatigue, fear, weakness, soreness, ailment, health conditions, and disabilities. There are 32 items with response options of "none," "a little," "some," "quite a lot," and "cannot do." An additional eight items will be completed by those who use canes or walkers.

Global Perceived Effect (GPE) scale (17) (Appendix L)

Participants will rate their upper limb and lower limb functioning, compared to a week ago. Response options will be: (1) much better than a week ago, (2) somewhat better than a week ago, (3) about the same as a week ago, (4) somewhat worse than a week ago, and (5) much worse than a week ago.

Performance tests

Jamar hand strength dynamometer (JHSD) (18) (Appendix M)

The handheld dynamometer provides a quantitative measure of isometric grip strength of the hand by determining the amount of static force that the hand can squeeze around a dynamometer (Paltamaa, 2005). The test will be administered, adopting standardised instructions and positioning recommended by the NIHR Southampton Biomedical Research Centre.

30-second chair stand test (19) (Appendix N)

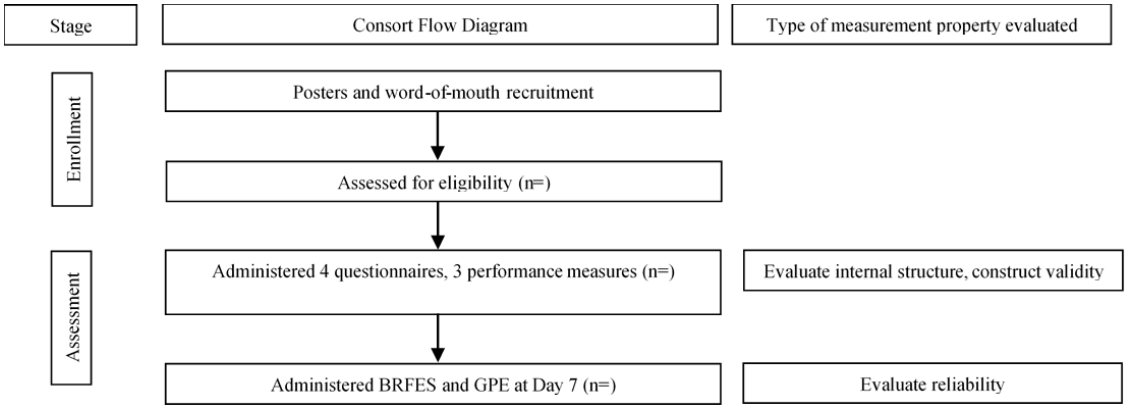
A quantitative measure used as test functional lower extremity strength as well as to obtain an indicator of functional independence with repeated performance of sit to stand from a chair within 30 seconds. The test will be administered adopting standardised instructions and positioning recommended by the Stopping Elderly Accidents, Deaths and Injuries (STEADI).

Mini BESTest (20) (Appendix O)

A 14-item clinical test focusing on dynamic balance contained items belonging four of the six sections from the original BESTest (21). The administration time is about 10 minutes, which makes it efficient and feasible for implementation. The Mini BESTest assesses "anticipatory postural adjustment", "postural responses", "sensory orientation" and "balance during gait".

5.4.2. Describe the protocol(s) to be used. If the research is a drug trial, please include information of the research drug and any other drugs that will be used in the trial.

The participants will complete the assessment as reflected by the CONSORT flow diagram.



The assessment will be conducted in a quiet area at SIT or the participating centre. A team member will administer the standardised form to obtain demographic data. Upon completion, all participants will self-complete the four questionnaires. During the session, the team member will provide any explanation or assistance when required by the participants. After completing the questionnaires, the team member will administer the performance measures. After seven days, participants will

return to SIT or the participating centre to complete the BRFES, GPE and report if they had experienced a fall, near-fall, or any incident during the seven days that might affect their balance recovery ability.

Protocol for Performance Measurements

Jamar hand strength dynamometer (JHSD) (18) (Appendix M)

The participant will sit comfortably in a chair with back support and fixed armrests. The forearms will be rested on the arms of the chair, and their feet will be kept flat on the floor. The apparatus will be gripped by the participant, positioning the thumb around one side and their fingers around the other side of the handle. The instrument should feel comfortable in their hand. Start with the right hand and then repeat the measurement with the left hand. The measurer will support the weight of the dynamometer by resting it on their palm while the participant holds the dynamometer. The measurer will encourage squeezing as long and as tightly as possible for the best result until the needle stops rising, stating "Squeeze……harder, harder…and stop squeezing". The measurer will record the measurement to the nearest 1kg. Repeat for a total of three readings for each hand, alternating sides.

30-second chair stand test (19) (Appendix N)

The participant will sit in the middle of the chair. Hands will be placed on the opposite shoulder crossed, at the wrist and feet placed flat on the floor. The measurer will command "Go" and begin timing. The participant will rise to a full standing position, then sit back down again for 30 seconds. The measurer will record the number of times the participant comes to a full standing position in 30 seconds.

Mini BESTest (20) (Appendix O)

The 14 items in the 4 sections are detailed as (1) sit to stand, rise to toes, stand on 1 leg (3 items for "Anticipatory Postural Adjustments", (2) taking a compensatory step in 4 different directions (3 items for "Reactive Postural Responses"), (3) stance-eyes open, foam surface-eyes closed, incline-eye closed (3 items for "Sensory Orientation"), (4) gait during change speed, head turns, pivot turns, obstacles; cognitive "Get Up and Go" with dual task (5 items for "Balance during Gait"). Each item is scored on a 3-point scale (0 representing worse performance and 3 representing best performance) with a total score of 28 points. Instructions and procedures will be executed as recommended by the Mini BESTest scoring form.

5.4.3. Include details on sample size calculation and the means by which data will be analysed and interpreted.

Sample size is determined at 200 referenced to the sample size recommendation made by Cappelleri (2014) (22). Based on classical test theory, this sample size is large enough to provide a desired level

of measurement precision or standard error of 0.07 around a correlation (23). Furthermore, the adequate sample size is directly dependent on the properties of the scale itself, i.e. the sample size should be calculated at ten times the number of items being analyzed, so a 20-item questionnaire would require at least 200 subjects. For the one-parameter (Rasch) IRT model polytomous items analysis, the item difficulty (and person measure) calibration can be evaluated to be within one logit of a stable value with 95% confidence (24).

The data will be analysed and interpreted through two measurement test theories using IBM SPSS Statistic V.26.0 (for CTT) and Winsteps V.4.5.0 (for RA). Details on unidimensionality, internal structure and reliability will be referred to Appendix P.

Test-retest reliability

The intraclass correlation coefficient (ICC) will be used to assess the test-retest reliability of the total score which are expected to remain stable. As this is an exploratory study, weighted Cohen's κ values will be also calculated to assess test-retest reliability at the item level. The scores are expected to remain stable, and we hypothesise a high intraclass correlation of 0.80.

Construct validity

Construct validity is defined as the degree to which the instrument's score is consistent with hypotheses established a priori based on the assumption that the instrument validly measures the construct to be measured (25). Hypotheses generated by the study team are based on the literature, experience of the study team and assumption that the BRFES validly measures the target construct (i.e. balance recovery confidence). The construct validity of the BRFES will be assessed by the degree to which the sum score of the BRFES is consistent with predefined hypotheses regarding the relationship between the BRFES and the other measures. Six hypotheses have been formulated.

PROMs Hypothesis	
1	A moderate positive correlation (0.30-0.59) was expected between the BRFES and ABC, a measure of balance confidence. BC and BRE are similar falls efficacy constructs with ABC focusing on pre-fall phase and BRFES targeting on near-fall phase based on the fall-continuum model.
2	A moderate positive correlation (0.30-0.59) was expected between BRFES and FES-I which measures fear of falling. Balance recovery confidence and fear of falling may be similar but unrelated constructs.
3	A moderate positive correlation (0.30-0.59) was expected between the BRFES and LLFDI. While both instruments measure perceived physical performance of an individual, LLFDI focuses activities performance and BRFES focuses balance recovery performance.
Performance Tests Hypothesis	
1	A strong positive correlation (≥ 0.60) was expected between BRFES and JHSD because JHSD measures handgrip strength. Handgrip strength is necessary for reach-to-grasp manoeuvres which relates to the balance recovery efficacy.
2	A strong positive correlation (≥ 0.60) was expected between BRFES and CST because CST measures lower limb strength. Lower limb strength is necessary for compensatory stepping manoeuvres which relates to the balance recovery efficacy

3	A strong positive correlation (≥ 0.60) was expected between BRFES and MBT because MBT measures anticipatory and reactive ability for balance and balance recovery. MBT and BRFES are measuring related constructs.

PROMs: patient reported outcome measures; BRFES: Balance recovery Falls Efficacy Scale; ABC: Activities-specific Balance Confidence Scale; BC: Balance Confidence; BRE: Balance Recovery Efficacy; FES-I: Falls Efficacy Scale – International; LLFDI: Late Life Function and Disability Instrument-Function component; JHSD: Jamar hand strength dynamometer; CST: 30-second chair stand test; MBT: Mini BESTest

5.4.4. List all subjects' related procedures. Please also describe the subject research visits (frequency and procedures involved). For studies with multiple visits, please attach visit schedule.

Participants will attend two sessions of the study.

Session 1 (Day 1)

Participants will complete a standardised form (for demographic data), four questionnaires (Balance recovery Falls Efficacy Scale, Activities-specific Balance Confidence Scale, Falls Efficacy Scale – International and Late-Life Function and Disability Instrument-Function) and three performance measures (Jamar hand strength dynamometer, 30-second chair stand test and Mini BESTest).

Session 2 (Day 7)

Participants will complete two questionnaires (Balance recovery Falls Efficacy Scale and Global Perceived Effect)

Details of each columns as indicated:

A. Total number of procedures to be received by each participant as part of protocol.
B. Average time taken per procedure (minutes, hours or days)
C. Details of who will conduct the procedure, and where will it take place.

Procedures	**A**	**B (in mins)**	**C**
Session 1 (Completed at SIT or participating centre)			
Complete standardised form	1	10 minutes	The participant will complete a standardised form administered by a team member
Questionnaires	4	5 minutes	The participant will self-complete four questionnaires.
Performance measures	3	10 minutes	The participant will complete three performance measures conducted by a team member.
Session 2 (Completed at SIT or participating centre)			
Questionnaires	1	10 minutes	Participants will self-complete two questionnaires at the 7th day

5.4.5. If samples of body fluids or tissues are taken as part of this research, state the amount and frequency at which these samples are taken. Will these samples be stored?

Not applicable

5.4.6. What are the anticipated benefits and risks to human subjects participating in this research?

The anticipated benefits of participation will allow participants to be more aware of their perceived balance recovery abilities as well as a better understanding of the different types of balance recovery strategies which they can apply into their interactions with the environment. This awareness may reduce the personal risk of falling. Findings and related knowledge emerging from the studies will be shared as a brief study summary to participants through different modes of communications, e.g. website as and whenever possible.

The anticipated risk of participating in this research is the mental fatigue that may arise during the completion of the four questionnaires. This risk will be managed by the study team to inform the participant that he or she can take a break whenever needed and will regularly check with the participant during the session.

5.4.7. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.

A potential difficulty faced during the study will be the possibility that participants may not turn up on the 7th day of the study. The team member will check with the participant if he or she can attend the second session on the next day, or the participant will be withdrawn from the study.

The second potential challenge would be the participants might have some difficulty reading the questionnaire. The team member will ensure that the print in the questionnaires should be clear and adequately sized, e.g. 14-point type size in New Times Roman font.

The third potential challenge would be a potential fall which may occur during administration of the performance-based measures. The scores obtained from the measures will be used to evaluate the construct validity of the instrument. To manage this issue, the assessor will check with the participants that they are feeling well before conducting the test. During assessment, the assessor will stand within reach distance to the participants which allow them to effectively hold onto the participants in case participants lose balance.

5.4.8. Will any part of the procedures be placed on audiotape, film/video, or other electronic media? ☐ Yes ☒ No

If Yes, what is the medium? Explain how the recorded information will be used? How long will the tapes, etc, be retained and how will they be disposed of?

Not applicable

Section 6 Participants and recruitment information

6.1. Please describe the recruitment process, e.g. how will the participants be contacted, who will initiate the contact with participants.

- Recruitment of the participants will be done through posters (Appendix E) dissemination and word-of-mouth recommendations through Singapore Institute of Technology (SIT) HSS cluster's network of older adults, clinical partners, e.g. St Luke's Hospital (Appendix Q) as well as using the study team's contact in the Singapore community, e.g. Residents' Networks (RN).
- Interested older adults will contact a study team member through the contact details listed in the recruitment posters or through word-of-mouth recommendations. Potential SLH participants will be identified and asked by SLH colleagues whether the older person will be keen to participate in the study. After the older adult expressed interest to participate in the study and agreed to be contacted, then the SLH colleague will inform a study team member to contact the older adult.
- A study team member will arrange a time and place (SIT or SLH) with the interested older adult to explain about the study and the eligibility criteria using the study information sheet (Appendix A). Any doubts or concerns by the eligible participants will be addressed by the study team member. After the older adults have given consent to participate, they will be recruited into the study.

6.2. Please provide details of the consent process for research participants in the study.

Note:

*a. **Implied Consent:** SBER studies involving surveys or interviews where personal, identifiable information will not be collected. Written consent is not required but participants must be given a participant information sheet.*

*b. **Written Consent:** Personal, identifiable information is collected as part of the study. Please attach a copy of the participant information sheet and consent form. Studies involving minors (< 21 years old for HBR & < 18 years old for SBER) must include parental consent form regardless of anonymity of the participants.*

A consent form (Appendix B) will be given to the older adult to complete if the older adult meets the eligibility criteria and has decided to participate in the study. All completed consent forms will be kept in a locked cabinet in the lead Principal Investigator's (lead PI) office.

6.3. What are the inclusion and exclusion criteria for the study? (e.g. health status, gender, race) Please elaborate on the rationale for the criteria.

Inclusion Criteria	Exclusion Criteria
65-year-old and above	Requiring any physical assistance from another person to walk within home
Able to read, write or communicate in English	Presenting with clinical observable severe cognitive impairment
Living independently in the community with or without the use of a walking aid	Unable to provide written consent to participate in the study

The eligibility criteria are established to ensure that the study population is relevant to the study. The broad eligibility criteria aim to include a sample population of community-dwelling older adults that meet the targeted age population, non-institutionalized, able to move around independently in the community and able to complete various questionnaires and performance measures.

***6.4. If waiver of consent is required**, please <u>justify</u> if your research meets the following criteria: (The SIT-IRB may waive the requirement to obtain informed consent if the SIT-IRB finds that the research meets the following 4 criteria.)*

6.4.1. The research involves no more than minimal risk to the subjects.

6.4.2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

6.4.3. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

6.4.4. The research could not practicably be carried out without the waiver or alteration.

Not applicable

Section 7 Confidentiality

7.1. Please provide details on storage and access of information collected during and after completion of study.

All hard-copied information generated in this research will be kept in a locked cabinet in the lead Principal Investigator's (lead PI) office. Electronic data files will be stored in a stand-alone office computer, which is protected using a security password known only to the Lead PI. Backup data will be stored in a SIT server which will be accessed using staff access password known only to the Lead PI. The Co-Principal Investigators and Collaborators will be able to access hard copied and soft copied information through the Lead PI. The collaborators who are affiliated with foreign universities may only have access to participant personal data (including scanned copies of signed consent forms) when necessary provision has been made for this and in accordance with PDPA's

Transfer Limitation Obligation rules. Confidentiality of the data will also meet the non-disclosure agreements signed between SIT and various healthcare institutions for purposes including but not limited to exploring potential opportunities for developing innovative healthcare solutions and evaluating the feasibility of different business relationship and opportunities between the parties.

Findings and related knowledge emerging from the studies will be shared as brief study summary to all participants through email or any other modes of communications, e.g. website as and whenever possible as well as through the publication of findings, presentations in conferences, seminars, workshops or related activities. Data will also be retained for further research which the information will be explained in the informed consent form. For these reasons, hard copied data and electronic data will be stored for ten years upon completion of the research study and then be securely destroyed.

7.2. How do you ensure that participants/data remain de-identified in the study?

Anonymisation techniques will be adopted, e.g. removal of direct identifiers. A list of numbers generated by an online code generator (Appendix F) will be used. This registry will be used to de-link the participants and the data obtained. For example, Mr Joe Phang will be identified as code number 102. For data use in analysis and presentation, the use of aggregation of variables will be adopted, e.g. 68 years old will be categorised in the range 65-69. The lead PI will be the only representative in the study team to have access to the registry.

The means by which the personal data can be associated with individuals will be stored for purpose of data clarification and accountability. For this reason, hard copied version and electronic version of the registry will be stored for three years upon completion of the research study and then be securely destroyed.

Reference List

1. Yoshikawa A, Smith ML. Mediating role of fall-related efficacy in a fall prevention program. Am J Health Behav. 2019;43(2):393-405.
2. Tinetti M, Richman D, Powell L. Falls efficacy as a measure of fear of falling. Journal of Gerontology: Psychological Sciences. 1990;45(6):239-43.
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