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## Feasibility of a ballet-inspired low-impact at-home workout programme for adults with stroke: A mixed-methods exploratory study protocol

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## Title Page

### Study title

Feasibility of a ballet-inspired low-impact at-home workout programme for adults with stroke: A mixed-methods exploratory study protocol

### Authors

Suzanne Hoi Shan Lo,<sup>1,\*</sup> Janita Pak Chun Chau,<sup>1</sup> Kai Chow Choi,<sup>1</sup> Jonas Hon Ming Yeung,<sup>2</sup> Siu Hung Li,<sup>3</sup> Marika Demers<sup>4</sup>

<sup>1</sup>The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong SAR, China

<sup>2</sup>Department of Medicine, Alice Ho Miu Ling Nethersole Hospital, Hospital Authority, Hong Kong SAR, China

<sup>3</sup>Department of Medicine, North District Hospital, Hospital Authority, Hong Kong SAR, China

<sup>4</sup>Division of Biokinesiology and Physical Therapy, Motor Behavior and Neurorehabilitation Lab, University of Southern California, Los Angeles, California, United States

### \*Correspondence to:

Dr. Suzanne Hoi Shan Lo

Postal Address: Room 826, 8/F, Esther Lee Building, Chung Chi College, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong SAR, China

Email: [suzannelo@cuhk.edu.hk](mailto:suzannelo@cuhk.edu.hk)

### Authors' details:

Suzanne Hoi Shan LO, PhD, Assistant Professor, The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong SAR

Email: [suzannelo@cuhk.edu.hk](mailto:suzannelo@cuhk.edu.hk) Tel: (852) 3943 4485 Fax: (852) 2603 5269

Janita Pak Chun CHAU, PhD, Professor, The Nethersole School of Nursing; Assistant Dean (Alumni Affairs), Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong SAR

1  
2  
3 Email: janitachau@cuhk.edu.hk Tel: (852) 3943 6226 Fax: (852) 2603 5269  
4  
5

6 Kai Chow CHOI, PhD, Senior Research Fellow, The Nethersole School of Nursing, Faculty of  
7 Medicine, The Chinese University of Hong Kong, Hong Kong SAR  
8

9 Email: kchoi@cuhk.edu.hk Tel: (852) 3943 4095 Fax: (852) 2603 5269  
10  
11

12  
13 Jonas Hon Ming YEUNG, MBChB, Neurology team-head, Alice Ho Miu Ling Nethersole  
14 Hospital and North District Hospital; Consultant, Department of Medicine, Alice Ho Miu Ling  
15 Nethersole Hospital, Hospital Authority, Hong Kong SAR  
16  
17

18 Email: yeunghmj@ha.org.hk Tel: (852) 2689 2255 Fax: (852) 2665 6436  
19  
20

21  
22 Siu Hung LI, MBChB, MRCP (UK), FRCP (Edin), Associate Consultant, Honorary Associate  
23 Professor (CUHK), Department of Medicine, North District Hospital, Hospital Authority, Hong  
24 Kong SAR  
25  
26

27 Email: lsh039@ha.org.hk Tel: (852) 2683 8888 Fax: (852) 2683 8383  
28  
29

30  
31 Marika DEMERS, PhD, Postdoctoral Research Fellow, Division of Biokinesiology and Physical  
32 Therapy, Motor Behavior and Neurorehabilitation Lab, University of Southern California, Los  
33 Angeles, California, 1540 Alcazar Street, 90089, United States  
34  
35

36 Email: demers@pt.usc.edu Tel: 1-323 442-1196  
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## ABSTRACT

**Introduction** Balancing problems are prominent in stroke survivors with unilateral paresis. Recent evidence supports that dance interventions are associated with significant improvements in gait, stability and walking endurance in people with neurological conditions. The aim of this study is to explore the feasibility of a novel ballet-inspired at-home workout programme (FBB) for stroke survivors.

**Methods and analysis** A mixed-methods exploratory study incorporating a randomised controlled trial and qualitative evaluation will be conducted. We will recruit 40 adults with a first-ever ischaemic or haemorrhagic stroke and mild-moderate lower limb paresis from two acute stroke units. The intervention group will receive usual care plus FBB, an 8-week home-based programme with ballet-inspired workouts underpinned by Bandura's principles of self-efficacy and outcome expectation. FBB will be delivered by trained lay and peer volunteers, with the support of volunteer healthcare professionals. Multiple data will be collected: Recruitment rate, adherence to FBB, semi-structured interviews and questionnaires on outcomes (balance, gait and memory) assessed at baseline and immediately post-intervention. The generalised estimating equations model will be used to compare differential changes on outcomes across time points between the two arms. Qualitative data will be coded and grouped to form themes and sub-themes.

**Ethics and dissemination** Ethical approval from the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee has been obtained. All eligible participants will provide written informed consent. Study results will be disseminated via publications in peer-reviewed journals and presentations at international conferences.

**Trial registration number** NCT04460794

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**Keywords:** Stroke, dance, randomised controlled trial, postural balance, feasibility

## ARTICLE SUMMARY

### Strengths and limitations of this study

- This study will establish the feasibility of a novel ballet-inspired low-impact at-home workout programme for community-dwelling stroke survivors with lower limb paresis, featuring the adoption of ballet-inspired workouts, mobilisation of community resources for capacity building, and the usage of theory-driven strategies to enhance survivors' self-efficacy and outcome expectations in performing the workouts at home.
- It will be the first study of its kind to assess the feasibility and preliminary effects of a ballet-inspired at-home intervention for Chinese stroke survivors; cross-cultural applicability can be examined.
- Due to the nature of the intervention, only research assistants who will conduct recruitment, baseline and follow-up assessments will be blinded to the participants' group allocations, while it is not possible for participants and the persons who will deliver the intervention.

## INTRODUCTION

Stroke is ranked as the second leading cause of global deaths and a major cause of disability.<sup>1</sup> Over 65% of stroke survivors have hemiparesis, considerably affecting their daily life and social functions.<sup>2</sup> Substantial evidence shows that people with hemiparesis have significantly higher risks of falls, depression, and stroke recurrence. Their disability is associated with increased burden on caregivers and healthcare resource utilisation.<sup>3</sup>

Balancing problems are prominent in stroke survivors with unilateral paresis. They exhibit imbalanced body alignment and gait deviations such as flexed, adducted and internally rotated arm, and extension with plantar flexion of foot on the affected side. These changes impair their postural control and functional mobility such as walking. Participation in balancing and muscle strengthening training is therefore very important.<sup>4</sup> However, as over 70% of stroke survivors also develop verbal, visual or informational memory loss, their executive and social functions are impaired. It causes them to have difficulties in memorising exercise steps, and hence hinders their participation and the effectiveness of recovery training.<sup>5</sup>

Contemporary evidence-based guidelines recommend early discharge from hospital to enhance stroke survivors' reintegration to society.<sup>6</sup> Hospital-based training often ends after survivors have attained a certain level of physical functions. A critical condition to sustain physical gains is the survivors' ability and willingness to continue their rehabilitation after discharge. Effective interventions to address their physical and cognitive needs are therefore necessary to support chronic recovery.

Dance is a combination of physical movements and musical beats. A systematic review of nine studies reports that dance interventions are associated with significant improvements in gait, stability and walking endurance in people with neurological conditions including stroke.<sup>7</sup> Another review suggests that dance interventions offer a new framework for neurorehabilitation.<sup>8</sup> Dance engages a person in both physical and cognitive stimulation. Repeated exercises in music and mental rehearsal of dance steps enhance ease to memorise and execute the planned sequences of movements. Simultaneous coordination of physical and cognitive activities enables dance interventions to take advantage of neuroplastic properties of the brain and bring about synergistic physical and cognitive benefits. The pleasurable experience and social engagement in dance interventions outweighs exercise alone as they increase adherence to interventions.<sup>8</sup>



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3 Recent evidence supports the feasibility of dance interventions for stroke survivors. A pre-  
4 post-test study of 20 survivors found a 10-week dance intervention (two 60-minute classes per  
5 week) held in community settings was potentially beneficial in improving balance. The classes  
6 featured dance movements of ballet, contemporary, jazz, folk and ballroom.<sup>9</sup> Another pre-post-test  
7 study of nine survivors reported that a 45-minute biweekly dance intervention integrating jazz  
8 dance and merengue offered in a rehabilitation setting improved their balance.<sup>10</sup>  
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14 There are some gaps identified in the literature. First, there has been no consensus on which  
15 dance style and regimen is more effective for promoting balance, gait and memory in stroke  
16 survivors. Second, dance interventions examined in previous studies were not underpinned by  
17 theoretical frameworks and thus limited the understanding of mechanisms of change in outcomes.  
18 Third, only one study was conducted in community settings and it required participants to have  
19 access to a community centre to receive the dance intervention.<sup>9</sup> Alternative means to remove  
20 physical barriers and reach more survivors would be of greater benefit. Fourth, current evidence  
21 showed that dance interventions for stroke survivors were all delivered by dance instructors and/or  
22 health professionals.<sup>9,10</sup> It is worthwhile to explore alternative approaches that can mobilise  
23 community resources more effectively and build community capacity in health promotion. Fifth,  
24 there is no study reporting the effects of dance interventions on Chinese stroke survivors.  
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### 32 **AIMS AND OBJECTIVES**

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34 We aim to establish the feasibility of a novel ballet-inspired low-impact at-home workout  
35 programme (“Footprints to Better Balance” (FBB)) by comparing FBB to a control group and  
36 preliminarily estimating its effects on stroke survivors’ gait, balance and memory for planning a  
37 future full-scale randomised controlled trial (RCT).  
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40 Since this is an exploratory feasibility trial, there will be no hypothesis.  
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42 Objectives are to:  
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- 44 1. evaluate the recruitment rate of participants;
- 45 2. identify the participants’ attendance and adverse events during FBB;
- 46 3. explore the facilitators, barriers and contextual factors that may influence the implementation  
47 of FBB;
- 48 4. test the acceptability of data collection procedures; and
- 49 5. assess the preliminary effects of FBB on the participants’ balance, gait and memory.  
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### 55 **METHODS AND DESIGN**

## Study design

This is a mixed-methods exploratory study which incorporates a parallel-arm, assessor-blind RCT and qualitative evaluation.

## Settings

Participants will be recruited from the acute stroke units (ASUs) of two acute public hospitals in Hong Kong. The novel FBB will be conducted face-to-face at the participants' home and followed up by phone or internet media. All baseline and post-intervention assessments will be conducted in a university laboratory.

## Participants

Participants will be included if they are/have: (1) 18 years old or above, (2) clinically diagnosed with a first-ever ischaemic or haemorrhagic stroke, (3) living at home, (4) mild-moderate lower limb paresis with a modified Functional Ambulation Classification (MFAC) of III (Dependent walker) or above, (5) a Montreal Cognitive Assessment (MoCA) score >20, (6) able to follow three-step directions, (7) able to communicate in Cantonese and read Traditional Chinese, and (8) given written consent to participate in the study.

Survivors will be excluded if they are/have: (1) diagnosed with transient ischaemic attack, subdural or epidural haemorrhage, (2) cerebrovascular event(s) due to tumours or head trauma, (3) pre-existing neurological, cardiovascular or orthopaedic condition that contradict dancing such as shoulder dislocation, myocardial infarction, seizures, or acute illness, (4) mental condition such as depression, schizophrenia, or personality disorder, (5) incomprehensible speech, or (6) severe hearing and/or visual disturbance.

## Sample size calculation

As an exploratory trial, we will recruit a total of 30 participants (15 per arm). This sample size meets the rule of thumb for sample size requirement in pilot studies.<sup>11</sup> Allowing for a potential attrition rate of 25%,<sup>12 13</sup> a total of 40 eligible participants (20 per arm) will be recruited.

## Randomisation

Participants will be randomly assigned at 1:1 ratio to an intervention (I) or a control (C) group after consenting and baseline assessment (see figure 1). Block randomisation (blocks of ten) will be used. An independent individual will generate a computer-generated random sequence of grouping identifiers (I or C). According to the sequence, the individual will place a grouping identifier into the opaque, identical, sealed and sequentially numbered envelopes. An independent

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3 mediator, who is not involved in recruitment, assessment or delivery of FBB, will store these  
4 envelopes in an undisclosed location, open the envelopes sequentially according to the  
5 participants' time of enrolment, record and inform the Principal Investigator about the participants'  
6 group allocations.  
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### 10 **Blinding**

11 Research assistants, who will conduct recruitment, baseline and follow-up assessments and data  
12 entry, will have no knowledge of the participants' group allocations. However, blinding is not  
13 possible for the participants and the persons delivering FBB due to the nature of the intervention.  
14 The research assistant, who will conduct qualitative evaluation with participants in the intervention  
15 group, will know the group allocation.  
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### 20 **Intervention**

21 Participants randomly allocated to the intervention group will receive FBB in addition to usual  
22 stroke care. FBB is an 8-week home-based programme aimed at improving stroke survivors'  
23 balance, gait, and memory. FBB was developed by the multidisciplinary healthcare team of the  
24 project in partnership with a ballet dance instructor and four stroke survivors (three females and  
25 one male, age 39-65 years, stroke duration 2-6 years). We chose ballet in lieu of other dance styles  
26 because it places emphasis on priori mastery of low-impact workouts to maintain proper body  
27 alignment, build core and lower extremity strengths and flexibility, before moving on to more  
28 complicated ballet movements. These workouts are particularly helpful for stroke survivors in  
29 correcting their balance and gait problems. Furthermore, ballet relies heavily on mental rehearsal  
30 of movements. It mirrors mental imagery to promote motor relearning and to enhance brain  
31 plasticity and cognitive functions.<sup>14 15</sup> Musical beats are also integrated in ballet training, requiring  
32 coordination of both cognitive and physical activities to move the body according to the planned  
33 sequence and time. With repeated and longer duration of practice, performing ballet-inspired  
34 movements also improves cardiorespiratory fitness. The movements can be practiced alone, with  
35 partners or in groups to facilitate social engagement.  
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48 Bandura's constructs of self-efficacy and outcome expectation<sup>16</sup> underpin the design and  
49 implementation of FBB. Strategies will be adopted to enhance participants' self-efficacy and  
50 outcome expectations of performing ballet-inspired workouts.<sup>12 13</sup>  
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53 Eight carefully selected ballet-inspired workouts are integrated:<sup>14 15</sup> basic body positions,  
54 trunk movement, pointed toes, turn in and out, tendus (sliding and extending foot), plies (bending  
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3 knees), elevés (lifting up on balls of feet) and coupés (shifting body weight). The workouts are  
4 aimed at enhancing participants' awareness of body parts and ability in maintaining proper body  
5 alignment and postural control. Participants will perform the workouts starting from a sitting  
6 position and progress to a standing position with or without physical support as their postural  
7 control improves. They will perform mental imagery of each workout after viewing  
8 demonstrations, and memorising the movements before performing. Each workout is designed to  
9 resemble a daily activity commonly performed by females or males.

15 We will integrate the workouts into a 60-minute structured session adapted from a typical  
16 ballet class. Participants will be asked to perform the 60-minute session two times per week.<sup>4</sup> To  
17 maintain an appropriate level of challenge, the difficulty of the workouts will increase  
18 progressively subject to participants' willingness and improved condition.

22 FBB will be delivered by trained lay and peer stroke volunteers with the support of volunteer  
23 healthcare professionals. The lay volunteers will provide home visits and virtual sessions to  
24 participants. The healthcare professionals will provide expert advice to volunteers during  
25 implementation. All volunteers will receive four days of structured training conducted by the  
26 Principal Investigator with over ten years of ballet experience. Lay and peer stroke volunteers will  
27 be asked to complete an exit test to demonstrate the ability to deliver the FBB independently.  
28 Training completion will be determined by a satisfactory performance in the test and completion  
29 of one supervised on-site session and one virtual session.

36 A self-directed resource package will be developed in form of a website and guidebook for  
37 participants' convenience of access. It will contain videos to demonstrate the workouts, animated  
38 videos to illustrate the information, and a suggested weekly goal-and-action plan for eight weeks.

41 FBB will consist of two weekly 90-minute at-home support sessions delivered by two lay  
42 volunteers (one of them will be a stroke survivor) in Weeks 1-2, and six weekly 15-minute virtual  
43 interactions (by phone or internet media) by either lay volunteer in the remaining weeks. The  
44 home-based sessions will introduce participants to FBB, the resources package and safety  
45 precautions. The lay volunteers will conduct virtual sessions and discuss strategies to address  
46 challenges in performing workouts, reinforcing outcome expectations, appraising incremental  
47 progress and reinforcing participation as planned for the following weeks. They will update the  
48 healthcare professionals about the participant's progress, and consult them for advice if needed.  
49 All adverse events will be documented and reported to the clinical research ethics committee.

### **Control group**

Control participants will continue their usual activities and exercises during the study period. In addition, they will be provided with an information sheet about recommendations with pictorial demonstrations on basic stretching and leg exercises for stroke survivors.

### **Recruitment and data collection procedures**

A research assistant will visit the ASUs regularly to screen for eligible participants. He/she will review the medical records of all stroke patients admitted, and approach the potentially eligible participants and explain to them and/or their relatives the study aim, objectives, intervention and data collection procedures. Participants will be asked to sign an informed consent form and will be given a participation card indicating their recruitment into the study. Then, the research assistant will record the participants' demographic and clinical information. After the patients are discharged from the hospital, the research assistant will contact them and schedule a baseline assessment. Participants will be informed about video-taking during assessment of their balance and gait. Face-to-face focus group interviews with all participants in the intervention group and all volunteers will be conducted immediately post-intervention in a university laboratory room. All interviews will be audio-taped. Cash allowance will be provided to participants after completing each assessment and interview; and to volunteers after completing a home visit to subsidise their travel expenses in the study.

### **Data collection**

Multiple data will be collected:

1. Recruitment: Review the research assistant's recruitment records and flow of participants in the study to calculate the participants' recruitment rate and the reasons for non-participation.
2. Characteristics of eligible and included/non-included stroke adults: Participants' age, gender, marital status, educational level, stroke history, comorbidities, living condition, and financial status will be extracted from the medical records.
3. Participant characteristics (completed versus dropout): Data such as age, gender, marital status, educational level, occupation, current financial aids received, type of housing, living condition, past and present medical history, assistive aids used, MoCA and MFAC scores will be extracted from the participants' records.
4. Home journal: Participants will document details of their participation in FBB in the website or guidebook, including date, time, number of workouts performed, presence of dyspnoea, injuries

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3 or accidents.

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5 5. Audio records: All home visits and virtual sessions of FBB, and volunteer training sessions  
6 will be audio recorded with the participants' and the volunteers' consent.

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8 6. Qualitative evaluation: Focus group semi-structured exit interviews will be conducted with  
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10 1) All participants in the intervention group to elicit their experiences of participating in FBB,  
11 facilitators of and barriers to participating in FBB, perspectives on feasibility, acceptability and  
12 usefulness of FBB, changes in behaviours after FBB, impression of research experience, and areas  
13 for enhancement; and 2) All volunteers to elicit their perceptions on the facilitators of and barriers  
14 to implementing FBB, perspectives on feasibility, acceptability and usefulness of FBB, and  
15 observations of the participants' participation in FBB.

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17 7. Outcomes: All participants will be assessed at baseline (T0) and at immediately post-  
18 intervention (T1) (within one week after the intervention).

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24 - **Balance:** The 14-item Mini-Balance Evaluation Systems Test (Mini-BESTest) will be used.<sup>17</sup>  
25 It measures four domains including the participants' anticipatory postural adjustments,  
26 reactive postural control, sensory orientation, and dynamic gait. All items are rated on a 3-  
27 level scale (0=Severe, 1=Moderate, 2=Normal). The summed total score is 0 to 28. A higher  
28 score represents better balance ability. The Cronbach alpha is 0.89-0.94.<sup>17</sup>  
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32 - **Balance confidence:** The 16-item Activities-specific Balance Confidence Scale (Chinese  
33 version)<sup>18</sup> will be adopted. The participants will rate their confidence in balance associated  
34 with performing 16 daily functional activities from 0% (absolutely no confidence) to 100%  
35 (fully confident). The summed total score is 0 to 100%. A higher score denotes higher  
36 confidence. The Cronbach alpha is 0.97.<sup>18</sup>  
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40 - **Gait:** The 31-item Gait Assessment and Intervention tool (G.A.I.T.) will be used to measure  
41 the participants' gait: upper extremity and trunk movement control; trunk and lower extremity  
42 (stance phase); trunk and lower extremity (swing phase). Each item is scored from 0 (normal)  
43 to 3, with gradients of variation from normal. The total score ranges from 0 (normal gait) to  
44 62 (greatest extent of gait deviations). G.A.I.T. demonstrates good intra-rater and interrater  
45 reliability.<sup>19</sup>  
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49 - **Walking endurance:** The 6-Minute Walk Test (MWT) will be performed in accordance with  
50 the American Thoracic Society guidelines.<sup>20</sup> The distance walked, the time stopped and  
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reason(s) for stopping prematurely will be recorded. The 6MWT, 12MWT, and self-paced gait speed were all significantly highly correlated ( $r>0.90$ ).<sup>21</sup>

- **Memory:** The 11-item Rivermead Behavioural Memory Test–Third Version (Chinese version) will be used to measure the participants’ memory function for performing daily tasks. For each task, the scores range from 0-2 (0-point=error; 1-point=intermediate; 2-points=normal). The total score ranges from 0 to 254. The higher the score, the better the memory performance. The test demonstrates high inter-rater reliability. The correlation between performance on parallel forms is 0.67-0.84.<sup>22</sup>

### **Data analysis**

All quantitative data will be summarised and presented using appropriate descriptive statistics. Recruitment rate will be calculated by the average of participants recruited per study venue per month. Outcome analysis will be performed based on the intention-to-treat principle. The generalised estimating equation model will be used to compare differential changes on each outcome across T0 and T1 between the two arms. Cohen’s D values will be calculated to estimate the effect sizes of the intervention on the outcome variables. All statistical analyses will be performed using IBM SPSS 24.0 (IBM Corp. Armonk, NY). All statistical tests will be two-sided (level of significance=0.05). Raw audio files will be transcribed verbatim and destroyed after completing transcription. The interview transcripts and participants’ home journals will be coded and analysed. The codes will be grouped to form major themes and sub-themes that correspond to the study aim and objectives. The qualitative data will supplement the quantitative outcome data by identifying convergence and differences between the two datasets.<sup>23</sup>

### **Patient and public involvement**

FBB was developed in partnership with a ballet instructor and four stroke survivors. Community-dwelling stroke survivors will be recruited to participate in the study. Adult lay and peer stroke volunteers will be recruited and trained to deliver FBB. Comments on the programme such as acceptability and usefulness, and areas of enhancement will be collected from the participants and the volunteers through semi-structured interviews. Preliminary effects of FBB will be assessed by the administration of questionnaires with the participants. The results of the study will be disseminated to the participants on request.

### **Reporting guidelines**

SPIRIT reporting guidelines were adhered to in this protocol.<sup>24</sup>

### **Ethical considerations and dissemination**

Ethical approval has been obtained from the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (Ref. No.: 2019.598). The research team will protect participants' rights and safety by adhering to local laws, the Declaration of Helsinki, institutional policies, and the International Conference on Harmonization - Good Clinical Practice (ICH-GCP). All research personnel will be asked to complete the modules of Good Clinical Practice. Agreement will be made in advance with the personnel in charge of ASUs for arranging participant recruitment. All eligible participants will provide written informed consent. All questionnaires will be anonymous. All information will be kept strictly confidential. All information will be destroyed six years after completion of the project. Study findings will be disseminated via publications in peer-reviewed journals and presentations at international conferences.

### **Acknowledgements**

We would like to thank the stroke survivors and the dance teacher for providing their valuable suggestions in the development of the dance intervention.

### **Author contributions**

SHSL and JPCC contributed to the conception and design of the study. MD, KCC, JHMY and SHL commented on the intervention contents. KCC was responsible for sample size calculation and statistical analyses. All authors are the applicants of the grant submission. SHSL wrote the manuscript and all authors read and approved the manuscript.

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### **Competing interests**

The authors declare that they have no competing interests.



### Patient and public involvement

Patients and the public were involved in the design, conduct, reporting, and/or dissemination plans of this study.

### Patient consent for publication

Not required.

### Provenance and peer review

Not commissioned; externally peer reviewed.

### Data statement

The datasets used and/or analysed during the current study will be available from the corresponding author on reasonable request.

### ORCID iD

Suzanne Hoi Shan Lo <https://orcid.org/0000-0002-9970-0642>

Janita Pak Chun Chau <https://orcid.org/0000-0002-3750-7396>

Kai Chow Choi <https://orcid.org/0000-0001-7157-8668>

Marika Demers <https://orcid.org/0000-0003-4075-1418>

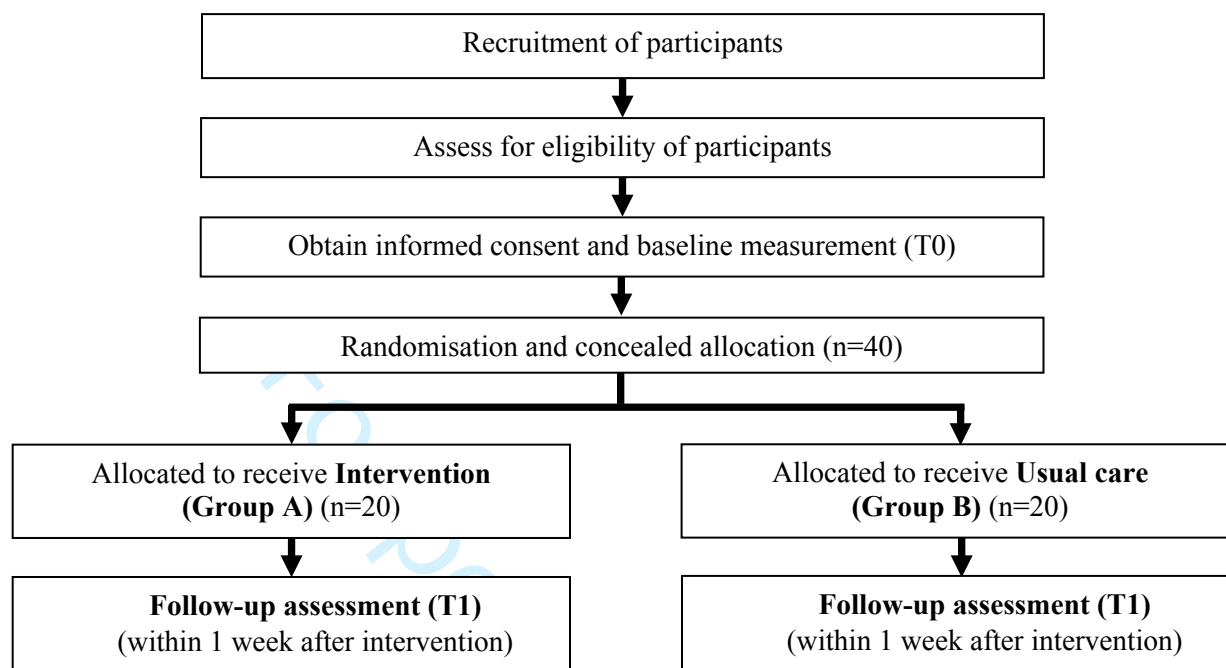
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15 [Guideline-for-Stroke-5t-\(1\).aspx](https://www.strokeaudit.org/SupportFiles/Documents/Guidelines/2016-National-Clinical-Guideline-for-Stroke-5t-(1).aspx)  
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**Figure 1** Flow of participants in the study.



# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

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			Page Number
<b>Administrative information</b>			
Title	<a href="#">#1</a>	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

1 2 3 4 5	Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet registered, name of intended registry	3
6 7 8 9 10	Trial registration: data set	<a href="#">#2b</a>	All items from the World Health Organization Trial Registration Data Set	n/a (not included)
11 12 13 14 15 16 17 18	Protocol version	<a href="#">#3</a>	Date and version identifier	n/a (one version only)
19 20 21 22 23 24	Funding	<a href="#">#4</a>	Sources and types of financial, material, and other support	13
25 26 27 28 29 30 31	Roles and responsibilities: contributorship	<a href="#">#5a</a>	Names, affiliations, and roles of protocol contributors	1-2, 13
32 33 34 35 36 37 38 39 40 41	Roles and responsibilities: sponsor contact information	<a href="#">#5b</a>	Name and contact information for the trial sponsor	n/a
42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Roles and responsibilities: sponsor and funder	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	13 (for funder)

1	Roles and	<a href="#">#5d</a>	Composition, roles, and responsibilities of the	n/a
2				
3	responsibilities:		coordinating centre, steering committee, endpoint	
4				
5	committees		adjudication committee, data management team, and	
6				
7			other individuals or groups overseeing the trial, if	
8				
9				
10			applicable (see Item 21a for data monitoring committee)	
11				
12				

## Introduction

13				
14				
15				
16	Background and	<a href="#">#6a</a>	Description of research question and justification for	5-6
17				
18	rationale		undertaking the trial, including summary of relevant	
19				
20			studies (published and unpublished) examining benefits	
21				
22			and harms for each intervention	
23				
24				

25				
26	Background and	<a href="#">#6b</a>	Explanation for choice of comparators	10
27				
28	rationale: choice of			
29				
30	comparators			
31				
32				

33				
34	Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	6
35				
36				

37	Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg,	7
38				
39			parallel group, crossover, factorial, single group),	
40				
41			allocation ratio, and framework (eg, superiority,	
42				
43			equivalence, non-inferiority, exploratory)	
44				
45				

## Methods:

Participants,  
interventions, and  
outcomes

1 2 3 4 5 6 7 8 9	Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
10 11 12 13 14 15 16 17 18 19 20	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
21 22 23 24 25 26 27 28	Interventions: description	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-10
29 30 31 32 33 34 35 36 37	Interventions: modifications	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a (not included)
38 39 40 41 42 43 44 45	Interventions: adherence	<a href="#">#11c</a>	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	8-10
46 47 48 49 50 51 52 53	Interventions: concomitant care	<a href="#">#11d</a>	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a (not relevant to study)
54 55 56 57 58 59 60	Outcomes	<a href="#">#12</a>	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood	10-12



pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome.

Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

Participant timeline [#13](#) Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) 12, 17

Sample size [#14](#) Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations 7

Recruitment [#15](#) Strategies for achieving adequate participant enrolment to reach target sample size 10

## Methods:

### Assignment of interventions (for controlled trials)

Allocation: sequence generation [#16a](#) Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document 7-8

that is unavailable to those who enrol participants or  
assign interventions

1			
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6	Allocation	<a href="#">#16b</a>	Mechanism of implementing the allocation sequence 7-8
7			
8	concealment		(eg, central telephone; sequentially numbered, opaque,
9			
10	mechanism		sealed envelopes), describing any steps to conceal the
11			
12			sequence until interventions are assigned
13			
14			
15	Allocation:	<a href="#">#16c</a>	Who will generate the allocation sequence, who will 7-8
16			
17	implementation		enrol participants, and who will assign participants to
18			
19			interventions
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21			
22			
23	Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to interventions 8
24			
25			(eg, trial participants, care providers, outcome
26			
27			assessors, data analysts), and how
28			
29			
30			
31	Blinding (masking):	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is n/a (not
32			
33	emergency		permissible, and procedure for revealing a participant's relevant
34			
35	unblinding		allocated intervention during the trial to study)
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38	<b>Methods: Data</b>		
39			
40	collection,		
41			
42	management, and		
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44	analysis		
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48	Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome, 10-12
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50			baseline, and other trial data, including any related
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52			processes to promote data quality (eg, duplicate
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54			measurements, training of assessors) and a description
55			
56			of study instruments (eg, questionnaires, laboratory
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tests) along with their reliability and validity, if known.

Reference to where data collection forms can be found,  
if not in the protocol

Data collection plan: [#18b](#) Plans to promote participant retention and complete 10-12  
retention follow-up, including list of any outcome data to be  
collected for participants who discontinue or deviate from  
intervention protocols

Data management [#19](#) Plans for data entry, coding, security, and storage, 12  
including any related processes to promote data quality  
(eg, double data entry; range checks for data values).  
Reference to where details of data management  
procedures can be found, if not in the protocol

Statistics: outcomes [#20a](#) Statistical methods for analysing primary and secondary 12  
outcomes. Reference to where other details of the  
statistical analysis plan can be found, if not in the  
protocol

Statistics: additional [#20b](#) Methods for any additional analyses (eg, subgroup and 12  
analyses adjusted analyses)

Statistics: analysis [#20c](#) Definition of analysis population relating to protocol non- 12  
population and adherence (eg, as randomised analysis), and any  
missing data statistical methods to handle missing data (eg, multiple  
imputation)

## Methods: Monitoring

1	Data monitoring:	<a href="#">#21a</a>	Composition of data monitoring committee (DMC);	n/a (not
2				
3	formal committee		summary of its role and reporting structure; statement of	relevant
4				
5			whether it is independent from the sponsor and	to study)
6			competing interests; and reference to where further	
7			details about its charter can be found, if not in the	
8			protocol. Alternatively, an explanation of why a DMC is	
9			not needed	
10				
11	Data monitoring:	<a href="#">#21b</a>	Description of any interim analyses and stopping	n/a (not
12				
13	interim analysis		guidelines, including who will have access to these	relevant
14			interim results and make the final decision to terminate	to study)
15			the trial	
16				
17				
18	Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and managing	12-13
19			solicited and spontaneously reported adverse events	
20			and other unintended effects of trial interventions or trial	
21			conduct	
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28	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if	n/a (not
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30			any, and whether the process will be independent from	relevant
31			investigators and the sponsor	to study)
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38	<b>Ethics and</b>			
39	<b>dissemination</b>			
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50	Research ethics	<a href="#">#24</a>	Plans for seeking research ethics committee /	13
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52	approval		institutional review board (REC / IRB) approval	
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1 2 3 4 5 6 7 8 9 10 11 12	Protocol amendments	<a href="#">#25</a>	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a (not relevant to study)
13 14 15 16 17 18 19 20	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10, 13
21 22 23 24 25 26 27 28	Consent or assent: ancillary studies	<a href="#">#26b</a>	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a (not applicable to study)
29 30 31 32 33 34 35 36 37	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10, 13
38 39 40 41 42 43	Declaration of interests	<a href="#">#28</a>	Financial and other competing interests for principal investigators for the overall trial and each study site	13
44 45 46 47 48 49 50	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
51 52 53 54 55 56 57 58 59 60	Ancillary and post-trial care	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a (not relevant to study)

1	Dissemination policy:	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate trial	3, 13
2				
3	trial results		results to participants, healthcare professionals, the	
4			public, and other relevant groups (eg, via publication,	
5			reporting in results databases, or other data sharing	
6			arrangements), including any publication restrictions	
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13	Dissemination policy:	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended use of	n/a (not
14	authorship		professional writers	intended)
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18	Dissemination policy:	<a href="#">#31c</a>	Plans, if any, for granting public access to the full	14
19	reproducible		protocol, participant-level dataset, and statistical code	
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21	research			
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26	<b>Appendices</b>			
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29	Informed consent	<a href="#">#32</a>	Model consent form and other related documentation	n/a (not
30	materials		given to participants and authorised surrogates	included)
31				
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35	Biological specimens	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and storage of	n/a (not
36			biological specimens for genetic or molecular analysis in	relevant
37			the current trial and for future use in ancillary studies, if	to study)
38			applicable	
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 46 BY-ND 3.0. This checklist can be completed online using <https://www.goodreports.org/>, a tool made  
 47 by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)  
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# BMJ Open

## Feasibility of a ballet-inspired low-impact at-home workout programme for adults with stroke: A mixed-methods exploratory study protocol

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Manuscript ID	bmjopen-2020-045064.R1
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<b>Primary Subject Heading</b>:	Health services research
Secondary Subject Heading:	Public health
Keywords:	Stroke < NEUROLOGY, PUBLIC HEALTH, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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**Title Page****Study title**

Feasibility of a ballet-inspired low-impact at-home workout programme for adults with stroke: A mixed-methods exploratory study protocol

**Authors**

Suzanne Hoi Shan Lo,<sup>1,\*</sup> Janita Pak Chun Chau,<sup>1</sup> Kai Chow Choi,<sup>1</sup> Jonas Hon Ming Yeung,<sup>2</sup> Siu Hung Li,<sup>3</sup> Marika Demers<sup>4</sup>

<sup>1</sup>The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong SAR, China

<sup>2</sup>Department of Medicine, Alice Ho Miu Ling Nethersole Hospital, Hospital Authority, Hong Kong SAR, China

<sup>3</sup>Department of Medicine, North District Hospital, Hospital Authority, Hong Kong SAR, China

<sup>4</sup>Division of Biokinesiology and Physical Therapy, Motor Behavior and Neurorehabilitation Lab, University of Southern California, Los Angeles, California, United States

**\*Correspondence to:**

Dr. Suzanne Hoi Shan Lo

Postal Address: Room 826, 8/F, Esther Lee Building, Chung Chi College, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong SAR, China

Email: [suzannelo@cuhk.edu.hk](mailto:suzannelo@cuhk.edu.hk)

**Authors' details:**

Suzanne Hoi Shan LO, PhD, Assistant Professor, The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong SAR

Email: [suzannelo@cuhk.edu.hk](mailto:suzannelo@cuhk.edu.hk) Tel: (852) 3943 4485 Fax: (852) 2603 5269

Janita Pak Chun CHAU, PhD, Professor, The Nethersole School of Nursing; Assistant Dean (Alumni Affairs), Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong SAR

1  
2  
3 Email: janitachau@cuhk.edu.hk Tel: (852) 3943 6226 Fax: (852) 2603 5269  
4  
5

6 Kai Chow CHOI, PhD, Senior Research Fellow, The Nethersole School of Nursing, Faculty of  
7 Medicine, The Chinese University of Hong Kong, Hong Kong SAR  
8

9 Email: kchoi@cuhk.edu.hk Tel: (852) 3943 4095 Fax: (852) 2603 5269  
10  
11  
12

13 Jonas Hon Ming YEUNG, MBChB, Neurology team-head, Alice Ho Miu Ling Nethersole  
14 Hospital and North District Hospital; Consultant, Department of Medicine, Alice Ho Miu Ling  
15 Nethersole Hospital, Hospital Authority, Hong Kong SAR  
16  
17

18 Email: yeunghmj@ha.org.hk Tel: (852) 2689 2255 Fax: (852) 2665 6436  
19  
20  
21

22 Siu Hung LI, MBChB, MRCP (UK), FRCP (Edin), Associate Consultant, Honorary Associate  
23 Professor (CUHK), Department of Medicine, North District Hospital, Hospital Authority, Hong  
24 Kong SAR  
25  
26

27 Email: lsh039@ha.org.hk Tel: (852) 2683 8888 Fax: (852) 2683 8383  
28  
29  
30

31 Marika DEMERS, PhD, Postdoctoral Research Fellow, Division of Biokinesiology and Physical  
32 Therapy, Motor Behavior and Neurorehabilitation Lab, University of Southern California, Los  
33 Angeles, California, 1540 Alcazar Street, 90089, United States  
34  
35

36 Email: demers@pt.usc.edu Tel: 1-323 442-1196  
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40 **Word count: 3,209**  
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## ABSTRACT

**Introduction** Balancing problems are prominent in stroke survivors with unilateral paresis. Recent evidence supports that dance interventions are associated with significant improvements in gait, stability and walking endurance in people with neurological conditions. The aim of this study is to explore the feasibility of a novel ballet-inspired at-home workout programme (FBB) for stroke survivors.

**Methods and analysis** A mixed-methods exploratory study incorporating a randomised controlled trial and qualitative evaluation will be conducted. We will recruit 40 adults with a first-ever ischaemic or haemorrhagic stroke and mild-moderate lower limb paresis from two acute stroke units. The intervention group will receive usual care plus FBB, an 8-week home-based programme with ballet-inspired workouts underpinned by Bandura's principles of self-efficacy and outcome expectation. FBB will be delivered by trained lay and peer volunteers, with the support of volunteer healthcare professionals. Multiple data will be collected: Recruitment rate, adherence to FBB, semi-structured interviews and questionnaires on outcomes (balance, gait and memory) assessed at baseline and immediately post-intervention. The generalised estimating equations model will be used to compare differential changes on outcomes across time points between the two arms. Qualitative data will be coded and grouped to form themes and sub-themes.

**Ethics and dissemination** Ethical approval from the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee has been obtained. All eligible participants will provide written informed consent. Study results will be disseminated via publications in peer-reviewed journals and presentations at international conferences.

**Trial registration number** NCT04460794

(Word count: 248)

**Keywords:** Stroke, dance, randomised controlled trial, postural balance, feasibility

## ARTICLE SUMMARY

### Strengths and limitations of this study

- This study will establish the feasibility of a novel ballet-inspired low-impact at-home workout programme for community-dwelling stroke survivors with lower limb paresis, featuring the adoption of ballet-inspired workouts, mobilisation of community resources for capacity building, and the usage of theory-driven strategies to enhance survivors' self-efficacy and outcome expectations in performing the workouts at home.
- It will be the first study of its kind to assess the feasibility and preliminary effects of a ballet-inspired at-home intervention for Chinese stroke survivors; cross-cultural applicability can be examined.
- Due to the nature of the intervention, only research assistants who will conduct recruitment, baseline and follow-up assessments will be blinded to the participants' group allocations, while it is not possible for participants and the persons who will deliver the intervention.

## INTRODUCTION

Stroke is ranked as the second leading cause of global deaths and a major cause of disability.<sup>1</sup> Over 65% of stroke survivors have hemiparesis, considerably affecting their daily life and social functions.<sup>2</sup> Substantial evidence shows that people with hemiparesis have significantly higher risks of falls, depression, and stroke recurrence. Their disability is associated with increased burden on caregivers and healthcare resource utilisation.<sup>3</sup>

Balancing problems are prominent in stroke survivors with unilateral paresis. They exhibit imbalanced body alignment and gait deviations such as extension with plantar flexion of foot on the affected side, decreased walking speed and shorter stride length.<sup>4,5</sup> These changes impair their postural control and functional mobility such as walking. Participation in balancing and muscle strengthening training is therefore very important. However, as over 70% of stroke survivors also develop verbal, visual or informational memory loss, their executive and social functions are impaired. It causes them to have difficulties in memorising exercise steps, and hence hinders their participation and the effectiveness of recovery training.<sup>6</sup>

Contemporary evidence-based guidelines recommend early discharge from hospital to enhance stroke survivors' reintegration to society.<sup>7</sup> Hospital-based training often ends after survivors have attained a certain level of physical functions. A critical condition to sustain physical gains is the survivors' ability and willingness to continue their rehabilitation after discharge.<sup>7</sup> Effective interventions to address their physical and cognitive needs are therefore necessary to support chronic recovery.

Dance is a combination of physical movements and musical beats. A systematic review of nine studies reports that dance interventions are associated with significant improvements in gait, stability and walking endurance in people with neurological conditions including stroke.<sup>8</sup> Another review suggests that dance interventions offer a new framework for neurorehabilitation.<sup>9</sup> Dance engages a person in both physical and cognitive stimulation. Repeated exercises in music and mental rehearsal of dance steps enhance ease to memorise and execute the planned sequences of movements. Simultaneous coordination of physical and cognitive activities enables dance interventions to take advantage of neuroplastic properties of the brain and bring about synergistic physical and cognitive benefits.<sup>8,9</sup> The pleasurable experience and social engagement in dance interventions outweighs exercise alone as they increase adherence to interventions.<sup>9</sup>

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3 Recent evidence supports the feasibility of dance interventions for stroke survivors. A pre-  
4 post-test study of 20 survivors found a 10-week dance intervention (two 60-minute classes per  
5 week) held in community settings was potentially beneficial in improving balance. The classes  
6 featured dance movements of ballet, contemporary, jazz, folk and ballroom.<sup>10</sup> Another pre-post-  
7 test study of nine survivors reported that a 45-minute biweekly dance intervention integrating jazz  
8 dance and merengue offered in a rehabilitation setting improved their balance.<sup>11</sup>  
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10  
11 Underpinning a complex intervention with a theoretical framework is integral to enable  
12 better understanding of the mechanism of changes in outcomes.<sup>12</sup> A systematic review suggests  
13 that Bandura's construct of self-efficacy is the most commonly used theoretical premise  
14 underpinning stroke self-management programmes.<sup>13</sup> A stroke self-management programme  
15 underpinned by Bandura's constructs of self-efficacy and outcome expectation was associated with  
16 significant improvements in satisfaction with performance of self-management behaviours and  
17 quality of life.<sup>14</sup>  
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19  
20 There are some gaps identified in the literature. First, there has been no consensus on which  
21 dance style and regimen is more effective for promoting balance, gait and memory in stroke  
22 survivors. Second, dance interventions examined in previous studies were not underpinned by  
23 theoretical frameworks and thus limited the understanding of mechanisms of change in outcomes.  
24 Third, only one study was conducted in community settings and it required participants to have  
25 access to a community centre to receive the dance intervention.<sup>10</sup> Alternative means to remove  
26 physical barriers and reach more survivors would be of greater benefit. Fourth, current evidence  
27 showed that dance interventions for stroke survivors were all delivered by dance instructors and/or  
28 health professionals.<sup>10,11</sup> It is worthwhile to explore alternative approaches that can mobilise  
29 community resources more effectively and build community capacity in health promotion. Fifth,  
30 there is no study reporting the effects of dance interventions on Chinese stroke survivors.  
31

### 32 **AIMS AND OBJECTIVES**

33  
34 We aim to establish the feasibility of a novel ballet-inspired low-impact at-home workout  
35 programme ("Footprints to Better Balance" (FBB)) by comparing FBB to a control group and  
36 preliminarily estimating its effects on stroke survivors' gait, balance and memory for planning a  
37 future full-scale randomised controlled trial (RCT).  
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39 Since this is an exploratory feasibility trial, there will be no hypothesis.

40 Objectives are to:  
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- 3 1. evaluate the recruitment rate of participants;
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- 5 2. identify the participants' attendance and adverse events during FBB;
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- 7 3. explore the facilitators, barriers and contextual factors that may influence the implementation
- 8 of FBB;
- 9
- 10 4. test the acceptability of data collection procedures; and
- 11
- 12 5. assess the preliminary effects of FBB on the participants' balance, gait and memory.
- 13

## 14 **METHODS AND DESIGN**

### 15 **Study design**

16 This is a mixed-methods exploratory study which incorporates a parallel-arm, assessor-blind RCT  
17 and qualitative evaluation.  
18

### 19 **Settings**

20 Participants will be recruited from the acute stroke units (ASUs) of two acute public hospitals in  
21 Hong Kong. The novel FBB will be conducted face-to-face at the participants' home and followed  
22 up by phone or internet media. All baseline and post-intervention assessments will be conducted  
23 in a university laboratory.  
24

### 25 **Participants**

26 Participants will be included if they are/have: (1) 18 years old or above, (2) clinically diagnosed  
27 with a first-ever ischaemic or haemorrhagic stroke, (3) living at home, (4) mild-moderate lower  
28 limb paresis with a modified Functional Ambulation Classification (MFAC) of III (Dependent  
29 walker) or above, (5) a Montreal Cognitive Assessment (MoCA) score >20, (6) able to follow  
30 three-step directions, (7) able to communicate in Cantonese and read Traditional Chinese, and (8)  
31 given written consent to participate in the study.  
32

33 Survivors will be excluded if they are/have: (1) diagnosed with transient ischaemic attack,  
34 subdural or epidural haemorrhage, (2) cerebrovascular event(s) due to tumours or head trauma, (3)  
35 pre-existing neurological, cardiovascular or orthopaedic condition that contradict dancing such as  
36 shoulder dislocation, myocardial infarction, seizures, or acute illness, (4) mental condition such as  
37 depression, schizophrenia, or personality disorder, (5) incomprehensible speech, or (6) severe  
38 hearing and/or visual disturbance.  
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### 40 **Sample size calculation**

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3 As an exploratory trial, we will recruit a total of 30 participants (15 per arm). This sample size  
4 meets the rule of thumb for sample size requirement in pilot studies.<sup>15</sup> Allowing for a potential  
5 attrition rate of 25%,<sup>13 14</sup> a total of 40 eligible participants (20 per arm) will be recruited.  
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### 8 **Randomisation**

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10 Participants will be randomly assigned at 1:1 ratio to an intervention (I) or a control (C) group  
11 after consenting and baseline assessment (see figure 1). Block randomisation (blocks of ten) will  
12 be used. An independent individual will generate a computer-generated random sequence of  
13 grouping identifiers (I or C). According to the sequence, the individual will place a grouping  
14 identifier into the opaque, identical, sealed and sequentially numbered envelopes. An independent  
15 mediator, who is not involved in recruitment, assessment or delivery of FBB, will store these  
16 envelopes in an undisclosed location, open the envelopes sequentially according to the  
17 participants' time of enrolment, record and inform the Principal Investigator about the participants'  
18 group allocations.  
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### 25 **Blinding**

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27 Research assistants, who will conduct recruitment, baseline and follow-up assessments and data  
28 entry, will have no knowledge of the participants' group allocations. However, blinding is not  
29 possible for the participants and the persons delivering FBB due to the nature of the intervention.  
30  
31 The research assistant, who will conduct qualitative evaluation with participants in the intervention  
32 group, will know the group allocation.  
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### 36 **Intervention**

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38 Participants randomly allocated to the intervention group will receive FBB in addition to usual  
39 care. FBB is an 8-week home-based programme aimed at improving stroke survivors' balance,  
40 gait, and memory. FBB was developed by the multidisciplinary healthcare team of the project in  
41 partnership with a ballet dance instructor and four stroke survivors (three females and one male,  
42 age 39-65 years, stroke duration 2-6 years). We chose ballet in lieu of other dance styles because  
43 it places emphasis on priori mastery of low-impact workouts to maintain proper body alignment,  
44 build core and lower extremity strengths and flexibility, before moving on to more complicated  
45 ballet movements. These workouts are particularly helpful for stroke survivors in correcting their  
46 balance and gait problems. Furthermore, ballet relies heavily on rehearsal of body movements  
47 mentally before putting the movements into actions. It mirrors mental imagery to promote motor  
48 relearning and to enhance brain plasticity and cognitive functions.<sup>16 17</sup> Musical beats are also  
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3 integrated in ballet training, requiring coordination of both cognitive and physical activities to  
4 move the body according to the planned sequence and time. With repeated and longer duration of  
5 practice, performing ballet-inspired movements also improves cardiorespiratory fitness. The  
6 movements can be practiced alone, with partners or in groups to facilitate social engagement.  
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10 Bandura's constructs of self-efficacy and outcome expectation<sup>18</sup> underpin the design and  
11 implementation of FBB. Strategies will be adopted to enhance participants' self-efficacy and  
12 outcome expectations of performing ballet-inspired workouts.<sup>13 14</sup>  
13  
14

15 Eight carefully selected ballet-inspired workouts are integrated:<sup>16 17</sup> basic body positions,  
16 trunk movement, pointed toes, turn in and out, tendus (sliding and extending foot), plies (bending  
17 knees), elevés (lifting up on balls of feet) and coupes (shifting body weight). The workouts are  
18 aimed at enhancing participants' awareness of body parts and ability in maintaining proper body  
19 alignment and postural control. Participants will perform the workouts starting from a sitting  
20 position and progress to a standing position with or without physical support as their postural  
21 control improves. They will perform mental imagery of each workout after viewing  
22 demonstrations, and memorising the movements before performing. Each workout is designed to  
23 resemble a daily activity commonly performed by females or males.  
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31 We will integrate the workouts into a 60-minute structured session adapted from a typical  
32 ballet class.<sup>4</sup> To maintain an appropriate level of challenge, the difficulty of the workouts will  
33 increase progressively subject to participants' willingness and improved condition.  
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36 FBB will be delivered by trained lay and peer stroke volunteers with the support of volunteer  
37 healthcare professionals. The lay volunteers will provide home visits and virtual sessions to  
38 participants. The healthcare professionals will provide expert advice to volunteers during  
39 implementation. All volunteers will receive four days of structured training conducted by the  
40 Principal Investigator with over ten years of ballet experience. Lay and peer stroke volunteers will  
41 be asked to complete an exit test to demonstrate the ability to deliver the FBB independently.  
42 Training completion will be determined by a satisfactory performance in the test and completion  
43 of one supervised on-site session and one virtual session.  
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50 A self-directed resource package will be developed in form of a website and guidebook for  
51 participants' convenience of access. It will contain videos to demonstrate the workouts, animated  
52 videos to illustrate the information, and a suggested weekly goal-and-action plan for eight weeks.  
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3 FBB will consist of two weekly 90-minute at-home support sessions delivered by two lay  
4 volunteers (one of them will be a stroke survivor) in Weeks 1-2, and six weekly 15-minute virtual  
5 interactions (by phone or internet media) by either lay volunteer in the remaining weeks.  
6 Participants will be asked to perform the 60-minute session two times per week during these eight  
7 weeks. The home-based sessions will introduce participants to FBB, the resources package and  
8 safety precautions. The lay volunteers will conduct virtual sessions and discuss strategies to  
9 address challenges in performing workouts, reinforcing outcome expectations, appraising  
10 incremental progress and reinforcing participation as planned for the following weeks. They will  
11 update the healthcare professionals about the participant's progress, and consult them for advice  
12 if needed. All adverse events will be documented and reported to the clinical research ethics  
13 committee.

14  
15 Strategies will be adopted to ensure safety of the participants during FBB. Participants are  
16 reminded to perform FBB each time starting from a sitting position and progressing to a standing  
17 position as their postural control improves. Family members or carers are encouraged to join FBB  
18 with participants and/or provide standby support to participants while they are doing FBB. The  
19 preparation of environment include preparing for a chair without wheels for support, adequate  
20 space and light, and a phone nearby for making contacts when necessary. The breaks are  
21 mandatory to avoid over exertion.

### 22 **Control group**

23 Control participants will receive usual care including usual stroke services available to the  
24 participants, including but not limited to, medical consultations offered by hospital, rehabilitation  
25 services by community-based organisations. In addition, they will be provided with an information  
26 sheet about recommendations with pictorial demonstrations on basic stretching and leg exercises  
27 for stroke survivors.

### 28 **Recruitment and data collection procedures**

29 A research assistant will visit the ASUs regularly to screen for eligible participants. He/she will  
30 review the medical records of all stroke patients admitted, and approach the potentially eligible  
31 participants and explain to them and/or their relatives the study aim, objectives, intervention and  
32 data collection procedures. Participants will be asked to sign an informed consent form and will  
33 be given a participation card indicating their recruitment into the study. Then, the research assistant  
34 will record the participants' demographic and clinical information. After the patients are  
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3 discharged from the hospital, the research assistant will contact them and schedule a baseline  
4 assessment. Participants will be informed about video-taking during assessment of their balance  
5 and gait. Face-to-face focus group interviews with all participants in the intervention group and all  
6 volunteers will be conducted immediately post-intervention in a university laboratory room. All  
7 interviews will be audio-taped. Cash allowance will be provided to participants after completing  
8 each assessment and interview; and to volunteers after completing a home visit to subsidise their  
9 travel expenses in the study.

### 15 **Data collection**

16 Multiple data will be collected:

- 17 1. Recruitment: Review the research assistant's recruitment records and flow of participants in  
18 the study to calculate the participants' recruitment rate and the reasons for non-participation.
- 19 2. Characteristics of eligible and included/non-included stroke adults: Participants' age,  
20 gender, marital status, educational level, stroke history, comorbidities, living condition, and  
21 financial status will be extracted from the medical records.
- 22 3. Participant characteristics (completed versus dropout): Data such as age, gender, marital  
23 status, educational level, occupation, current financial aids received, type of housing, living  
24 condition, past and present medical history, assistive aids used, MoCA and MFAC scores will be  
25 extracted from the participants' records.
- 26 4. Home journal: Participants will document details of their participation in FBB in the website  
27 or guidebook, including date, time, number of workouts performed, presence of dyspnoea, injuries  
28 or accidents.
- 29 5. Audio records: All home visits and virtual sessions of FBB, and volunteer training sessions  
30 will be audio recorded with the participants' and the volunteers' consent.
- 31 6. Qualitative evaluation: Focus group semi-structured exit interviews will be conducted by an  
32 independent research assistant with 1) All participants in the intervention group to elicit their  
33 experiences of participating in FBB, facilitators of and barriers to participating in FBB,  
34 perspectives on feasibility, acceptability and usefulness of FBB, changes in behaviours after FBB,  
35 impression of research experience, and areas for enhancement; and 2) All volunteers to elicit their  
36 perceptions on the facilitators of and barriers to implementing FBB, perspectives on feasibility,  
37 acceptability and usefulness of FBB, and observations of the participants' participation in FBB.
- 38 7. Outcomes: All participants will be assessed at baseline (T0) and at immediately post-

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3 intervention (T1) (within one week after the intervention).  
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- 5 - **Balance:** The 14-item Mini-Balance Evaluation Systems Test (Mini-BESTest) will be used.<sup>19</sup>  
6 It measures four domains including the participants' anticipatory postural adjustments,  
7 reactive postural control, sensory orientation, and dynamic gait. All items are rated on a 3-  
8 level scale (0=Severe, 1=Moderate, 2=Normal). The summed total score is 0 to 28. A higher  
9 score represents better balance ability. The Cronbach alpha is 0.89-0.94.<sup>19</sup>
- 10 - **Balance confidence:** The 16-item Activities-specific Balance Confidence Scale (Chinese  
11 version)<sup>20</sup> will be adopted. The participants will rate their confidence in balance associated  
12 with performing 16 daily functional activities from 0% (absolutely no confidence) to 100%  
13 (fully confident). The summed total score is 0 to 100%. A higher score denotes higher  
14 confidence. The Cronbach alpha is 0.97.<sup>20</sup>
- 15 - **Gait:** The 31-item Gait Assessment and Intervention tool (G.A.I.T.) will be used to measure  
16 the participants' gait: upper extremity and trunk movement control; trunk and lower extremity  
17 (stance phase); trunk and lower extremity (swing phase). Each item is scored from 0 (normal)  
18 to 3, with gradients of variation from normal. The total score ranges from 0 (normal gait) to  
19 62 (greatest extent of gait deviations). G.A.I.T. demonstrates good intra-rater and interrater  
20 reliability.<sup>21</sup>
- 21 - **Walking endurance:** The 6-Minute Walk Test (MWT) will be performed in accordance with  
22 the American Thoracic Society guidelines.<sup>22</sup> The distance walked, the time stopped and  
23 reason(s) for stopping prematurely will be recorded. The 6MWT, 12MWT, and self-paced  
24 gait speed were all significantly highly correlated ( $r>0.90$ ).<sup>23</sup>
- 25 - **Memory:** The 11-item Rivermead Behavioural Memory Test–Third Version (Chinese  
26 version) will be used to measure the participants' memory function for performing daily tasks.  
27 For each task, the scores range from 0-2 (0-point=error; 1-point=intermediate; 2-  
28 points=normal). The total score ranges from 0 to 254. The higher the score, the better the  
29 memory performance. The test demonstrates high inter-rater reliability. The correlation  
30 between performance on parallel forms is 0.67-0.84.<sup>24</sup>

### 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 **Data analysis**

51 All quantitative data will be summarised and presented using appropriate descriptive statistics.  
52 Recruitment rate will be calculated by the average of participants recruited per study venue per  
53 month. Cohen's D values will be calculated to estimate the effect sizes of the intervention on the  
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3 outcome variables. All statistical analyses will be performed using IBM SPSS 24.0 (IBM Corp.  
4 Armonk, NY). Raw audio files will be transcribed verbatim and destroyed after completing  
5 transcription. The interview transcripts and participants' home journals will be transcribed  
6 verbatim from the audio recordings by an independent research assistant and analysed  
7 thematically. Initial codes will be developed by two independent researchers (SHSL and JPCC),  
8 and grouped them to form major themes and sub-themes that correspond to the study aim and  
9 objectives. Discrepancies in the major themes and sub-themes will be resolved by discussion  
10 between the two researchers. The qualitative data will supplement the quantitative outcome data  
11 by identifying convergence and differences between the two datasets.<sup>25</sup>

### 12 **Patient and public involvement**

13 FBB was developed in partnership with a ballet instructor and four stroke survivors. Community-  
14 dwelling stroke survivors will be recruited to participate in the study. Adult lay and peer stroke  
15 volunteers will be recruited and trained to deliver FBB. Comments on the programme such as  
16 acceptability and usefulness, and areas of enhancement will be collected from the participants and  
17 the volunteers through semi-structured interviews. Preliminary effects of FBB will be assessed by  
18 the administration of questionnaires with the participants. The results of the study will be  
19 disseminated to the participants on request.

### 20 **Reporting guidelines**

21 SPIRIT reporting guidelines were adhered to in this protocol.<sup>26</sup>

### 22 **Ethical considerations and dissemination**

23 Ethical approval has been obtained from the Joint Chinese University of Hong Kong-New  
24 Territories East Cluster Clinical Research Ethics Committee (Ref. No.: 2019.598). The research  
25 team will protect participants' rights and safety by adhering to local laws, the Declaration of  
26 Helsinki, institutional policies, and the International Conference on Harmonization - Good Clinical  
27 Practice (ICH-GCP). All research personnel will be asked to complete the modules of Good  
28 Clinical Practice. Agreement will be made in advance with the personnel in charge of ASUs for  
29 arranging participant recruitment. All eligible participants will provide written informed consent.  
30 All questionnaires will be anonymous. All information will be kept strictly confidential. All  
31 information will be destroyed six years after completion of the project. Study findings will be  
32 disseminated via publications in peer-reviewed journals and presentations at international  
33 conferences.

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We would like to thank the stroke survivors and the dance teacher for providing their valuable suggestions in the development of the dance intervention.

## **Author contributions**

SHSL and JPCC contributed to the conception and design of the study. MD, KCC, JHMY and SHL commented on the intervention contents. KCC was responsible for sample size calculation and statistical analyses. All authors are the applicants of the grant submission. SHSL wrote the manuscript and all authors read and approved the manuscript.

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## **Competing interests**

The authors declare that they have no competing interests.

## **Patient and public involvement**

Patients and the public were involved in the design, conduct, reporting, and/or dissemination plans of this study.

## **Patient consent for publication**

Not required.

## **Provenance and peer review**

Not commissioned; externally peer reviewed.

## **Data statement**

The datasets used and/or analysed during the current study will be available from the corresponding author on reasonable request.

### ORCID iD

Suzanne Hoi Shan Lo <https://orcid.org/0000-0002-9970-0642>

Janita Pak Chun Chau <https://orcid.org/0000-0002-3750-7396>

Kai Chow Choi <https://orcid.org/0000-0001-7157-8668>

Marika Demers <https://orcid.org/0000-0003-4075-1418>

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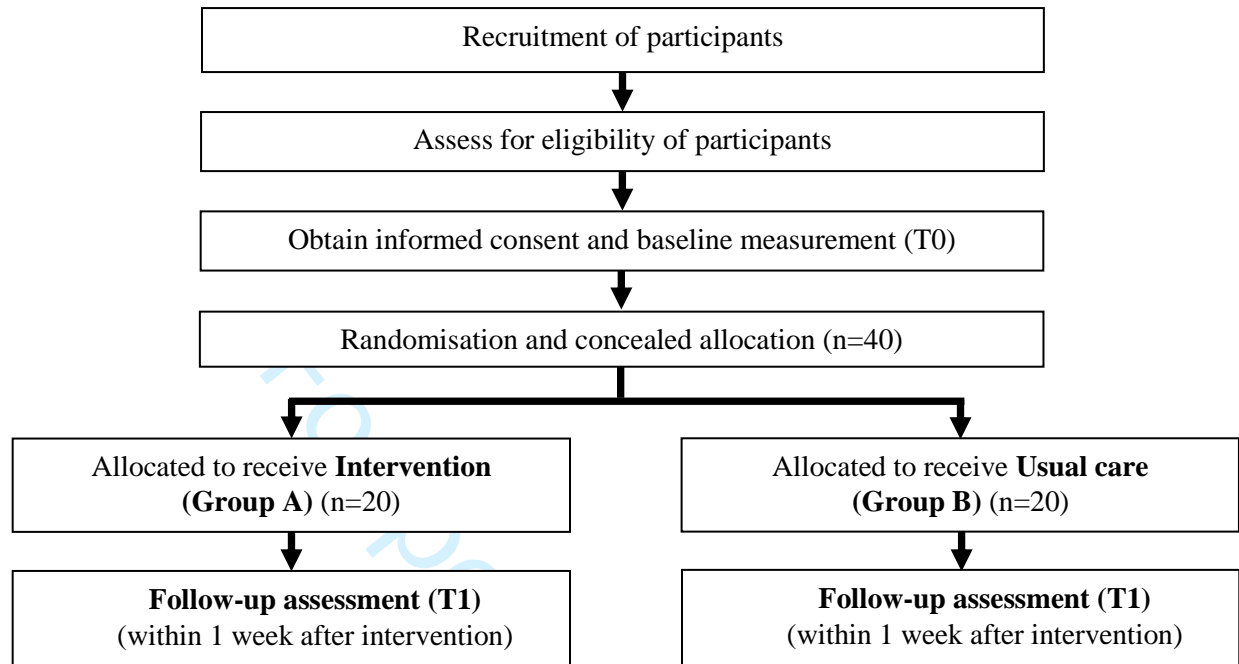
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## Figure legend

**Figure 1** Flow of participants in the study.

**Figure 1** Flow of participants in the study.

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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			Page
	Reporting Item		Number
<b>Administrative information</b>			
Title	<a href="#">#1</a> Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym		1

1	Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet registered,	3
2				
3				
4			name of intended registry	
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6	Trial registration:	<a href="#">#2b</a>	All items from the World Health Organization Trial	n/a (not
7				
8	data set		Registration Data Set	included)
9				
10				
11	Protocol version	<a href="#">#3</a>	Date and version identifier	n/a (one
12				
13				
14				version
15				
16				only)
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18				
19	Funding	<a href="#">#4</a>	Sources and types of financial, material, and other	13
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21			support	
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23				
24				
25	Roles and	<a href="#">#5a</a>	Names, affiliations, and roles of protocol contributors	1-2, 13
26				
27	responsibilities:			
28				
29	contributorship			
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32	Roles and	<a href="#">#5b</a>	Name and contact information for the trial sponsor	n/a
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34	responsibilities:			
35				
36	sponsor contact			
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38	information			
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42	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study	13 (for
43				
44	responsibilities:		design; collection, management, analysis, and	funder)
45				
46	sponsor and funder		interpretation of data; writing of the report; and the	
47				
48				
49			decision to submit the report for publication, including	
50				
51			whether they will have ultimate authority over any of	
52				
53			these activities	
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1 Roles and [#5d](#) Composition, roles, and responsibilities of the n/a  
 2  
 3 responsibilities:  
 4 coordinating centre, steering committee, endpoint  
 5 committees  
 6 adjudication committee, data management team, and  
 7  
 8 other individuals or groups overseeing the trial, if  
 9  
 10 applicable (see Item 21a for data monitoring committee)  
 11  
 12

## 13 Introduction

14  
 15  
 16 Background and [#6a](#) Description of research question and justification for 5-6  
 17 rationale  
 18 undertaking the trial, including summary of relevant  
 19 studies (published and unpublished) examining benefits  
 20 and harms for each intervention  
 21  
 22  
 23  
 24

25  
 26 Background and [#6b](#) Explanation for choice of comparators 10  
 27 rationale: choice of  
 28 comparators  
 29  
 30  
 31  
 32

33  
 34 Objectives [#7](#) Specific objectives or hypotheses 6  
 35  
 36

37 Trial design [#8](#) Description of trial design including type of trial (eg, 7  
 38 parallel group, crossover, factorial, single group),  
 39 allocation ratio, and framework (eg, superiority,  
 40 equivalence, non-inferiority, exploratory)  
 41  
 42  
 43  
 44  
 45  
 46

## 47 Methods:

48  
 49 Participants,  
 50  
 51 interventions, and  
 52  
 53 outcomes  
 54  
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 56  
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1	Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic,	7
2			academic hospital) and list of countries where data will	
3			be collected. Reference to where list of study sites can	
4			be obtained	
5				
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7				
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10				
11	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If	7
12			applicable, eligibility criteria for study centres and	
13			individuals who will perform the interventions (eg,	
14			surgeons, psychotherapists)	
15				
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20				
21	Interventions:	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow	8-10
22	description		replication, including how and when they will be	
23			administered	
24				
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28				
29	Interventions:	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated	n/a (not
30	modifications		interventions for a given trial participant (eg, drug dose	included)
31			change in response to harms, participant request, or	
32			improving / worsening disease)	
33				
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38				
39	Interventions:	<a href="#">#11c</a>	Strategies to improve adherence to intervention	8-10
40	adherence		protocols, and any procedures for monitoring adherence	
41			(eg, drug tablet return; laboratory tests)	
42				
43				
44				
45				
46	Interventions:	<a href="#">#11d</a>	Relevant concomitant care and interventions that are	n/a (not
47	concomitant care		permitted or prohibited during the trial	relevant
48				to study)
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54	Outcomes	<a href="#">#12</a>	Primary, secondary, and other outcomes, including the	10-12
55			specific measurement variable (eg, systolic blood	
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pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome.

Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

Participant timeline [#13](#) Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) 12, 17

Sample size [#14](#) Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations 7

Recruitment [#15](#) Strategies for achieving adequate participant enrolment to reach target sample size 10

## Methods:

### Assignment of interventions (for controlled trials)

Allocation: sequence generation [#16a](#) Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document 7-8

that is unavailable to those who enrol participants or  
assign interventions

1			
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6	Allocation	<a href="#">#16b</a>	Mechanism of implementing the allocation sequence 7-8
7			
8	concealment		(eg, central telephone; sequentially numbered, opaque,
9			
10	mechanism		sealed envelopes), describing any steps to conceal the
11			
12			sequence until interventions are assigned
13			
14			
15	Allocation:	<a href="#">#16c</a>	Who will generate the allocation sequence, who will 7-8
16			
17	implementation		enrol participants, and who will assign participants to
18			
19			interventions
20			
21			
22			
23	Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to interventions 8
24			
25			(eg, trial participants, care providers, outcome
26			
27			assessors, data analysts), and how
28			
29			
30			
31	Blinding (masking):	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is n/a (not
32			
33	emergency		permissible, and procedure for revealing a participant's relevant
34			
35	unblinding		allocated intervention during the trial to study)
36			
37			
38	<b>Methods: Data</b>		
39			
40	collection,		
41			
42	management, and		
43			
44	analysis		
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47			
48	Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome, 10-12
49			
50			baseline, and other trial data, including any related
51			
52			processes to promote data quality (eg, duplicate
53			
54			measurements, training of assessors) and a description
55			
56			of study instruments (eg, questionnaires, laboratory
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tests) along with their reliability and validity, if known.

Reference to where data collection forms can be found,  
if not in the protocol

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Data collection plan: <a href="#">#18b</a>	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	10-12
18 19 20 21 22 23 24 25 26 27 28 29	Data management <a href="#">#19</a>	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
30 31 32 33 34 35 36 37 38 39	Statistics: outcomes <a href="#">#20a</a>	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
40 41 42 43 44	Statistics: additional analyses <a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
45 46 47 48 49 50 51 52 53 54	Statistics: analysis population and missing data <a href="#">#20c</a>	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12

## Methods: Monitoring

1	Data monitoring:	<a href="#">#21a</a>	Composition of data monitoring committee (DMC);	n/a (not
2				
3	formal committee		summary of its role and reporting structure; statement of	relevant
4				
5			whether it is independent from the sponsor and	to study)
6			competing interests; and reference to where further	
7			details about its charter can be found, if not in the	
8			protocol. Alternatively, an explanation of why a DMC is	
9			not needed	
10				
11	Data monitoring:	<a href="#">#21b</a>	Description of any interim analyses and stopping	n/a (not
12				
13	interim analysis		guidelines, including who will have access to these	relevant
14			interim results and make the final decision to terminate	to study)
15			the trial	
16				
17				
18	Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and managing	12-13
19			solicited and spontaneously reported adverse events	
20			and other unintended effects of trial interventions or trial	
21			conduct	
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28	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if	n/a (not
29				
30			any, and whether the process will be independent from	relevant
31			investigators and the sponsor	to study)
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38	<b>Ethics and</b>			
39	<b>dissemination</b>			
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50	Research ethics	<a href="#">#24</a>	Plans for seeking research ethics committee /	13
51				
52	approval		institutional review board (REC / IRB) approval	
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1 2 3 4 5 6 7 8 9 10 11 12	Protocol amendments	<a href="#">#25</a>	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a (not relevant to study)
13 14 15 16 17 18 19 20	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10, 13
21 22 23 24 25 26 27 28	Consent or assent: ancillary studies	<a href="#">#26b</a>	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a (not applicable to study)
29 30 31 32 33 34 35 36 37	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10, 13
38 39 40 41 42 43	Declaration of interests	<a href="#">#28</a>	Financial and other competing interests for principal investigators for the overall trial and each study site	13
44 45 46 47 48 49 50	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
51 52 53 54 55 56 57 58 59 60	Ancillary and post-trial care	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a (not relevant to study)

1	Dissemination policy:	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate trial	3, 13
2				
3	trial results		results to participants, healthcare professionals, the	
4			public, and other relevant groups (eg, via publication,	
5			reporting in results databases, or other data sharing	
6			arrangements), including any publication restrictions	
7				
8	Dissemination policy:	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended use of	n/a (not
9				
10	authorship		professional writers	intended)
11				
12	Dissemination policy:	<a href="#">#31c</a>	Plans, if any, for granting public access to the full	14
13				
14	reproducible		protocol, participant-level dataset, and statistical code	
15				
16	research			
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19	<b>Appendices</b>			
20				
21	Informed consent	<a href="#">#32</a>	Model consent form and other related documentation	n/a (not
22				
23	materials		given to participants and authorised surrogates	included)
24				
25	Biological specimens	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and storage of	n/a (not
26				
27			biological specimens for genetic or molecular analysis in	relevant
28			the current trial and for future use in ancillary studies, if	to study)
29			applicable	
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47	by the <a href="#">EQUATOR Network</a> in collaboration with <a href="#">Penelope.ai</a>			
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# BMJ Open

## Feasibility of a ballet-inspired low-impact at-home workout programme for adults with stroke: A mixed-methods exploratory study protocol

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Manuscript ID	bmjopen-2020-045064.R2
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<b>Primary Subject Heading</b>:	Health services research
Secondary Subject Heading:	Public health
Keywords:	Stroke < NEUROLOGY, PUBLIC HEALTH, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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**Title Page****Study title**

Feasibility of a ballet-inspired low-impact at-home workout programme for adults with stroke: A mixed-methods exploratory study protocol

**Authors**

Suzanne Hoi Shan Lo,<sup>1,\*</sup> Janita Pak Chun Chau,<sup>1</sup> Kai Chow Choi,<sup>1</sup> Jonas Hon Ming Yeung,<sup>2</sup> Siu Hung Li,<sup>3</sup> Marika Demers<sup>4</sup>

<sup>1</sup>The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong SAR, China

<sup>2</sup>Department of Medicine, Alice Ho Miu Ling Nethersole Hospital, Hospital Authority, Hong Kong SAR, China

<sup>3</sup>Department of Medicine, North District Hospital, Hospital Authority, Hong Kong SAR, China

<sup>4</sup>Division of Biokinesiology and Physical Therapy, Motor Behavior and Neurorehabilitation Lab, University of Southern California, Los Angeles, California, United States

**\*Correspondence to:**

Dr. Suzanne Hoi Shan Lo

Postal Address: Room 826, 8/F, Esther Lee Building, Chung Chi College, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong SAR, China

Email: [suzannelo@cuhk.edu.hk](mailto:suzannelo@cuhk.edu.hk)

**Authors' details:**

Suzanne Hoi Shan LO, PhD, Assistant Professor, The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong SAR

Email: [suzannelo@cuhk.edu.hk](mailto:suzannelo@cuhk.edu.hk) Tel: (852) 3943 4485 Fax: (852) 2603 5269

Janita Pak Chun CHAU, PhD, Professor, The Nethersole School of Nursing; Assistant Dean (Alumni Affairs), Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong SAR

1  
2  
3 Email: janitachau@cuhk.edu.hk Tel: (852) 3943 6226 Fax: (852) 2603 5269  
4  
5

6 Kai Chow CHOI, PhD, Senior Research Fellow, The Nethersole School of Nursing, Faculty of  
7 Medicine, The Chinese University of Hong Kong, Hong Kong SAR  
8

9 Email: kchoi@cuhk.edu.hk Tel: (852) 3943 4095 Fax: (852) 2603 5269  
10  
11

12  
13 Jonas Hon Ming YEUNG, MBChB, Neurology team-head, Alice Ho Miu Ling Nethersole  
14 Hospital and North District Hospital; Consultant, Department of Medicine, Alice Ho Miu Ling  
15 Nethersole Hospital, Hospital Authority, Hong Kong SAR  
16  
17

18 Email: yeunghmj@ha.org.hk Tel: (852) 2689 2255 Fax: (852) 2665 6436  
19  
20

21  
22 Siu Hung LI, MBChB, MRCP (UK), FRCP (Edin), Associate Consultant, Honorary Associate  
23 Professor (CUHK), Department of Medicine, North District Hospital, Hospital Authority, Hong  
24 Kong SAR  
25  
26

27 Email: lsh039@ha.org.hk Tel: (852) 2683 8888 Fax: (852) 2683 8383  
28  
29

30  
31 Marika DEMERS, PhD, Postdoctoral Research Fellow, Division of Biokinesiology and Physical  
32 Therapy, Motor Behavior and Neurorehabilitation Lab, University of Southern California, Los  
33 Angeles, California, 1540 Alcazar Street, 90089, United States  
34  
35

36 Email: demers@pt.usc.edu Tel: 1-323 442-1196  
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39 **Word count: 3,209**  
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## ABSTRACT

**Introduction** Balancing problems are prominent in stroke survivors with unilateral paresis. Recent evidence supports that dance interventions are associated with significant improvements in gait, stability and walking endurance in people with neurological conditions. The aim of this study is to explore the feasibility of a novel ballet-inspired at-home workout programme (FBB) for stroke survivors.

**Methods and analysis** A mixed-methods exploratory study incorporating a randomised controlled trial and qualitative evaluation will be conducted. We will recruit 40 adults with a first-ever ischaemic or haemorrhagic stroke and mild-moderate lower limb paresis from two acute stroke units. The intervention group will receive usual care plus FBB, an 8-week home-based programme with ballet-inspired workouts underpinned by Bandura's principles of self-efficacy and outcome expectation. FBB will be delivered by trained lay and peer volunteers, with the support of volunteer healthcare professionals. Multiple data will be collected: Recruitment rate, adherence to FBB, semi-structured interviews and questionnaires on outcomes (balance, gait and memory) assessed at baseline and immediately post-intervention. The generalised estimating equations model will be used to compare differential changes on outcomes across time points between the two arms. Qualitative data will be coded and grouped to form themes and sub-themes.

**Ethics and dissemination** Ethical approval from the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee has been obtained. All eligible participants will provide written informed consent. Study results will be disseminated via publications in peer-reviewed journals and presentations at international conferences.

**Trial registration number** NCT04460794

(Word count: 248)

**Keywords:** Stroke, dance, randomised controlled trial, postural balance, feasibility

## ARTICLE SUMMARY

### Strengths and limitations of this study

- This study will establish the feasibility of a novel ballet-inspired low-impact at-home workout programme for community-dwelling stroke survivors with lower limb paresis, featuring the adoption of ballet-inspired workouts, mobilisation of community resources for capacity building, and the usage of theory-driven strategies to enhance survivors' self-efficacy and outcome expectations in performing the workouts at home.
- It will be the first study of its kind to assess the feasibility and preliminary effects of a ballet-inspired at-home intervention for Chinese stroke survivors; cross-cultural applicability can be examined.
- Due to the nature of the intervention, only research assistants who will conduct recruitment, baseline and follow-up assessments will be blinded to the participants' group allocations, while it is not possible for participants and the persons who will deliver the intervention.

## INTRODUCTION

Stroke is ranked as the second leading cause of global deaths and a major cause of disability.<sup>1</sup> Over 65% of stroke survivors have hemiparesis, considerably affecting their daily life and social functions.<sup>2</sup> Substantial evidence shows that people with hemiparesis have significantly higher risks of falls, depression, and stroke recurrence. Their disability is associated with increased burden on caregivers and healthcare resource utilisation.<sup>3</sup>

Balancing problems are prominent in stroke survivors with unilateral paresis. They exhibit imbalanced body alignment and gait deviations such as extension with plantar flexion of foot on the affected side, decreased walking speed and shorter stride length.<sup>4,5</sup> These changes impair their postural control and functional mobility such as walking. Participation in balancing and muscle strengthening training is therefore very important. However, as over 70% of stroke survivors also develop verbal, visual or informational memory loss, their executive and social functions are impaired. It causes them to have difficulties in memorising exercise steps, and hence hinders their participation and the effectiveness of recovery training.<sup>6</sup>

Contemporary evidence-based guidelines recommend early discharge from hospital to enhance stroke survivors' reintegration to society.<sup>7</sup> Hospital-based training often ends after survivors have attained a certain level of physical functions. A critical condition to sustain physical gains is the survivors' ability and willingness to continue their rehabilitation after discharge.<sup>7</sup> Effective interventions to address their physical and cognitive needs are therefore necessary to support chronic recovery.

Dance is a combination of physical movements and musical beats. A systematic review of nine studies reports that dance interventions are associated with significant improvements in gait, stability and walking endurance in people with neurological conditions including stroke.<sup>8</sup> Another review suggests that dance interventions offer a new framework for neurorehabilitation.<sup>9</sup> Dance engages a person in both physical and cognitive stimulation. Repeated exercises in music and mental rehearsal of dance steps enhance ease to memorise and execute the planned sequences of movements. Simultaneous coordination of physical and cognitive activities enables dance interventions to take advantage of neuroplastic properties of the brain and bring about synergistic physical and cognitive benefits.<sup>8,9</sup> The pleasurable experience and social engagement in dance interventions outweighs exercise alone as they increase adherence to interventions.<sup>9</sup>

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3       Recent evidence supports the feasibility of dance interventions for stroke survivors. A pre-  
4 post-test study of 20 survivors found a 10-week dance intervention (two 60-minute classes per  
5 week) held in community settings was potentially beneficial in improving balance. The classes  
6 featured dance movements of ballet, contemporary, jazz, folk and ballroom.<sup>10</sup> Another pre-post-  
7 test study of nine survivors reported that a 45-minute biweekly dance intervention integrating jazz  
8 dance and merengue offered in a rehabilitation setting improved their balance.<sup>11</sup>  
9

10  
11       Underpinning a complex intervention with a theoretical framework is integral to enable  
12 better understanding of the mechanism of changes in outcomes.<sup>12</sup> A systematic review suggests  
13 that Bandura's construct of self-efficacy is the most commonly used theoretical premise  
14 underpinning stroke self-management programmes.<sup>13</sup> A stroke self-management programme  
15 underpinned by Bandura's constructs of self-efficacy and outcome expectation was associated with  
16 significant improvements in satisfaction with performance of self-management behaviours and  
17 quality of life.<sup>14</sup>  
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20       There are some gaps identified in the literature. First, dance interventions examined in  
21 previous studies were not underpinned by theoretical frameworks and thus limited the  
22 understanding of mechanisms of change in outcomes. Second, only one study was conducted in  
23 community settings and it required participants to have access to a community centre to receive  
24 the dance intervention.<sup>10</sup> Alternative means to remove physical barriers and reach more survivors  
25 would be of greater benefit. Third, current evidence showed that dance interventions for stroke  
26 survivors were all delivered by dance instructors and/or health professionals.<sup>10,11</sup> It is worthwhile  
27 to explore alternative approaches that can mobilise community resources more effectively and  
28 build community capacity in health promotion. Fourth, there is no study reporting the effects of  
29 dance interventions on Chinese stroke survivors.  
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### 31 32 33 34 35 36 37 38 39 40 41 42 43 **AIMS AND OBJECTIVES**

44 We aim to establish the feasibility of a novel ballet-inspired low-impact at-home workout  
45 programme ("Footprints to Better Balance" (FBB)) by comparing FBB to a control group and  
46 preliminarily estimating its effects on stroke survivors' gait, balance and memory for planning a  
47 future full-scale randomised controlled trial (RCT).  
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49 Since this is an exploratory feasibility trial, there will be no hypothesis.  
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51 Objectives are to:  
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- 53 1. evaluate the recruitment rate of participants;  
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2. identify the participants' attendance and adverse events during FBB;
3. explore the facilitators, barriers and contextual factors that may influence the implementation of FBB;
4. test the acceptability of data collection procedures; and
5. assess the preliminary effects of FBB on the participants' balance, gait and memory.

## METHODS AND DESIGN

### Study design

This is a mixed-methods exploratory study which incorporates a parallel-arm, assessor-blind RCT and qualitative evaluation.

### Settings

Participants will be recruited from the acute stroke units (ASUs) of two acute public hospitals in Hong Kong. The novel FBB will be conducted face-to-face at the participants' home and followed up by phone or internet media. All baseline and post-intervention assessments will be conducted in a university laboratory.

### Participants

Participants will be included if they are/have: (1) 18 years old or above, (2) clinically diagnosed with a first-ever ischaemic or haemorrhagic stroke, (3) living at home, (4) mild-moderate lower limb paresis with a modified Functional Ambulation Classification (MFAC) of III (Dependent walker) or above, (5) a Montreal Cognitive Assessment (MoCA) score >20, (6) able to follow three-step directions, (7) able to communicate in Cantonese and read Traditional Chinese, and (8) given written consent to participate in the study.

Survivors will be excluded if they are/have: (1) diagnosed with transient ischaemic attack, subdural or epidural haemorrhage, (2) cerebrovascular event(s) due to tumours or head trauma, (3) pre-existing neurological, cardiovascular or orthopaedic condition that contradict dancing such as shoulder dislocation, myocardial infarction, seizures, or acute illness, (4) mental condition such as depression, schizophrenia, or personality disorder, (5) incomprehensible speech, or (6) severe hearing and/or visual disturbance.

### Sample size calculation

As an exploratory trial, we will recruit a total of 30 participants (15 per arm). This sample size meets the rule of thumb for sample size requirement in pilot studies.<sup>15</sup> Allowing for a potential attrition rate of 25%,<sup>13 14</sup> a total of 40 eligible participants (20 per arm) will be recruited.

### **Randomisation**

Participants will be randomly assigned at 1:1 ratio to an intervention (I) or a control (C) group after consenting and baseline assessment (see figure 1). Block randomisation (blocks of ten) will be used. An independent individual will generate a computer-generated random sequence of grouping identifiers (I or C). According to the sequence, the individual will place a grouping identifier into the opaque, identical, sealed and sequentially numbered envelopes. An independent mediator, who is not involved in recruitment, assessment or delivery of FBB, will store these envelopes in an undisclosed location, open the envelopes sequentially according to the participants' time of enrolment, record and inform the Principal Investigator about the participants' group allocations.

### **Blinding**

Research assistants, who will conduct recruitment, baseline and follow-up assessments and data entry, will have no knowledge of the participants' group allocations. However, blinding is not possible for the participants and the persons delivering FBB due to the nature of the intervention. The research assistant, who will conduct qualitative evaluation with participants in the intervention group, will know the group allocation.

### **Intervention**

Participants randomly allocated to the intervention group will receive FBB in addition to usual care. FBB is an 8-week home-based programme aimed at improving stroke survivors' balance, gait, and memory. FBB was developed by the multidisciplinary healthcare team of the project in partnership with a ballet dance instructor and four stroke survivors (three females and one male, age 39-65 years, stroke duration 2-6 years). We chose ballet in lieu of other dance styles because it places emphasis on priori mastery of low-impact workouts to maintain proper body alignment, build core and lower extremity strengths and flexibility, before moving on to more complicated ballet movements. These workouts are particularly helpful for stroke survivors in correcting their balance and gait problems. Furthermore, classical ballet training emphasises motor learning for smooth performance of movements.<sup>16</sup> When put in practice for rehabilitation training, we also emphasised to survivors on rehearsal of body movements mentally before putting the movements into actions. It mirrors mental imagery to promote motor relearning and to enhance brain plasticity and cognitive functions.<sup>16</sup> <sup>17</sup> Musical beats are also integrated in ballet training, requiring coordination of both cognitive and physical activities to move the body according to the planned

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3 sequence and time. With repeated and longer duration of practice, performing ballet-inspired  
4 movements also improves cardiorespiratory fitness. The movements can be practiced alone, with  
5 partners or in groups to facilitate social engagement.  
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8 Bandura's constructs of self-efficacy and outcome expectation<sup>18</sup> underpin the design and  
9 implementation of FBB. Strategies will be adopted to enhance participants' self-efficacy and  
10 outcome expectations of performing ballet-inspired workouts.<sup>13 14</sup>  
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13 Eight carefully selected ballet-inspired workouts are integrated:<sup>16 17</sup> basic body positions,  
14 trunk movement, pointed toes, turn in and out, tendus (sliding and extending foot), plies (bending  
15 knees), elevés (lifting up on balls of feet) and coupes (shifting body weight). The workouts are  
16 aimed at enhancing participants' awareness of body parts and ability in maintaining proper body  
17 alignment and postural control. Participants will perform the workouts starting from a sitting  
18 position and progress to a standing position with or without physical support as their postural  
19 control improves. They will perform mental imagery of each workout after viewing  
20 demonstrations, and memorising the movements before performing. Each workout is designed to  
21 resemble a daily activity commonly performed by females or males.  
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29 We will integrate the workouts into a 60-minute structured session adapted from a typical  
30 ballet class.<sup>4</sup> To maintain an appropriate level of challenge, the difficulty of the workouts will  
31 increase progressively subject to participants' willingness and improved condition.  
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34 FBB will be delivered by trained lay and peer stroke volunteers with the support of volunteer  
35 healthcare professionals. The lay volunteers will provide home visits and virtual sessions to  
36 participants. The healthcare professionals will provide expert advice to volunteers during  
37 implementation. All volunteers will receive four days of structured training conducted by the  
38 Principal Investigator with over ten years of ballet experience. Lay and peer stroke volunteers will  
39 be asked to complete an exit test to demonstrate the ability to deliver the FBB independently.  
40 Training completion will be determined by a satisfactory performance in the test and completion  
41 of one supervised on-site session and one virtual session.  
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48 A self-directed resource package will be developed in form of a website and guidebook for  
49 participants' convenience of access. It will contain videos to demonstrate the workouts, animated  
50 videos to illustrate the information, and a suggested weekly goal-and-action plan for eight weeks.  
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53 FBB will consist of two weekly 90-minute at-home support sessions delivered by two lay  
54 volunteers (one of them will be a stroke survivor) in Weeks 1-2, and six weekly 15-minute virtual  
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3 interactions (by phone or internet media) by either lay volunteer in the remaining weeks.  
4 Participants will be asked to perform the 60-minute session two times per week during these eight  
5 weeks. The home-based sessions will introduce participants to FBB, the resources package and  
6 safety precautions. The lay volunteers will conduct virtual sessions and discuss strategies to  
7 address challenges in performing workouts, reinforcing outcome expectations, appraising  
8 incremental progress and reinforcing participation as planned for the following weeks. They will  
9 update the healthcare professionals about the participant's progress, and consult them for advice  
10 if needed. All adverse events will be documented and reported to the clinical research ethics  
11 committee.

12  
13 Strategies will be adopted to ensure safety of the participants during FBB. Participants are  
14 reminded to perform FBB each time starting from a sitting position and progressing to a standing  
15 position as their postural control improves. Family members or carers are encouraged to join FBB  
16 with participants and/or provide standby support to participants while they are doing FBB. The  
17 preparation of environment include preparing for a chair without wheels for support, adequate  
18 space and light, and a phone nearby for making contacts when necessary. The breaks are  
19 mandatory to avoid over exertion.

### 20 21 **Control group**

22 Control participants will receive usual care including usual stroke services available to the  
23 participants, including but not limited to, medical consultations offered by hospital, rehabilitation  
24 services by community-based organisations. In addition, they will be provided with an information  
25 sheet about recommendations with pictorial demonstrations on basic stretching and leg exercises  
26 for stroke survivors.

### 27 28 **Recruitment and data collection procedures**

29 A research assistant will visit the ASUs regularly to screen for eligible participants. He/she will  
30 review the medical records of all stroke patients admitted, and approach the potentially eligible  
31 participants and explain to them and/or their relatives the study aim, objectives, intervention and  
32 data collection procedures. Participants will be asked to sign an informed consent form and will  
33 be given a participation card indicating their recruitment into the study. Then, the research assistant  
34 will record the participants' demographic and clinical information. After the patients are  
35 discharged from the hospital, the research assistant will contact them and schedule a baseline  
36 assessment. Participants will be informed about video-taking during assessment of their balance



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3 and gait. Face-to-face focus group interviews with all participants in the intervention group and all  
4 volunteers will be conducted immediately post-intervention in a university laboratory room. All  
5 interviews will be audio-taped. Cash allowance will be provided to participants after completing  
6 each assessment and interview; and to volunteers after completing a home visit to subsidise their  
7 travel expenses in the study.  
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## 10 11 **Data collection**

12 Multiple data will be collected:

- 13 1. Recruitment: Review the research assistant's recruitment records and flow of participants in  
14 the study to calculate the participants' recruitment rate and the reasons for non-participation.
  - 15 2. Characteristics of eligible and included/non-included stroke adults: Participants' age,  
16 gender, marital status, educational level, stroke history, comorbidities, living condition, and  
17 financial status will be extracted from the medical records.
  - 18 3. Participant characteristics (completed versus dropout): Data such as age, gender, marital  
19 status, educational level, occupation, current financial aids received, type of housing, living  
20 condition, past and present medical history, assistive aids used, MoCA and MFAC scores will be  
21 extracted from the participants' records.
  - 22 4. Home journal: Participants will document details of their participation in FBB in the website  
23 or guidebook, including date, time, number of workouts performed, presence of dyspnoea, injuries  
24 or accidents.
  - 25 5. Audio records: All home visits and virtual sessions of FBB, and volunteer training sessions  
26 will be audio recorded with the participants' and the volunteers' consent.
  - 27 6. Qualitative evaluation: Focus group semi-structured exit interviews will be conducted by an  
28 independent research assistant with 1) All participants in the intervention group to elicit their  
29 experiences of participating in FBB, facilitators of and barriers to participating in FBB,  
30 perspectives on feasibility, acceptability and usefulness of FBB, changes in behaviours after FBB,  
31 impression of research experience, and areas for enhancement; and 2) All volunteers to elicit their  
32 perceptions on the facilitators of and barriers to implementing FBB, perspectives on feasibility,  
33 acceptability and usefulness of FBB, and observations of the participants' participation in FBB.
  - 34 7. Outcomes: All participants will be assessed at baseline (T0) and at immediately post-  
35 intervention (T1) (within one week after the intervention).
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3 - **Balance:** The 14-item Mini-Balance Evaluation Systems Test (Mini-BESTest) will be used.<sup>19</sup>  
4 It measures four domains including the participants' anticipatory postural adjustments,  
5 reactive postural control, sensory orientation, and dynamic gait. All items are rated on a 3-  
6 level scale (0=Severe, 1=Moderate, 2=Normal). The summed total score is 0 to 28. A higher  
7 score represents better balance ability. The Cronbach alpha is 0.89-0.94.<sup>19</sup>  
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11 - **Balance confidence:** The 16-item Activities-specific Balance Confidence Scale (Chinese  
12 version)<sup>20</sup> will be adopted. The participants will rate their confidence in balance associated  
13 with performing 16 daily functional activities from 0% (absolutely no confidence) to 100%  
14 (fully confident). The summed total score is 0 to 100%. A higher score denotes higher  
15 confidence. The Cronbach alpha is 0.97.<sup>20</sup>  
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18 - **Gait:** The 31-item Gait Assessment and Intervention tool (G.A.I.T.) will be used to measure  
19 the participants' gait: upper extremity and trunk movement control; trunk and lower extremity  
20 (stance phase); trunk and lower extremity (swing phase). Each item is scored from 0 (normal)  
21 to 3, with gradients of variation from normal. The total score ranges from 0 (normal gait) to  
22 62 (greatest extent of gait deviations). G.A.I.T. demonstrates good intra-rater and interrater  
23 reliability.<sup>21</sup>  
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26 - **Walking endurance:** The 6-Minute Walk Test (MWT) will be performed in accordance with  
27 the American Thoracic Society guidelines.<sup>22</sup> The distance walked, the time stopped and  
28 reason(s) for stopping prematurely will be recorded. The 6MWT, 12MWT, and self-paced  
29 gait speed were all significantly highly correlated ( $r>0.90$ ).<sup>23</sup>  
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32 - **Memory:** The 11-item Rivermead Behavioural Memory Test–Third Version (Chinese  
33 version) will be used to measure the participants' memory function for performing daily tasks.  
34 For each task, the scores range from 0-2 (0-point=error; 1-point=intermediate; 2-  
35 points=normal). The total score ranges from 0 to 254. The higher the score, the better the  
36 memory performance. The test demonstrates high inter-rater reliability. The correlation  
37 between performance on parallel forms is 0.67-0.84.<sup>24</sup>  
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## 48 Data analysis

49 All quantitative data will be summarised and presented using appropriate descriptive statistics.  
50 Recruitment rate will be calculated by the average of participants recruited per study venue per  
51 month. Cohen's D values will be calculated to estimate the effect sizes of the intervention on the  
52 outcome variables. All statistical analyses will be performed using IBM SPSS 24.0 (IBM Corp.  
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3 Armonk, NY). Raw audio files will be transcribed verbatim and destroyed after completing  
4 transcription. The interview transcripts and participants' home journals will be transcribed  
5 verbatim from the audio recordings by an independent research assistant and analysed  
6 thematically. Initial codes will be developed by two independent researchers (SHSL and JPCC),  
7 and grouped them to form major themes and sub-themes that correspond to the study aim and  
8 objectives. Discrepancies in the major themes and sub-themes will be resolved by discussion  
9 between the two researchers. The qualitative data will supplement the quantitative outcome data  
10 by identifying convergence and differences between the two datasets.<sup>25</sup>

### 17 **Patient and public involvement**

18 FBB was developed in partnership with a ballet instructor and four stroke survivors. Community-  
19 dwelling stroke survivors will be recruited to participate in the study. Adult lay and peer stroke  
20 volunteers will be recruited and trained to deliver FBB. Comments on the programme such as  
21 acceptability and usefulness, and areas of enhancement will be collected from the participants and  
22 the volunteers through semi-structured interviews. Preliminary effects of FBB will be assessed by  
23 the administration of questionnaires with the participants. The results of the study will be  
24 disseminated to the participants on request.

### 31 **Reporting guidelines**

32 SPIRIT reporting guidelines were adhered to in this protocol.<sup>26</sup>

### 34 **Ethical considerations and dissemination**

35 Ethical approval has been obtained from the Joint Chinese University of Hong Kong-New  
36 Territories East Cluster Clinical Research Ethics Committee (Ref. No.: 2019.598). The research  
37 team will protect participants' rights and safety by adhering to local laws, the Declaration of  
38 Helsinki, institutional policies, and the International Conference on Harmonization - Good Clinical  
39 Practice (ICH-GCP). All research personnel will be asked to complete the modules of Good  
40 Clinical Practice. Agreement will be made in advance with the personnel in charge of ASUs for  
41 arranging participant recruitment. All eligible participants will provide written informed consent.  
42 All questionnaires will be anonymous. All information will be kept strictly confidential. All  
43 information will be destroyed six years after completion of the project. Study findings will be  
44 disseminated via publications in peer-reviewed journals and presentations at international  
45 conferences.

### **Acknowledgements**

We would like to thank the stroke survivors and the dance teacher for providing their valuable suggestions in the development of the dance intervention.

### **Author contributions**

SHSL and JPCC contributed to the conception and design of the study. MD, KCC, JHMY and SHL commented on the intervention contents. KCC was responsible for sample size calculation and statistical analyses. All authors are the applicants of the grant submission. SHSL wrote the manuscript and all authors read and approved the manuscript.

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### **Competing interests**

The authors declare that they have no competing interests.

### **Patient and public involvement**

Patients and the public were involved in the design, conduct, reporting, and/or dissemination plans of this study.

### **Patient consent for publication**

Not required.

### **Provenance and peer review**

Not commissioned; externally peer reviewed.

### **Data statement**

The datasets used and/or analysed during the current study will be available from the corresponding author on reasonable request.

## ORCID iD

Suzanne Hoi Shan Lo <https://orcid.org/0000-0002-9970-0642>

Janita Pak Chun Chau <https://orcid.org/0000-0002-3750-7396>

Kai Chow Choi <https://orcid.org/0000-0001-7157-8668>

Marika Demers <https://orcid.org/0000-0003-4075-1418>

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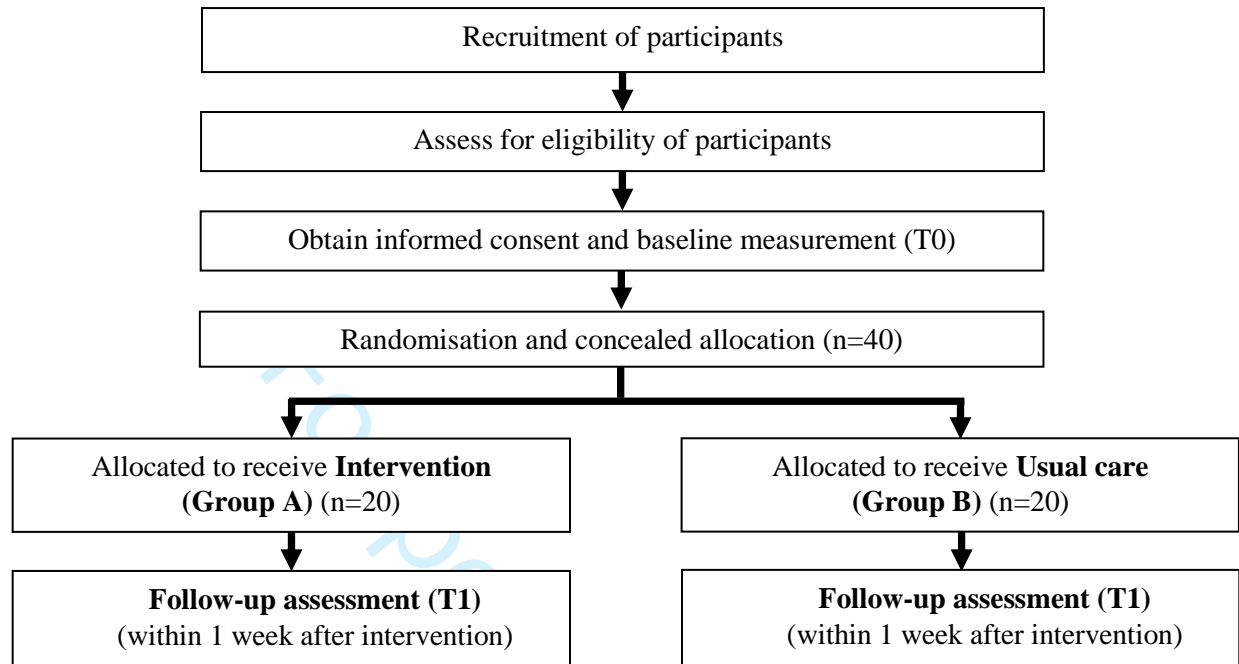
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## Figure legend

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**Figure 1** Flow of participants in the study.

**Figure 1** Flow of participants in the study.





# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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			Page Number
<b>Administrative information</b>			
Title	<a href="#">#1</a>	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

1	Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet registered,	3
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6	Trial registration:	<a href="#">#2b</a>	All items from the World Health Organization Trial	n/a (not
7				
8	data set		Registration Data Set	included)
9				
10				
11	Protocol version	<a href="#">#3</a>	Date and version identifier	n/a (one
12				
13				
14				version
15				
16				only)
17				
18				
19	Funding	<a href="#">#4</a>	Sources and types of financial, material, and other	13
20				
21			support	
22				
23				
24				
25	Roles and	<a href="#">#5a</a>	Names, affiliations, and roles of protocol contributors	1-2, 13
26				
27	responsibilities:			
28				
29	contributorship			
30				
31				
32	Roles and	<a href="#">#5b</a>	Name and contact information for the trial sponsor	n/a
33				
34	responsibilities:			
35				
36	sponsor contact			
37				
38	information			
39				
40				
41				
42	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study	13 (for
43				
44	responsibilities:		design; collection, management, analysis, and	funder)
45				
46	sponsor and funder		interpretation of data; writing of the report; and the	
47				
48				
49			decision to submit the report for publication, including	
50				
51			whether they will have ultimate authority over any of	
52				
53			these activities	
54				
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1 Roles and [#5d](#) Composition, roles, and responsibilities of the n/a  
 2  
 3 responsibilities:  
 4 coordinating centre, steering committee, endpoint  
 5 committees  
 6 adjudication committee, data management team, and  
 7  
 8 other individuals or groups overseeing the trial, if  
 9  
 10 applicable (see Item 21a for data monitoring committee)  
 11  
 12

## 13 Introduction

14  
 15  
 16 Background and [#6a](#) Description of research question and justification for 5-6  
 17 rationale  
 18 undertaking the trial, including summary of relevant  
 19 studies (published and unpublished) examining benefits  
 20 and harms for each intervention  
 21  
 22  
 23  
 24

25  
 26 Background and [#6b](#) Explanation for choice of comparators 10  
 27 rationale: choice of  
 28 comparators  
 29  
 30  
 31  
 32

33  
 34 Objectives [#7](#) Specific objectives or hypotheses 6  
 35  
 36

37 Trial design [#8](#) Description of trial design including type of trial (eg, 7  
 38 parallel group, crossover, factorial, single group),  
 39 allocation ratio, and framework (eg, superiority,  
 40 equivalence, non-inferiority, exploratory)  
 41  
 42  
 43  
 44  
 45  
 46

## 47 Methods:

48  
 49 Participants,  
 50  
 51 interventions, and  
 52  
 53 outcomes  
 54  
 55  
 56  
 57  
 58  
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 60

1	Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic,	7
2			academic hospital) and list of countries where data will	
3			be collected. Reference to where list of study sites can	
4			be obtained	
5				
6				
7				
8				
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10				
11	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If	7
12			applicable, eligibility criteria for study centres and	
13			individuals who will perform the interventions (eg,	
14			surgeons, psychotherapists)	
15				
16				
17				
18				
19				
20				
21	Interventions:	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow	8-10
22	description		replication, including how and when they will be	
23			administered	
24				
25				
26				
27				
28				
29	Interventions:	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated	n/a (not
30	modifications		interventions for a given trial participant (eg, drug dose	included)
31			change in response to harms, participant request, or	
32			improving / worsening disease)	
33				
34				
35				
36				
37				
38				
39	Interventions:	<a href="#">#11c</a>	Strategies to improve adherence to intervention	8-10
40	adherence		protocols, and any procedures for monitoring adherence	
41			(eg, drug tablet return; laboratory tests)	
42				
43				
44				
45				
46	Interventions:	<a href="#">#11d</a>	Relevant concomitant care and interventions that are	n/a (not
47	concomitant care		permitted or prohibited during the trial	relevant
48				to study)
49				
50				
51				
52				
53				
54	Outcomes	<a href="#">#12</a>	Primary, secondary, and other outcomes, including the	10-12
55			specific measurement variable (eg, systolic blood	
56				
57				
58				
59				
60				

pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome.

Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Participant timeline	<a href="#">#13</a>	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12, 17
Sample size	<a href="#">#14</a>	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7	
Recruitment	<a href="#">#15</a>	Strategies for achieving adequate participant enrolment to reach target sample size	10	
<b>Methods:</b>				
<b>Assignment of interventions (for controlled trials)</b>				
Allocation: sequence generation	<a href="#">#16a</a>	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document	7-8	

that is unavailable to those who enrol participants or  
assign interventions

1			
2			
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4			
5			
6	Allocation	<a href="#">#16b</a>	Mechanism of implementing the allocation sequence 7-8
7			
8	concealment		(eg, central telephone; sequentially numbered, opaque,
9			
10	mechanism		sealed envelopes), describing any steps to conceal the
11			
12			sequence until interventions are assigned
13			
14			
15	Allocation:	<a href="#">#16c</a>	Who will generate the allocation sequence, who will 7-8
16			
17	implementation		enrol participants, and who will assign participants to
18			
19			interventions
20			
21			
22			
23	Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to interventions 8
24			
25			(eg, trial participants, care providers, outcome
26			
27			assessors, data analysts), and how
28			
29			
30			
31	Blinding (masking):	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is n/a (not
32			
33	emergency		permissible, and procedure for revealing a participant's relevant
34			
35	unblinding		allocated intervention during the trial to study)
36			
37			
38	<b>Methods: Data</b>		
39			
40	collection,		
41			
42	management, and		
43			
44	analysis		
45			
46			
47			
48	Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome, 10-12
49			
50			baseline, and other trial data, including any related
51			
52			processes to promote data quality (eg, duplicate
53			
54			measurements, training of assessors) and a description
55			
56			of study instruments (eg, questionnaires, laboratory
57			
58			
59			
60			

tests) along with their reliability and validity, if known.

Reference to where data collection forms can be found,  
if not in the protocol

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Data collection plan: <a href="#">#18b</a>	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	10-12
18 19 20 21 22 23 24 25 26 27 28 29	Data management <a href="#">#19</a>	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
30 31 32 33 34 35 36 37 38 39	Statistics: outcomes <a href="#">#20a</a>	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
40 41 42 43 44	Statistics: additional analyses <a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
45 46 47 48 49 50 51 52 53 54	Statistics: analysis population and missing data <a href="#">#20c</a>	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12

## Methods: Monitoring

1	Data monitoring:	<a href="#">#21a</a>	Composition of data monitoring committee (DMC);	n/a (not
2				
3	formal committee		summary of its role and reporting structure; statement of	relevant
4				
5			whether it is independent from the sponsor and	to study)
6			competing interests; and reference to where further	
7			details about its charter can be found, if not in the	
8			protocol. Alternatively, an explanation of why a DMC is	
9			not needed	
10				
11	Data monitoring:	<a href="#">#21b</a>	Description of any interim analyses and stopping	n/a (not
12				
13	interim analysis		guidelines, including who will have access to these	relevant
14			interim results and make the final decision to terminate	to study)
15			the trial	
16				
17				
18	Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and managing	12-13
19			solicited and spontaneously reported adverse events	
20			and other unintended effects of trial interventions or trial	
21			conduct	
22				
23				
24				
25				
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27				
28	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if	n/a (not
29				
30			any, and whether the process will be independent from	relevant
31			investigators and the sponsor	to study)
32				
33				
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38	<b>Ethics and</b>			
39	<b>dissemination</b>			
40				
41				
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51	Research ethics	<a href="#">#24</a>	Plans for seeking research ethics committee /	13
52				
53	approval		institutional review board (REC / IRB) approval	
54				
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1 2 3 4 5 6 7 8 9 10 11 12	Protocol amendments	<a href="#">#25</a>	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a (not relevant to study)
13 14 15 16 17 18 19 20	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10, 13
21 22 23 24 25 26 27 28	Consent or assent: ancillary studies	<a href="#">#26b</a>	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a (not applicable to study)
29 30 31 32 33 34 35 36 37	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10, 13
38 39 40 41 42 43	Declaration of interests	<a href="#">#28</a>	Financial and other competing interests for principal investigators for the overall trial and each study site	13
44 45 46 47 48 49 50	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
51 52 53 54 55 56 57 58 59 60	Ancillary and post-trial care	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a (not relevant to study)

1	Dissemination policy:	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate trial	3, 13
2				
3	trial results		results to participants, healthcare professionals, the	
4			public, and other relevant groups (eg, via publication,	
5			reporting in results databases, or other data sharing	
6			arrangements), including any publication restrictions	
7				
8	Dissemination policy:	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended use of	n/a (not
9				
10	authorship		professional writers	intended)
11				
12	Dissemination policy:	<a href="#">#31c</a>	Plans, if any, for granting public access to the full	14
13				
14	reproducible		protocol, participant-level dataset, and statistical code	
15				
16	research			
17				
18				
19	<b>Appendices</b>			
20				
21	Informed consent	<a href="#">#32</a>	Model consent form and other related documentation	n/a (not
22				
23	materials		given to participants and authorised surrogates	included)
24				
25	Biological specimens	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and storage of	n/a (not
26				
27			biological specimens for genetic or molecular analysis in	relevant
28			the current trial and for future use in ancillary studies, if	to study)
29			applicable	
30				
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 47 by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)  
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