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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

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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.[1] Over 65% of stroke survivors have hemiparesis, considerably affecting their daily life and social functions.[2] 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.[3]

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.[4] 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.[5]

Contemporary evidence-based guidelines recommend early discharge from hospital to enhance stroke survivors' reintegration to society.[6] 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.[7] Another review suggests that dance interventions offer a new framework for neurorehabilitation.[8] 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.[8]

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

There are some gaps identified in the literature. First, there has been no consensus on which dance style and regimen is more effective for promoting balance, gait and memory in stroke survivors. Second, dance interventions examined in previous studies were not underpinned by theoretical frameworks and thus limited the understanding of mechanisms of change in outcomes. Third, only one study was conducted in community settings and it required participants to have access to a community centre to receive the dance intervention.[9] Alternative means to remove physical barriers and reach more survivors would be of greater benefit. Fourth, current evidence showed that dance interventions for stroke survivors were all delivered by dance instructors and/or health professionals.[9,10] It is worthwhile to explore alternative approaches that can mobilise community resources more effectively and build community capacity in health promotion. Fifth, there is no study reporting the effects of dance interventions on Chinese stroke survivors.

AIMS AND OBJECTIVES

We aim to establish the feasibility of a novel ballet-inspired low-impact at-home workout programme ("Footprints to Better Balance" (FBB)) by comparing FBB to a control group and preliminarily estimating its effects on stroke survivors' gait, balance and memory for planning a future full-scale randomised controlled trial (RCT).

Since this is an exploratory feasibility trial, there will be no hypothesis.

Objectives are to:

1. evaluate the recruitment rate of participants;
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.[11] Allowing for a potential attrition rate of 25%,[12 13] 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 stroke 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, ballet relies heavily on mental rehearsal of movements. It mirrors mental imagery to promote motor relearning and to enhance brain plasticity and cognitive functions.[14 15] Musical beats are also integrated in ballet training, requiring coordination of both cognitive and physical activities to move the body according to the planned sequence and time. With repeated and longer duration of practice, performing ballet-inspired movements also improves cardiorespiratory fitness. The movements can be practiced alone, with partners or in groups to facilitate social engagement.

Bandura's constructs of self-efficacy and outcome expectation[16] underpin the design and implementation of FBB. Strategies will be adopted to enhance participants' self-efficacy and outcome expectations of performing ballet-inspired workouts.[12 13]

Eight carefully selected ballet-inspired workouts are integrated:[14 15] basic body positions, trunk movement, pointed toes, turn in and out, tendus (sliding and extending foot), plies (bending

knees), eleves (lifting up on balls of feet) and coupes (shifting body weight). The workouts are aimed at enhancing participants' awareness of body parts and ability in maintaining proper body alignment and postural control. Participants will perform the workouts starting from a sitting position and progress to a standing position with or without physical support as their postural control improves. They will perform mental imagery of each workout after viewing demonstrations, and memorising the movements before performing. Each workout is designed to resemble a daily activity commonly performed by females or males.

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

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

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

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

or accidents.

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

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

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

- **Balance:** The 14-item Mini-Balance Evaluation Systems Test (Mini-BESTest) will be used.[17] It measures four domains including the participants' anticipatory postural adjustments, reactive postural control, sensory orientation, and dynamic gait. All items are rated on a 3-level scale (0=Severe, 1=Moderate, 2=Normal). The summed total score is 0 to 28. A higher score represents better balance ability. The Cronbach alpha is 0.89-0.94.[17]
- **Balance confidence:** The 16-item Activities-specific Balance Confidence Scale (Chinese version)[18] will be adopted. The participants will rate their confidence in balance associated with performing 16 daily functional activities from 0% (absolutely no confidence) to 100% (fully confident). The summed total score is 0 to 100%. A higher score denotes higher confidence. The Cronbach alpha is 0.97.[18]
- **Gait:** The 31-item Gait Assessment and Intervention tool (G.A.I.T.) will be used to measure the participants' gait: upper extremity and trunk movement control; trunk and lower extremity (stance phase); trunk and lower extremity (swing phase). Each item is scored from 0 (normal) to 3, with gradients of variation from normal. The total score ranges from 0 (normal gait) to 62 (greatest extent of gait deviations). G.A.I.T. demonstrates good intra-rater and interrater reliability.[19]
- **Walking endurance:** The 6-Minute Walk Test (MWT) will be performed in accordance with the American Thoracic Society guidelines.[20] The distance walked, the time stopped and

reason(s) for stopping prematurely will be recorded. The 6MWT, 12MWT, and self-paced gait speed were all significantly highly correlated (r>0.90).[21]

- **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.[22]

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 Crop. 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.[23]

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.[24]

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.

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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.

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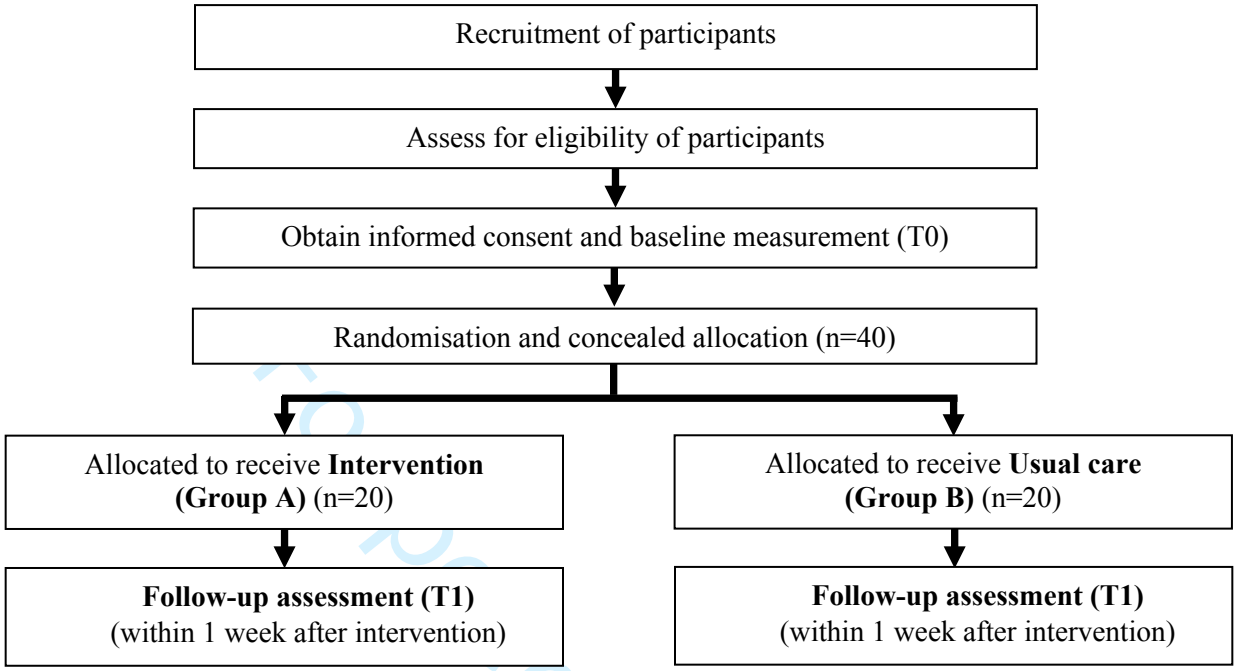
Figure 1 Flow of participants in the study.



Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

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		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a (not included)
Protocol version	#3	Date and version identifier	n/a (one version only)
Funding	#4	Sources and types of financial, material, and other support	13
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1-2, 13
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	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)

Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	10
Objectives	#7	Specific objectives or hypotheses	6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			

Study setting	#9	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
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-10
Interventions: modifications	#11b	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)
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	8-10
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a (not relevant to study)
Outcomes	#12	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
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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	
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7-8
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7-8
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a (not relevant to study)
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory	10-12

		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: retention	#18b	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
Data management	#19	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
Statistics: outcomes	#20a	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
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
Statistics: analysis population and missing data	#20c	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			

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a (not relevant to study)
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a (not relevant to study)
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	12-13
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a (not relevant to study)
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	13

Protocol amendments	#25	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)
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10, 13
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a (not applicable to study)
Confidentiality	#27	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
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	#30	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)

Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	3, 13
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a (not intended)
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	14
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a (not included)
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a (not relevant to study)

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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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

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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.[1] Over 65% of stroke survivors have hemiparesis, considerably affecting their daily life and social functions.[2] 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.[3]

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.[4 5] 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.[6]

Contemporary evidence-based guidelines recommend early discharge from hospital to enhance stroke survivors' reintegration to society.[7] 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.[7] 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.[8] Another review suggests that dance interventions offer a new framework for neurorehabilitation.[9] 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.[8 9] The pleasurable experience and social engagement in dance interventions outweighs exercise alone as they increase adherence to interventions.[9]

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

Underpinning a complex intervention with a theoretical framework is integral to enable better understanding of the mechanism of changes in outcomes.[12] A systematic review suggests that Bandura's construct of self-efficacy is the most commonly used theoretical premise underpinning stroke self-management programmes.[13] A stroke self-management programme underpinned by Bandura's constructs of self-efficacy and outcome expectation was associated with significant improvements in satisfaction with performance of self-management behaviours and quality of life.[14]

There are some gaps identified in the literature. First, there has been no consensus on which dance style and regimen is more effective for promoting balance, gait and memory in stroke survivors. Second, dance interventions examined in previous studies were not underpinned by theoretical frameworks and thus limited the understanding of mechanisms of change in outcomes. Third, only one study was conducted in community settings and it required participants to have access to a community centre to receive the dance intervention.[10] Alternative means to remove physical barriers and reach more survivors would be of greater benefit. Fourth, current evidence showed that dance interventions for stroke survivors were all delivered by dance instructors and/or health professionals.[10,11] It is worthwhile to explore alternative approaches that can mobilise community resources more effectively and build community capacity in health promotion. Fifth, there is no study reporting the effects of dance interventions on Chinese stroke survivors.

AIMS AND OBJECTIVES

We aim to establish the feasibility of a novel ballet-inspired low-impact at-home workout programme ("Footprints to Better Balance" (FBB)) by comparing FBB to a control group and preliminarily estimating its effects on stroke survivors' gait, balance and memory for planning a future full-scale randomised controlled trial (RCT).

Since this is an exploratory feasibility trial, there will be no hypothesis.

Objectives are to:

1. evaluate the recruitment rate of participants;
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.[15] Allowing for a potential attrition rate of 25%,[13 14] 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, ballet relies heavily 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.[16 17] Musical beats are also

integrated in ballet training, requiring coordination of both cognitive and physical activities to move the body according to the planned sequence and time. With repeated and longer duration of practice, performing ballet-inspired movements also improves cardiorespiratory fitness. The movements can be practiced alone, with partners or in groups to facilitate social engagement.

Bandura's constructs of self-efficacy and outcome expectation[18] underpin the design and implementation of FBB. Strategies will be adopted to enhance participants' self-efficacy and outcome expectations of performing ballet-inspired workouts.[13 14]

Eight carefully selected ballet-inspired workouts are integrated:[16 17] basic body positions, trunk movement, pointed toes, turn in and out, tendus (sliding and extending foot), plies (bending knees), eleves (lifting up on balls of feet) and coupes (shifting body weight). The workouts are aimed at enhancing participants' awareness of body parts and ability in maintaining proper body alignment and postural control. Participants will perform the workouts starting from a sitting position and progress to a standing position with or without physical support as their postural control improves. They will perform mental imagery of each workout after viewing demonstrations, and memorising the movements before performing. Each workout is designed to resemble a daily activity commonly performed by females or males.

We will integrate the workouts into a 60-minute structured session adapted from a typical ballet class.[4] To maintain an appropriate level of challenge, the difficulty of the workouts will increase progressively subject to participants' willingness and improved condition.

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

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

FBB will consist of two weekly 90-minute at-home support sessions delivered by two lay volunteers (one of them will be a stroke survivor) in Weeks 1-2, and six weekly 15-minute virtual interactions (by phone or internet media) by either lay volunteer in the remaining weeks. Participants will be asked to perform the 60-minute session two times per week during these eight weeks. The home-based sessions will introduce participants to FBB, the resources package and safety precautions. The lay volunteers will conduct virtual sessions and discuss strategies to address challenges in performing workouts, reinforcing outcome expectations, appraising incremental progress and reinforcing participation as planned for the following weeks. They will update the healthcare professionals about the participant's progress, and consult them for advice if needed. All adverse events will be documented and reported to the clinical research ethics committee.

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

Control group

Control participants will receive usual care including usual stroke services available to the participants, including but not limited to, medical consultations offered by hospital, rehabilitation services by community-based organisations. 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 or accidents.
5. Audio records: All home visits and virtual sessions of FBB, and volunteer training sessions will be audio recorded with the participants' and the volunteers' consent.
6. Qualitative evaluation: Focus group semi-structured exit interviews will be conducted by an independent research assistant with 1) All participants in the intervention group to elicit their experiences of participating in FBB, facilitators of and barriers to participating in FBB, perspectives on feasibility, acceptability and usefulness of FBB, changes in behaviours after FBB, impression of research experience, and areas for enhancement; and 2) All volunteers to elicit their perceptions on the facilitators of and barriers to implementing FBB, perspectives on feasibility, acceptability and usefulness of FBB, and observations of the participants' participation in FBB.
7. Outcomes: All participants will be assessed at baseline (T0) and at immediately post-

intervention (T1) (within one week after the intervention).

- **Balance:** The 14-item Mini-Balance Evaluation Systems Test (Mini-BESTest) will be used.[19] It measures four domains including the participants' anticipatory postural adjustments, reactive postural control, sensory orientation, and dynamic gait. All items are rated on a 3-level scale (0=Severe, 1=Moderate, 2=Normal). The summed total score is 0 to 28. A higher score represents better balance ability. The Cronbach alpha is 0.89-0.94.[19]
- **Balance confidence:** The 16-item Activities-specific Balance Confidence Scale (Chinese version)[20] will be adopted. The participants will rate their confidence in balance associated with performing 16 daily functional activities from 0% (absolutely no confidence) to 100% (fully confident). The summed total score is 0 to 100%. A higher score denotes higher confidence. The Cronbach alpha is 0.97.[20]
- **Gait:** The 31-item Gait Assessment and Intervention tool (G.A.I.T.) will be used to measure the participants' gait: upper extremity and trunk movement control; trunk and lower extremity (stance phase); trunk and lower extremity (swing phase). Each item is scored from 0 (normal) to 3, with gradients of variation from normal. The total score ranges from 0 (normal gait) to 62 (greatest extent of gait deviations). G.A.I.T. demonstrates good intra-rater and interrater reliability.[21]
- **Walking endurance:** The 6-Minute Walk Test (MWT) will be performed in accordance with the American Thoracic Society guidelines.[22] The distance walked, the time stopped and reason(s) for stopping prematurely will be recorded. The 6MWT, 12MWT, and self-paced gait speed were all significantly highly correlated (r>0.90).[23]
- **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.[24]

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. 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 Crop. Armonk, NY). Raw audio files will be transcribed verbatim and destroyed after completing transcription. The interview transcripts and participants' home journals will be transcribed verbatim from the audio recordings by an independent research assistant and analysed thematically. Initial codes will be developed by two independent researchers (SHSL and JPCC), and grouped them to form major themes and sub-themes that correspond to the study aim and objectives. Discrepancies in the major themes and sub-themes will be resolved by discussion between the two researchers. The qualitative data will supplement the quantitative outcome data by identifying convergence and differences between the two datasets.[25]

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.[26]

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.

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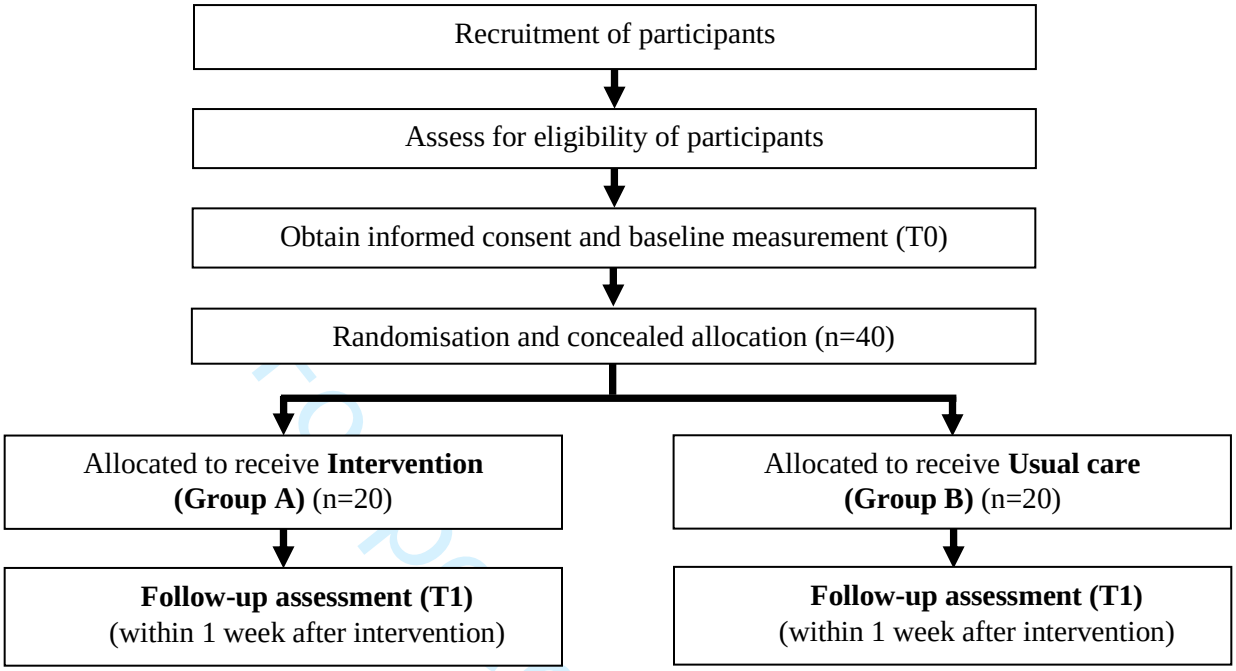
Figure legend

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.

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		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a (not included)
Protocol version	#3	Date and version identifier	n/a (one version only)
Funding	#4	Sources and types of financial, material, and other support	13
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1-2, 13
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	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)

Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	10
Objectives	#7	Specific objectives or hypotheses	6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			

Study setting	#9	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
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-10
Interventions: modifications	#11b	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)
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	8-10
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a (not relevant to study)
Outcomes	#12	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	
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7-8
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7-8
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a (not relevant to study)
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory	10-12

		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: retention	#18b	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
Data management	#19	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
Statistics: outcomes	#20a	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
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
Statistics: analysis population and missing data	#20c	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			

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a (not relevant to study)
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a (not relevant to study)
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	12-13
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a (not relevant to study)
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	13

Protocol amendments	#25	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)
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10, 13
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a (not applicable to study)
Confidentiality	#27	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
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	#30	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)

Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	3, 13
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a (not intended)
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	14
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a (not included)
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a (not relevant to study)

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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Primary Subject Heading:	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

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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.[1] Over 65% of stroke survivors have hemiparesis, considerably affecting their daily life and social functions.[2] 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.[3]

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.[4 5] 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.[6]

Contemporary evidence-based guidelines recommend early discharge from hospital to enhance stroke survivors' reintegration to society.[7] 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.[7] 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.[8] Another review suggests that dance interventions offer a new framework for neurorehabilitation.[9] 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.[8 9] The pleasurable experience and social engagement in dance interventions outweighs exercise alone as they increase adherence to interventions.[9]

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

Underpinning a complex intervention with a theoretical framework is integral to enable better understanding of the mechanism of changes in outcomes.[12] A systematic review suggests that Bandura's construct of self-efficacy is the most commonly used theoretical premise underpinning stroke self-management programmes.[13] A stroke self-management programme underpinned by Bandura's constructs of self-efficacy and outcome expectation was associated with significant improvements in satisfaction with performance of self-management behaviours and quality of life.[14]

There are some gaps identified in the literature. First, dance interventions examined in previous studies were not underpinned by theoretical frameworks and thus limited the understanding of mechanisms of change in outcomes. Second, only one study was conducted in community settings and it required participants to have access to a community centre to receive the dance intervention.[10] Alternative means to remove physical barriers and reach more survivors would be of greater benefit. Third, current evidence showed that dance interventions for stroke survivors were all delivered by dance instructors and/or health professionals.[10,11] It is worthwhile to explore alternative approaches that can mobilise community resources more effectively and build community capacity in health promotion. Fourth, there is no study reporting the effects of dance interventions on Chinese stroke survivors.

AIMS AND OBJECTIVES

We aim to establish the feasibility of a novel ballet-inspired low-impact at-home workout programme ("Footprints to Better Balance" (FBB)) by comparing FBB to a control group and preliminarily estimating its effects on stroke survivors' gait, balance and memory for planning a future full-scale randomised controlled trial (RCT).

Since this is an exploratory feasibility trial, there will be no hypothesis.

Objectives are to:

1. evaluate the recruitment rate of participants;

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.[15] Allowing for a potential attrition rate of 25%,[13 14] 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.[16] 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.[16 17] Musical beats are also integrated in ballet training, requiring coordination of both cognitive and physical activities to move the body according to the planned

sequence and time. With repeated and longer duration of practice, performing ballet-inspired movements also improves cardiorespiratory fitness. The movements can be practiced alone, with partners or in groups to facilitate social engagement.

Bandura's constructs of self-efficacy and outcome expectation[18] underpin the design and implementation of FBB. Strategies will be adopted to enhance participants' self-efficacy and outcome expectations of performing ballet-inspired workouts.[13 14]

Eight carefully selected ballet-inspired workouts are integrated:[16 17] basic body positions, trunk movement, pointed toes, turn in and out, tendus (sliding and extending foot), plies (bending knees), eleves (lifting up on balls of feet) and coupes (shifting body weight). The workouts are aimed at enhancing participants' awareness of body parts and ability in maintaining proper body alignment and postural control. Participants will perform the workouts starting from a sitting position and progress to a standing position with or without physical support as their postural control improves. They will perform mental imagery of each workout after viewing demonstrations, and memorising the movements before performing. Each workout is designed to resemble a daily activity commonly performed by females or males.

We will integrate the workouts into a 60-minute structured session adapted from a typical ballet class.[4] To maintain an appropriate level of challenge, the difficulty of the workouts will increase progressively subject to participants' willingness and improved condition.

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

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

FBB will consist of two weekly 90-minute at-home support sessions delivered by two lay volunteers (one of them will be a stroke survivor) in Weeks 1-2, and six weekly 15-minute virtual

interactions (by phone or internet media) by either lay volunteer in the remaining weeks. Participants will be asked to perform the 60-minute session two times per week during these eight weeks. The home-based sessions will introduce participants to FBB, the resources package and safety precautions. The lay volunteers will conduct virtual sessions and discuss strategies to address challenges in performing workouts, reinforcing outcome expectations, appraising incremental progress and reinforcing participation as planned for the following weeks. They will update the healthcare professionals about the participant's progress, and consult them for advice if needed. All adverse events will be documented and reported to the clinical research ethics committee.

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

Control group

Control participants will receive usual care including usual stroke services available to the participants, including but not limited to, medical consultations offered by hospital, rehabilitation services by community-based organisations. 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 or accidents.
5. Audio records: All home visits and virtual sessions of FBB, and volunteer training sessions will be audio recorded with the participants' and the volunteers' consent.
6. Qualitative evaluation: Focus group semi-structured exit interviews will be conducted by an independent research assistant with 1) All participants in the intervention group to elicit their experiences of participating in FBB, facilitators of and barriers to participating in FBB, perspectives on feasibility, acceptability and usefulness of FBB, changes in behaviours after FBB, impression of research experience, and areas for enhancement; and 2) All volunteers to elicit their perceptions on the facilitators of and barriers to implementing FBB, perspectives on feasibility, acceptability and usefulness of FBB, and observations of the participants' participation in FBB.
7. Outcomes: All participants will be assessed at baseline (T0) and at immediately post-intervention (T1) (within one week after the intervention).

- **Balance:** The 14-item Mini-Balance Evaluation Systems Test (Mini-BESTest) will be used.[19] It measures four domains including the participants' anticipatory postural adjustments, reactive postural control, sensory orientation, and dynamic gait. All items are rated on a 3-level scale (0=Severe, 1=Moderate, 2=Normal). The summed total score is 0 to 28. A higher score represents better balance ability. The Cronbach alpha is 0.89-0.94.[19]
- **Balance confidence:** The 16-item Activities-specific Balance Confidence Scale (Chinese version)[20] will be adopted. The participants will rate their confidence in balance associated with performing 16 daily functional activities from 0% (absolutely no confidence) to 100% (fully confident). The summed total score is 0 to 100%. A higher score denotes higher confidence. The Cronbach alpha is 0.97.[20]
- **Gait:** The 31-item Gait Assessment and Intervention tool (G.A.I.T.) will be used to measure the participants' gait: upper extremity and trunk movement control; trunk and lower extremity (stance phase); trunk and lower extremity (swing phase). Each item is scored from 0 (normal) to 3, with gradients of variation from normal. The total score ranges from 0 (normal gait) to 62 (greatest extent of gait deviations). G.A.I.T. demonstrates good intra-rater and interrater reliability.[21]
- **Walking endurance:** The 6-Minute Walk Test (MWT) will be performed in accordance with the American Thoracic Society guidelines.[22] The distance walked, the time stopped and reason(s) for stopping prematurely will be recorded. The 6MWT, 12MWT, and self-paced gait speed were all significantly highly correlated (r>0.90).[23]
- **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.[24]

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. 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 Crop.

Armonk, NY). Raw audio files will be transcribed verbatim and destroyed after completing transcription. The interview transcripts and participants' home journals will be transcribed verbatim from the audio recordings by an independent research assistant and analysed thematically. Initial codes will be developed by two independent researchers (SHSL and JPCC), and grouped them to form major themes and sub-themes that correspond to the study aim and objectives. Discrepancies in the major themes and sub-themes will be resolved by discussion between the two researchers. The qualitative data will supplement the quantitative outcome data by identifying convergence and differences between the two datasets.[25]

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.[26]

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

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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.

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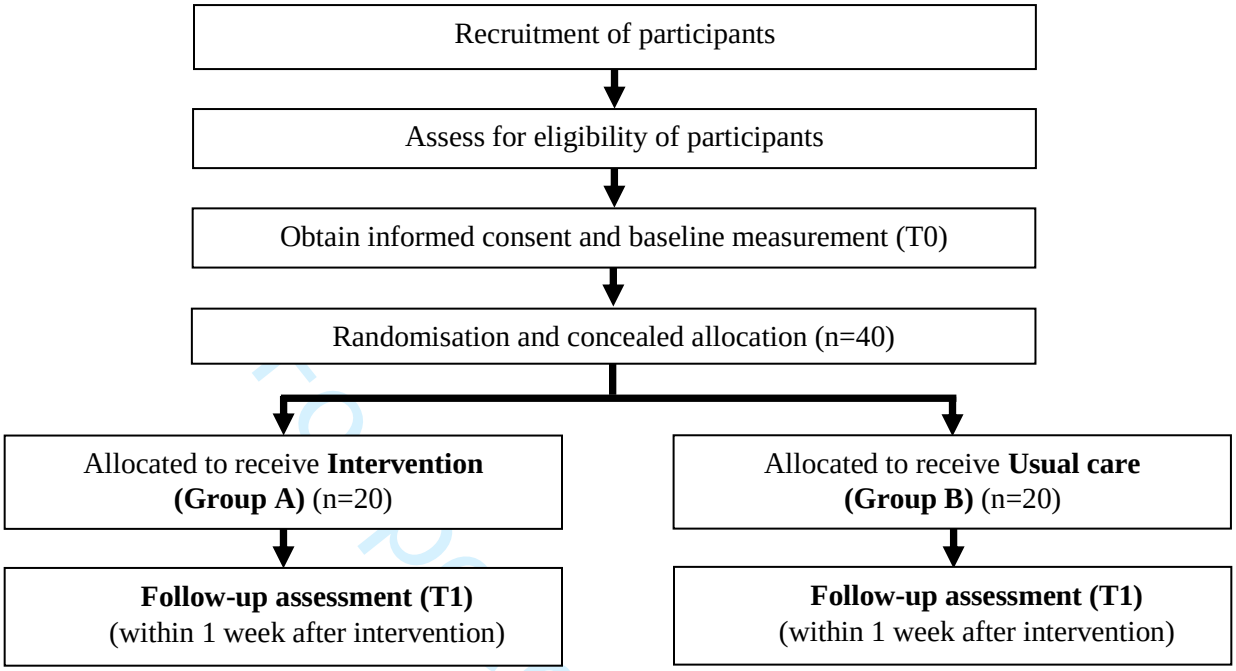
Figure legend

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.

Upload your completed checklist as an extra file when you submit to a journal.

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

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a (not included)
Protocol version	#3	Date and version identifier	n/a (one version only)
Funding	#4	Sources and types of financial, material, and other support	13
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1-2, 13
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	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)

Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	10
Objectives	#7	Specific objectives or hypotheses	6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			

Study setting	#9	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
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-10
Interventions: modifications	#11b	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)
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	8-10
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a (not relevant to study)
Outcomes	#12	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	
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7-8
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7-8
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a (not relevant to study)
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory	10-12

		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: retention	#18b	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
Data management	#19	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
Statistics: outcomes	#20a	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
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
Statistics: analysis population and missing data	#20c	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			

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a (not relevant to study)
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a (not relevant to study)
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	12-13
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a (not relevant to study)
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	13

Protocol amendments	#25	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)
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10, 13
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a (not applicable to study)
Confidentiality	#27	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
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	#30	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)

Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	3, 13
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a (not intended)
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	14
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a (not included)
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a (not relevant to study)