Research proposal (Date 19.9.2025)

Project title: Effects of a sitting Tai Chi programme for chronic stroke survivors with post-stroke cognitive impairment: A pilot randomised controlled trial

Introduction

Stroke remains the third leading cause of death and disability combined (GBD Stroke Risk Factor Collaborators, 2024). The number of people who experience a stroke, die from it, or live with a disability after a stroke has increased significantly worldwide between 1990 and 2021. The estimated global cost of stroke exceeds US$ 890 billion (0.66% of the global Gross Domestic Product) annually and is projected to nearly double by 2050 (Feigin et al., 2025). Post-stroke cognitive impairment (PSCI) is a common neurological sequela that may affect up to 80% of stroke survivors. Stroke survivors with PSCI experience a lower quality of life due to reduced self-management capabilities and difficulty engaging socially (Chau et al., 2023; Qu et al., 2015).

Several systematic reviews and studies indicate that Tai Chi can support stroke rehabilitation, with evidence showing significant improvements in physical functions and psychological well-being, including limb functions, ambulation, activities of daily living (ADL), quality of life (QoL), and cognitive function (Lyu et al., 2018; Song et al., 2021; Yu et al., 2022). Shao et al.'s (2024) review also indicates that Tai Chi benefits patients with mild cognitive impairment, leading to significant improvement in cognitive function as measured by the Montreal Cognitive Assessment (MoCA).

Our previous study adopted a tailored sitting Tai Chi programme for the rehabilitation of subacute stroke survivors without any cognitive impairment. The results of the randomised controlled trial (RCT) showed that upper limb function, balance control, ADL, depressive symptoms, and QoL were significantly improved compared to the control group (Zhao et al., 2022). To better understand the usefulness of the sitting Tai Chi programme for chronic stroke survivors with cognitive impairment and how it might affect other rehabilitation outcomes, this study was proposed to examine its feasibility and preliminary effectiveness.

Aims and objectives

The aim of this pilot RCT is to assess the feasibility, acceptability and preliminary effectiveness of a sitting Tai Chi programme using a mixed methods approach. Specifically, the objectives are to explore 1) whether and in what way this pilot RCT of the intervention is feasible and can be carried out as planned; 2) to what extent the intervention is satisfying and useful for chronic stroke survivors with PSCI and health professionals planning stroke rehabilitation; and 3) how the intervention is able to achieve its objectives.

Hypothesis:

Compared with the usual care, sitting Tai Chi leads to positive of outcomes regarding: Coginitve function, upper limb function, balance control, depressive symptoms, ADL and QoL.

Methods

Study design

An outcome assessor-blinded RCT will be conducted. Participants will be randomised with a 1:1 allocation ratio to either the intervention group or the waiting list control group.

Setting

We will recruit participants from a geriatric rehabilitation ward (caring for older patients with long hospital stays) at a tertiary rehabilitation hospital in Kunming, Yunnan, mainland China. The intervention will also be conducted in the same study wards.

Participants

Individuals who meet the following criteria will be recruited:

i. aged 18 years or above;
ii. have been admitted to a hospital with a clinical diagnosis of first or recurrent ischaemic or haemorrhagic stroke, and meet the diagnostic criteria of PSCI (classified according to DSM-5 criteria);
iii. in the chronic stage of stroke;
iv. MoCA score: 19–25 (two points are added if the individual has ≤ 6 years of education; one point is added if the individual has > 6 and ≤ 12 years of education, no points are added for the individual with > 12 years of education);
v. be able to sit independently with or without sitters;
vi. be able to use and raise at least one arm while sitting (upper extremity muscle strength ≥ III);
vii. have a primary caregiver (a paid or unpaid person who provides most assistance to the stroke survivor);
viii. be able to communicate in Chinese and provide informed consent;
ix. is currently hospitalised in this geriatric rehabilitation ward and unlikely to be discharged within 3 months.

Inclusion criteria for caregivers:

i. age ≥ 18 years;
ii. be able to communicate in Chinese and provide informed consent;
iii. medically stable and physically able to provide support.

Individuals will be excluded if other causes of cognitive impairment are present, such as Alzheimer's disease, acquired immune deficiency syndrome, a National Institutes of Health Stroke Scale (NIHSS) score >16, severe hearing or visual impairment, severe complications following a stroke (e.g., limited comprehension and receptive aphasia, venous thrombosis), a history of severe medical conditions or current serious illnesses

(e.g. myocardial infarction, use of a cardiac pacemaker or a defibrillator, organ failure, malignancy, mental diseases, other neurological diseases such as multiple sclerosis or Parkinson's disease, having received thrombolytic therapy or surgery, joint replacement surgeries or fractures within the past six months), pregnant or lactating women; prior regular (at least three times/week) Tai Chi practice or other mind-body exercises (e.g., Yoga, Qigong, Ba Duanjin, or mindfulness training) within the past six months; and those participating in other clinical trials that might influence this study.

Exclusion criteria for caregivers include impaired cognitive functions (Abbreviated Mental Test, AMT $\leqslant$ 7), being a medical resident/trainee or a physical therapist, having prior regular (at least three times/week) Tai Chi practice or other mind-body exercises (e.g., Yoga, Qigong, Ba Duanjin, or mindfulness training) within the past six months; and those participating in other clinical trials that might influence affect this study.

Sample size calculation

Since the aim of this study is to assess the feasibility, acceptability and potential effectiveness, we did not undertake a formal sample size calculation for the RCT. We applied the criterion of Teare et al. (2014) that an external pilot study should have at least 70 measured participants (35 per group) when estimating the pooled standard deviation for a continuous outcome. Allowing for 20% dropout, the number of dyads in each arm will be 44. A total number of 88 dyads (176 participants) including 44 stroke survivors and 44 caregivers will be recruited in each group.

For the qualitative part, a purposive sample of 30 stroke survivors with low, medium and high satisfaction scores will be invited to participate in a 30-45-minute interview to explore their perceptions of participation in sitting Tai Chi to aid recovery and improve rehabilitation outcomes.

Intervention

Sitting Tai Chi group: Participants in the sitting Tai Chi group will receive 12 weeks of 10-form sitting Tai Chi exercise training with a frequency of three days a week and 40 minutes a day, including 5 minutes warm-up, 30 minutes Tai Chi training, and 5 minutes cool-down. A registered nurse (RN) with experience with Tai Chi training and who participated in our previous study will lead the training session. To avoid contamination, the training will be in a separate room and then tell the participants not to teach others. The RN will receive refresher training in sitting Tai Chi and learn the basics about the condition of PSCI and the characteristics of survivors with PSCI. The RN will begin to conduct the intervention after completing an assessment conducted by an associate professor of Tai Chi and two graduate students in Tai Chi (who participated in the development of this sitting Tai Chi programme).

Control group: Participants in the control group will receive usual care. That is, regular inpatient treatment and care, without additional rehabilitation treatment. At the end of the intervention follow-up assessment, they will be invited to participate in the sitting Tai Chi exercise led by the same nurse as well.

Five series of sitting Tai Chi exercises for stroke survivors with physical impairments, each with a target of strengthening the muscles for upper limb function and balance while taking into consideration survivors' physical limitations, were developed. Series 1 consisted of a 10-form sitting Tai Chi adapted from the 10-form Yang-style Wheelchair Tai Chi, which was offered for stroke survivors with minor weakness (upper limbs' muscle strength: 4 or 5). Series 2 to 5 were also ready to cater to the needs of stroke survivors with hemiparesis or hemiplegia (upper limbs' muscle strength: ≤3).

Caregivers will be involved to ensure the safety of stroke participants, encourage their participation, and supervise them. Adherence to the treatment protocol will be recorded by a research assistant.

Person responsible for project implementation

The co-investigator Ms. Shi Jinping will be responsible for the study implementation in Yunnan. She is the nursing leader of the Geriatric Rehabilitation Ward, The Second People's Hospital of Kunming. She has over 10 years nursing experience in post-stroke rehabilitation. She was major in traditional Chinese medicine nursing. She has more than 3 years of experience in Tai Chi practice and has participated in our team's previous intervention study on sitting Tai Chi for stroke survivors. She has the ability and experience to ensure the implementation of the study.

Assessment and measurement

Primary outcomes include cognitive function, upper limb function, balance control, and depressive symptoms. They will be assessed at baseline, eight weeks, and 12 weeks after the commencement of the sitting Tai Chi training.

(a) Cognitive function will be measured using the MoCA scale, a cognitive screening instrument developed and validated to detect mild cognitive impairment. MoCA is a brief (approximately 10 min) test that evaluates visuospatial/executive functions, naming, verbal memory registration, learning, attention, abstraction, 5-min delayed verbal memory and orientation, with a total score of 0–30 (a higher score equals better function). The Chinese version of MoCA (Beijing version) is widely used in mainland China with good validity, reliability and sensitivity. According to Tan's study, two points are added if the participant has ≤ 6 years of education; one point is added if the participant has > 6 and ≤ 12 years of education, and no points are added for the participant with > 12 years of education (Tan et al., 2015).

(b) Upper limb function

Upper limb function will be measured using Fugl-Meyer Test Upper Limb section (FMT-UL) and Wolf Motor Function Test (WMFT) (Thompson-Butel et al., 2015).

FMT-UL will be used to evaluate upper extremity function in the International Classification of Functioning, Disability and Health (ICF) body function and structure level. The scale includes eight items related to function of wrist and hand, evaluation results are on a 3-point scale ranging from 0 ('unable accomplish') to 2 ('completely accomplish'), and has a maximum score of 66. A higher score indicates better upper extremity function. The Chinese version is reported to have excellent reliability and validity, with an intra-rater intraclass correlation coefficient (ICC) of 0.997 and an inter-rater ICC of 0.990.

The WMFT was often used alongside the FMT-UL to provide a complementary description of upper limb function in the ICF activity level. It consists of 17 items including time, functional ability and strength domains. Items seven and 14 are strength

test with recording the exact weight which the participants can afford. The remaining 15 items are scored ranging from 0 (‘does not attempt’) to 5 (‘movement appears to be normal’), with a total score ranging from 0 to 75. A higher score indicates better function. The Chinese version of WMFT was reported to be reliable and valid (intra and inter-rater: ICC > 0.981).

(c) Balance control

Balance control will be measured using the Berg Balance Scale (BBS) and the Trunk Impairment Scale (TIS).

The 14 items BBS will be used to evaluate the ability to maintain positions, from sitting to standing, to close standing, and finally to standing on one leg in the ICF body function and structure level. The total score ranges from 0 to 56, with a higher score indicates better balance control. The Chinese version of BBS has been reported with good reliability and validity (intra and inter-rater ICC: 0.968–0.985 and 0.992–0.998)

The Trunk Impairment Scale (TIS) was designed to assess the sitting balance and trunk control among stroke survivors. It has 17 items which consists of three subscales: static sitting balance, dynamic sitting balance and coordination. The total score ranges from zero to 23 points, with a higher score indicating a better performance. It has 17 items which consists of three subscales: static sitting balance, dynamic sitting balance, and coordination. The original English TIS, along with versions in Norwegian, Italian, and Spanish has been reported as a valid and reliable scale. The Cronbach α of the Chinese version of TIS was 0.86 (Zhao et al., 2021).

(d) Depressive symptoms

The 15 items Geriatric Depression Scale short form (GDS-15) will be used to assess depressive symptoms. Each item is scored in a dichotomous format: 1= (‘yes’), 0= (‘no’) in response to symptoms of depression. The total score is summed (range 0-15). A higher score indicates a higher level of depressive symptoms. A score of nine or above indicates moderate or severe depression. The Chinese version of GDS-15 has demonstrated good validity and reliability (Cronbach’s α: 0.78) (Chau et al., 2006).

Secondary outcomes include ADL and QoL

(a) ADL

The Modified Barthel Index (MBI) will be used to assess ADL in the ICF activity level. The scale consists of 10 items to score the ability of a person to care for himself which includes feeding, moving, and toileting. The total scores range from 0 to 100. A higher score suggests better ADL. The psychometric properties of the Chinese version of MBI is good (inter and intra rater ICC: 0.968 ~ 0.997 and 0.866 ~ 0.990).

(b) QoL

QoL will be assessed using the Chinese version of Stroke-Specific Quality of Life Scale SS-QOL. The scale is specific to the activity and participation domains of the ICF. It includes 12 areas affected following a stroke, as covered by 49 items. For each item, there are five response options in which the score varies from one to five. Thus, the overall scores range from 49 (worst perception of QoL) to 245 (best perception of QoL). Higher scores indicate better QoL. The Chinese version of SS-QOL has been reported with acceptable validity and good reliability (Cronbach’s α 0.93) (Lo et al., 2017).

Feasibility and Acceptability

This pilot RCT evaluates the feasibility of the sitting Tai Chi programme. Feasibility is evaluated based on recruitment and retention rates from baseline to follow-up. All

participants will be invited to fill in a satisfaction survey with the sitting Tai Chi programme and the usefulness of its components.

Satisfaction

A self-developed User Satisfaction Questionnaire (USQ) will be used to assess stroke survivors' satisfaction with the tailored sitting Tai Chi programme in terms of usability, acceptability, and applicability. The USQ measures stroke survivors' level of satisfaction from three different aspects, including clarity and applicability of the sitting Tai Chi programme, the appropriateness and adequacy of the audio-visual demonstration, and the transferability and sustainability of the sitting Tai Chi programme in the home environment. Each item is rated on a 5-point Likert scale, and a higher score indicates a higher level of satisfaction.

Adverse events measurements

Any unexpected adverse events during the intervention period will be monitored by the site supervisor, reported to a research assistant, and adverse event causality relating to the Tai chi exercise intervention and the severity of adverse events will be analysed. Serious adverse events will be reported to the ethics committee immediately.

Semi-structured interview

We will conduct semi-structured in-depth interviews using a pre-designed semi-structured interview guide.

Interview guide

1. Please share your recovery experience after discharge. Prompts: positives and negatives of rehabilitative experiences, post-stroke psychological status and participation restrictions
2. What sort of physical activity have you engaged in recently? Prompts: type, frequency, duration
3. How do you feel about the sitting Tai Chi exercise you have learned? Prompts: usefulness, ease of following, enjoyment, or dissatisfaction
4. Have you practised sitting Tai Chi recently?
5. How often do you practice sitting Tai Chi? What is the average time it takes you?
6. What effects has Tai Chi brought about? Prompts: physical benefits, mental benefits
7. What do you think made you start practising Tai Chi? Prompts: Availability of support, recommended by healthcare providers
8. What do you think caused you to stop practising Tai Chi? Prompts: fatique, pain, short hospital stay, inability to remember all the movements, lack of support
9. What do you think are the barriers to practising Tai Chi? Prompts: fear of falling, physical discomfort, lack of motivation
10. What are your suggestions for improving the Tai Chi training? Prompts: intervention components, forms of sitting Tai Chi, dissemination methods, guidance
11. Will you continue to practice sitting Tai Chi?
12. Do you have anything we haven't mentioned that you want to share?

Ethical considerations

Ethical approval will be applied from the Joint Chinese University of Hong Kong- New Territories East Cluster Clinical Research Ethics Committee and the study hospital's research ethics committee. Written consent will be obtained from the eligible participants.

Agreements will be made with the wards of the study hospital on schedules and arrangements for participant recruitment. Eligible participants will be informed about the study, potential risks or benefits, right to confidentiality, and right to withdrawal with no negative consequences. Those who agree to participate in the study will be asked to sign a written consent. A card (Appendix 1) indicating participants' involvement in the study and means of urgent contact was provided to each participant after obtaining consent. An information sheet about the study and a copy of the signed informed consent form was given to the participants. All questionnaires were anonymous. All information obtained from the study was kept strictly confidential and would be destroyed six years after completion of the study. Each participant will be assigned a study ID prior to data collection. Each participant's name along with their unique study ID will be documented on a separate file in a locked cabinet. This document will be stored separately from other data documents. The data documents will be kept in secure locations, and computerised records will be assigned with security codes by the PI. Only the PI has access to the information. The federal and institutional ethical standards, Hong Kong Personal Data (Privacy) Ordinance, Declaration of Helsinki, and ICH-GCP were upheld throughout the study.

The major potential risk of exercise would be fall. The stroke survivors will perform the sitting Tai Chi using a seated position in a wheelchair or stable chair with a seat belt fastened. Each participant was required to have their caregiver by their side to provide safety protection when doing Tai Chi training. The participant may have a normal reaction during exercise at the beginning of the exercise session (e.g. muscle soreness, fatigue).

The inpatient training will be performed in a room right in front of the nurse's station. The health professionals could be on the scene of them. The physical assessments will be conducted in a seated position and the assessors will stay close to the participants, which could effectively prevent falls. The assessments will be conducted at the bedsides.

Data collection, consent, and sample storage

A sociodemographic and clinical data sheet will be used to record the corresponding information. The research assistants will screen potentially eligible participants by daily reviewing the medical records of all stroke survivors admitted to the study venues.

Data processing and analysis

Statistics analysis will be conducted using the IBM SPSS version 29.0. All primary analyses will be conducted on an intention-to-treat basis. Descriptive statistics will be used to present participants ' baseline characteristics and outcome variables. All continuous outcomes will be assessed for normality in distribution. Appropriate transformation of skewed data will be performed before analysis. Chi-square tests and independent t-tests will be used to compare the demographic and clinical characteristics, and mean scores of outcomes between the intervention and control groups at baseline. A generalized estimating equations (GEE) model will be employed to compare differential change of each of the primary and secondary outcomes across the study time points between the two groups.

Content analysis will be used to analyse the qualitative data from the participants.

Data collected from the USQ and semi-structured interviews will be used to identify areas for improvement and to guide future enhancements to the sitting Tai Chi programme.

Trial registry

This trial will be registered in the ClinicalTrials.gov

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