

Official Title: The Effects of Simplified 10-step Tai-chi
Programme on the Motor Performance and Fall Prevention of
Community-dwelling Older People With Dementia: a Pilot Cluster
Randomized Control Trial

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A. Background of Research

Falls in older people are prevalent worldwide. Fall-induced injuries are important health issues in the elderly population and became one of the top leading causes of death in older adults^{10, 11}. Falls are particularly problematic for people with dementia (PWD). Studies have shown that PWD have a significantly higher incidence of falls and also suffered more serious consequences from fractures and hospitalization¹. A meta-analysis of 27 studies reported a strong negative correlation between an increased risk of falling and cognitive functions¹².

Strong evidence exists that falls can be prevented among community-dwelling older people, but there is limited evidence of effective approaches for PWD². In particular, there is a considerable amount of evidence that Tai-chi has beneficial effects on the prevention of falls among older people, including that it reduces their fall rates and fall risks^{13, 14}, enhances their of static balance and flexibility and relieves their fear of falling^{15, 16}.

Tai-chi, a traditional Chinese martial art, is regarded as a body-mind exercise that combines relaxed physical movements and meditation. Although there is considerable evidence that Tai-chi has beneficial effects on physical and mental health in cognitively intact older adults, the underlying mechanisms explaining its effects remain largely unclear. A study conducted in 2014 preliminarily revealed the mechanisms by which Tai-chi improves dynamic postural control in older adults. Tai-chi was shown to increase the centre of pressure (CoP) mediolateral excursions and the resultant CoP centre of mass distance in the medial and forward conditions in the postural phase¹⁷. Older adults who have received training in Tai-chi have higher CoP mediolateral displacement and velocity in the locomotion phase¹⁷ which contribute to better balance and gait performance, leading to a reduction in their fall risks.

Due to neurodegenerative processes associated with dementia, some risk factors for falls are unique to PWD. These include a decrease in executive functioning, visuospatial difficulties, wandering, and agitation¹. As cognition deteriorates with the progress of the disease, a person's executive function will be affected. This will affect that person's memory, ability to plan and ability to pay attention¹⁸. This would possibly affect a person's ability to learn and to adopt fall prevention strategies in their daily life. Therefore, it should not be assumed that a fall prevention programme effective for cognitively intact older people would also be effective for PWD. This may partially explain why the study by Shaw¹⁹ (replicating a previous successful falls prevention RCT with cognitively intact older adults²⁰) showed no statistically significant findings when used among PWD⁴. Since most of the clinical trials that evaluated Tai-chi as a fall prevention strategy excluded people with dementia or cognitive impairment, the effectiveness of Tai-chi on preventing falls among PWD remains unknown.

Studies have shown that PWD still have the ability to learn and retain new information when the information is appropriately presented and when they are trained to do so²¹. Several research studies obtained preliminary positive effects on PWD from Tai-chi training after the training strategies had been modified to fit the special characteristics of this population group^{9, 22-24}. For example, a pilot cluster randomized trial of a 20-week Tai-chi programme involving 55 older people with mild cognitive impairment and knee osteoarthritis showed that the pain and physical functions of these participants who were randomly assigned to the Tai-chi group improved significantly over time²³. Another study involving 22 pairs of PWD and their caregivers assessed the feasibility, acceptability and the preliminary findings concerning adherence and effects of a 16-week Tai-chi programme. The results showed that 86.4% PWD completed the 16-week programme. In addition, significant physical improvements were identified in PWD after they had completed the programme⁹. When implementing the programme, both teams of researchers modified their Tai-chi training programme and tailor-made it for PWD. This is believed to be a key factor in the positive outcome of their study, demonstrating the feasibility and adaptability of the Tai-chi programme for PWD^{8, 25}.

Below is a summary of the strategies that were used in the abovementioned Tai-chi studies, which were considered to support high levels of engagement of PWD in Tai-chi training:

- 1) Involving caregivers as exercise partners so as to provide support and assistance.
- 2) Accommodating the preferences of individuals, and taking particular account of their current abilities when designing the Tai-chi steps. The steps must be simple to reduce the demands on their cognition. Studies have shown that simplified, short forms of Tai-chi that are based on movement improve the balance of older people and reduce their risk of falling in samples without dementia²⁶,²⁷. Thus, simplified instead of traditional Tai-chi steps should be used among PWD.
- 3) Employing special teaching methods to deal with cognitive impairment – such as teaching one step at a time and gradually adding new steps in later sessions according to the participants' progress, using both visual and verbal cues during the instruction, introducing simple Tai-chi steps and using additional tools such as photographs and clear booklets that enable the participants to record their progress and help them to adhere to the exercise regime²⁵.
- 4) Adopting positive emotional motivation techniques to enhance enjoyment of the Tai-chi programme – besides receiving verbal encouragement from the Tai-chi instructors and their caregivers, the participants should also be given an incentive or reward according to their own preferences before or after the Tai-chi practice. These strategies have been shown the effectiveness in enhancing PWD's adherence to the Tai-chi training^{8,9}.

Tai-chi has many known benefits for reducing the risk of falls. However, clinical trials with Tai-chi interventions have tended to exclude PWD, who may be at a high risk of falling but have difficulty participating in formal fall prevention programmes. After tailor-made strategies for PWD were incorporated in Tai-chi training programmes, some preliminary positive effects were noted in several studies, in terms of the feasibility and acceptability of the programmes and their impact on the functional mobility of PWD. However more studies are still required to verify the appropriate strategies for engaging PWD in Tai-chi fall prevention programmes so as to be able to make evidence-based recommendations on reducing fall rates in PWD.

B. Research plan and methodology (Appendix 1: Research flowchart)

Aim: The aims of this study are to determine the feasibility and acceptability of the simplified 10-step Tai-chi programme for PWD, and to explore the preliminary effects of this intervention on the motor performance of PWD.

Design: A single-blinded cluster RCT will be used to compare the experimental and the control groups. An independent, trained research assistant (RA-assessor) who is blinded to the group assignment will perform the outcome assessments and data entries. A descriptive, qualitative design with focus groups or individual interviews will be used to evaluate the process of implementing the intervention from the perspectives of the participants, their caregivers, and the Tai-chi instructor.

Setting and Sampling: Four community health centres which provide services to PWD will be invited by a convenience sampling method to participate in the study. We will only recruit those community health centres that are funded by the Hong Kong (HK) government and that are under the supervision of Social Welfare Department, which meet a specific set of standardized regulations and criteria on practices, and which provide similar sets of care services for community-dwelling older people. The study's target population is community-dwelling older people with mild to moderate dementia.

The inclusion criteria for participants are: 1) community-dwelling older people of either gender; 2) who are able to communicate in Cantonese to ensure that they understand our instructions during the training, 3) who are able to walk independently with no walking aid or no more than a single point stick for at least 10 minutes so as to ensure their mobility is good enough to allow them

to take part in the Tai-chi training. 4) They must also have received a formal diagnosis of any form of dementia. Their level of cognitive impairment will be assessed using an Abbreviated Mental Test (AMT)^{28, 29} with a score ranging between 5 and 8 to indicate mild to moderate cognitive impairment. 5) Finally, they must identify a caregiver who is willing to work as an exercise partner and facilitator for their practice of Tai-chi.

Sample size: Thirty participants will be recruited for each group. A small sample of 30 per group would be sufficient to test the feasibility of a pilot study³⁰. Twenty participants from the experimental group will be randomly selected to join the focus groups after completing the entire programme.

Sample recruitment procedures: The centres will be randomized into the control or the Tai-chi groups by using computer-generated random numbers for each of the four centres generated by an independent statistician. We will publicize/promote this study by displaying posters in the centres and asking the centre-in-charges to encourage and refer the eligible subjects to participate. A leaflet containing information about the study and an invitation letter with a reply slip for the participants to indicate their interest in participating in the study will also be mailed to all potential subjects to invite them to participate in this study. A convenience sampling method will be used to recruit participants in the community health centres.

The Interventions

The experimental condition: A 16-week 10-step simplified Tai-chi group training programme will be arranged for the Tai-chi group. During the intervention period, the participants in the Tai-chi group will receive two 1-hour centre-based Tai-chi group training sessions every week.

The participants will be required to pair up with their caregiver to take part in the training sessions together. They will be encouraged to practice the Tai-chi exercises at home for 30 minutes for at least three times per week. Adding up all of the group sessions and the time spent practising at home, each participant should have undergone at least 56 hours of Tai-chi practice during the intervention period. A high dose of 50 hours of exercise practice has been shown to be more effective in reducing fall rates than exercise interventions that require less than 50 hours of practice³¹. A maximum of 7-8 pairs of participants and their caregivers will be supervised by a qualified Tai-chi instructor during each training session. To encourage the participants to practise the Tai-chi exercises at home, a compact disc and a pamphlet describing the 10-step Tai-chi programme will be distributed.

The control condition: As no active fall prevention treatments have been employed among local older people with dementia, the control group will only take part in group recreational activities organized by the district centres. The number and timing of the activities will be similar to those organized in the Tai-chi training session for the experimental group. The participants in the control group will be also instructed to continue their usual lifestyles and levels of physical activity.

Instruments and Measures

Social-demographic data (age, gender, marital status, exercise habits, living conditions, and level of education) will be collected. The participants' health-related information will also be collected, including their morbidities, cognitive status, fall history, and medications taken in the past 12 months.

The feasibility assessment includes the ease of recruitment, the acceptance rate, the dropout rate, the engagement of PWD when attending the Tai-chi training sessions, the adherence to practising Tai-chi at home and at training sessions, the occurrence of adverse events, and feedback from the participants (caregivers) as well as the Tai-chi instructor.

- **Ease of recruitment** – if any difficulties encounter during the recruitment phase will be recorded to consider for improvements in the future main study.
- **Acceptance rate** refers to the proportion of subjects who provide proxy consent to join the study over the eligible participants will be calculated for the acceptance rate.

- Dropout rate – percentage of participants withdrawing from the study will be recorded and the reasons for withdrawal will be asked
- Engagement of participants when attending the Tai-chi training sessions will be assessed by the Non-pharmacological Therapy- Experience Scale (NPT-ES). This scale was developed by Muñiz et al in 2011 with an aim to measure the immediate emotional and social effects of any kind of non-pharmacological interventions delivered to PWD³³. It is a 5-item scale which includes participation, pleasure, relationship with others, displeasure and rejection (the last two are reverse items). Each item is rated on a 4-point scale from 0 =Never to 3= Always. By summing up all five item scores to get the total score ranged from zero to fifteen, higher scores indicating more positive experience. All Tai-chi training sessions will be video-taped. The well-trained research assistant (RA) will assess the engagement of each participant during each training session based on both real time and the video observations. The Tai-chi instructor will also be required to comment on the engagement of each participant in terms of whether or not a particular participant can follow each Tai-chi step appropriately based on her observations during the training sessions.
- Exercise adherence will be assessed weekly based on the caregiver report in an exercise diary on the days and duration that the participant practises Tai-chi. This diary will be collected every week during the 16-week training period. Weekly phone calls will be made by an RA to remind the participants to return the diary as well as to verify the records. Attendance in the Tai-chi training sessions will also be recorded as evidence of adherence to the training programme.
- The occurrence of adverse events will be recorded which include the date, the time, the unanticipated bodily response and symptoms (e.g. fall, fatigue, dizziness), and the immediate treatment provided.
- Collection of feedback from all stakeholders – Feedback from participants and their caregivers will be collected by focus group within two weeks after completing the entire Tai-chi programme. An individual interview will be conducted to collect opinions from the Tai-chi master. The interview guides for different stakeholders will be set up. A panel of experts will be invited to review the interview guide to evaluate the appropriate of the questions. The interview will be audiotape recorded and transcribed verbatim.

Preliminary outcomes assessment: motor performance

- Mobility will be assessed by the Timed-up-and-Go (TUG) test^{34,35}. The time taken by participants to execute the tasks – stand up from a standard chair, walk three meters, turn around, walk back to the chair and sit down will be recorded in seconds.
- Functional limb muscle strength will be assessed the Timed-Chair-Stand (TCS) test³⁶. Each participant will be asked to sit at the front edge of a standard chair with their arms crossed, and instructed to stand up fully and sit down five times as quickly as possible. Time to complete this task will be recorded.
- Dynamic bilateral stance balance will be assessed by the Functional Reach (RF) test³⁷. Participants will stand beside a wall with their feet apart for about 10 cm and raise their dominant arm to 90 degrees. They will then be instructed to lean forward as far as possible with the hand remaining at shoulder level. The FR score will be the additional reach of the raised hand from the starting position in cm.
- Dynamic single leg standing balance will be assessed by the Step Test (ST) test³⁸. Participants will stand with their feet parallel and apart for about 10 cm. A block / step with 7.5 cm height will be placed 5 cm in front of the participants. They will be instructed to place the whole foot onto the block, then return it fully back down to the floor repeatedly as fast as possible for 15 seconds. Each leg will be tested separately, and performance on the left or right side with the least number of steps will be the result.

The number of falls will be also recorded by the caregivers and the participants in a monthly falls calendar, in which they will note down any fall accidents that have happened to the participant during the 16-week study period. Monthly phone calls will be made by an RA-observer to remind the participants to return the calendar as well as to verify the records. A fall will be defined as “an unexpected event in which participants come to rest on the floor or lower level⁴¹.” This will be used to guide the participants (caregivers) in recording their fall accidents. The severity of the injuries will also be recorded.

Procedures (randomization, allocation concealment, blinding)

After ethical approval has been obtained, all potential participants will be screened for their eligibility to participate in the study. The participants and their caregivers will then be interviewed to obtain their proxy informed consent, socio-demographic data, and baseline assessment. After that, the four community centres will be randomized to the control or the experimental groups. The participants from each centre will be placed into their centre’s corresponding group to avoid ‘contaminating’ other participants. The changes in the above mentioned preliminary outcome scores from the baseline to interim assessment at Week 8 (T1:Mid-term of intervention) and intervention effects at immediate (T2) after completion of the 16-week interventions will be compared between the groups by the RA-observer.

Twenty participants from the Tai-chi group will be randomly selected to join the focus groups within two weeks after completing the entire programme. Each focus group will contain between 5 and 10 people. The Tai-chi instructor will also be interviewed individually. All interviews will be conducted by the PI in the community health centres to collect the opinions on the design of the intervention. (Appendix II: Timeline of the study)

Intervention fidelity and RA training

User guidelines for each instrument will be obtained by the instrument developers/ literature review. The principal investigator (PI) and a Co-I (KH) who is a professor in physiotherapy, specialized in rehabilitation sciences and have rich experiences in conducting research studies on fall prevention among older people will train the RA on how to use all of the outcome instruments, so that the RA can serve as an independent outcome assessor. This RA will be blinded to the group allocation. He/she will practise using all of the instruments with various clinical vignettes and on-site practise. The PI will evaluate the assessor on his/her use of all of the instruments to ensure that quality assessments are performed as intended prior to the start of the study, and on a monthly basis throughout the data collection period. Additionally, intra-class correlations (ICC) will be used to test the intra-rater reliabilities. Acceptable levels of reliability (ICC ≥ 0.9) will be established by comparing the scores rated by the assessor and the PI prior to the start of the study, and checking them on a monthly basis throughout the data collection period.

The protocols of the Tai-chi and pre-Tai-chi training workshops will be developed and used to guide the implementation of the entire programme so as to ensure standardization of the intervention/study procedure. The PI and the Co-I (CL) who are specialized in gerontological nursing and have rich experiences in conducting research studies on PWD, will develop the contents of the two pre-programme workshops for the caregivers. They will also be responsible to train an RA to conduct the workshops. The training will include lectures, role play, and on-site practices under the close supervision of the PI. The research team will supervise the pre-intervention practice on one or two small groups of the caregivers of PWD. The simplified 10-step Tai-chi protocol was tested with positive results in a previous trial by members of the research team²⁶. This training protocol will be modified by the PI and CL after consulting the opinions of an experienced Tai-chi master. As

mentioned above, the modifications will mainly tailor-make the intervention to meet the special learning needs and characteristics of PWD.

All workshops and Tai-chi sessions must follow the protocols and will be run by the same RA/Tai-chi instructor to ensure intervention consistency. Intervention fidelity checking will be conducted in the training period and then monthly to bimonthly during the intervention period based on the workshop/ Tai-chi checklists. Achieving a fidelity rate of >90% will be considered acceptable, based on the recommendations of the NIH Behaviour Change Consortium⁴². This is to ensure that all of the interventions are executed by the Tai-chi instructor or the RA as intended. Monthly to bi-monthly quality-control meetings with all research personnel (the Tai-chi instructor and the RA) will be arranged to evaluate their instruction / facilitation skills in this study.

Statistical Analysis

SPSS will be used for data analysis. Descriptive statistics will be generated for the demographic data. Normality assumptions for the variables will be checked. The paired t-test or Wilcoxon's signed rank test will be used to examine any significant difference in outcome measurements in the experimental group before and after the implementation of the combined intervention. Student's T-test or the Mann-Whitney U test will be used to examine any significant differences between the control and experimental groups in terms of the outcome variables. For categorical and dichotomous outcome variables, a χ^2 test will be used to identify any significant differences between the groups. A p-value < 0.05 will be considered statistically significant. Mixed effect modelling (MEM) will be further used to measure changes in the outcome measures after intervention with respect to its baseline, and to see the effectiveness of the intervention. Multiple imputations will be adopted to manage missing data.

All interviews will be transcribed and analyzed by content analysis so as to understand participants', caregivers' and the Tai-chi instructor's opinions about the intervention. ???Coding will occur independently by two members of the research team. Differences in coding between the independent coders will be resolved through discussion between the coders.

Ethical Consideration

Ethical approval will be obtained from the Ethics Review Committee of The HK Polytechnic University. Permission to perform the study will be sought from the person in-charge of each community centre. Informed proxy consents will be sought from the legal guardians or next of kin of all participants. A letter clearly explaining the nature of the study will be provided to all participants and their caregivers. The nature, conduct and potential risks and benefits of the study will be fully explained to the participants and their caregivers. The confidentiality of the data will be assured in accordance with the Privacy Ordinance throughout the study. The research personnel involved will work closely together to monitor the occurrence of untoward effects in the participants. Standard guidelines for the management of falls will be used. Individual advice by the physiotherapist / the PI (registered nurse) on an ad hoc basis will be made to ensure the safety of the participants. (Appendix III: Fall preventions Management Protocol)

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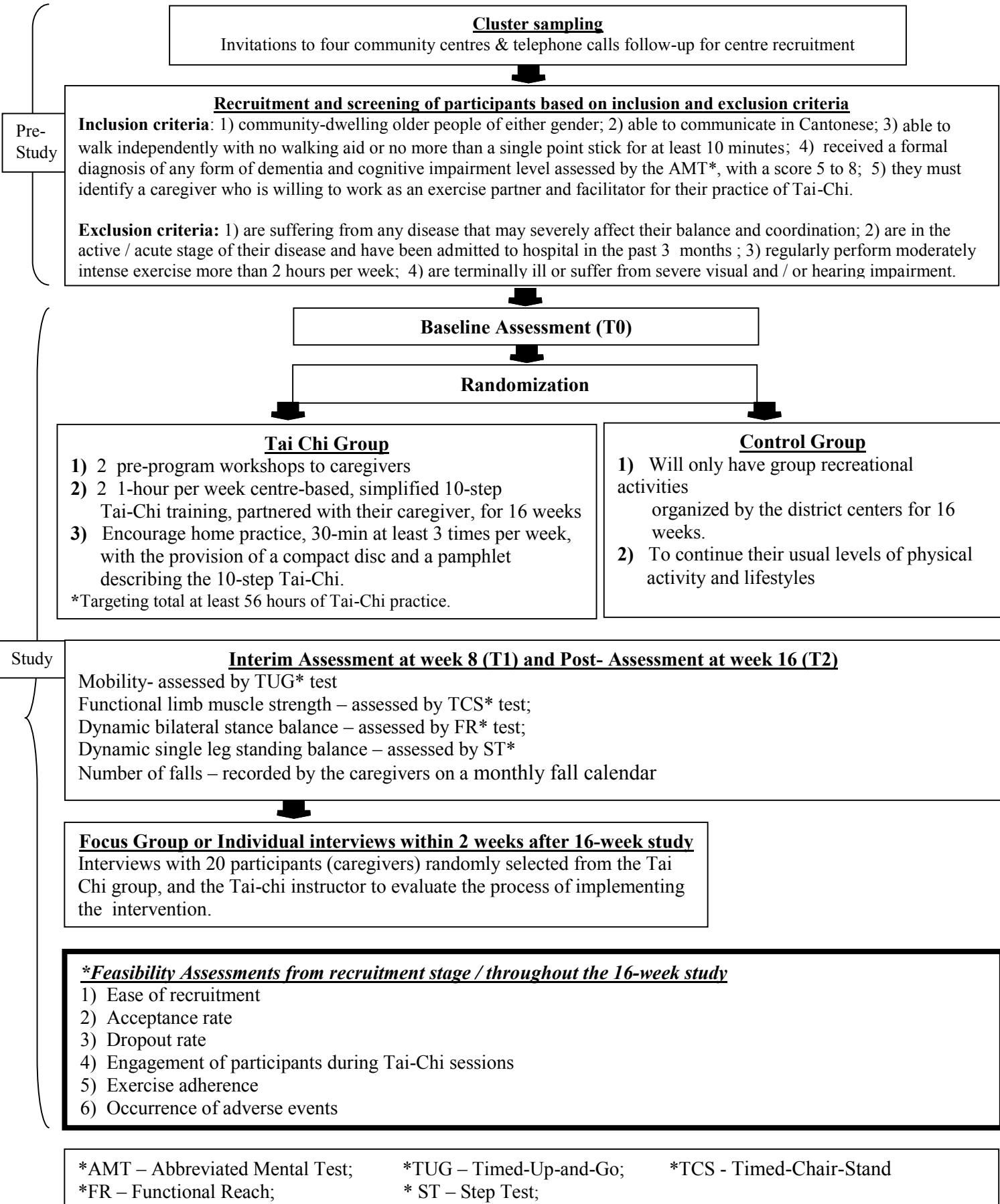
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Appendix I: Research Flowchart

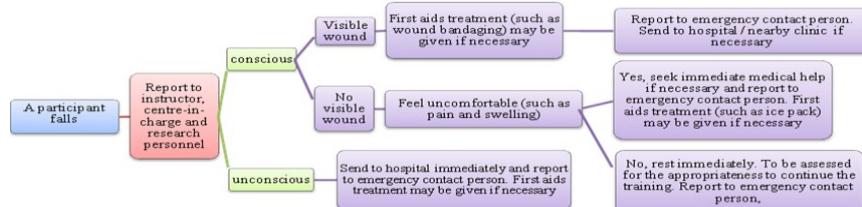


Appendix II: Timeline of the study:

Work / Months	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	18
Design confirmation stage:																	
- Literature review to validate the protocol, measurements and analysis of the study																	
Preparation stage:																	
- Recruit / train research personnel and recruit Tai Chi instructor																	
- Prepare materials (Tai Chi manual & CD, and stationery) and invitation letter and data collection form																	
Study conduction stage:																	
- Invite centers, recruit and screen participants																	
- Baseline data collection																	
- Conduct the interventions																	
- Outcome assessment and interviews																	
- Data management																	
Project completion stage:																	
- Data analysis																	
- Literature review																	
- Report writing																	
- Dissemination of findings and Manuscript writing																	

Appendix III: Fall management flowchart and guidelines:

*Fall management flowchart during Tai-Chi training lessons (English):



**Follow up :

- 1) All fall accidents will be reported to the research team.
- 2) In all cases, a follow-up phone call will be conducted by the research assistant and will be referred to PI, if any problems.

Guidelines for managing older people who fall while doing Tai-chi / exercise at home (English):

After slipping and falling, elderly people should take the following steps to help themselves:

- 1) Keep calm.
- 2) Assess the level of injury; move slowly if not severe.
- 3) Move along the ground to walls or stable furniture, then climb up with the support of the furniture.
- 4) If you cannot stand up, you may make a call by using the Personal Emergency Link Service / open the main door and ask loud for help.
- 5) Clean the wound first if you get an abrasion.
- 6) Consult a doctor quickly if you note any problems. You may have a fracture if you have difficulty moving or are in severe pain, even without any obvious wound.
- 7) All fall accidents should be reported to the research team.
- 8) In all cases, a follow-up phone call will be conducted by the research assistant and will be referred to PI, if any problems.

*These guidelines have been adopted from Fall prevention. (2011). In Department of Health. Retrieved Feb.12, 2015, from http://www.info.gov.hk/elderly/english/health_tips/eng/falls.htm