



Feasibility and preliminary efficacy of Ai Chi aquatic exercise training in Hong Kong's older adults with risk of falling: Design and methodology of a randomized controlled trial

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ABSTRACT

Falls in older adults are a major global public health concern. Group exercise could mitigate fall risk but the traditional land-based group exercise may not be always suitable for older adults at risk of falling, especially for those with musculoskeletal problems. Ai Chi aquatic exercise program could provide a safe and low-impact exercise training for older adults. However, the feasibility and efficacy of the program has not been well-investigated. The objective of this study is to investigate the feasibility and efficacy of the Ai Chi aquatic exercise program, compared to the land-based exercise program for older adults with moderate to high risk of falling. Forty community-dwelling older adults aged 65 or above with moderate to high fall risk will be recruited. They will be randomly allocated in the Ai Chi Aquatic Exercise Group (intervention) or the Land-based Exercise Group (active control) receiving 16 sessions (8 weeks) of specific exercise training. Feasibility of both exercise groups will be examined by recruitment, adherence, retention, feedback, subjective exercise experiences and satisfaction. Preliminary efficacy will be determined by whether physical and psychological fall risk factors could be mitigated. Physical fall risk assessment will include tests for flexibility, muscle strength, gait and balance. Psychological fall risk will be evaluated by preliminary cognitive function, anxiety level, level of depression and fear of falling. The results could establish a solid foundation for worldwide development of a feasible, safe and effective Ai Chi aquatic exercise program for prevention of falls in older adults with risk of falling.

1. Introduction

With global aging, fall-related injuries among older adults have been increased continuously, stressing our healthcare systems [1]. A previous study revealed that the prevalence of falls and recurrent falls among Hong Kong older adults was 19.3% and 4.75%, respectively [2]. It is not uncommon that falls lead to undesirable physical and psychological consequences in older adults, such as immobility and fear of falling [3]. In severe incidences, falls may even result in deaths. Therefore, falling has been a prominent health-related problem in the older population in Hong Kong. In 2017, for example, there were 277 registered deaths and 44150 in-patient discharges and deaths in Hong Kong due to falls [4]. The fallers inevitably require additional resources to cure their fall-related health problems. As a result, falling in older adults imposes an extremely heavy economic burden to not only older fallers themselves but also the worldwide health care system. With the frightening trend towards a progressively increasing aging population

[5], these problems are likely to affect the society more comprehensively.

It is widely agreed that “prevention is better than cure”. Therefore, prevention of falls in older adults is of ultimate importance. According to a recent systematic review, one of the most effective interventions for fall prevention is group exercise [6]. Very strong evidence had illustrated that performing a well-structured group exercise program regularly by older adults could reduce the risk and rate of falls [6]. The favourable influences of group exercise program as a single fall prevention intervention had been demonstrated to be comparable to those of multi-faceted interventions [6]. It has also been suggested that exercise components essential in preventing falls of older adults include strength, balance, flexibility and reaction time [7]. Nevertheless, owing to aging-related physiological changes, such as loss of bone density and diminishing muscular mass [8], land-based exercises are not always be suitable for those older adults who have high risk of falling due to the fear issues [9]. In order to address such influential limitations of land-

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based fall prevention group exercise program, aquatic group exercise program could potentially provide the effective components (i.e., strength and balance training) of fall prevention [7], while minimizing potential problematic issues (e.g., increasing joint pain and fear of falling). Aquatic group exercise program may provide an alternative training to land-based exercise for those older adults who have degenerative joint problems and fear of falling. It may also result in better fall prevention and rehabilitation outcomes.

The characteristics of water (e.g., buoyancy & viscosity) could be utilized in aquatic exercise to provide a 'cushion' environment by reducing loads on weight-bearing joints but at the same instance deliver graded levels of resistance for older adults during exercise [10]. Based on these characteristics, aquatic exercise could provide a potentially feasible, safe and effective therapeutic environment for older adults to perform exercise. Aquatic exercise is indeed well proven, with its benefits in promoting balance and functional mobility. For instance, Lord et al. [10] reported that older adults who completed an aquatic exercise program for nine sessions gained significant improvements in lower limb muscle strength, postural sway, flexibility and joint pain compared with the control group. Comparable results were also found by Tsourlou et al. [11] showing that a 24-week aquatic training program of older adults improved muscular strength. Participants were found to have improvements in muscular strength, flexibility, trunk flexion as well as functional mobility. Providing such benefits, different aquatic exercises, for example, water aerobic exercises, water walking and water dancing had been developed in current fitness program for health improvement and rehabilitation of both healthy older adults and those with disabilities.

One potentially feasible, safe and effective aquatic exercise program for fall prevention in older adults is called Ai Chi, which involves slow-and-broad movements of the limbs and body (Tai Chi element) in a continuously flowing pattern and deep breathing (Qi Gong element) [12]. Ai Chi involves the 19-style aquatic exercise program of 1, Contemplating, 2, Floating, 3, Uplifting, 4, Enclosing, 5, Folding, 6, Soothing, 7, Gathering, 8, Freeing, 9, Shifting, 10, Accepting, 11, Accepting with grace, 12, Rounding, 13, Balancing, 14, Flowing, 15, Reflecting, 16, Suspending, 17, Encircling, 18, Surrounding, and 19, Nurturing [12]. Despite the relatively small number of previous studies, pilot research had demonstrated its potential effectiveness in improving postural balance control for older adults with high and medium risk of falling [13]. Being an aquatic exercise program, Ai Chi provides a safe and low-impact training environment that has been well-recognized as a desirable exercise training environment for older adults [9]. Furthermore, Ai Chi has potential benefits beyond those associated with traditional aquatic exercise. The rationale is that Ai Chi's oriental roots echo well with exercises such as Tai Chi and Qi Gong, which Hong Kong older adults are likely to engage in. Therefore, Ai Chi may be considered as a potentially feasible, safe and effective fall-prevention exercise program for older adults in Hong Kong.

According to a recent review of water-based Tai Chi, there was scanty number of studies investigating on the effect of Ai Chi in reduction of fall risk factors for older adults [14]. The Ai Chi program conducted in previous pilot research was varied and may have not been designed by a group of qualified Ai Chi and rehabilitation experts [13]. In order to enhance the beneficial effects of Ai Chi in fall prevention, an Ai Chi aquatic exercise program for fall prevention in Hong Kong has to be developed by a group of Ai Chi and rehabilitation experts in Hong Kong. To examine the feasibility and preliminary efficacy of this developed Ai Chi aquatic exercise program, the feasibility and preliminary efficacy of this developed program should be compared to the traditional land-based exercise program.

This study protocol aims to investigate the feasibility and preliminary efficacy of the Ai Chi aquatic exercise program that was developed by a group of Ai Chi and rehabilitation experts in Hong Kong through a randomized controlled trial. With reference to the past pilot research, the Ai Chi aquatic exercise program may be more feasible and

effective than the traditional land-based fall prevention exercise program [13]. It is hypothesised that the expertly-designed Ai Chi aquatic exercise program could be as feasible as the land-based exercise program in the context of recruitment, adherence, retention and participants' feedback, subjective exercise experience and satisfaction of participants. It is also hypothesised that the expertly-designed Ai Chi aquatic exercise program is more effective in mitigating physical and psychological fall risk factors of Hong Kong's older adults with medium to high risk of falling, compared to the land-based exercise program.

2. Method

2.1. Study design

This study will be a randomized controlled trial. Eligible participants will be randomly assigned by concealed block randomization by an independent person with a sealed and opaque envelope system to either the Ai Chi Aquatic Exercise Group (intervention) or the Land-based Exercise Group (active control group). All participants will undergo two assessment sessions before training at baseline (T0) and just after completion of all exercise sessions (T1). In the baseline assessment (T0), a structural questionnaire will be used to ask for demographics, detailed medical history, detailed history of fall incident, social history and socio-economic status of the participants. During the two assessment sessions (T0 and T1), physical and psychological fall risk factors will be assessed. Feasibility outcome variables will be measured during and at the end of the whole study.

2.2. Participants

Forty older adults with moderate to high risk of falling will be recruited from different elderly community centres in Hong Kong by convenience sampling. Participants will only be included if they are aged 65 or above, score a total score of equal or more than 24 in the Chinese version of the Mini-Mental State Examination (MMSE-C) [15], score less than 24/28 in the Tinetti Balance Assessment Tool [16], have no history of any neurological diseases, and have no contraindication for aquatic exercises. The sample size was estimated based on a pilot study conducted by Teixeira and colleagues to compare the effect of a 6-week Ai Chi exercise group with control group on balance ability of older adults, an effect size of $= 1.1$ of the primary outcome (balance score of the Tinetti Balance Assessment Tool) was suggested [13]. Therefore, the result of sample size calculation of the current study suggests that a sample size of 15 older adult participants (effect size $= 1.1$, $\alpha = 0.05$, power $= 0.8$) per group was required for sufficient power to detect the difference in terms of the improvement of balance ability between participants in the Ai Chi exercise and control group. Conservatively, we plan to recruit 30% more participants to account for potential dropouts. As a result, 20 older adult participants per group and total participants of 40 will be recruited for the current study.

2.3. Outcomes

The feasibility and preliminary efficacy of the Ai Chi Aquatic Exercise Group and the Land-based Exercise Group will be assessed. Feasibility of the Ai Chi Aquatic Exercise Group will be examined quantitatively and qualitatively in the context of recruitment, adherence, retention, feedback, subjective exercise experiences and satisfaction of the participants. Recruitment will be assessed by the proportion of potential applicants that remain interested after randomization and being informed about the procedures of the whole study. Adherence will be measured by means of attendance to exercise sessions and compliance to the exercise styles of the participants in different groups. Retention will be determined by the attrition rate as discontinuation of the intervention by different exercise groups. A

structural assessment form will be used to record all participants' feedback. All Participants' subjective exercise experiences and satisfaction will be measured by a Subjective Exercise Experience Scale and a Participant Satisfaction Questionnaire, respectively.

Additionally, preliminary efficacy of the two exercise groups will be identified through examining the mitigation of various physical and psychological fall risk factors. A series of assessment will be completed to assess various physical and psychological fall risk factors of the participants in all two assessment sessions (T0 & T1). Physical fall risk factors assessed will include flexibility, muscle strength, and clinical gait and balance. Flexibility will be measured by the 'sit-and-reach' test [17]. Longer reaching distance represents better flexibility. Muscle strength of the major lower limb's muscles groups (e.g., knee & hip extensors) will be measured using the well-recognized Lafayette manual muscle testing system (e.g., Model 01165). Higher score represents better muscle strength. Clinical gait and balance assessment will be done by the Tinetti Balance Assessment Tool [16], Timed 'Up & Go' Tests (TU&G) [18] and the Berg Balance Scale (BBS) [19]. The Tinetti Balance Assessment tool assess gait (12 points) and balance (16 points) components (i.e., total score of 28 points) at the same time [16]. Lower score represents higher risk of falling. The TU&G requires participants to stand up from a chair, walk 3 m at a comfortable speed, turn around, walk back for 3 m, turn around and then sit down on the chair. Longer time to complete the TU&G represents higher risk of falling. The BBS consists of 14-item tasks (daily activities) in which participants need to maintain balance in performing the tasks and each item can be scored 0 to 4 marks giving a maximum total score of 56. Lower score represents poorer balance ability and therefore higher risk of falling. Psychological fall risk factors assessment will include preliminary cognitive function, anxiety level, level of depression and fear of falling. The Chinese version Mini-Mental State Examination (MMSE-C) [16] will be used to evaluate the preliminary cognitive function at the beginning of training as a screening tool. Anxiety level will be measured by the valid Chinese version of the State-Trait Anxiety Inventory [20]. Higher score represents higher anxiety level and therefore higher risk of falling. Level of Depression will be assessed by the Chinese version 4-item Geriatric Depression Scale (GDS-4C) [21]. The GDS-4C is a reliable and valid psychological measurement of depression in older adults and was demonstrated to be an excellent alternative of the 15-item and 30-item version of the Geriatric Depression Scale with good sensitivity (60–76%) and specificity (65–81%) using the cut-off point of 2 or more [21]. Higher score represents higher level of depression and therefore higher risk of falling. The Chinese version of the Falls Efficacy Scale International (FES-I (Ch)) [22] will be implemented to assess the fear of falling. Higher score represents higher fear of falling and therefore higher risk of falling.

2.4. Intervention

Participants in both Ai Chi Aquatic Exercise Group and Land-based Exercise Group will be invited to participate in their assigned group's sixteen exercise sessions (about 60 mins each) twice per week for a total of 8 weeks (Fig. 1). All training sessions will be conducted by two experienced certified Ai Chi trainers (Ai Chi Aquatic Exercise Group) or two experienced certified fitness instructors (Land-based Exercise Group) under the supervision of a Registered Physical Therapist in Hong Kong who is required to have the professional qualifications of both Ai Chi and exercise specialists. During the group exercise session, participants will practice either a nineteen-style Ai Chi aquatic exercise program or a nineteen-style land-based exercise program, depending on their randomly assigned group. The two exercise programs were developed by a group of qualified Ai Chi and rehabilitation experts in Hong Kong based on the Ai Chi styles that was originated from Mr. Jun Konno or the Otago Exercise program to prevent falls in older adults, respectively. In the Ai Chi Aquatic Exercise Group, participants practised the 19-style aquatic exercise program of 1, Contemplating, 2,

Floating, 3, Uplifting, 4, Enclosing, 5, Folding, 6, Soothing, 7, Gathering, 8, Freeing, 9, Shifting, 10, Accepting, 11, Accepting with grace, 12, Rounding, 13, Balancing, 14, Flowing, 15, Reflecting, 16, Suspending, 17, Encircling, 18, Surrounding, and 19, Nurturing. In the Land-based Exercise Group, participants practised the 19-style of Otago exercise program of 1, Trunk Movements, 2, Back Extension, 3, Ankle Movements, 4, Front Knee Strengthening Exercise, 5, Stand to Sit (No Hands), 6, Back Knee Strengthening Exercise, 7, Side Hip Strengthening Exercise, 8, Calf Raises (No Support), 9, Toe Raises (No Support), 10, Knee Bends (No Support), 11, Backwards Walking (No support), 12, Walking and Turning Around, 13, Sideways Walking, 14, Heel Toe Standing (No Support), 15, Heel Toe Walking (No Support), 16, One Leg Standing (No Support), 17, Heel Walking (No Support), 18, Toe Walking (No Support), and 19, Heel Toe Walking Backwards.

2.5. Data processing and analysis

Intention-to-treat (ITT) analysis will be adopted. For the feasibility, descriptive statistics will be used to compare the recruitment, adherence, retention and feedback of the participants in the Ai Chi Aquatic Exercise Group and the Land-based Exercise Group. Independent t-tests will be employed to compare the scores of the Subjective Exercise Experience Scale and Participant Satisfaction Questionnaire between the Ai Chi Aquatic Exercise Group and the Land-based Exercise Group.

For the preliminary efficacy, Analysis of Variance (ANOVA) with repeated measures and additional statistical tests, will be utilized to investigate the within group differences (i.e., T0 and T1) and between group differences (i.e., Ai Chi Aquatic Exercise Group & Land-based Exercise Group) in all physical and psychological fall risk factors (i.e., flexibility, muscle strength, scores of the clinical gait and balance assessments, anxiety level, level of depression and fear of falling). We could also determine the Minimal Clinically Important Differences (MCID) of the primary outcome measures (e.g., BBS) in order to help us know more about whether the intervention can lead to reducing fall risk factors.

3. Discussion

It is not uncommon among older adults, both in Hong Kong and worldwide, to suffer from falls and even fall-related injuries that required hospitalization. Given the progressively cumulating evidence to support the role of aquatic exercises for fall prevention in older adults, an expertly-designed Ai Chi aquatic exercise program could provide an alternative exercise choice for older adults who are at risk of falling. Therefore, our current study attempts to examine the feasibility and preliminary efficacy of the Ai Chi aquatic exercise program that was developed by a group of Ai Chi and rehabilitation experts in Hong Kong. If the results can provide evidence that the Ai Chi aquatic exercise program is feasible and can significantly mitigate fall risk factors in Hong Kong's older adults with moderate to high risk of falling compared to the land-based Exercise program, the structural Ai Chi aquatic exercise program could be considered to be incorporated into the standard fall prevention routine program of the Hong Kong's and even worldwide health care system.

The strength of our study is that it represents the first attempt to conduct a randomized controlled trial to examine the feasibility and preliminary efficacy of the expertly-designed Ai Chi aquatic exercise program that was developed by a group of Ai Chi and rehabilitation experts in Hong Kong. The result could provide a foundation to inform a large scale and cross-country randomized controlled trial to further investigate the effectiveness of the Ai Chi aquatic exercise program for prevention of falls in older adults in different countries. The current study may therefore with considerable global public health significance as the results could enhance our contemporary understanding of the structural Ai Chi aquatic exercise program with high practical

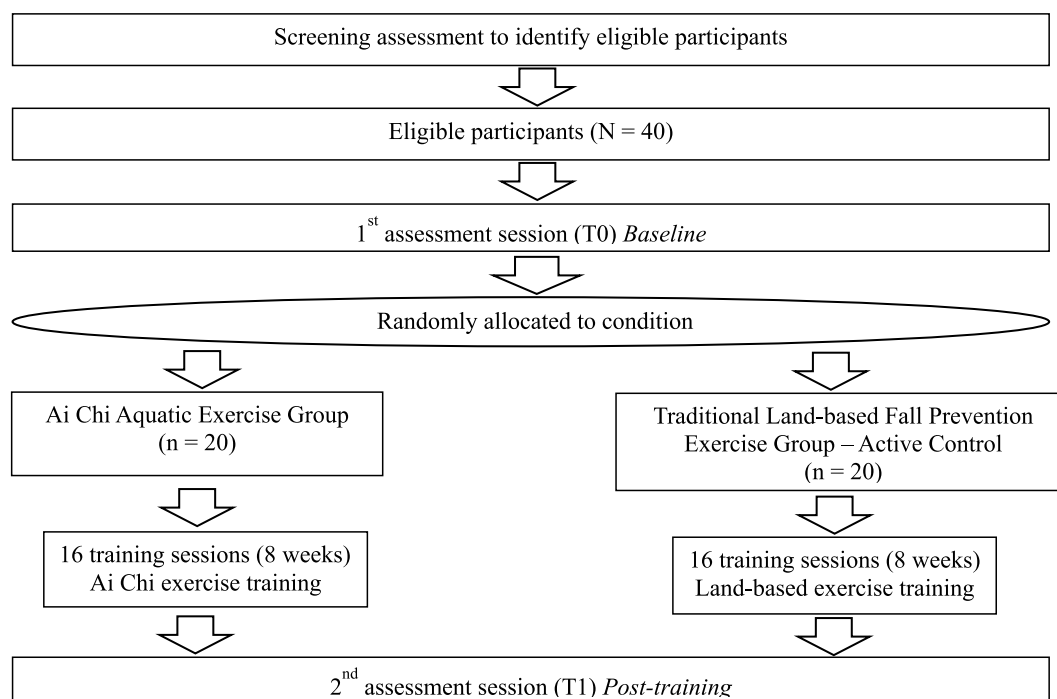


Fig. 1. Schematic diagram of the study design (randomized controlled trial).

implication for older adults. Based on the results of the current study, a large scale and cross-country clinical trial would be needed to further assess and confirm the effectiveness of the Ai Chi aquatic exercise program in different culture before it could be fully incorporated in the routine fall prevention program.

In conclusion, this study contributes to evaluating the effectiveness of two imperial community fall prevention exercise programs in Hong Kong. By comparing the feasibility and preliminary efficacy of the programs (i.e., the Ai Chi aquatic exercise program and the land-based exercise program), the feasibility, effectiveness and suitability of the programs for older adults in Hong Kong could be better understood, benefiting future design of the fall prevention protocol. Consequently, this research will provide a contemporary contribution to the global evidence-based practice of fall prevention in older adults by Physical Therapists. Future follow-up study could consider evaluating the long term adherence of the Ai Chi aquatic exercise program.

Ethics approval

Ethical approval was obtained from the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (IRB Reference Number: UW 18-065). The informed consent will be obtained for eligible participants. At the first meeting with all participants, the study protocol and informed consent form will be described in detail, where all participants will be offered the opportunity to review and ask questions. An incentive of \$50 (Hong Kong Dollars) will be paid to each participant as reimbursement for costs that are associated with travelling in each attended session.

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Clinical trial registration

The trial was registered in the HKU Clinical Trial Registry (HKUCTR-2528).

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.conctc.2019.100376>.

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