

BMJ Open Effects of a structured Tai Chi program on improving physical activity levels, exercise self-efficacy and health outcomes among pregnant women: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Tai Chi is a traditional Chinese martial art developed over 300 years ago. Although studies report that Tai Chi benefits practitioners' cardiovascular health, respiratory system and psychological outcomes, only limited studies have evaluated the effects of Tai Chi on pregnant women. More evidence is needed to examine the effects of a Tai Chi exercise programme among pregnant women.

Methods and analysis This is a randomised controlled trial to investigate the effects of a 12-week theory-based Tai Chi programme on improving physical activity levels, exercise self-efficacy and health outcomes among pregnant women. A total of 136 low-risk pregnant women (68 per group) were recruited and randomly assigned to receive usual care or usual care with the Tai Chi programme consisting of two group-based educational sessions and three Tai Chi sessions over 3 months. A Tai Chi video was provided to the participants to facilitate self-practice at home. Outcomes including physical activity levels, exercise self-efficacy, weight gain, prenatal depressive symptoms and prenatal anxiety symptoms were evaluated at baseline (T0), 6th week after intervention commencement (T1) and 1 week after intervention completion (ie, post-intervention) (T2). Intention-to-treat analysis and generalised estimating equations model will be used to analyse repeated outcome measures.

Ethics and dissemination The study has been approved by the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (Ref. 2022.043-T). Written consent was obtained from each participant. The findings will be disseminated in peer-reviewed journals and conference presentations.

Trial registration number ChiCTR2200059920.

INTRODUCTION

Performing moderate-intensity exercise for at least 150 min per week or 20–30 min per day or most days of the week is commonly recommended by prenatal exercise guideline.¹ However, the percentage of women following physical activity (PA) recommendations during pregnancy was only 14%–35%.^{2,3}

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This Tai Chi programme adopted a prospective, single-blinded, two-arm randomised controlled trial with a repeated measure design.
- ⇒ The Tai Chi programme for pregnant women was underpinned by a behavioural theory.
- ⇒ Blinding of participants and interveners was impossible; this represented a limitation.
- ⇒ The major limitation was the generalisability since this study was conducted in China and among pregnant Chinese women only.

Furthermore, as pregnancy progresses, weekly PA frequency and intensity tend to decrease. The third trimester sees further reduction in PA levels compared with the first trimester, whereas time spent on leisure-time sedentary behaviour increases.⁴ Therefore, there is a need to develop exercise programmes to motivate prenatal exercise.

Tai Chi, meaning 'supreme ultimate', also called Tia ji Quan or Taiji, is a traditional Chinese martial art developed for more than 300 years.⁵ Tai Chi is a light-to-moderate intensity aerobic exercise appealing to both young and older adults.⁶ It comprises mental concentration, physical balance, muscle relaxation and breathing, which are integrated into graceful body movements and thought to assist in the balance between one's body and mind.⁷ Tai Chi is claimed to be able to relieve insomnia, dizziness, neurasthenia and headache caused by cerebral cortex activity.⁸ As a form of aerobic exercise, Tai Chi enhances microcirculatory function by influencing blood viscosity, elasticity and platelet function.⁹ It is also effective in preventing diabetes in practitioners.¹⁰

High levels of enjoyment and a high adherence rate among participants performing Tai Chi have been reported in studies aiming to increase PA among older women.^{11 12} Evidence reveals that Tai Chi is effective in improving health-related quality of life and emotional well-being in women with cancer, type II diabetes or cardiovascular diseases.^{13–15} Moreover, as the major component of Tai Chi, abdominal breathing reduces prenatal anxiety, stress and the risk of preterm delivery.^{16 17}

However, only limited studies have evaluated the effects of Tai Chi exercise programmes among pregnant women. One randomised controlled trial (RCT) conducted in the USA evaluated the effects of a 12-week Tai Chi programme on improving health outcomes among 92 pregnant women, showing that Tai Chi significantly reduced prenatal anxiety and depression.¹⁸ Although Tai Chi is popular in China,¹⁹ only one two-group pretest and post-test quasi-experimental study involving 17 pregnant women was found to evaluate the impact of a 20-week Tai Chi programme on pregnant women's health.²⁰ In this study, Tai Chi significantly reduced symptoms of discomfort, blood pressure, prenatal depression, prenatal anxiety and enhanced respiratory function.²⁰ Although these two studies indicated that pregnant women might benefit from the Tai Chi programme,^{18 20} evidence is limited. Therefore, more evidence is needed to examine the effects of a Tai Chi exercise programme on pregnant women.

Interventions guided by a theoretical construct are more effective in changing behaviours, and might have longer-lasting impacts than those without a theoretical basis.²¹ Theories or conceptual frameworks can be used to guide the planning, implementation and evaluation of therapeutic interventions.²¹ However, none of the prenatal Tai Chi studies adopted a conceptual framework to guide their interventions.^{18 20} Thus, a high-quality, theory-based Tai Chi programme during pregnancy is needed.

STUDY AIMS AND OBJECTIVES

The aim is to develop a theory-driven Tai Chi programme during pregnancy and evaluate its effects on pregnant women. The objectives are as follows:

1. To develop a Tai Chi programme for pregnant women underpinned by a behavioural theory.
2. To evaluate the effects of the Tai Chi programme on improving PA levels, exercise self-efficacy and health outcomes (including weight gain, gestational diabetes mellitus (GDM), prenatal anxiety symptoms and prenatal depressive symptoms) among pregnant women.

METHODS AND ANALYSIS

Design and settings

This study employed a prospective, single-blinded and two-arm RCT design with repeated measurements to evaluate the effects of a structured Tai Chi programme among

pregnant women. The participants were recruited during their prenatal visits at the obstetric clinic in Guangzhou Women and Children's Medical Center in Guangzhou, mainland China. Participant recruitment commenced in June 2022 and lasted until December 2022. The study is anticipated to end in May 2023.

Participants

Inclusion and exclusion criteria

Convenience sampling was used. Participants were recruited if they are: (1) local residents who decide to have regular prenatal visits in Guangzhou, (2) no less than 18 years of age, (3) ultrasonic-confirmed viable intrauterine single pregnancy, (4) between 12 and 15 weeks of gestation (based on the ultrasound), (5) able to do exercise, (6) able to read and communicate in Chinese and (7) possessing a mobile phone.

Participants were excluded if they are: (1) with medical or midwifery restrictions for moderate-intensity PA, including the incompetent cervix, ruptured membranes, premature delivery, persistent vaginal bleeding, pre-eclampsia, mild/moderate cardiovascular disease or respiratory disease, poorly controlled asthma, uncontrolled diabetes, uncontrolled hypertension, uncontrolled thyroid disease, bone or joint problems that may be made worse by PA, placenta praevia, symptomatic anaemia, eating disorders, malnutrition and intrauterine growth restriction,¹ (2) with psychological diseases or mental disorders, (3) performing moderate-intensity PA for more than 150 min per week in the first trimester and (4) participating in other lifestyle programmes/interventions.

Sample size determination

An effect size of 0.53 based on the primary outcome of PA levels was used to estimate the sample size.²² The attribution rate of PA interventions ranged from 0% to 33%.^{22–24} Accordingly, an average attrition rate of 15% was applied in this study. A sample size of 57 in each group was estimated by G*Power (V.3.1) with a power of 80% at a significance level of 0.05. Considering an attrition rate of 15%, a total of 136 pregnant women with 68 for each group were recruited in this study.

Randomisation and blinding

A randomisation sequence was generated using an online randomisation programme (<http://www.randomisation.com/>) by a research assistant who is a registered nurse and has a master's degree in nursing. The research assistant was not involved in participant recruitment, intervention implementation or outcome assessment. Participants were allocated to the study arms using permuted block randomisation with varying block sizes in a 1:1 ratio. The card that indicated the group allocation was placed in sealed envelopes by the research assistant; then these sealed envelopes were numbered in sequence by the research assistant and distributed sequentially to the

Table 1 Application of the theoretical framework

| Elements | Application | |
|-------------------------|--|---|
| Self-efficacy sources | Performance accomplishment | Setting a series of sub goals from easy to difficult; Giving feedback on people's achievement |
| | Vicarious experiences | Provision of information about modelled achievements of others |
| | Verbal persuasion | Provision of strong verbal encouragement for the benefits of the behaviour and the progress the one has made in achieving the behaviour |
| | Emotional arousal | Relaxation training, including breathing techniques and muscle relaxation |
| Outcome expectations | Provision of knowledge of the positive effects of the behaviour on physical and psychological factors | |
| Sociostructural factors | Identification of impediments and facilitators (eg, socioculture difference, exercise facilities, socio-promotion and so on) | |
| Goals | Setting goals and plans and strategies for realising them | |

participants. Accordingly, the participants were randomly assigned to either the intervention or the control groups.

Due to the content of the exercise intervention, blinding of participants and interveners would be impossible. The outcome assessors were blinded to group allocation before completing all data collection, aiming to prevent their understanding or expectations of the group assignment from affecting the research results.

Research content

Theoretical framework

Social cognitive theory (SCT) was adopted as the theoretical basis for designing the Tai Chi programme for pregnant women in this study. The core determinants of SCT include knowledge of health consequences of different health practices; perceived self-efficacy, people's belief to produce desired effects by their actions, outcomes, expectations about the expected costs and benefits for the healthy lifestyles, the health goals, and plans and strategies for realising them; and the perceived facilitators and social and structural impediments to the changes people seek.²⁵ Self-efficacy is one of the main constructs of the SCT and plays a central role in motivating people to engage in a behaviour.²⁵ People develop self-efficacy from four primary sources: performance accomplishment, vicarious experiences, verbal persuasion and emotional arousal.²⁶ The application of the theoretical framework in this study is seen in [table 1](#).^{16 25 27}

Interventions

The proposed 12-week Tai Chi programme began from 16 weeks of gestation, as the second trimester is identified as the best time to begin a prenatal exercise programme²⁸ and prenatal exercise interventions beginning from 16 weeks of gestation were shown to be effective in increasing participants' PA levels.^{22 29} The intervention package included two face-to-face educational sessions in the first week, three weekly face-to-face Tai Chi sessions in the first 3 weeks, a Tai Chi video, 12-week home-based Tai Chi practice, a written educational booklet, a logbook and 12 weekly booster phone calls.

[Table 2](#) shows the content and delivery of the training sessions. Based on the evidence, the following topics are included in the first face-to-face educational session: (1) knowledge of pregnancy and delivery; (2) benefits of prenatal exercise and Tai Chi and (3) exercise precautions and safety tips.^{1 23} The content of the educational booklet is the same as the first educational session. In the second educational session, the following topics that aim to provide behaviour change education are included: (1) setting goals; (2) action planning; (3) self-monitoring skills; (4) problem-solving skills and (5) social support.²⁵ The principal investigator gave two educational sessions. Each educational session lasted for 60–70 min.

The Eight-form Easy Tai Chi was taught to pregnant women (see [table 3](#)). Following a gradual process in which Tai Chi forms change from simple to complex, the Eight-form Easy Tai Chi starts with upper body movements (including arms, shoulders and torso movements). Each form was practised at a slow and self-controlled speed suitable for pregnant women.^{20 30} The 6th form (Golden cock stands on one leg, 金鸡独立) and the 7th form (Heel kick, 蹬脚) in the original version have been omitted to increase safety (see [table 1](#)).³¹ Each sequence of the Eight-form Easy Tai Chi was supposed to be completed in 3 min, and at least five forms were attempted, along with 8–10 repetitions of each form.^{30 31} When practising Tai Chi, oral instructions and exercise precautions were given by the Tai Chi coach.

A Tai Chi video and an educational booklet were given to participants to facilitate home practice. As suggested, participants were instructed to practice Tai Chi at home 3–4 times per week for 30–60 min each time.¹ An experienced midwife and an obstetrician were on call in case of an emergency. Tai Chi practice compliance was monitored using a self-reported logbook and weekly booster phone calls from the principal investigator. During the phone call, Tai Chi training compliance and the personal condition of the participants were evaluated. Adherence to Tai Chi practice and recording in the logbook was emphasised at the end of each phone call.

Table 2 The content and delivery of the educational sessions and Tai Chi training sessions

| Session | Format | Content | Intervention delivered by |
|-----------------------|---------------------------------------|--|---------------------------|
| Educational session 1 | Face-to-face, Group-based (60–70 min) | <ul style="list-style-type: none"> ▶ The benefits of exercise and Tai Chi during pregnancy ▶ Recommended exercise frequency, intensity, time and types ▶ Cautions regarding when to do exercise and Tai Chi | Principal investigator |
| Educational session 2 | Face-to-face, Group-based (60–80 min) | <ul style="list-style-type: none"> ▶ Setting goals. To set the goal of doing exercise for 30–60 min per time, 3–5 times per week ▶ Action planning. To specify the planned exercise time, the location, duration, intensity and frequency ▶ Self-monitoring skills. To hand out an e-logbook to each participant and ask them to record the exercise type, intensity, time and duration when they do exercises at home ▶ Problem-solving skills. To prompt the participants to identify the barriers preventing them from doing exercises and discuss ways in which they can overcome them ▶ Social support. To provide techniques for developing and maintaining social support for exercise | Principal investigator |
| Tai Chi session 3–5 | Face-to-face, Group based (60–70 min) | <ul style="list-style-type: none"> ▶ Warm up (10 min) ▶ Demonstration of Tai Chi (20 min) ▶ Cool down (5 min) ▶ Break up (10 min) ▶ The participants practice Tai Chi (15–25 min) | Tai Chi coach |

The content validity of the educational booklet and exercise videos was evaluated by an expert panel consisting of eight experts. The experts used a five-point Likert scale to rate the relevance, adequacy and accuracy of the educational booklet and Tai Chi video modules. The content validity index (CVI) of each module of the brochure and videos ranged from 0.975 to 0.995, indicating good content validity for a panel of six or more experts.³²

Patient and public involvement

In order to develop the patient-tailored intervention, participants meeting the eligibility criteria were invited to

provide insights regarding their exercise experiences and the facilitators and barriers to exercise participation to inform the development of the intervention. Participants who met the inclusion and exclusion criteria were first involved in the study during their first prenatal visit to the Guangzhou Women and Children's Medical Center. After intervention delivery, participants' satisfaction and comments on the intervention's usefulness and acceptability will be collected through an investigator-generated satisfaction questionnaire and in-depth interviews.

Control group

The control group received placebo control, including routine prenatal care (including general health education advice given by obstetricians or midwives during regular prenatal visits at obstetric clinics), knowledge of pregnancy provided by the principal investigator at baseline and 12 weekly phone calls to ask about their general health condition.

Outcome measures

Primary outcome

PA levels were assessed using the Chinese version of the Pregnancy Physical Activity Questionnaire (PPAQ) at baseline (T0), 6th week of intervention (T1) and immediately after the intervention (T2).^{33 34} The weekly energy expenditure on PA per week was calculated by multiplying the time (hour-week-1) and relating metabolic equivalents of tasks which are given in the questionnaire.³⁴ The Chinese version of the PPAQ was translated. The CVI ranged from 0.98 to 0.99, and the test-retest reliability was 0.60 to 0.72,^{33 35} indicating that PPAQ is a reliable measurement to assess PA levels during pregnancy.

Table 3 Forms in Eight-Form Easy Tai Chi

| Form | Movement direction/ number of repetitions |
|---|---|
| 1. Commencing form (起势) | Both hands rise to shoulder level |
| 2. Reverse reeling forearm (倒卷肱) | Left and right |
| 3. Brush knee and step forward (搂膝拗步) | Left and right |
| 4. Part the wild horse' mane (野马分鬃) | Left and right |
| 5. Wave hands like clouds (云手) | Left side leads, 3 times |
| 6. Grasp the bird's tail (揽雀尾): ward off (棚), rollback (捋), press (挤), push (按) | Left, then right |
| 7. Cross hands (十字手) | Left, then right |
| 8. Closing form (收势) | Both hands fall to the side, left leg drawn to the right leg. |

Secondary outcomes

Exercise self-efficacy

Exercise self-efficacy was assessed using the Chinese version of the Pregnancy Exercise Self-efficacy Scale (P-ESES) at T0, T1 and T2.³⁶ This scale has one dimension and 10 items. The options for each item are ‘strongly agree’, ‘agree’, ‘neutral’, ‘disagree’ and ‘strongly disagree’, with 5, 4, 3, 2 and 1 points, correspondingly. The scores were added up to get a total score which ranges from 10 to 50 points. According to the total score, exercise self-efficacy is divided into three levels: high (41–50), medium (21–40) and low (10–20).³⁷ The Cronbach’s α of the Chinese version of P-ESES was 0.804.³⁶

Weight gain

Participants’ weight (kg) at T0, T1 and T2 were recorded. The same electronic weight scale was used. Participants were required to wear light clothes and take off shoes when measuring their weight. The principal investigator helped them use the weight scale and record their weight.

Gestational diabetes mellitus

The 75g 2-hour oral glucose tolerance test (OGTT) was used as the screening tool for GDM.³⁸ Participants had their OGTT between 24 and 28 weeks of gestation. GDM is diagnosed if one or more glucose values meet or exceed the following diagnostic thresholds: fasting plasma glucose level ≥ 5.1 mmol/L, 1-hour plasma glucose level ≥ 10 mmol/L and 2-hour plasma glucose level ≥ 8.5 mmol/L.³⁸

Prenatal anxiety symptoms

The Chinese version of the Self-rating Anxiety Scale (SAS) was used to evaluate prenatal anxiety symptoms among pregnant women.³⁹ The SAS includes 20 items about psychotic emotional symptoms, psychomotor disturbance, somatic disorders and mental disorders of anxiety or depression. Participants selected the option that best describes their mental state when answering each question. Each question is scored on a Likert-type scale of 1–4 or reverses scoring (‘a little of the time’, ‘some of the time’, ‘a good part of the

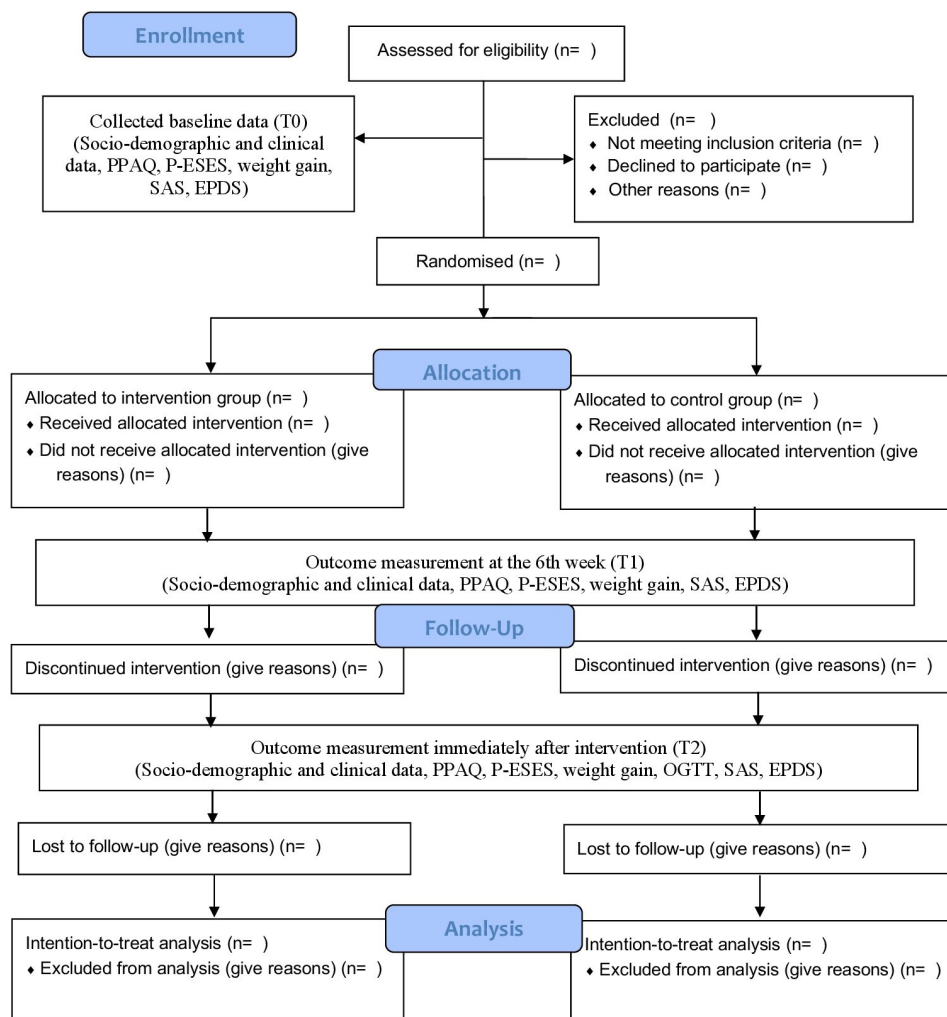


Figure 1 CONSORT flowchart of the study. EPDS, Edinburgh Postnatal Depression Scale; OGTT, Oral Glucose Tolerance Test; P-ESES, Pregnancy Exercise Self-efficacy Scale; PPAQ, Pregnancy Physical Activity Questionnaire; SAS, Self-rating Anxiety Scale.

Table 4 SPIRIT schedule of the trial

| Time point | Enrollment | Allocation | Post-allocation | |
|--|------------|------------|-----------------|----|
| | T0 | | T1 | T2 |
| Enrolment | X | | | |
| Eligibility screen | X | | | |
| Informed consent | X | | | |
| Randomisation | X | | | |
| Allocation | | X | | |
| <i>Interventions</i> | | | | |
| Educational sessions | | X | | |
| Tai Chi sessions | | X | | |
| Tai Chi video | | | ←————→ | |
| Weekly phone calls | | | ←————→ | |
| <i>Assessment</i> | | | | |
| Sociodemographic data | X | | | |
| Clinical data | X | | | |
| Physical activity level | X | | X | X |
| Weight | X | | X | X |
| Exercise self-efficacy | X | | X | X |
| Prenatal anxiety symptoms | X | | X | X |
| Prenatal depression symptoms | X | | X | X |
| Compliance of Tai Chi | | | X | X |
| Gestational diabetes mellitus | | | | X |
| The participants' satisfaction towards the Tai Chi programme | | | | X |

SPIRIT, Standard Protocol Items: Recommendations for Interventional Trial.

time' and 'most of the time'). The Chinese version of the SAS has been widely used among the Chinese population, and it is reliable in epidemiological surveys (with a Cronbach's alpha of 0.85).⁴⁰ It also has an internal consistency of 0.66–0.80 among pregnant Chinese women,⁴¹ indicating that the SAS is a suitable instrument.

Prenatal depressive symptoms

The Edinburgh Postnatal Depression Scale (EPDS) was used to assess prenatal depressive symptoms among pregnant women. The EPDS was developed by Cox *et al*⁴² and translated to simplified Chinese in 2009.⁴³ It has 10 items, and each item is rated on a four-level Likert scale (0–3). The total score is 0–30, and a higher score indicates a higher level of depressive symptoms.⁴² The CVI of the Chinese version of the EPDS is 0.93, and the Cronbach's alpha is 0.76.⁴³ The EPDS has been shown to have an optimal critical value in screening prenatal depression among pregnant women, and the optimal critical value is 9.5, with the sensitivity, specificity and the area under the curve being 0.786, 0.834 and 0.845, respectively.⁴⁴

Other measurements

Sociodemographic and clinical data

Sociodemographic and clinical data were collected at baseline. Sociodemographic data includes age, marital status,

educational level, employment status and economic level. Clinical data were collected, including gestational weeks, the number of pregnancies, deliveries and children, pre-pregnancy weight and height.

Participants' satisfaction

A self-developed user satisfaction questionnaire was used to evaluate the satisfaction of the participants. It includes items about participants' perceived usefulness and ease of practising Tai Chi under supervision or at home. A 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree) was used. A score above 4 indicates satisfaction with the Tai Chi programme.

Compliance of Tai Chi

An attendance sheet was used to record the number of times each participant participated in the inpatient training. A logbook was given to participants to record exercise time (min) and date on the logbook when they perform Tai Chi at home.

Data collection

The Consolidated Standards of Reporting Trials flowchart is presented in [figure 1](#). After obtaining informed consent, the sociodemographic, clinical and baseline data (T0) (including PA levels, exercise self-efficacy,

weight, prenatal anxiety symptoms and prenatal depressive symptoms) were collected by outcome assessors blinded to the group allocation. An outcome assessor trained by the principal investigator collected follow-up data at T1 and T2. The GDM data and participants' satisfaction with the Tai Chi programme were collected at T2. The data collection procedures are presented in table 4.

Process evaluation

The following strategies were adopted to promote intervention fidelity of this study: (1) a study protocol was developed to guide intervention delivery; (2) every step of the intervention followed the checklist of the intervention implementation; (3) a standardised educational booklet containing the content of the intervention and a Tai Chi video was passed to the Tai Chi coach and participants; (4) the Tai Chi coach was instructed to learn pregnancy knowledge from the principal investigator, and the intervention was delivered by the same researcher and Tai Chi coach using same intervention content; (5) after discharge, weekly phone calls were conducted to record, encourage and remind the participants to self-practice; (6) logbooks were given to the participants to record their self-practice and (7) attendance rate of each participant was recorded.

Data analysis

SPSS V.25.0 software (IBM SPSS, Chicago, Illinois, USA) will be used for data analysis. Before data analysis, a cross-checking of data entering will be conducted. Descriptive statistics will be used to summarise the socio-demographic data, clinical characteristics and outcome variables. Frequency and percentages will be used to describe categorical data. Means, SD, maximums and minimums will be employed to describe continuous variables. Before data analysis, the normality of continuous data will be determined by inspecting Q-Q plots and skewness and kurtosis statistics. Appropriate transformation of skewed data will be conducted. The homogeneity of the included participants will be assessed using a parametric or non-parametric approach based on the variable types. For continuous variables, independent t-tests will be used if the data were normally distributed; otherwise, a non-parametric test of Mann-Whitney U tests will be performed. For the categorical variables, the χ^2 and Fisher's exact tests will be committed to comparing differences between groups.

Intention-to-treat analysis will be adopted in this study to preserve the integrity of randomisation, as recommended by the Consolidated Standards of Reporting Trials statement.⁴⁵ The generalised estimating equations model will be used to analyse repeated outcome measures. The effect size of continuous and categorical variables will be assessed in terms of Cohen's d statistics and OR, respectively. The effect sizes of statistically significant results will be calculated.

Reporting guidelines

Standard Protocol Items: We adhered to the Recommendations for Interventional Trials reporting guidelines in this protocol⁴⁶ (see online supplemental appendix 1 and 2).

Ethical issues

The study was approved by the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (Ref. 2022.043-T) on 22 April 2022. Written consent was obtained from each participant. Any identifying information of the participants will not be presented in the study report. The data from participants will only be used for research purposes and kept in a secure location. Only the principal investigator has access to the data. All the data will be destroyed 5 years after the completion of the study. Participation is voluntary. The findings will be disseminated in peer-reviewed journals and conference presentations.

DISCUSSION

To the best of our knowledge, this is the first prospective, single-blinded, two-arm RCT with a repeated measure design to evaluate the effects of a theory-based or theory-driven Tai Chi programme for pregnant women. The findings could guide the development of exercise interventions and add to the body of knowledge about the effects of Tai Chi programmes on PA levels, exercise self-efficacy and health outcomes among pregnant women.

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