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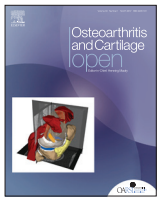

Clinical Study Protocol

An unsupervised online Tai Chi program for people with knee osteoarthritis ("My Joint Tai Chi"): Study protocol for the RETREAT randomised controlled trial

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ABSTRACT

Background: Knee osteoarthritis (OA) is a leading contributor to global disability, with exercise proven to be an effective treatment. Tai Chi is a recommended type of exercise, but it is primarily done in person which imposes an accessibility issue. This study aims to evaluate the effects of an online unsupervised program, when provided with online educational information and exercise adherence support, on changes in knee pain and physical function, when compared to online education control for people with knee OA.

Methods: A two-arm, superiority parallel-design, pragmatic randomised controlled trial will be conducted involving 178 people with a clinical diagnosis of knee OA. After completing baseline assessment, participants will be randomly assigned to either: i) "My Joint Education", an education control website containing OA information only; or ii) "My Joint Tai Chi", an intervention website containing the same information as the control, a 12-week unsupervised online Tai Chi program to be undertaken at home 3 times a week, and information about an exercise adherence support app. All participants will be reassessed at 12 weeks after randomisation. Primary outcomes are overall knee pain during walking and physical function using the Western Ontario and McMaster Universities Osteoarthritis Index subscale.

Discussion: This randomised controlled trial will provide evidence about the effectiveness of the "My Joint Tai Chi" website compared to "My Joint Education" website on self-reported knee pain and physical function for people with knee OA.

Trial registration: Prospectively registered with the Australia New Zealand Clinical Trials Registry (ID: ACTRN12623000780651) on 18th July 2023.

1. Background

Osteoarthritis (OA) affecting the knee joints is a leading contributor to global disability [1]. Around 654 million individuals aged 40 years and older have knee OA worldwide in 2020, with a 75 % increase expected by 2050 [2,3]. Pain and impaired function, together with co-morbidities including low mood, are commonly reported by people with knee OA [4,5]. Supporting patients to self-manage is key in the treatment of knee OA, with all clinical guidelines recommending education and physical activity, including structured exercise, as the cornerstone of conservative management, irrespective of disease severity [6–8]. Evidence suggests land-based therapeutic exercise regardless of the type, when performed regularly, can provide benefit in terms of reduced knee pain and improved physical function and quality of life [9].

Tai Chi is one exercise option recommended in high quality clinical guidelines for people with knee OA [6,8]. Tai Chi is a traditional Chinese mind-body exercise that combines meditation with slow, gentle movements, deep diaphragmatic breathing and relaxation. It is a popular form of land-based exercise that is less monotonous and intense, requiring minimal equipment compared to other forms of exercise like resistance or

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aerobic training [10]. A study in US adults shows that the use of Tai Chi has significantly increased [11], especially amongst physically inactive people, the elderly, and females, all of whom have an increased risk of developing knee OA [12,13]. Tai Chi is generally performed in person in a group class setting. Clinical trials of Tai Chi delivered in this manner have shown it to be effective in reducing pain and improving function and quality of life for people with OA [6,10,14–17]. With its meditative and mindfulness component, Tai Chi has also been shown to have multidimensional effects including improved psychological health, cognitive function and sleep quality [18,19]. There are likely multiple mechanisms underpinning the benefits of Tai Chi in people with knee OA. These include optimised knee biomechanical loading, improved muscle strength, proprioception and joint stability, and reduced systemic inflammation [20,21].

However, in-person group Tai Chi classes may be inconvenient or difficult for many patients to access, especially in regional or rural areas where exercise services may be limited and where there is a higher prevalence of OA [22]. There can also be financial barriers to attending Tai Chi classes, with most generally involving a cost. Increasingly, people are accessing health and exercise resources online [23], given that 5.4 billion people worldwide used the internet in 2023, accounting for 67 % of the world population [24]. Specifically, during the Covid-19 pandemic, 100 million telehealth services were delivered across Australia [25], and there was a surge of telemedicine care across the US [26]. Online exercise interventions have the potential to reach a wide audience regardless of location and at less cost to users and the health-care system [27].

An online unsupervised Tai Chi program is a scalable way to help patients undertake Tai Chi in their own home. There is some evidence demonstrating the effectiveness and feasibility of online Tai Chi programs in other chronic conditions, such as cancer and cognitive impairment [28–30]. However, these programs have required health practitioner or administrative personnel involvement thus are not fully unsupervised. There are no studies investigating the effectiveness and safety of an unsupervised online Tai Chi program for people with knee OA. We previously developed an unsupervised online yoga intervention for people with knee OA consisting of a 12-week progressive yoga program guided by an instructor in a pre-recorded format, OA education content and physical activity guidance housed on a website “My Joint Yoga” [31]. We compared this 12-week unsupervised online yoga program with online education alone in a randomised controlled trial (RCT) of 212 people with knee OA [32]. The results showed greater improvement in physical function, but not knee pain, at 12 weeks with benefits for some secondary outcomes [32]. The program has now been made freely available to the general public and to date has had nearly 6200 users from 61 countries since 2022. This highlights the global interest in unsupervised online exercise programs in this population group. Considering that Tai Chi is less intense than other forms of exercise, it may be ideally suited for individuals who have higher pain severity and poorer physical function - subgroups that have been shown to receive the most benefit from therapeutic exercises [33].

We will now evaluate a 12-week evidence-based unsupervised online Tai Chi program that we have developed with input from Tai Chi instructors, OA consumers and physiotherapists [34]. The primary objective of this study is to evaluate the effectiveness of the “My Joint Tai Chi” website containing the unsupervised online Tai Chi program plus educational information and an exercise adherence support app (“My Exercise Messages” app) on change in knee pain during walking and change in physical function after 12 weeks, compared with “My Joint Education” website containing educational information alone, for people with knee OA.

The secondary objectives are to:

i) evaluate whether the “My Joint Tai Chi” website will improve secondary outcomes (Knee Injury and Osteoarthritis Outcome Score (KOOS) subscales of pain, function in sport and recreation and knee-related quality of life; physical and mental well-being; global change in knee condition; fear of movement; pain self-efficacy; balance confidence; positive activated affect; sleep quality and use of oral pain medications) at 12 weeks.
ii) determine user experience (acceptability, satisfaction, credibility, usability, user-reported adherence, perceived impact) of “My Joint Tai Chi” website for people with knee OA using a range of process measures.
iii) investigate whether pain self-efficacy and outcome expectations regarding Tai Chi moderate the effects of the intervention on knee pain during walking and on physical function (primary outcomes) compared to control at 12 weeks.

2. Methods

2.1. Study design

This is a two-arm, parallel-design, superiority pragmatic RCT designed according to SPIRIT guidelines [35]. The SPIRIT document is attached as additional document to this manuscript. The trial was registered prospectively (Australian and New Zealand Clinical Trials Registry, ACTRN12623000780651). Findings will be reported according to the CONSORT statement [36] and TIDieR guidelines [37]. If amendments are made to the trial protocol, we will inform the institutional ethics committee and update the trial registry as appropriate.

2.2. Participants

178 people with persistent knee pain consistent with a clinical diagnosis of knee OA [7] will be recruited from the Australian-wide community via advertisements (e.g., social media), internet-based newspapers and our centre’s website. Eligibility criteria are presented below. Informed consent will be obtained prior to baseline questionnaires from participants via online forms using REDCap™ (Research Electronic Data Capture) hosted at the University of Melbourne [38,39]. Ethics approval was obtained.

Inclusion criteria are as follows:

i) National Institute for Health and Care Excellence clinical criteria for knee OA: [7]a. age ≥45 years;b. activity-related knee joint pain;c. no morning knee stiffness or morning knee stiffness ≤30 min;
ii) live in Australia;
iii) report knee pain for ≥3 months;
iv) report knee pain on most days in the past month;
v) report overall average knee pain in the past week during walking ≥4 on 11-point numerical rating scale (NRS; 0 = no pain, 10 = worst pain possible);
vi) have a home internet connection and a computer/tablet device that enables access to the internet
vii) have a suitable smartphone to download an app
viii) able to give informed consent.

Exclusion criteria are as follows:

i) inability to speak or read English;
ii) recent knee surgery (past 6 months);
iii) on waiting list for/planning knee surgery in next 3 months;
iv) previous knee joint replacement on affected side;
v) participated in regular (one or more times per week) exercise (home-based leg strengthening exercises, swimming/water exercises, cycling or attending a gym or group exercise classes such as Tai Chi, Yoga, Pilates) over the past 3 months;
vi) unable to walk unaided (without use of a frame or walking stick);

vii) self-reported inflammatory arthritis (e.g. rheumatoid arthritis);
viii) history of fall (past 12 months) and no general practitioner (GP) clearance to participate;
ix) house-bound due to immobility and no GP clearance to participate;
x) have a health condition(s) listed on the Exercise and Sports Science Australia stage 1 pre-exercise screening questionnaire that might compromise exercise safety [19] and do not receive medical clearance from a GP to participate;
xi) unable to commit to study requirements; and/or
xii) currently taking part in another OA study

2.3. Procedures

Fig. 1 outlines trial phases. Participants will first complete eligibility screening via an online survey (REDCap™). The survey outlines trial details and participant requirements. Those eligible following online screening will be contacted by a member of the research team (SZ) by telephone to confirm eligibility and provide verbal information about the study. Eligible participants will then be emailed a link to REDCap™ which contains the Plain Language Statement and consent form. Those who complete the consent form will receive a link to the online baseline questionnaire. All participants who complete the 12-week re-assessment will be given a $50 gift voucher in recognition for the time they have invested in the trial.

2.4. Randomisation, blinding and allocation concealment

Participants will be enrolled into the study on completion of baseline questionnaires and randomised into the intervention or control group. Computer-generated randomisation (1:1 ratio) will be prepared by an independent biostatistician in permuted random blocks of varying sizes. The randomisation list will be managed by a researcher not involved in either participant recruitment or administration of outcome measures to ensure concealment. Group allocation will be revealed by this same researcher after baseline assessment. Immediately after randomisation, participants will receive an email from the research team, which contains details of their group allocation, how to access the website (the URL and their unique username and password) and a request to access the website within 3 days. Participants will also receive a welcome text message prompting them to access the website as soon as possible (within 3 days).

Participants will be unblinded to study groups. Participants will be informed that this research will test the effectiveness of an unsupervised

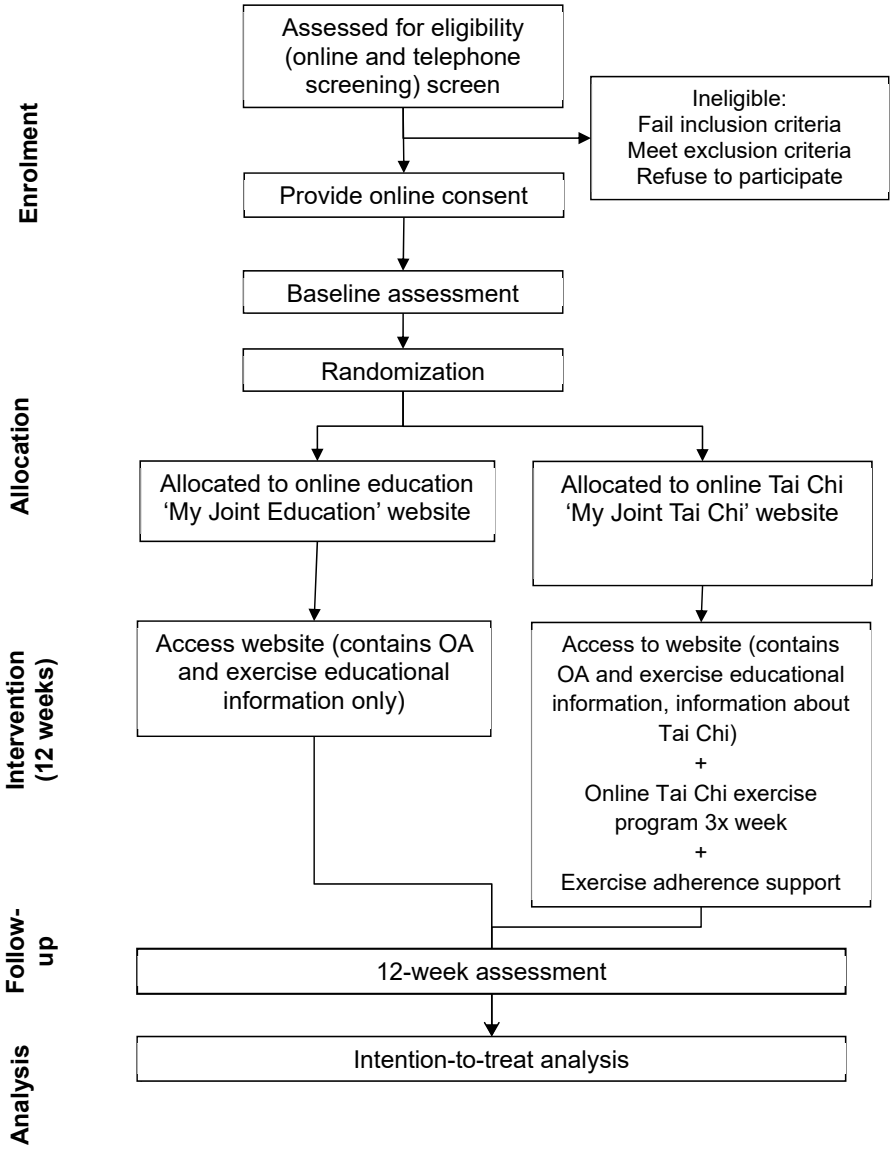

Fig. 1. Participant flow through the RCT.

online Tai Chi exercise intervention compared with online education alone. As the primary and secondary outcomes are self-reported, and participants are not blinded, by default the assessors of these outcomes are not blinded. However, the statistical analyses plan will be written and published, and the main analyses will be performed while the biostatisticians are blinded to group names.

2.5. Interventions

2.5.1. "My Joint Tai Chi" website (intervention group)

Participants in the intervention group will have access to a bespoke website ("My Joint Tai Chi"). The "My Joint Tai Chi" website was constructed by the authors and developed in accordance with recommendations outlined by The Health on the Net Foundation's Code of Conduct [40]. It contains a home page with a video tutorial explaining how to use the website and four sections explained in detail below. The website is not yet widely publicly available.

Fig. 2 outlines the contents of the website. The website development process is published elsewhere under a Creative Commons Attribution 4.0 International License [34].

2.5.1.1. About Tai Chi. This section provides introductory information, including a definition of Tai Chi and Qigong. It explains important principles of movement and outlines the health benefits associated with Tai Chi and Qigong practice.

2.5.1.2. My Joint Tai Chi program. This section contains an unsupervised 12-week progressive Tai Chi program ("My Joint Tai Chi" program) guided by an instructor delivering the program in a series of 12 pre-recorded videos (one per week). Each video (40–45 min) includes a warm-up consisting of an introduction by the instructor, standing meditation, breathing exercises, and Qigong. The central portion of each video uses a modified 10-form Yang style Tai Chi which involves slow and controlled movements. Modifications to the movements were made to ensure suitability for people with lower limb OA and little prior Tai Chi experience. Each video ends with a cool-down consisting of breathing practices and relaxation exercises. The 12-week program starts with simple Tai Chi movements and new movements are progressively added throughout the program. Participants are asked to undertake the program in their home using their own device at a time of their choosing. They are asked to complete the Tai Chi program 3 times per week for 12 weeks. This section also provides an introduction to the Tai Chi program, how to prepare, information on managing exercise pain, optional resources including a skill video and a printable Tai Chi movement sequence, and suggestions for people about what to do after completing the 12-week program.

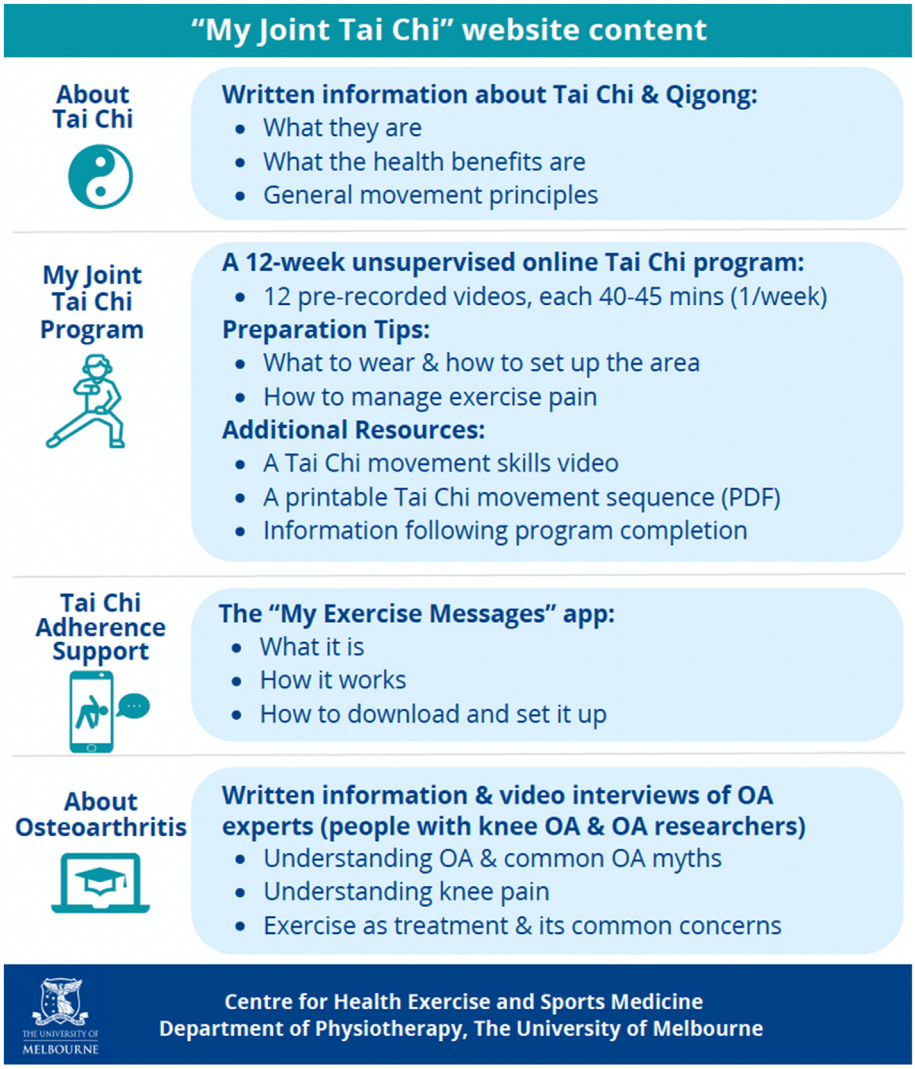

Fig. 2. Description of the content in the four discrete sections of the "My Joint Tai Chi" website [34].

2.5.1.3. Tai Chi adherence support - "My Exercise Messages" app. The "My Exercises Messages" app was specifically designed for people with hip and/or knee OA to help them adhere to an exercise program [41]. The My Joint Tai Chi program recommends users download and commence using the app in week 1 of their Tai Chi program and encourages them to use it for the full duration of the program (12 weeks). The My Exercise Messages app is free to download from the App Store (Apple devices) and Google Play Store (Android devices). After downloading the app, the app will prompt users to input i) their name; ii) the duration of the exercise program (12 weeks); and iii) the number of days per week they are

Table 1
Schedule of enrolment, intervention and assessments.

Timepoint	Enrolment	Allocation	Post- allocation					Close-out
		0	2w	4w	6w	8w	10w	12w
Enrollment:								
Eligibility screen	x							
Informed consent	x							
Allocation		x						
Interventions:								
"My joint education" website (control group)		←	—	—	—	—	—	→
"My Joint Tai Chi" website (intervention group)		←	—	—	—	—	—	→
Assessments:								
Primary outcomes								
Overall average knee pain during walking (11- point NRS) [42]	x							x
Physical function (WOMAC function subscale) [43]	x							x
Secondary outcomes	x							x
Knee pain (KOOS subscale) [44]	x							x
Sport and recreation (KOOS subscale) [44]	x							x
Knee-related quality of life (KOOS subscale) [44]	x							x
Physical well-being (SF-12 physical component score) [45]	x							x
Mental well-being (SF-12 mental component score) [45]	x							x
Perceived global rating of overall change in knee condition								x
Fear of movement (BFOM) [46]	x							x
Pain self-efficacy (ASES pain subscale) [47]	x							x
Self-reported balance (ABC-6 scale) [48]	x							x
Positive activated affect (I-PANAS-SF subscale) [49]	x							x
Sleep quality (single question from PSQI) [50,51]	x							x
Use of oral pain medications for knee pain								x
Other measures								
Age	x							
Sex	x							
Gender	x							
Height	x							
Weight	x							
BMI	x							
Ethnicity	x							
Education level	x							
Current employment status	x							
Geographical location	x							
Location of knee OA	x							
Duration of symptoms	x							
Problems in other joints	x							
Joint replacement in hip or non-study knee	x							
Comorbidities (SCQ) [52]	x							
Use of oral pain medications for knee pain	x							
Other knee OA treatments	x							
Past experience with Tai Chi	x							
Physical activity level (IPEQ-W) [53]	x							
Tai Chi outcome expectation	x							
Effect of OA	x							x
Presence of current and past OA flare	x							x
Flare in knee OA (flare-OA-16 questionnaire) [54]	x							x
Health professional consultation	x							x
Co-interventions								x
Adverse events								x
Process measure (Intervention group only)								
Number of days My Joint Tai Chi undertaken			x	x	x	x	x	x
Use of My exercises messages App								x
Tai Chi adherence (EARS Section-B) [55]								x
Likelihood of recommending program								x
Overall satisfaction with program								x
Acceptability of program (TFAQ) [56]								x
Credibility of program								x
Usability of program (SUS) [57]								x
Positive and negative aspects of program								x

OA-osteoarthritis; NRS - Numeric Rating Scale; WOMAC - Western Ontario and McMaster Universities Osteoarthritis Index; KOOS - Knee Injury and Osteoarthritis Outcome Score; SF-12 - Short Form 12; BFOM- Brief Fear of Movement Questionnaire ASES - Arthritis Self Efficacy Scale; ABC - Activities-Specific Balance Confidence; SCQ - Self-administered Co-morbidity Questionnaire; I-PANAS-SF - International Positive and Negative Affect Schedule - Short form; BMI - Body mass index; PSQI - Pittsburgh Sleep Quality of Index; EARS - Exercise Adherence Rating Scale; TFAQ - Theoretical Framework of Acceptability Questionnaire; SUS - System Usability Scale.

aiming to complete their exercise (3 days per week). Seven days after setting up the app (and each week thereafter), they will receive a smartphone notification, from the app, prompting them to enter the app and record the number of days they completed their recommended Tai Chi exercise, in the past week. If they report less than three days in the past week, they will then be prompted to select a reason from a pre-specified list of common exercise barriers for people with OA. Users will then receive a tailored message containing a behaviour change technique suggestion to help them overcome their identified exercise barrier in the coming week. Users also receive 2 notifications each week containing messages designed to facilitate regular exercise participation.

2.5.1.4. About osteoarthritis. This section contains general information about living with knee OA, knee OA treatments, and exercise management in a written format. Written information is complemented by video interviews of OA experts (people with lived experience of OA and OA researchers). The website recommends that participants read the educational material and watch the videos while doing the "My Joint Tai Chi program".

2.5.2. "My Joint Education" website (control group)

Participants in the control group have access to a different bespoke website "My Joint Education" that contains the same educational information about osteoarthritis and exercise management but does not contain an exercise program nor information about Tai Chi or the "My Exercise Messages" app. The online content can be accessed as many times as the participant wishes. "My Joint Education" website is also not yet widely publicly available.

2.6. Outcome measures

Table 1 lists the participant-reported primary, secondary and other outcome measures relative to the timing of enrolment and intervention. All outcomes will be completed remotely via online questionnaires (REDCap™).

2.6.1. Primary outcomes

The two primary outcomes are self-reported measures collected at baseline and 12 weeks after randomisation.

Overall knee pain during walking in the past week will be assessed via a 11-point NRS [42] from 0 = "no pain" to 10 = "worst pain possible".

Physical function will be assessed using the Physical Function subscale of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). This is extracted from the Activity of Daily Living subscale of the KOOS [43]. It is scored using 17 questions with 5 Likert response options from 0 = "none" to 4 = "extreme". The total score has a range from 0 to 68 with higher scores indicating greater dysfunction.

2.6.2. Secondary outcome measures

Self-reported secondary outcomes will be measured at baseline and 12 weeks, unless otherwise specified.

Pain, function in sport and recreation and knee-related quality of life in the last week will be assessed via subscales of the KOOS [44] including i) pain (9-items), ii) sport and recreation function (5-items) and iii) knee-related quality of life quality of life (4-items). These will be scored on a 5-point scale. Scores for each subscale will be calculated with a range from 0 to 100 with 0 indicating worst possible symptoms.

Physical well-being will be assessed via the Short Form 12 (SF-12, Physical component score) [45]. It is scored using 12 questions regarding eight health domains. Summary physical component score (PCS-12) will be reported. Scores range from 0 to 50 with higher scores indicating better physical health functioning.

Mental well-being will be assessed via the Short Form 12 (SF-12, Mental component score) [45]. It is scored using 12 questions regarding eight health domains. Summary mental component score (MCS-12) will be reported. Scores range from 0 to 50 with higher scores indicating better mental health functioning.

Perceived global rating of overall change in knee condition will be assessed on a 5-point Likert scale from "markedly improved" to "markedly worsened" at 12 weeks only. Participants who indicate that are "markedly improved" or "moderately improved" will be classified as improved, and all others as not improved.

Fear of movement will be assessed using the Brief Fear of Movement Scale for Osteoarthritis [46] which asks about 6 statements each scored on a 4-point Likert scale from 1 = "strongly disagree" to 4 = "strongly agree". Scores ranges from 6 to 24 with higher scores indicating greater fear of movement.

Pain self-efficacy will be assessed from the Arthritis Self-Efficacy Scale (ASES pain subscale) [47] which asks about 5 statements each scored on a 10-point NRS from 1 = "very uncertain" to 10 = "very certain". Score is the mean of all items for a total score range of 1–10, with higher scores indicating greater pain self-efficacy.

Self-reported balance will be assessed via Activities-Specific Balance Confidence Scale (ABC-6) [48] which asks about 6 statements each scored on the scale from 0 % (no confidence) to 100 % (completely confident). Score will be calculated by using the mean of 6 responses (score range from 0 % to 100 %), where higher score indicates a higher level of balance confidence.

Positive activated affect will be assessed via the International Positive and Negative Affect Schedule - Short form (I-PANAS-SF subscale) [49] which has 10 items regarding positive and negative affect in the past week, each scored on a 5-point Likert Scale from "Very slightly or not at all" to "Extremely". Scores are from 5 selected questions regarding positive affect (feeling of "alert", "inspired", "determined", "attentive" and "active") ranging from 5 to 25, with higher scores indicating higher levels of positive affect.

Sleep quality will be assessed from a single modified sleep quality question ("During the past 7 days, how would you rate your sleep quality overall?") from the Pittsburgh Sleep Quality of Index [50,51] on a 4-point Likert scale of "very good," "fairly good," "fairly bad," and "very bad." Participants indicating "very good" or "fairly good" will be classified as having good sleep quality.

Use of oral pain medications will be assessed via self-reported use of common oral pain-relieving medications at least once a week in the prior month for knee pain at 12 weeks only. Participants are asked to select Yes/No from options: oral non-steroidal anti-inflammatory drugs, oral non-steroidal anti-inflammatory cox-2 inhibitors, analgesics (paracetamol combinations), oral corticosteroids and oral opioids.

2.6.3. Other measures

i) Sample characteristics

Baseline self-reported descriptive measures include age, sex, gender, height, weight, body mass index, ethnicity, education level, current employment status, geographical location, location of knee OA; duration of symptoms; problems in other joints; joint replacement in hip joints or non-study knee joint; comorbidities (assessed using Self-administered Comorbidity Questionnaire, SCQ) [52]; use of oral pain medications for knee pain; Other knee OA treatments (assessed using a custom-developed table).

ii) Past experience with Tai Chi

At baseline, participants will be asked: "Have you undertaken any Tai Chi practice in the past 2 years?". Number and proportion of participants responding 'yes' will be reported.

iii) Physical activity level using Incidental and Planned Exercise Questionnaire, version W (IPEQ-W) [53].

At baseline, participants will be asked 10 questions regarding frequency and duration of incidental and planed walking, sport, and recreational activities over the past 7 days. Scores will be calculated as the product of the frequency score and duration score to create a total duration of physical activity for the week. Higher scores indicate higher amounts of activity.

iv) Tai Chi outcome expectation

At baseline, participants will be asked "What effect do you think a Tai Chi program will have for your knee condition?" on a 5-point Likert scale from 1 = "no effect at all" to 5 = "complete recovery".

v) Effect of OA

At baseline and 12 weeks, participants will be asked: "Considering all the ways your knee osteoarthritis affects you, how are you doing today?" on a 5-point Likert scale with options from "Very good" to "Very poor".

vi) Presence of current and past OA flare

At baseline and 12 weeks, participants will complete custom questions to indicate presence of a current OA flare: "Today, do you have a flare of your osteoarthritis?", and past OA flare: "During the past four weeks, have you had flare of your osteoarthritis?". Responses options are Yes/No. For each item 'Yes' is selected, participant will be asked to report the number of days they had an OA flare.

vii) Flare in knee OA using Flare-OA-16 questionnaire [54].

At baseline and 12 weeks, participants will be asked 16 questions regarding flare in knee OA in the past month, each rated on 11-point NRS from 0 = "not at all" to 10 = "absolutely". Score ranges from 0 to 160 with a higher score indicating higher flare-up of knee osteoarthritis.

viii) Health professional consultation

At baseline and 12 weeks, participants will be asked if they have visited any of the health professionals (GP, physiotherapist, exercise physiologist, dietician, psychologist, pharmacist, podiatrist, occupational therapist, rheumatologist, sports and exercise physician, orthopaedic surgeon) for their knee condition in the past 3 months, with response options Yes/No.

ix) Other knee OA co-interventions

At 12 weeks, participants will complete a custom-developed table to indicate their use (over the past 3 months) of a range of knee treatments. Additionally, for participants in the Tai Chi group, they will be asked "In the last 3 months, did you take part in any other Tai Chi class (in person/online) apart from the study My Joint Tai Chi program?" with response options of Yes/No. If 'Yes' is selected, they will be asked to report the number of weeks they undertook *other* Tai Chi practice. For participants in the control group, they will be asked "Over the past 3 months, did you undertake any Tai Chi practice?" with response options Yes/No. For each item 'Yes' is selected, they will be asked to report the number of weeks they undertake Tai Chi practice.

2.6.4. Process measures (intervention group only)

Participants in the Tai Chi group will be asked additional questions at 12 weeks, unless otherwise stated, including:

i) Number of weekly My Joint Tai Chi sessions completed: Every 2 weeks after the study commences (at 2,4,6,8,10,12 weeks), participants will be asked "In the past two weeks, on how many days did you do the My Joint Tai Chi program?". The average number of weekly days Tai Chi was performed will be calculated for 0–12 weeks (averaged from fortnightly data).
ii) Use of My Exercises Messages App: Participants will be asked "Did you use the My Exercises Message App at all in the past 3 months?" with response options of Yes/No.
iii) Exercise Adherence Rating Scale Section B [55]: Participants will be asked to answer 6 questions regarding their Tai Chi exercise adherence, each rated on a 5-point Likert scale from 0 – "completely agree" to 4 – "completely disagree". Score ranges from 0 to 24 with higher score indicating better adherence.
iv) Likelihood of recommending program to others: Participants will be asked to score on 11-point NRS for "How likely would you be to recommend the My Joint Tai Chi program to others with knee osteoarthritis?" from 0 = "not at all likely" to 10 = "extremely likely".
v) Overall satisfaction with program: Participants will be asked to score on 11-point NRS for "Overall, how satisfied are you with the My Joint Tai Chi program?" from 0 = "not at all satisfied" to 10 = "extremely satisfied".
vi) Acceptability of program using Theoretical Framework of Acceptability Questionnaire [56]: Participants will be asked to score 8 items regarding the acceptability of the My Joint Tai Chi program, each with 5 Likert response options from 1 to 5. Total mean score will be calculated with higher scores indicating higher acceptability.
vii) Credibility of program: Participants will be asked to score 2 items regarding how logical and trustworthy the My Joint Tai Chi program was, using 11-point NRS from 0 = "not at all" and 10 = "extremely", and 1 item regarding how believable the program was, using 11-point NRS from 0 = "not at all" and 10 = "fully". Higher score indicates that the program is more logical, believable or trustworthy.
ix) Usability of program using System Usability Scale [57]: Participants will be asked to score 10 items regarding the usability of My Joint Tai Chi program, using 5-point Likert scale from 1 = "Strongly disagree" to 5 = "Strongly agree". Score will be converted to a range from 0 to 100 with higher scores indicating higher usability.
x) Positive and negative aspects of program: Participants will be asked to provide up to 3 free text answers each to "List the most negative aspect(s)" and "List the most positive aspect(s)". Responses will be analysed using qualitative content analysis.

2.7. Adverse events

Adverse events will be captured using custom survey questions in the 12-week questionnaires. Related adverse events will be defined as "any problem experienced in the study knee or elsewhere in the body deemed to be a result of participating in the trial AND at least one of i) caused negative/adverse symptoms/effects for two days or more, and/or ii) resulted in the participant seeking treatment or taking medication". A serious adverse event will be defined as any untoward medical occurrence that; i) results in death; ii) is life-threatening; iii) requires hospitalisation or prolongation of existing inpatients hospitalisation; iv) results in persistent or significant disability or incapacity; v) is a congenital anomaly or birth defect, or; vi) any other important medical condition which, although not included in the above, may require medical or surgical intervention to prevent one of the outcomes listed. Due to the low-risk nature of the intervention in this trial, related serious adverse events are unlikely. Participants will be advised to report any serious adverse events to the Trial Coordinator as soon as they can by telephone or email, which will be documented and reported to the Sponsor (University of Melbourne) within 24 h of the research staff becoming aware of the event. Any adverse events reported by telephone or in questionnaires will be reported to the internal Trial Monitoring Committee who will be responsible for deciding what action if any is needed on a case-by-case

basis and whether the reported adverse events are likely to be related to the intervention.

We will report the number and proportion of participants who: withdraw from the study due to a related adverse event; experience one or more serious related adverse events and their types; and experience one or more non-serious related adverse events and their types.

2.8. Sample size calculations

A sample of 178 (89 per arm) is necessary to detect a difference in change between-groups that meets or exceeds a pre-specified minimal clinically important difference on either of the primary outcomes of knee pain on walking or WOMAC physical function, with 80 % power and a two-sided 5 % significance level split equally across the two primary outcomes. The MCIDs are 1.8 units for NRS knee pain [58] and 6 units for WOMAC physical function [59], assuming equal between-participant standard deviations of 2.5 for pain and 13 for function for both groups and a correlation between pre- and post-measurements of 0.25 for pain and 0.4 for function [32], and accounting for 15 % loss to follow up. We will consider the intervention to be effective if at least one of the two primary outcomes shows a significant between-group difference.

2.9. Statistical analysis plan

A Statistical Analysis Plan will be written and published on the Centre for Health, Exercise and Sports Medicine's website prior to commencement of data analysis and while blind to group allocation. Analyses comparing the two groups will be performed by the statistician blind to group names using all available data from all randomised participants based on intention-to-treat. Multiple imputation will occur if either primary outcome has more than 5% of data missing at 12 weeks. The primary analysis will then use multiply imputed data, with a sensitivity analysis using complete case data.

Demographic and baseline characteristics of participants will be summarised as appropriate. For primary outcomes, mean differences in change (baseline minus follow up) will be compared between groups using linear regression models, adjusted for baseline levels of these outcomes to obtain an estimated mean difference, corresponding two-sided adjusted 95% confidence interval and p-value. Model assumptions will be assessed using standard diagnostic plots. The proportion of participants in each group that achieve the minimal clinically important difference in improvement in knee pain (1.8 NRS units) and function (6 WOMAC units) will be calculated and analysed. Continuous secondary outcomes will be analysed similar to the primary outcomes. Binary secondary outcomes will be compared between groups using log-binomial regression, adjusting for the outcome at baseline if available, with results reported as risk ratios and risk differences. Should the log-binomial regression models fail to converge, logistic regression models adjusting for the outcome at baseline will be fitted, with results reported as risk ratios and risk differences.

A sensitivity analysis will estimate treatment effects on the primary outcomes at 12-weeks assuming 'acceptable' adherence to the unsupervised online Tai Chi program ('acceptable' adherence will be defined as performing Tai Chi an average of 2 or more times per week over the 12 weeks). Complier average causal effects will be estimated using an instrumental variables approach (where randomisation is the instrument for adherence). Two-stage least squares models will be fitted [60] with complier average causal effects reported with 95 % confidence intervals and p-values.

2.10. Monitoring

The research team will meet fortnightly for the review and monitoring of recruitment and trial progress.

2.11. Patient and public involvement

35 Tai Chi instructors and 3 people with lived experience of OA were involved in developing the "My Joint Tai Chi" program via online surveys and focus group panel meeting. One Tai Chi instructor is part of the research team (JH) and was involved in the filming of the Tai Chi program. Additionally, usability testing of the My Joint Tai Chi website was conducted with 5 people with knee OA using a "think aloud" process. After each user's review, we considered the feedback received and incorporated changes into the subsequent website iteration.

Patient and public involvement in the 'My Joint Tai Chi' development process is described in detail elsewhere [34].

2.12. Dissemination

Findings from the RETREAT RCT will be disseminated via presentations at conferences; peer-reviewed journals; lay summaries to participants and via our Centre's social media channels and Knowledge Translation Network. Once the RCT evaluation is complete and subsequently any required modifications are made, we anticipated making the "My Joint Tai Chi" website available for public access at no cost to the user.

3. Discussion

This RETREAT RCT will determine whether "My Joint Tai Chi" website that contains an unsupervised online Tai Chi program, online OA educational information, and an exercise adherence support app improves self-reported knee pain during walking and physical function for people with knee osteoarthritis at 12 weeks, compared to online OA educational information alone ("My Joint Education"). The effects of the intervention on other clinical outcomes will also be investigated at 12 weeks. A nested qualitative study will be undertaken with a subset of participants randomised to the intervention group to explore their experience in participating in this unsupervised online Tai Chi program. This will further aid implementation and translation of findings. The qualitative study will be reported separately to the main trial.

3.1. Trial status

This is the first protocol version dated on 18th July 2023. This trial was prospectively registered with the Australia New Zealand Clinical Trials Registry (clinical trial ID: ACTRN12623000780651) on 18th July 2023. The first patient recruitment started on 9th August 2023. The recruitment is expected to be completed on 30st November 2024.

Ethics approval and consent to participate

Ethical approval for this trial was obtained (Reference number 2023-26838-47588-6) on 23rd May 2023 by The Human Research Ethics Committee of The University of Melbourne. The trial was prospectively registered on the Australian New Zealand Clinical Trials Registry on 18th July 2023. Written Informed consent will be obtained prior to baseline questionnaires from participants via online forms using REDCap™ (Research Electronic Data Capture) hosted at the University of Melbourne. Participant recruitment commenced in August 2023 and is anticipated to be completed in December 2024. The trial is scheduled for completion in February 2025 with all participants completing 12 week data collection.

Consent for publication

Not applicable.

Availability of data and material

The datasets used and/or analysed during the current study will be made available from the corresponding author on reasonable request following completion of the study.

Authors' contributions

SZ is a PhD candidate with this trial contributing to a doctoral dissertation. She is supervised by KLB, RSH and RKN. SZ, KLB, RSH and RKN conceived the idea for the trial. SZ, KLB, RSH, RKN, JH and AK designed the intervention and developed the website. KLB obtained funding. ADS and PL formulated and is responsible for the sample size, and statistical analyses plan. SZ drafted this manuscript and all authors read and approved the final submitted version.

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Declaration of competing interest

JH owns and runs a Tai Chi school and makes financial profits from teaching Tai Chi. KLB receives royalties from Wolter Kluwers for UpToDate OA clinical guidelines. All other authors have no conflicts to declare.

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