

Mind-body exercises for mild to moderate Knee osteoarthritis: non-inferiority study protocol for a parallel, single-center randomized controlled trial

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Study protocol

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Abstract

Background: Knee osteoarthritis engenders a profound societal and economic burden while significantly compromising the well-being of patients. Present clinical guidelines advocate for non-pharmacological conservative approaches encompassing exercise, health education, and weight reduction as pivotal therapeutic modalities. Notably, mind-body exercises such as Taichi and Yoga are highly recommended due to their substantial efficacy in alleviating knee osteoarthritis (KOA). However, the comparative evaluation of these exercises remains insufficient. Consequently, the objective of this study is to assess the efficacy and safety of Taichi and Yoga while exploring the level of acceptance among patients.

Methods: This pilot trial adopts a randomized, controlled, and blinded design, both for the assessor and statistician. A total of 72 participants will be recruited and randomly assigned to either the Taichi group (n = 36) or the Yoga group (n = 36). The Taichi group will undergo an 8-week intervention involving Modified Eight-Stage Taichi therapy, followed by a 16-week follow-up period. On the other hand, the Yoga group will receive an 8-week intervention employing Hatha Yoga therapy, followed by a 16-week follow-up period. The primary outcome measure will be the alteration in the total Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores. The secondary outcome measures will include the numerical rating scale (NRS), Outcome Measures in Rheumatology-Osteoarthritis Research Society International (OMERACT-OARSI), the Patient Global Assessment (PGA), the Arabic Arthritis Self-Efficacy Scale-8 (ASES-8), the Short Form 12 (SF-12), EuroQol-5D (EQ-5D), and patient acceptance. Data will be collected at baseline and at weeks 1, 4, 8, 12, and 24.

Discussion: The study endeavors to evaluate the feasibility and effectiveness of Modified Eight-Stage of Taichi and Hatha yoga in ameliorating symptoms and enhancing the quality of life for KOA patients. The outcomes of this trial will contribute to the formulation of standardized mind-body exercise interventions for KOA, thereby establishing a solid clinical foundation for future large-scale clinical trials.

Trial registration: A randomized controlled trial of modified eight-stage Taichi for intervention in mild to moderate knee osteoarthritis ([ChiCTR2300067546](#)) Registered on 2023/01/11

Background

Knee osteoarthritis (KOA), a prevalent and debilitating musculoskeletal disorder affecting elderly individuals, is a complex and multifaceted ailment that gives rise to an assortment of unpleasant symptoms, including pain, stiffness, functional impairment, and diminished quality of life (QOL)(1–7). With an estimated 14 million adults in the United States and 120 million in China afflicted by KOA(1, 8), this disease burden has assumed global significance.

The management of KOA presents challenging, owing to its high comorbidity with other chronic ailments such as cardiovascular diseases and diabetes, as well as the enormous economic burden imposed by medical treatments, hospitalizations, and productivity loss(9). To alleviate this burden, prevailing clinical guidelines advocate a spectrum of non-pharmacological conservative strategies, encompassing

physiotherapeutic modalities, manual therapy, exercise, health education, and weight reduction, as fundamental therapeutic approaches(10–12). Previous research has evidenced the efficacy of mind-body exercises, such as Taichi and yoga, in ameliorating pain and enhancing physical function among KOA patients. .

A systematic review of randomized controlled trials (RCTs) exploring the effectiveness of mind-body exercises in KOA patients has suggested that Taichi and yoga exhibit notable efficacy in reducing pain, enhancing physical function, and improving quality of life, while being well-tolerated and safe for patients(13). Notably, yoga has been found to augment functional mobility through the elongation of major muscle groups and stimulation of stretch receptors, consequently bolstering physical strength and flexibility. Conversely, Taichi has demonstrated superior efficacy in pain reduction, gait stability improvement, and enhancement of health-related quality of life (HRQoL), possibly attributed to its direct influence on the cerebral cortex for pain regulation and its holistic integration of physical, psychosocial, spiritual, and behavioral elements, ultimately promoting overall physical and mental well-being.(13, 14).

However, despite the encouraging findings from previous studies, a dearth of comparative studies directly assessing the effectiveness of diverse mind-body exercises in KOA patients remains. Hence, we have designed a parallel non-inferiority RCT to compare the clinical effectiveness, acceptance, and safety of Taichi and yoga for KOA, guided by the theoretical framework of exercise therapy for KOA treatment. Through an investigation into the efficacy of standardized mind-body exercise for KOA, our study aims to provide insights into the most effective exercises for different KOA populations, thereby advancing the management of this debilitating condition.

Methods

Study design

This clinical trial will employ a positive-controlled, parallel, randomized design. Participants will be allocated to either the Taichi or Yoga group. Both groups will undergo a 24-week study period. Eligible subjects will be randomly assigned in a 1:1 ratio to the Taichi and Yoga groups, with both groups undergoing an 8-week Taichi/Yoga program followed by a 16-week follow-up period. Data will be collected at baseline and at weeks 1, 4, 8, 12, and 24.

The Institutional Review Committee of Dongzhimen Hospital has granted approval for the study (2021DZMEC-123-02) prior to patient recruitment. The trial will be conducted in accordance with the Declaration of Helsinki. The research protocol (version 2, 2021.11) has been submitted to ClinicalTrials.gov (ChiCTR2300067546) and will be updated accordingly. The research protocol adheres the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines and includes the SPIRIT-PRO and CERT checklists as supplementary files. Researchers, participants, assessors, and statisticians will all be blinded to group allocation and patient information throughout the trial. The flow chart is presented in Fig. 1, and the assessment time points are illustrated in Table 1.

Table 1
The assessment time points and Outcomes

Item	Week 0	Week 1	Week 4	Week 8	Week 12	Week 24
Demographic Information	□					
Informed Consent	□					
WOMAC	□	□	□	□	□	□
NRS	□	□	□	□	□	□
OMERACT-OARSI	□	□	□	□	□	□
PGA	□	□	□	□	□	□
ASES-8	□	□	□	□	□	□
SF-12	□	□	□	□	□	□
EQ-5D	□	□	□	□	□	□
Acceptance by patients	□			□		
Treatment-induced discomfort		□		□		
Expectation of effectiveness	□					
Adverse events		□	□	□	□	□

Participants

Inclusion criteria

To qualify for participation, individuals must satisfy the following criteria:

- 1) Diagnosis of KOA (9)
- 2) Aged 40-75 years (either sex)
- 3) Mild to moderate KOA (Kellgren–Lawrence score 1–3) (15)
- 4) Total pain NRS score not exceeding 7.
- 5) In the case of patients with KOA in both legs, the leg displaying greater severity will be selected for study and evaluation
- 6) No previous history of engaging Taichi or yoga exercises
- 7) Patients who willingly provide informed consent

Exclusion Criteria:

Individuals will be ineligible for the study if they meet any of the following exclusion criteria:

- 1) Individuals with a history of knee surgery or those placed on a waiting list for knee surgery
- 2) Individuals experiencing knee pain resulting from other conditions (e.g., infectious arthritis, sprain, contusion or other trauma), or with foot deformities, in addition to patients with severe osteoporosis.
- 3) Patients presenting with a skin condition or skin damage at the intended site of application
- 4) Individuals with severe underlying medical conditions, including cardiovascular, cerebrovascular, gastrointestinal, hepatic, renal, hematopoietic (coagulation abnormalities), endocrine, malignant neoplasms, infectious diseases, or mental disorders
- 5) Individuals who have undergone arthroscopy within the past 12 months or received intra-articular injections within the past 6 months
- 6) Individuals who have engaged in a knee exercise training program within the last 6 months
- 7) Individuals who have received acupuncture or tuina treatment within the last 3 months
- 8) Pregnant or lactating women, as well as those planning to conceive
- 9) Individuals who have participated in other clinical trials within the past 3 months

Withdrawal criteria

Participants will be withdrawn from the study if the following conditions arise:

Withdrawal by the investigator:

- 1) The patient demonstrates an inability to endure the treatment modality throughout the duration of the trial.
- 2) The patient experiences significant comorbidity, complications, or specific physiological changes that render the continuation of the trial inappropriate.
- 3) The subject exhibits poor compliance during the trial and is unable to adhere to the prescribed protocol.
- 4) The administration of relevant concurrent care and interventions for the knee joint, such as acupuncture and tuina, is prohibited during the designated study period□

Withdrawal by participants:

(1) Patients who express an unwillingness or inability to continue their participation in the clinical trial and formally request withdrawal from the trial under the guidance of a qualified physician, irrespective of the reason.

2) patients who cease receiving treatment and testing, leading to missed visits, even if they have not explicitly requested to withdraw from the trial.

Study setting and recruitment

This study will be conducted at Dongzhimen Hospital from June 2023 to June 2024. Recruitment efforts will be carried out through targeted advertisements in community centers and media outlets, with the objective of enrolling a total of 72 patients.

Upon selection for participation in the trial, baseline data will be collected simultaneously. Subjects unable to participate due to any reasons will receive comprehensive explanations and be offered appropriate healthcare guidance or alternative care options. The recruitment process will be managed by LLP, while YCH will assume responsibility for generating the allocation order and assigning participants to their respective interventions.

Randomization and allocation concealment

To achieve randomization and allocation concealment, the block randomization method will be employed using the "Proc plan" program of SAS 9.3 statistical analysis software. A random sequence, with a block size of 4, will be generated to ensure the equitable allocation of eligible individuals into the Taichi and Yoga group.

The randomization process will be overseen by an independent researcher who will be responsible for impartially and randomly assigning eligible participants to the two groups. Opaque envelopes containing randomized serial numbers for group allocation will be prepared and managed by an independent researcher who is not involved in the trial. Upon eligible participants signing the informed consent form, the clinical researcher will receive an envelope from the independent researcher, providing group allocation information based on the assigned sequence numbers.

Blinding

Maintaining blinding among clinical volunteers and researchers presents challenges due to the unique nature of the therapies involved. However, in this study, only the statisticians and outcome evaluators responsible for collecting, storing, and analyzing the data will be blinded. The unblinding of the study will be conducted once the statistical analyses have been completed.

Sample size estimation

The primary aim of this study was to compare the change in WOMAC (the WOMAC total score of 96) among the Taichi and Yoga groups from baseline to 4 weeks. In accordance with a previous study, we

established a non-inferiority margin (NIM) of 9.5 for variables at 4 weeks, along with a SD of 10.7(16) for both the Group Taichi and Group Yoga. To ensure a statistical power of 80% at a significance level of 0.025 (one-sided), sample size calculations were conducted.

Using a non-inferiority test design in PASS 15 software, we initially determined a sample size of 41 participants. However, considering potential data fluctuations during sample size estimation and an estimated loss of follow-up data of 20%, we increased the required number to 30 individuals per group. Consequently, a total of 72 patients will be randomized for this study.

Intervention

The Taichi group was administered the Modified Eight-stage of Taichi protocol, while the Yoga group underwent the Yoga exercise regimen. These interventions spanned a duration of 8 weeks, with both interventions being conducted three times per week. At the conclusion of the treatment period, a four-month follow-up phase was implemented.

In the first four weeks after randomization, one of the three weekly Taichi/Yoga sessions comprised a group exercise session conducted in a dedicated venue. Each session lasted for 60 mins, with the initial 20 mins dedicated to the explanation of Taichi theory, movements, breathing techniques, and intentions by professional staff. This was followed by a 5-min warm-up exercise, 30 mins of guided movement practice under the supervision of trained professionals, and a concluding 5-min relaxation and stretching session.

From the 1th to the 4th week, participants performed home exercises twice per week, which increased to three times per week from the 5th to the 8th week. These home exercise sessions were self-administered by the patients and included a 5-min warm-up, 30 mins of prescribed exercises, and a 5-min muscle relaxation and stretching routine. The total duration of each home training session amounted to approximately 40 mins.

Taichi group

The Taichi group will follow the practice regimen known as the Modified Eight-stage Taichi, which has been previously established by our research group(17). Attendance during practice sessions will be meticulously monitored and recorded to ensure adherence. The Modified Eight-stage Taichi consists of the following sequence: Starting position, rush Knee and Twist Step on Both Side, Hold the Lute, Forearm Rollings on Both Sides, Cloud Hands, Kick with Right and Left Heel, golden chicken independence, Closing Form.

Yoga group

The exercise routine for the Yoga group has been carefully curated by experts, selecting asanas commonly used in Hatha Yoga that are known to enhance lower limb function in patients with KOA. Attendance during practice sessions will be closely monitored and recorded to ensure adherence. The following asanas have been identified for the exercise program: Mountain Pose, Wind Blown Tree Pose, Chair Pose, Standing Backbend Pose, Warrior Pose I, Warrior Pose II, Extended Side Angle Pose, Triangle Pose. (Supplementary file)

Concomitant Treatment

At the initial visit following randomization, all participants will receive an informative pamphlet containing instructions on self-management strategies. This comprehensive resource will provide education and guidance on self-management techniques.

Outcomes and measurements

Primary outcomes

The primary outcome measure will be the change in the total Western Ontario and McMaster Universities Arthritis Index (WOMAC) score at weeks 8.

The WOMAC (WOMAC total score of 96) is a comprehensive questionnaire consisting of 24 items that assess three subscales: pain (5 items), stiffness (2 items), and joint function (17 items). Higher scores on the WOMAC indicate a greater severity of symptoms.

Secondary outcomes

The secondary outcome measurements will include the following assessments: WOMAC, NRS, OMERACT-OARSI, PGA, ASES-8, SF-12, EQ-5D. These assessments will be conducted at the baseline assessment and at weeks 1, 4, 8, 12, 24.

1)WOMAC

WOMAC total and subscales score at weeks 1, 4, 12, 24.

2)NRS for pain

The 0-10 NRS score evaluates the level of bodily pain, with 0 indicating no pain and 10 indicating severe and intolerable pain.

3)OMERACT-OARSI

The OMERACT-OARSI assessment employs a univariate approach to evaluate the three core symptoms: pain, function, and overall patient improvement

4)PGA

Participants will be asked to rate the improvement in their knee joint since treatment using the following options: 1. greatly improved; 2. much improved; 3. some improved; 4. no change; 5. slightly worse; 6. significantly worse; 7. especially bad

5)ASES-8

The ASES-8 is a reliable measure of arthritis-specific self-efficacy. It utilizes a 1-10 scale to assess individuals' confidence in managing arthritis symptoms, with higher scores indicating greater self-efficacy.

6)SF-12

The SF-12 is a widely used tool for assessing QoL. It comprises 12 items categorized into the Physical Component Score (PCS) and Mental Component Score (MCS) subscales. The SF-12 has been validated and demonstrated reliability among ethnic Chinese populations. Higher scores on the SF-12 indicate better quality of life.

7)EQ-5D-5L

The EQ-5D scale includes the EQ-5D Health Description System and the EQ-VAS (a visual health scale). The EQ-5D Health Description System comprises five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-VAS is a vertical visual scale ranging from 0 to 100, where respondents mark their health status

8)Acceptance by patients

Patients will be asked to rate their preference as unacceptable (0), acceptable (1), or easy to accept (2), with those selecting "unacceptable" required to provide reasons.

Data will be collected at the beginning and end of treatment, and mean values will be calculated.

9)Treatment-induced discomfort

The maximum level of discomfort experienced during the treatment will be evaluated using the NRS scale.

Data collection will occur after the 1st treatment and at the end of treatment, and mean values will be recorded.

10)Expectation of effectiveness

Patients will be presented with a set of five inquiries utilizing the expectation of effectiveness scale, where their anticipation of treatment outcomes will be assessed during the baseline evaluation. These questions will encompass whether they have previously undergone a comparable treatment, whether their family and friends have undergone similar interventions, their belief in the potential effectiveness of

the treatment in alleviating their symptoms, and a request to indicate their perception of the treatment modality's efficacy within their assigned group using a rating scale. Additionally, participants will be asked to express their preference between the Modified Eight-stage of Taichi and Yoga.

The collection of data for this assessment will take place before the initiation of the study, as part of the baseline assessment.

11)Adverse events

Occurrences of untoward incidents during the course of therapy will be meticulously documented and managed by medical professionals. Any severe adverse events will prompt an immediate suspension of the trial, followed by the implementation of appropriate measures.

Data collecting and monitoring

To gather relevant data, the evaluator will utilize a paper-based Case Report Form (CRF). All study-related information, including participant identification, collected data pertaining to the study, and medical records, will be treated as confidential. Original hard copies of CRFs and all study data will be securely stored in a designated locker, with exclusive access granted to the involved researchers. Data integrity will be overseen by our team's data researchers (YCH) and monitored by the Ethics Committee of Dongzhimen Hospital. The researcher responsible for reviewing the frequency and procedures of trial conduct will operate independently from the primary investigator.

Quality control

The study protocol has been developed through extensive document research and pre-study analysis. Furthermore, it has undergone rigorous review by renowned experts in the fields of exercise therapies, methodology, and statistics. Prior to enrolling the first set of patients, all staff members will be required to participate in a comprehensive training session covering the overall study protocol, standardized treatment procedures, the investigator's brochure, and completion of the CRF.

Statistical analysis

The principle of intention-to-treat (ITT) will guide the statistical analysis, ensuring that all participants who were randomized are included in the analysis. Missing data will be handled using approaches such as the last observation carried forward and multiple imputations, enabling sensitivity analysis. Demographic and social characteristics will be characterized using descriptive statistics, with chi-square or Fisher's exact test employed for categorical variables. Continuous variables will be presented as mean $\pm$ standard deviations or median $\pm$ quartile ranges, while categorical variables will be expressed as frequency and percentile (%)

The primary analysis will involve assessing the change in total WOMAC score from baseline to week 8 through intergroup comparisons, providing insights into treatment effectiveness. Non-inferiority testing

will be conducted using analysis of covariance, independent t-test, or Wilcoxon's rank-sum test, with the NIM set at 10% of the primary outcome for the Yoga Group. Secondary outcomes and repeated measures will be analyzed using repeated measures ANOVA or a mixed-effect model with repeated measures. All analyses will be performed using SAS software, and a one-tailed significance level of 2.5% will be employed for all tests.

Discussion

KOA is a prevalent ailment that can lead to substantial debilitation, yet the underlying etiology of KOA remains enigmatic. Research has revealed that the degeneration of articular cartilage and alterations in synovial composition are pivotal pathological changes associated with this condition(19). Clinical guidelines offer divergent recommendations(10-12) encompassing both pharmacological and non-pharmacological interventions to address the symptoms of KOA. Nevertheless, pharmacological treatments are not without limitations, including the potential for adverse effects, warranting their restricted usage for short-term pain relief.

In order to alleviate the symptoms of KOA, a combination of pharmacological and non-pharmacological interventions has been advocated. However, pharmacological treatments possess inherent drawbacks, such as the risk of adverse effects, discouraging their prolonged administration. Conversely, non-pharmacological modalities, including exercise, play a pivotal role in the management of KOA. Contemporary clinical guidelines endorse non-pharmacological treatments as the primary approach, with MBEs, such as yoga and Tai Chi, exhibiting promising outcomes as adjunctive therapies.

MBE represents a promising and efficacious adjunctive therapy for KOA, involving deliberate and synchronized bodily movements coupled with musculoskeletal system, controlled breathing, and a meditative mental state(20-22). Robust evidence from clinical trials substantiates that MBE can significantly alleviate pain, enhance function, and promote physical activity levels in individuals with KOA. Furthermore, MBE improves muscle strength and flexibility, posture, balance, cardiovascular health, and immune function(21). However, the specific MBE modalities that yield optimal efficacy for patients with KOA have yet to be determined(20).

Taichi and yoga represent efficacious mind-body exercises; however, they differ in their methodologies, philosophies, and therapeutic impacts. Taichi, a traditional Chinese mind-body practice, is regarded as a viable approach for managing KOA. It integrates meditation with deliberate, gentle, and graceful movements, along with deep breathing and relaxation. Taichi has demonstrated significant efficacy in reducing pain, improving gait stability, alleviating depression, and enhancing HRQoL in individuals with KOA. Nevertheless, there exist multiple styles of Taichi, with the number of movements ranging from 10 to 60. A review encompassing 12 studies(23) examined nine Taichi styles as interventions, but evidence regarding the comparative effectiveness of different Taichi types for KOA remains limited. In our previous research, we have identified key Taichi movements that confer benefits for KOA and developed a movement analysis framework for Chinese traditional qigong interventions, aiming to minimize the risk

of adverse events and enhance therapeutic efficacy. Moreover, the simplified exercise protocol known as the "modified eight-stage Taichi" primarily emphasizes strengthening the hip and thigh muscles, while also targeting proprioception and lower limb flexibility. This protocol is easily learned and enhances compliance among patients.

Yoga, serving as a representative of mind-body medicine in Western countries, has formulated exercise regimens for various ailments and exhibits superior functional mobility and motor function compared to Tachi(13). Hatha yoga (HA), a physical form of yoga, effectively reduces pain and stiffness in osteoarthritis. It involves realigning the skeletal structure, strengthening the muscles surrounding the joints, and stretching tight joint structures(24). The mindful and meditative approach of combining breathwork with stretching exercises in HA yields relaxation benefits and stress reduction. Consequently, this may lead to diminished pain sensitivity and exert analgesic effects(25). However, the demanding level of expertise required to perform yoga, the necessity of assistive tools, and the high time and material costs associated with patient treatment have become barriers to the acceptance of this therapeutic modality. Therefore, we have chosen to incorporate Hatha Yoga poses that target the same muscle groups as the Taichi protocol and are relatively easy to perform.

Therefore, further research is imperative to gain deeper insights into the potential advantages of MBE for the management of KOA and to ascertain the most efficacious MBE modalities for individual patients. Our objective is to conduct a parallel, single-blinded, single-center clinical trial, led by experienced and qualified physicians, ensuring a meticulous methodology and extensive professional expertise. The chosen evaluation tools, including WOMAC, NRS, OMERACT-OARSI, PGA, ASES-8, SF-12, and EQ-5D, are well-suited for assessing the clinical efficacy of KOA.

This study endeavors to assess the feasibility and effectiveness of the Modified Eight-Stage of Taichi and Hatha Yoga in alleviating symptoms and improving the quality of life in patients with KOA. The research will yield valuable data regarding the efficacy of Taichi and yoga for KOA, with a 16-week follow-up period subsequent to the completion of treatment. The outcomes will contribute to future investigations on the potential benefits of standardized mind-body exercises for individuals with KOA.

Limitations

The therapists and participants will not be able to maintain a state of unawareness due to the inherent nature of the intervention. Consequently, we have made the deliberate decision to uphold blindness among the outcome assessors and statisticians as a means of mitigating the potential introduction of other biases in the trial. The pragmatic design of this study may not furnish definitive evidence regarding the efficacy of each component of exercise therapy. Nonetheless, it affords an opportunity to scrutinize the current treatment modalities for KOA within the confines of a real-world clinical milieu. It is important to note that this study follows a single-center design with a modest sample size, thereby warranting the need for larger, multicenter trials.

Conclusion

This parallel, assessor-blinded RCT will examine the efficacy and safety of Taichi and yoga interventions for KOA, furnish compelling evidence, evaluate the feasibility and relevance of Taichi and yoga study designs, enhance the standardization of mind-body exercise for KOA, and lay a clinical groundwork for future large-scale pluralistic clinical trials. The findings of this study will provide guidance in selecting the most efficacious MBE treatment options for patients suffering from KOA and will facilitate informed clinical or policy decisions.

Abbreviations

KOA: Knee osteoarthritis

MBE: Mind-body exercises

WOMAC: Western Ontario and McMaster Universities Arthritis Index

NRS: numerical rating scale

OMERACT-OARSI: Outcome Measures in Rheumatology- Osteoarthritis Research Society International

PGA : the Patient Global Assessment

ASES-8: the Arabic Arthritis Self-Efficacy Scale-8

SF-12: the Short Form 12

EQ-5D : EuroQol-5D

Declarations

Trial status

Protocol version 2.0 is dated November 13, 2022. The recruitment process has not yet started. The authors expect to begin this procedure on June 2023.

Ethics and dissemination

The study is registered at chictr.org.cn (ChiCTR2300067546), and conducted in accordance with the Declaration of Helsinki. Ethics approval for this trial has been granted by the Institutional Review Boards of Dongzhimen Hospital, Beijing University of Traditional Chinese Medicine (Approval No. 2022DZMEC-

120-02). The result of the present study will be published in a peer-reviewed journal. Volunteers need to participate in the trial voluntarily and sign an informed consent form.

Consent for publication

Not Applicable

Availability of data and materials

Not applicable. We have no datasets included in this study protocol. In this research, volunteers will provide informed consent to ensure that data can be used in this study, and these data are not applicable to other channels. The results of this study will be communicated with others via a peer-reviewed journal. The full protocol will be accessible upon reasonable request after the trial is complete.

Competing interests

There are no conflicts of interest.

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Authors' contributions

Changhe Yu ,Xiyu Wang conceptualized the study responsible for the PRO content.

Luping Liu and Yixuan Gao designed the study and drafted the manuscript.

Lingyun Zhang ,Yi An, Mengmeng Zhang, Chenrui Yuan helped to design the study.

Luping Liu, Lingyun Zhang , and Shouguo Jia will perform this study.

Yixuan Gao helped to revise the manuscript.

The authors read and approved the final manuscript.

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Authors' information (optional)

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Figures

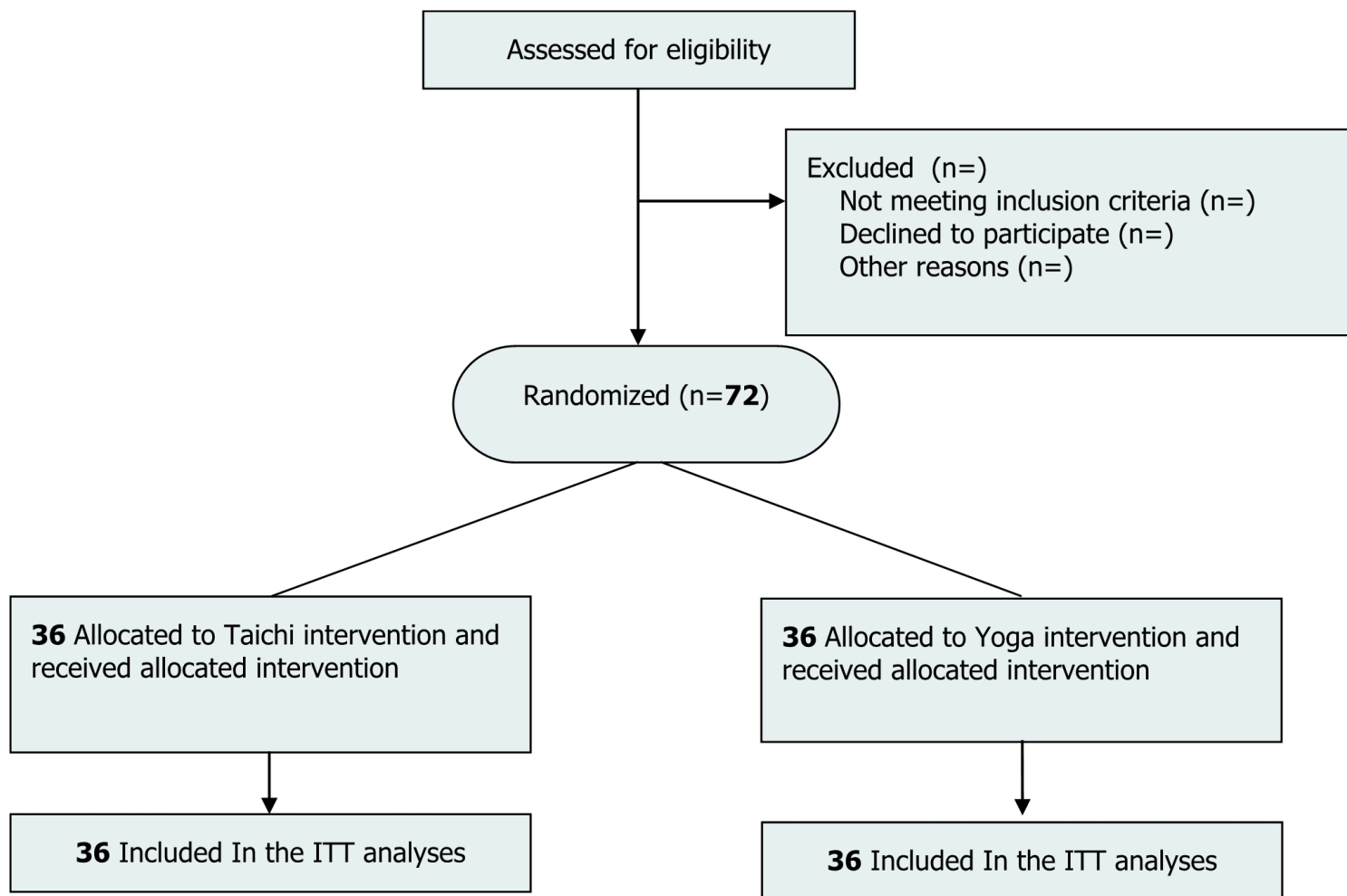


Figure 1

The flow chart

Abbreviation: ITT: Intention-To-Treat

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