

Effects of a therapeutic lifestyle modification intervention on cardiometabolic health, sexual functioning and health-related quality of life in perimenopausal Chinese women: protocol for a randomised controlled trial

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ABSTRACT

Introduction Perimenopause is a critical transitional period in reproductive ageing. A set of physiological and psychological changes can affect perimenopausal women's quality of life and further threaten their older adult health conditions. In China, less than one-third of midlife women with menopausal symptoms have actively sought professional healthcare. Regarding the public health significance of comprehensive menopause management, the current study aims to investigate the effects of a therapeutic lifestyle modification (TLM) intervention on cardiometabolic health, sexual functioning and health-related quality of life among perimenopausal Chinese women.

Method and analysis A randomised controlled trial with two parallel arms will be conducted at the gynaecology outpatient department of Yunnan Provincial Hospital of Traditional Chinese Medicine in China. 94 eligible perimenopausal women aged between 40 and 55 years will be recruited for the study. The TLM intervention consists of four elements: menopause-related health education, dietary guidance, pelvic floor muscle training and Bafa Wubu Tai Chi exercise. Participants will be randomly assigned (1:1) to receive either the 12-week TLM intervention or routine care via stratified blocked randomisation. The primary outcome is quality of life; secondary outcomes of interest include sexual functioning and cardiometabolic health. The outcome measures will be assessed at baseline and post-intervention. To explore the effects of the intervention, linear mixed models will be applied to test the changes between the two groups over time in each outcome based on an intention-to-treat analysis.

Ethics and dissemination The Research Ethics Review Committee of Chulalongkorn University (COA No 178/66) and the Medical Ethics Committee of Yunnan Provincial Hospital of Traditional Chinese Medicine (IRB-AF-027-2022/02-02) approved the study protocol. Written informed consent will be obtained from all participants. Results will be published in peer-reviewed journals and disseminated through conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This clinical trial aims to recruit participants with diverse sociodemographic features using multi-pronged strategies.
- ⇒ The methodological strengths of the trial include an appropriate sample size calculation, stratified permuted block randomisation, allocation concealment, intention-to-treat analysis and planned sensitivity analysis.
- ⇒ The study outcomes will be assessed using a combination of subjective measures and clinical biomarkers.
- ⇒ As this study is designed as a single-centre trial, we recommend multicentre trials going forward to explore the effects of the intervention on a larger perimenopausal population.

Trial registration number ChiCTR2300070648.

INTRODUCTION

Perimenopause is the gateway to reproductive ageing for women. Based on the classification of the Stages of Reproductive Aging Workshop (STRAW), it is defined as the time around the final menstrual period (FMP), which starts at a persistent difference of 7 days or more in the length of consecutive menstrual cycles and ends 12 months after the FMP (as shown in figure 1).¹ During this transitional period, women are expected to experience a series of physiological and psychological changes that may lead to adverse health outcomes and could further negatively impact their quality of life.²

For the past four decades, a set of longitudinal cohort studies has been conducted

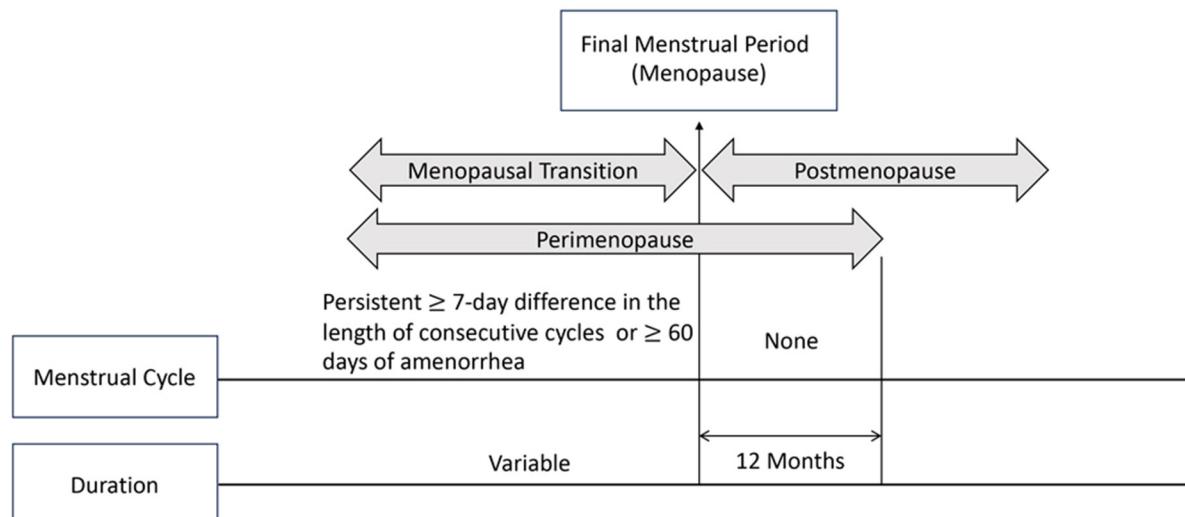


Figure 1 The relationships between different stages around the final menstrual period. This figure was modified from Ambikairajah et al.⁷⁰

across the world to advance the understanding of reproductive ageing and to characterise its natural development trajectories.^{3–8} The findings yielded by these studies contributed to identifying menopausal symptoms, elucidating the aetiology of menopause-related dysfunction and revealing their influence on midlife women's health.⁹ In general, menopausal symptoms can be categorised into four dimensions, namely, vasomotor symptoms (VMS), psychological symptoms, genitourinary syndrome and somatic symptoms. In particular, VMS are the most common clinical complaints and account for the highest prevalence. Approximately 80% of middle-aged women were reported to have experienced VMS during perimenopause.^{7,10} Moreover, the associations between frequent VMS, social impairment, work-related difficulties and an increased socioeconomic burden have been reported in previous research.¹¹ In terms of negative moods, depressive and anxiety symptoms are the two major psychological manifestations during perimenopause. A recent systematic review and meta-analysis showed that the overall prevalence of psychological symptoms for perimenopausal women is 42.1%.¹² Genitourinary syndrome of menopause is another concern in relation to sexual and reproductive health, which also draws increasing attention in geriatrics globally.¹³ More than one-third of perimenopausal women were influenced by the troublesome genitourinary syndrome, and sexual functioning decline was identified as the predominant health concern among them with a prevalence ranging from 18.4% to 45%.^{12,14} Additionally, somatic symptoms including sleep disturbance, fatigue, palpitations, joint aches and physical functioning decline are also frequently reported by midlife women.¹⁵

Because of the impacts of these multifaceted changes, approximately 23.5% to 30.2% of perimenopausal women reported a significant decrease in health-related quality of life (HRQOL).¹⁶ Meanwhile, a chain reaction brought on by these changes also threatens

perimenopausal women's health by increasing the risk of metabolic syndrome (MetS), cardiovascular diseases and osteoporosis.^{17–19} Apart from menopausal symptoms, other female reproductive histories have also been proven independently to be relevant to midlife health and psychosocial well-being. In particular, a history of miscarriage was identified as being associated with worsening sleep quality while the number of parities was relevant to severely depressed mood and lack of enjoyment.²⁰ Other salient female reproductive histories such as the onset age of menarche and breast feeding have been recognised as being significantly associated with cardiovascular risk factors including obesity and obesity-related hypertension.²¹ Besides the negative influences of the female reproductive histories and menopausal characteristics, further literature reviews on midlife women's health research disclosed that the deterioration of HRQOL was additionally attributed to non-biological factors involving unhealthy lifestyles (eg, sedentary behaviours and tobacco use), a conservative cultural environment, poor socioeconomic status and a lack of family and social support.^{2,22,23} An ongoing Chinese population-based cohort study found that women with higher education reported fewer menopausal symptoms, suggesting that a relatively good socioeconomic status may affect menopausal experiences by actively seeking healthcare and adopting healthier lifestyle behaviours (eg, avoiding alcoholic beverages, taking regular physical exercise and adopting a soya-rich diet).²⁴

Against this background, focusing on perimenopause shows imperative implications for better promoting a stable transition from the reproductive phase to the postmenopausal phase and subsequent health among older women. Furthermore, the significantly prolonged older adult period²⁵ together with a rapid increase in the ageing population²⁶ drive a surge in demand for midlife healthcare, which also points to the necessity of enhancing perimenopausal health management and self-healthcare.

In China, most perimenopausal women would rather endure the adverse impacts of menopausal symptoms than seek professional healthcare proactively. A community-based cross-sectional study conducted in Shanghai revealed that only 26% of midlife women with symptoms had sought healthcare for menopause management.¹⁵ One of the main reasons lies in women's dissatisfaction with menopause-specific healthcare services.^{27–28} As the most effective treatment available currently for menopausal symptoms, menopause hormone therapy (MHT) is very much recommended by clinical guidelines worldwide.^{29–30} However, it is a medical measure that is only applicable in the presence of indications and absence of contraindications.³¹ Additionally, women's fear of the potential risks of developing cancers and limited knowledge about MHT are common barriers against its use.^{32–33} In summary, perimenopausal women still lack professional guidance that addresses self-healthcare and alternative therapeutic options.

Given the public health significance of perimenopausal management, the current research has developed a therapeutic lifestyle modification (TLM) intervention based on the concept of lifestyle medicine.³⁴ TLM is a complementary therapy that integrates multifactorial elements including health education, exercise maintenance and dietary guidance.³⁵ Previous studies have applied it to patients diagnosed with obesity, MetS and cognitive disorders, while its beneficial effects in lowering lipid profiles, reducing weight and stabilising blood pressure demonstrated its potential for improving comprehensive midlife health management.^{36–39}

Specifically in terms of physical exercise, several studies have explored the effects of various therapeutic exercise prescriptions on widely health-related outcomes such as cognitive performance,⁴⁰ bone health,⁴¹ cardiometabolic risk factors,^{42–43} weight loss,⁴⁴ sexual functioning⁴⁵ and menopausal quality of life.^{46–49} These diverse exercise modalities included brief sessions of high-impact exercise, aerobic cardiorespiratory fitness exercise, muscle resistance training, yoga stretching, rhythmic aerobic dancing, Pilates training and traditional exercises such as Tai Chi. The results revealed that physical exercise serves as a public health strategy that has a positive potential to promote the improvement of physical functioning. Among numerous exercise interventions, yoga is the most frequently used method for addressing menopausal women's quality of life issues.⁵⁰ However, based on a meta-analysis,⁴⁶ although yoga demonstrated a significant improvement in the physical dimension of the quality of life, its effects on other subdimensions in terms of psychological, sexual and menopausal symptoms further require the confirmation of future well-designed experimental trials. Moreover, the long-term effects of TLM on perimenopause-related health issues remain controversial or unclear,⁵¹ and further recommendations still call for more high-quality randomised controlled trials to provide robust evidence to appraise its efficacy.

Therefore, this study protocol is designed as a randomised controlled trial with two parallel arms, which aims to investigate the effects of the TLM intervention on cardiometabolic health, sexual functioning and HRQOL measures among perimenopausal women in China.

METHOD AND ANALYSIS

Study design and setting

This study is designed as a single-centre, 12-week, randomised controlled trial with two parallel arms. 94 perimenopausal women who meet the eligibility criteria will be recruited and randomly allocated to the TLM group or the control group at a 1:1 ratio. The study is projected to be conducted at the gynaecology outpatient department of Yunnan Provincial Hospital of Traditional Chinese Medicine, Kunming City, China, in 2023. This is a tertiary teaching hospital affiliated with Yunnan University of Chinese Medicine, which provides comprehensive health services in terms of obstetrics, gynaecology and rehabilitation therapy. Study recruitment began on 1 May 2023, and the study is expected to be concluded in June 2024. We followed the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Statement to report the current study protocol.⁵² An overview of the study design is presented in figure 2 (based on the Consolidated Standards of Reporting Trials (CONSORT) 2010 guideline).⁵³

This clinical trial was registered prospectively in the Chinese Clinical Trial Registry on 19 April 2023 (registration number: ChiCTR2300070648) (see table 1). Ethical approval for the study protocol and the informed consent sheet were issued by the Research Ethics Review Committee of Chulalongkorn University and the Medical Ethics Committee of Yunnan Provincial Hospital of Traditional Chinese Medicine.

Participant eligibility and recruitment

94 study participants will be recruited from perimenopausal women who come to the gynaecology outpatient clinic of Yunnan Provincial Hospital of Traditional Chinese Medicine for consultation and medical care.

To make this trial more representative of the target population, the research team will apply a multi-pronged strategy to approach potential eligible participants with diverse sociodemographic characteristics from a wide background. These strategies include: (1) reviewing patients' information and electronic medical records; (2) disseminating the recruitment leaflets on social media platforms (eg, WeChat) and the information board in the clinics; and (3) using community health centres as an outreach strategy.

Inclusion criteria

1. Women aged between 40 and 55 years old with perimenopausal symptoms;
2. Having a sedentary lifestyle for at least 12 months;
3. Self-identified as sexually active;

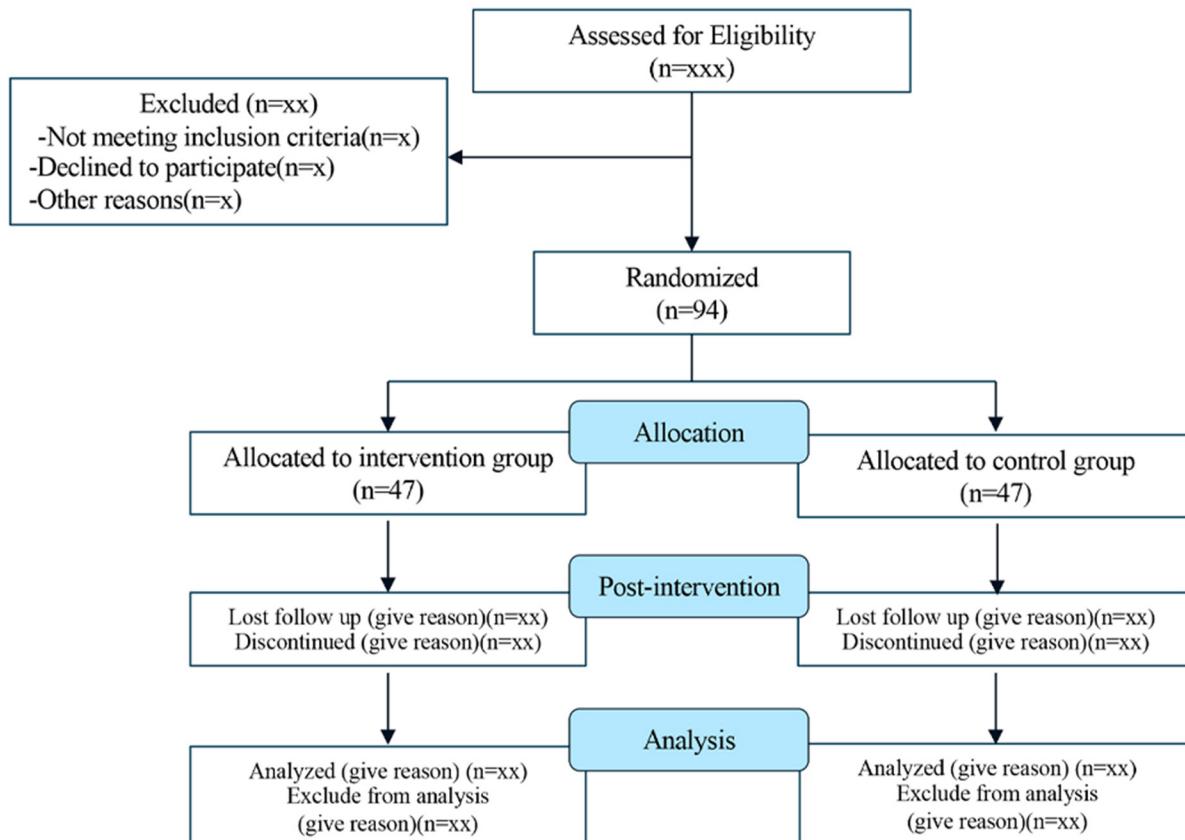


Figure 2 Consolidated Standards of Reporting Trials flow diagram of the study.

4. No use of hormone therapy and psychoactive medication within the last 3 months;
5. Being willing to participate and make a commitment to follow the instructions of the present programme.

Exclusion criteria

1. Diagnosed with a severe physical or psychiatric illness (eg, uncontrolled high blood pressure or major depression);
2. Iatrogenic menopausal status induced by any therapy (eg, chemotherapy or radiotherapy);
3. Undergoing any other non-pharmacotherapies (eg, psychological treatment);
4. Having auditory or visual impairments or communication disorders.

Recruitment procedure and informed consent

Potentially interested participants will receive a detailed introduction to this clinical trial via a telephone or face-to-face consultation. Those who are willing to participate will then be screened for eligibility. To identify eligible participants, two medical specialists from the research team will be responsible for medical history reviews and inquiring whether potential participants are undergoing any medical or psychological treatment.

Eligible study participants will be asked to provide written informed consent before the baseline assessment and randomisation. The consent sheet clearly states the study objective, procedure, potential benefits and risks,

and compensation for follow-up visits. In addition, all participants will be told that they have the right to withdraw from the study at any time without giving a reason.

Randomisation, allocation concealment and blinding

After completing the baseline assessment, participants will be randomly assigned to either the TLM intervention group or the control group using stratified permuted block randomisation. This is a randomisation technique combining stratified randomisation with permuted block randomisation.⁵⁴ Based on the findings from previous longitudinal studies,^{9 55} the prevalence of common symptoms varies by different menopausal transition status; hence, participants will first be stratified by age (40–45, 46–50 and 51–55 years old, respectively). Then, participants within each stratum will be randomly allocated to one of the two groups using permuted block randomisation. To reduce the predictability of the allocation sequence, the principal investigator (PI) will apply a website-based randomisation plan generator (www.randomization.com) to generate the allocation sequence by allocating randomly mixed block sizes (with block sizes of 2, 4 and 6). The allocation sequence will be placed in sequentially numbered, opaque, sealed envelopes (SNOSEs) and then kept concealed from the researchers involved in participants' enrolment and assessment. An external research assistant will gain access to the SNOSEs from the PI and implement the allocation once the predetermined

Table 1 Trial registration data

Data category	Information
Primary registry and trial identifying number	Chinese Clinical Trial Registry (ChiCTR), ChiCTR2300070648
Date of registration in primary registry	19 April 2023
Secondary identifying numbers	None
Source(s) of monetary or material support	The 90th Anniversary of Chulalongkorn University Scholarship under the Ratchadapisek Somphot Endowment Fund
Primary sponsor	Chulalongkorn University
Secondary sponsor(s)	None
Contact of public queries	Pramon Viwattanakulvanid, PhD (Email address: Pramon.V@chula.ac.th)
Contact of scientific queries	Pramon Viwattanakulvanid, PhD College of Public Health Sciences, Chulalongkorn University
Public title	Effects of a Therapeutic Lifestyle Modification Intervention on Sexual Functioning, Cardiometabolic Health and Health-Related Quality of Life in Perimenopausal Chinese Women: A Randomised Controlled Trial
Scientific title	Effects of a Therapeutic Lifestyle Modification Intervention on Sexual Functioning, Cardiometabolic Health and Health-Related Quality of Life in Perimenopausal Chinese Women: A Randomised Controlled Trial
Countries of recruitment	People's Republic of China (PRC)
Health condition(s) or problem(s) studied	Quality of Life in Perimenopausal Women
Intervention(s)	Experimental group: Therapeutic Lifestyle Modification intervention, 12 weeks Control group: General health education, 12 weeks
Key inclusion and exclusion criteria	Age eligible for study: women aged ≥40 to 55 years old; Sex eligible for study: female; Accepts healthy volunteers: no Inclusion criteria: women aged between 40 and 55 years old with perimenopausal symptoms; being in a sedentary lifestyle for at least 12 months; self-identified as sexually active; non-use of hormone therapy and psychoactive medication within the last 3 months; willing to participate Exclusion criteria: diagnosed with severe physical or psychiatric illness; iatrogenic menopausal status; patients who are ongoing any other non-pharmacotherapies; having communication disorders
Study type	Interventional Allocation: stratified permuted block randomisation; Intervention model: parallel assignment; Masking: a biostatistician who supervises the data analysis Primary purpose: promote midlife women's quality of life Phase III
Date of first enrolment	1 May 2023
Target sample size	94 participants
Recruitment status	Recruiting
Primary outcomes	Menopause-specific quality of life (time frame: 12 weeks)
Key secondary outcomes	Sexual function, pelvic floor muscle strength; cardiometabolic health (systolic blood pressure, diastolic blood pressure, resting heart rate, lipid profiles, fasting plasma glucose, HbA1C, body mass index, body fat percentage, waist circumference)

recruitment size has been achieved. As most behavioural interventions cannot be blinded to participants and the researchers delivering the intervention, only the biostatistician who supervises the data analysis will be masked in this trial.

Intervention description

Overview of the interventions

The overall duration of the interventions will be 12 weeks. Participants allocated to the intervention arm will receive a TLM programme. This is a multi-component intervention that has been developed based on the HRQOL conceptual model. This programme consists of four elements: menopause-related health education, dietary guidance, pelvic floor muscle training (PFMT) and a programme of Bafa Wubu Tai Chi exercise. Participants assigned to the control arm will receive the usual care simultaneously.

Participants in the two arms may receive the same over-the-counter traditional Chinese medicine (TCM) prescription as the concomitant care during the study period. A gynaecology specialist working independently of this trial will, as required, prescribe the same dosage and course of treatment for both groups according to the indications of medication.

Research team building and training

During the study preparation phase, the PI will obtain permission from the hospital's authority to recruit hospital personnel as research team members. The research team will consist of a physical therapist of TCM, two gynaecologists, a trained nurse and a biostatistical analyst. Medical specialists in the team should hold a master's degree in the reproductive health field and have clinical experience of working perimenopausal patients.



Orientation will be provided via a Hyflex training workshop (in both online and onsite formats) to address fidelity to the interventions and quality control of the study. The PI will serve as the main trainer and a chief physician with extensive clinical experience will act as the co-trainer. The training content will include a detailed introduction to the study protocol, a review of the current clinical management guidelines for the care of perimenopausal women, teaching the communication skills required to develop and maintain rapport with participants during the study process, a standard operating procedure for use in response to emergencies, referral assistance, and specific instructions concerning data collection and confidentiality. Also, the PI will discuss and clarify specific task allocations with the research team members. After completing the training, all trainees will take a quiz and practice in various mock scenarios. Two trainers will evaluate their performance and give constructive feedback to aid further improvement.

Experimental group: therapeutic lifestyle modification (TLM) program

Participants will receive a 12-week group intervention aimed at modifying a range of lifestyles among perimenopausal women. The group sessions will be performed sequentially as one session per week, combining psycho-educational therapy with appropriate dietary guidance, Tai Chi exercise and pelvic floor function rehabilitation training. The detailed content of each component is described below:

Menopause-related health education

Menopause-related health education is a psycho-educational approach which is grounded in cognitive behavioural therapy and aims to alleviate a wide range of menopausal symptoms including VMS, mood swings, sleep disturbance, and sexual problems.⁵⁶

A trained gynaecologist will be responsible for delivering the group education. There will be five 30 min sessions covering three major topics. First, participants will receive a general introduction to perimenopause covering its commencement age, average duration, the common physical and psychological changes, and its significance in reproductive ageing. Second, participants will gain an understanding of the impact of perimenopause on cardiometabolic health and related risk factors. Third, participants will learn to recognise early genitourinary symptoms and several cognitive distortions regarding sexual concerns will also be clarified. Finally, participants will be equipped with coping strategies to deal with anxieties related to these health concerns, raise positive intimate conversations and actively engage in shared clinical decision-making.

Dietary guidance

To promote healthy eating behaviour to achieve a balanced nutritional intake and maintain a healthy weight, the current dietary guidance is designed based

on consensus among Chinese experts on core information of menopause health management.⁵⁷ The content includes an interpretation of the newest Chinese Food Guide Pagoda and eight dietary guidelines; providing a food matching framework tailored to individual needs, preferences and Chinese dietary patterns; balancing the caloric intake and energy consumption easily; sharing the three main dietary strategies for weight loss; an introduction to prevalent diet models (eg, the Mediterranean diet and the Ketogenic diet) and related health benefits.

An accredited nurse who has undergone nutrition training will give 30 min slide presentations over 3 weeks. The PI will act as the coordinator during the presentations.

Bafa Wubu Tai Chi exercise

The newly formed Bafa Wubu Tai Chi is a simplified form of Tai Chi developed in 2018 and has been subsequently promoted by the General Administration of Sport in China. It comprises eight fixed arm movements and five lower limb shifting movements.⁵⁸

During the 12-week intervention period, participants will be asked to perform Bafa Wubu Tai Chi exercises three times per week, with one supervised group exercise and the other two conducted at home. Each exercise session consists of 10 min warm-up activities, a 45 min Bafa Wubu Tai Chi practice session and 5 min cool-down activities for 60 min in total. The supervised group exercise will be conducted in the study hospital's physical treatment room supervised by the instructor, who is a certificated physiotherapist in TCM. Before each group exercise, the instructor will emphasise safety issues regarding the exercise and will remind all participants to wear loose clothing and sneakers. Any adverse events occurring during the group exercise will be recorded and addressed, strictly following the relevant regulations of clinical trials.

Additionally, a Bafa Wubu Tai Chi training video will be produced with verbal instructions and subtitles to help participants perform the exercises at home. Participant adherence will be monitored using the attendance rate of weekly group exercises. To enhance training adherence and assess fidelity to the training, participants will be asked to upload their weekly home-based exercise videos to a pre-established WeChat participant group. The step-by-step exercise instructions for Bafa Wubu Tai Chi are attached in online supplemental appendix 1.

Pelvic floor muscle training

Participants will undertake weekly supervised PFMT combined with daily practice at home. A gynaecologist with relevant experience in treating pelvic floor dysfunction will be responsible for conducting this training in the physical treatment room of the study hospital. With consideration for individual privacy, every participant will be assigned to an independent cubicle separated by a curtain.

The core training curriculums of PFMT include guiding participants to identify the location of pelvic floor muscles; training them to perform the movements

of contracting, holding and relaxing correctly; and practicing daily contraction in a given rhythm until they develop an exercise routine.⁵⁹

In the supervised group training process, participants will practice PFMT under the verbal instructions of the trainer as follows: (1) be sure to empty your bladder every time before the planned exercise; (2) start with slow maximum voluntary contractions, hold each contraction for 6–10 s and then relax completely for 10 s; (3) perform five sets of rapid contractions and relaxation; (4) perform these fast and slow pelvic floor muscle contractions 10 times per set; (5) practice 10 sets of these movements per day. The PFMT instructions are attached in online supplemental appendix 2.

As with the Tai Chi exercise, PFMT will be delivered in 20 min group training sessions once per week throughout the 12-week intervention. A trained nurse will coordinate with the main instructor to evaluate participant performance and provide additional training assistance if a participant encounters any difficulty during the practice. A teaching video will also be disseminated to participants to facilitate their own daily exercise carried out at home.

Control group: usual care

Participants allocated to the control group will receive general health education as the usual care after the baseline assessment, including a brief introduction to common perimenopausal symptoms, advice on nutritional supplements and fitness regimes, and appropriate contraceptive measures. In addition, the control group may be offered over-the-counter TCM prescriptions as concomitant care during the study period with the same dosage and course of treatment as the intervention group.

When the study is completed, a package, if the effectiveness of the TLM is verified as being superior to the usual care, a package of TLM including the teaching materials and exercise training videos will then be provided to the participants in the control group by trained nurses.

Outcome measures

The primary outcome of interest is the quality of life of perimenopausal women. Secondary outcomes include cardiometabolic health and sexual functioning. All outcomes will be measured at two points: as a baseline assessment before the randomisation allocation and as a post-assessment after the completion of the intervention. Participants' demographic characteristics, including age, educational attainment, household income, employment status, smoking behaviour, alcohol-drinking behaviour and comorbidities (eg, primary hypertension and diabetes mellitus), will be collected only at the baseline assessment. Additionally, since previous research has identified an association between menopausal symptoms and quality of life,⁶⁰ participants' menopausal symptoms at baseline will be evaluated using the Menopause Rating Scale. This is a standard clinical scale that groups 11 common perimenopausal symptoms into three major categories (somatic symptoms, psychological symptoms

and urogenital symptoms). The sum score will be further converted into four severity levels (none or minimal, mild, moderate and severe respectively) based on cut-off points.⁶¹ The schedule for the planned participant enrolment, interventions, time points for outcome measures and applied measurement tools are presented in table 2.

Primary outcome

The Menopause-specific Quality Of Life (MENQOL) questionnaire will be employed to evaluate HRQOL among perimenopausal women. This is a self-administered questionnaire that has been applied frequently in previous studies.⁶² The original version is in English and consists of 29 items which represent the four subdomains of menopausal transition: vasomotor (items 1 to 3), psychological (items 4 to 10), physical (items 11 to 26) and the sexual domain (items 27 to 29). Participants will be asked to indicate whether they have experienced any of these problems in the past month and, if so, to rate the extent to which it has troubled them on a 7-point Likert scale ranging from 0 to 6. Each item score ranges from 1 to 8. Since the weightings of the subdomains are not equivalent, using the average subdomain score instead of the sum score is recommended for analysis. A higher score in each subdomain represents a worse quality of life. The approximate time for completing the questionnaire is 7 to 15 min.⁶³

The Chinese version of the MENQOL was translated by Nie and colleagues⁶⁴ and back-translated to confirm the translation's consistency and accuracy. Its reliability was examined through the internal consistency reliability test with Cronbach's α coefficients of all four subdomains found to be greater than 0.8. Its construct, criterion and discriminant validity were also fully assessed and reported.

Secondary outcomes

Cardiometabolic health

This trial adopts composite indicators to assess cardiometabolic health including cardiovascular markers, body composition and metabolic biomarkers.

Cardiovascular markers consist of systolic blood pressure, diastolic blood pressure and resting heart rate which will be measured via an automatic sphygmomanometer (Omron HEM-6181, Japan), and participants will receive two-time measurements within a 5 min interval and the averages will be recorded.

Body composition includes weight (kilograms), height (metres), body mass index (BMI, kg/m²), waist circumference (centimetres) and body fat percentage. A Bioelectrical Impedance Analysis (BIA) scale (Tanita BC-534 InnerScan Body Composition Monitor) will be used to measure body weight and body fat percentage. Before the BIA measurement, the study participants will be instructed to avoid any food and beverages such as tea, water for at least 2 hours before the assessment. Body height is measured using a wall-mounted stadiometer. The BMI will then be computed as weight divided by the square of height. Waist circumference is measured

Table 2 Schedule of enrolment, interventions and outcome assessments

	Enrolment	Baseline assessment (T1)	Randomisation	1–4 weeks	5–8 weeks	9–12 weeks	Post-assessment (T2)
Eligibility screen	X						
Informed consent	X						
Allocation			X				
Intervention							
TLM		↑	↓				
Usual care		↑	↓				
Assessment							
Demographics		X					
Menopausal Rating Symptoms		X					
Primary outcome				X			
Health-related quality of life (MENQOL)				X			
Secondary outcomes					X		
Sexual functioning	FSFI		X				
	PFM strength		X				
Cardiometabolic health	Cardiovascular markers		X				
	Body composition		X				
	Metabolic biomarkers		X				

at 1 cm above the navel using a soft measuring tape. The same researcher will perform the pre-assessments and post-assessments, and participants will be requested to wear thin clothing and take their shoes off during the measurement process.

Metabolic biomarkers refer to fasting plasma glucose, haemoglobin A1C and lipid profiles including high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, total cholesterol and triglycerides. Participants will be instructed to fast for at least 8 hours before each assessment. The blood samples will be sent to the clinical laboratory of the study hospital for photometric assay (Roche Cobas c 702 analyzer, Roche Diagnostics GmbH, Germany). All the blood samples collected from participants will be destroyed after use following the clinical laboratory regulations.

Sexual functioning

Sexual functioning will be assessed by both subjective and objective measures. The Female Sexual Function Index (FSFI) questionnaire, a multidimensional self-report instrument, will be applied to subjectively assess female sexual function. It consists of 19 items measuring six sexual function dimensions, namely, desire, arousal, lubrication, orgasm, satisfaction and pain. The full score ranges from 2 to 36, with a lower score indicating poorer sexual function.⁶⁵

The Chinese Version of the Female Sexual Function Index (CVFSFI) was developed and validated by Sun *et al*⁶⁶ and demonstrated good internal consistency reliability (Cronbach's α coefficients of each dimension greater than 0.84) and satisfactory content, criterion and discriminant validity.

Participants' pelvic floor muscle strength will be assessed objectively by vaginal palpation. Pre-assessments and post-assessments of each participant will be performed by the same gynaecologist and rated using the Modified Oxford Scale. It is the most commonly used scale in clinical practice quantifying the voluntary contraction of a woman's pelvic floor muscles into six levels (0=no contraction, 1=flicker, 2=weak, 3=moderate, 4=good, 5=strong). This scale embodies moderate to strong reliability. Its validity has also been verified compared with other 'gold standard' instruments such as transvaginal manometry or ultrasound.^{67 68}

Since Chinese traditional culture has a conservative attitude toward sexual issues, a quiet and private examination room without disturbance will be independently arranged for participants to engage in the FSFI questionnaire interviews and pelvic floor muscle strength assessments.

Data collection, management and monitoring

The data will be collected at baseline and post-intervention (after 12 weeks). A web-based electronic data capture (EDC) system (Research Manager, ResMan www.medresman.org) will be applied to facilitate data collection, management and monitoring. The PI will set

up the online case record form (CRF), create the data codebook and provide detailed instructions regarding outcome measurement and recording, data entry and data security to the research team. Only research team members will be authorised to access the online CRF and will conduct double data entry by logging in to the EDC system using a password. To promote efficient data management, this CRF was designed with logical jump functions and restricted value ranges for each variable. Therefore, any input errors will be recognised automatically and then shown in an error reminder box. Once data has been input and stored, any modification to the original data will be tracked and monitored automatically by this EDC system. Therefore, no extra data monitoring committee is proposed for the current trial, and routine research team meetings will be held to address related issues throughout the data collection process.

Data entry will be de-identified and only the PI will have access to the original dataset for security consideration. Strategies to promote participant retention and follow-up assessments include offering online questionnaire submission services, making follow-up appointments flexibly based on an individual's schedule, and sending regular message reminders.

Auditing and potential harms

An independent supervisor with extensive experience in the field of complementary medicine and no competing interests with the PI will be responsible for auditing the conduct of the trial. This supervisor will convene the research team for weekly meetings to report on the process of the trial. The trial implementation procedure will be reported following the Good Clinical Practice (GCP) regulations strictly, and all auditing records will be uploaded to the EDC system.

Any adverse events occurring during the study will be documented promptly in the CRF and reported to both the Research Ethics Review Committee of Chulalongkorn University and the Medical Ethics Committee of Yunnan Provincial Hospital of Traditional Chinese Medicine. The PI will be responsible for the cost of treatments for the study-related adverse events as set down in the GCP regulations.

Sample size calculation

The authors used G*Power software (V. 3.1 Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany) to calculate the sample size. Based on a previous study that also aimed to promote HRQOL in menopausal women,⁴⁹ it was estimated that a total sample of 84 (with 42 subjects in each arm) would have 80% test power to detect a difference in the mean scores of the MENQOL between two groups, at a 95% confidence level ($\alpha<0.05$). After accounting for a 10% attrition rate, a total sample size of 94, with 47 subjects per group, will be required.

Statistical analysis

The unit of analysis in this trial is individual participants. The primary data analysis strategy is intention-to-treat



analysis, which includes all randomised participants regardless of their intervention adherence. Researchers will strive to control the proportion of missing data within 10%. The baseline observation carried forward method will be applied to deal with missing data if it is determined as missing at random. Statistical analysis will be carried out by using Stata V.17.0. All tests are two-tailed with a significant level set as $p<0.05$.

Descriptive statistics will be used to summarise participants' baseline characteristics in terms of age, educational attainment, employment status, household income, smoking and alcohol-drinking behaviours, and the severity of menopausal symptoms. Continuous data will be presented with mean and SD or median and IQR based on the data distribution, while categorical data will be described by frequency and percentage.

To examine the homogeneity of participants' baseline characteristics between the intervention group and the control group, the independent t-test will be applied for continuous data with normal distribution, while the Mann-Whitney U test will be used if the normality assumption is found to be violated. Categorical data will be compared by χ^2 or Fisher's exact tests as appropriate.

To explore the effects of the interventions between the intervention and the control groups on both the primary and the secondary outcomes, linear mixed models will be applied to test the changes between the two groups over time in MENQOL scores, cardiometabolic health indicators and the FSFI scores. In the mixed models, individuals will be considered a random effect, and the fixed effects include groups, times and their interaction. To specify the model with different types of its variance-covariance structures in the linear mixed model, we will use Akaike Information Criterion, an information criteria-based relative fit index, with the lowest score for choosing the best fit of the model. Participants' pelvic floor muscle strength between the two groups will be compared by χ^2 or Fisher's exact tests as applicable.

To explore the robustness of the results and evaluate the possible impact of intervention adherence on primary outcomes, a sensitivity analysis will be conducted through per-protocol (PP) analysis, which will only include those participants who complete all of the 12-week sessions.

Patient and public involvement

No patients or the public were involved in the study design, nor will be in the conduct of the study, and the result interpretation. When the study is completed, the pre-intervention and post-intervention assessment results will then be disseminated to all participants through individual medical consultations. If the effectiveness of the TLM is verified as being superior to the usual care, a package of TLM including the teaching materials and exercise training videos will then be provided to the participants in the control group by trained nurses.

Ethics and dissemination

Ethics approval and informed consent

The Research Ethics Review Committee of Chulalongkorn University (COA No 178/66) and the Medical Ethics Committee of Yunnan Provincial Hospital of Traditional Chinese Medicine (IRB-AF-027-2022/02-02) approved the study protocol, informed consent sheets, participant recruitment flyer, research instruments and the PI's curriculum vitae. Any significant amendments made to the protocol will be resubmitted to these two committees for ethical review and mentioned in the subsequent publication.

The research team will provide all potential participants with a detailed introduction to the current trial regarding research objectives, eligibility criteria, research procedure, potential risks and health benefits that participants will obtain from this trial. All eligible study participants will be given a written informed consent sheet (see online supplemental appendix 3) by the PI before the randomised allocation. Participants will also be clearly informed that they have the right to withdraw from this study at any time without giving any reason, and it will not have any negative impact on their relationship with their physician. The authors declare that they have no competing interests.

Confidentiality considerations

As per the study protocol, to ensure the participants' comfort and privacy, the researchers will arrange for the FSFI questionnaire interviews and pelvic floor muscle strength assessments to be conducted in a quiet, private examination room without disturbance. This approach will help avoid any potential embarrassment the participants may feel during the evaluation process. All data collected from participants will be de-identified and stored in a web-based EDC system for confidential consideration. Participants' data and biological specimens will be used for the current study only and destroyed once the study is completed.

All participants will receive compensation for their time and inconvenience related to follow-up visits after the study completion. In addition, the control group will receive the whole video of the TLM intervention. As participants' health is our priority, those who attend the eligibility screening will receive the necessary professional guidance and information related to perimenopausal self-healthcare regardless of whether they decide to join the programme or not.

Dissemination

The research team will follow the CONSORT to report the study results. The main findings of the study will be published in peer-reviewed journals on health promotion and disease prevention. Additionally, we will present the study results at international conferences. If this novel TLM intervention is verified as an effective programme, it has the potential to be integrated into standard clinical pathways for perimenopause health management and to

be available to other perimenopausal populations in the future.

Individual participant data sharing plan

In accordance with the proposal of the International Committee of Medical Journal Editors (ICMJE) regarding sharing clinical trial data,⁶⁹ we will upload the original trial dataset and the study protocol to Research Manager (ResMan) for public access once the study is completed. The data will be de-identified to maintain confidentiality.

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Contributors PV serves as guarantor for this work and accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish. The study concept and design was conceived by both YW and PV. YW and XM will be responsible for data collection. Analyses will be conducted by both PV and YW. YW prepared the first draft of the manuscript. PV critically revised the manuscript. All authors approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

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