Tai chi or cognitive behavioural therapy for treating insomnia in middle aged and older adults: randomised non-inferiority trial

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ABSTRACT

OBJECTIVE

To assess whether tai chi is non-inferior to cognitive behavioural therapy for insomnia (CBT-I), the first line treatment, for managing chronic insomnia in middle aged and older adults.

DESIGN

Randomised, assessor masked, non-inferiority trial.

SETTING

A single research site in Hong Kong with participants recruited from the local community between 18 May 2020 and 14 July 2022.

PARTICIPANTS

Chinese participants aged ≥50 years with chronic insomnia diagnosed according to the *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition.

INTERVENTIONS

Tai chi and CBT-I interventions were delivered in group format over three months, consisting of one hour sessions twice a week for a total of 24 sessions.

MAIN OUTCOME MEASURES

The primary outcome was the change in perceived insomnia severity measured by the Insomnia Severity Index after the intervention (month 3) and at 12 month follow-up (month 15). To assess whether tai chi is non-inferior to CBT-I, a threshold of four points was used as the margin of non-inferiority.

RESULTS

200 participants were randomised (1:1) to receive tai chi (n=100) or CBT-I (n=100). The per protocol principle was adopted. At month 3, the tai chi group showed a reduction of 6.67 (95% confidence interval 5.61 to 7.73) in Insomnia Severity Index scores, while the CBT-I group had a reduction of 11.19 (10.06 to 12.32), resulting in a between group difference of 4.52 (−∞ to 5.81). Tai chi was deemed inferior to CBT-I at month 3 because the upper confidence limit exceeded the non-inferiority margin. At month 15, the reductions for tai chi and CBT-I were 9.51 (8.47 to 10.54) and 10.18 (8.97 to 11.40), respectively, with a between group difference of 0.68 (−∞ to 2.00). At this point, tai chi was considered non-inferior to CBT-I because the upper confidence limit fell within the non-inferiority margin. Results from the intention-to-treat analysis were consistent with the per protocol findings. No adverse events occurred during the intervention period.

CONCLUSION

Tai chi was inferior to CBT-I at month 3 but non-inferior at month 15. This finding supports the use of tai chi as an alternative approach for the long term management of chronic insomnia in middle aged and older adults.

TRIAL REGISTRATION

ClinicalTrials.gov NCT04384822

WHAT IS ALREADY KNOWN ON THIS TOPIC

Tai chi has been found to be non-inferior to cognitive behavioural therapy for insomnia (CBT-I), which is the first line treatment for chronic insomnia, after a three month intervention period and a 12 month post-intervention follow-up in patients with insomnia and a history of breast cancer

The long term clinical potential of tai chi for managing chronic insomnia in middle aged and older adults needs further investigation because patients with insomnia and a history of cancer have different characteristics

WHAT THIS STUDY ADDS

This randomised non-inferiority trial compared the effects of tai chi and CBT-I on chronic insomnia in middle aged and older adults

The efficacy of the tai chi intervention was found to be non-inferior to CBT-I at the 12 month post-intervention follow-up, but not after the 3 month intervention

These results support the use of tai chi for the long term management of chronic insomnia in middle aged and older adults

Introduction

Chronic insomnia is one of the most common sleep disorders in middle aged and older adults, with global prevalence rates ranging from 4% to 22%, depending on the diagnostic criteria used.[1] In Hong Kong, 30-50% of middle aged and older adults report having insomnia problems, with old age considered to be a main predictor.[2 3] Chronic insomnia has a median duration of three years, with up to 74% of patients experiencing persistent symptoms over the past year.[4] Chronic insomnia in middle aged and older adults has been associated with increased risk of cardiovascular diseases, mental disorders, and cognitive impairment, which prospectively increases hospital admission and mortality rates.[5] Therefore, a large financial burden is placed on healthcare and socioeconomic systems, with the direct and indirect costs of insomnia treatments estimated to be $150bn (£114bn; €130bn) each year in the United States alone.[6]

Cognitive behavioural therapy for insomnia (CBT-I) is the first line treatment for chronic insomnia owing to its excellent treatment efficacy and minimal side effects.[7] However, accessibility to CBT-I is often limited because of the associated high costs and the low availability of trained therapists, preventing its wider implementation in the community.[8] In the US, it was reported that only 4% of primary care providers working in Veterans Affairs healthcare used CBT-I in their practice,[9] while less than 10% of patients with insomnia at university medical centres were referred

for CBT-I.[10] Data from 12 European countries indicate that only 4-10% of patients are prescribed non-pharmacological insomnia treatments such as CBT-I.[11] Limited access in primary care settings and insufficient education on the therapeutic potential of CBT-I have been recognised as key factors hindering the use of CBT-I in the community.[9 10] Therefore, a pressing need exists to explore alternative treatment approaches that are effective, accessible, and inexpensive to meet the demands of the increasing number of patients with chronic insomnia. Considering the high persistence of insomnia symptoms,[4] treatment approaches with sustainable efficacy should also be explored to improve the long term management of insomnia.[5]

Tai chi, a form of mind-body exercise that is widely practiced in Chinese communities, is becoming increasingly popular in "western" countries.[12] Each year, more than 100 cities in over 80 countries recognise and celebrate the World Tai Chi and Qigong Day, reflecting the global popularity of tai chi and mind-body exercises.[13 14] One recent survey in the US reported that approximately 4.05 million people reported practicing tai chi or other mind-body exercises over the past year for health purposes.[15] Tai chi is perceived as a suitable exercise modality for middle aged and older adults, even among those who are inactive or unfit.[16 17] Tai chi is inexpensive, easily accessible, and amenable to middle aged and older adults, which can enable its large scale implementation in the community. Previous clinical trials and meta-analyses support the beneficial effects of tai chi in middle aged and older adults with insomnia, with improvements that can be sustained for up to 24 months.[16 18 19] However, most studies used passive control designs (eg, stretching) or compared it with other exercise modalities (eg, aerobic exercise), while direct comparisons with first line insomnia treatments (eg, CBT-I) in middle aged and older adults with primary chronic insomnia are currently lacking. Therefore, we need studies assessing the clinical efficacy of tai chi as an alternative insomnia treatment to manage chronic insomnia in middle aged and older adults.

To validate the use of tai chi as an alternative approach to manage chronic insomnia in middle aged and older adults, this study aimed to examine whether a three month tai chi intervention (experimental treatment) is non-inferior to a three month CBT-I intervention (first line treatment for chronic insomnia) for treating insomnia; and whether tai chi is non-inferior to CBT-I in sustaining beneficial improvements 12 months after the intervention. A non-inferiority evaluation was used to determine the acute and long term treatment efficacy of tai chi in improving sleep to establish its potential as an alternative approach for managing chronic insomnia in middle aged and older adults. We hypothesised that tai chi is non-inferior to CBT-I for treating insomnia in middle aged and older adults, and sustaining the sleep improvements 12 months after the intervention.

Methods

Study design

This randomised, assessor blinded, non-inferiority trial adhered to the Consolidated Standards of Reporting Trials (CONSORT) extension for non-inferiority and equivalence trials.[20] Participants were enrolled between 18 May 2020 and 14 July 2022, with the last follow-up ending on 2 November 2023. The study was approved by the University of Hong Kong/Hospital Authority Hong Kong West institutional review board (IRB approval No UW 18-621). Written informed consent was obtained on a voluntary basis before baseline assessments. The study was conducted in accordance with the Declaration of Helsinki. The study was prospectively registered at ClinicalTrials.gov (NCT04384822) on 12 May 2020. Details about the protocol, including outcomes and intervention content, are further described in the trial protocol paper published on 4 November 2022 (supplementary material I).[21]

Participants and settings

This study was conducted at a single research site in Hong Kong. Participants were recruited from the community using study leaflets and posters. To be included, participants needed to be middle aged and older adults aged ≥50 years who were ethnic Chinese and had a diagnosis of chronic insomnia (including difficulty in getting to sleep or maintaining sleep, early morning awakening, complaints of impaired daytime functioning, and sleep disturbances occurring at least three nights each week and lasting for at least three months) according to the *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition. Exclusion criteria were the following: inability to walk without an assistive device (eg, a cane); somatic condition that limits tai chi participation (eg, limb loss); regular participation in aerobic exercise or mind-body exercise such as tai chi, yoga, qigong, or meditation (more than three times a week for >60 minutes each session); severe chronic disease that may profoundly affect sleep (eg, active cancer, end stage renal disease); receiving treatments or drugs that can affect sleep (eg, chemotherapy for cancer); dementia or receiving dementia treatments; untreated sleep disorder such as obstructive sleep apnea; current or past CBT-I treatment; and shift worker. Participants with common physical or mental chronic conditions, or both, including central obesity, hypertension, diabetes, depression and anxiety, were still included in the study. However, participants who might be disruptive during the group sessions, such as those showing uncontrolled violence or psychotic symptoms, were excluded.

Randomisation and masking

Eligible participants were randomly assigned to the two intervention groups in a 1:1 ratio. Randomisation was conducted using an online random generator (https://www.sealedenvelope.com/) with block sizes of four to six. The computer generated randomised allocation

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sequence was securely placed in sealed opaque envelopes and kept by an independent researcher who did not interact with the participants during recruitment or during the interventions. A second independent researcher who was responsible for conducting the group allocation needed to contact the first independent researcher to retrieve the allocation sequence after the baseline assessments and before the start of the interventions. These two independent researchers were not involved in participant recruitment or outcome assessment. Participants and intervention instructors were not blinded to the group allocation because of the nature of the tai chi and CBT-I interventions. Outcome assessors were blinded to the group allocation and participants were instructed not to disclose their group allocation to the outcome assessors during the outcome assessments.

Interventions

Tai chi

Participants in the tai chi group attended a three month, instructor led training programme, with 8-12 participants in each group, delivered by two certified tai chi instructors. The programme adopted the 24 form Yang style of tai chi, the most common style adopted in the literature.[22] We examined the feasibility and efficacy of this intervention in improving sleep in older adults with chronic insomnia in our previously published randomised controlled trial.[16] The intervention was prescribed as a three month programme consisting of a one hour session twice a week for a total of 24 sessions. The tai chi intervention was delivered in the first two months followed by one month of consolidation. The instructors discussed safety issues, proper training principles, and introduced the skills in the first class to minimise any avoidable adverse events caused by improper skills or practice. Each tai chi session consisted of 10 minutes of breathing and relaxation as warm-up exercises, followed by 45 minutes of tai chi practice, and then five minutes of cool-down exercises. Supplementary material II gives details of the 24 sessions of the CBT-I intervention.

Cognitive behavioural therapy for insomnia

Participants in the CBT-I group attended a three month, instructor led training programme, with 8-12 participants in each group, delivered by two certified CBT-I therapists. We also evaluated the feasibility and efficacy of this therapy in our previous study.[23] The intervention covers typical CBT-I components, including sleep education, stimulus control, sleep restriction, relaxation training, and cognitive therapy. The intervention was prescribed as a three month programme with a one hour session twice a week for a total of 24 sessions. The intervention was delivered in the first two months followed by one month of consolidation. Supplementary material II gives details of the 24 sessions of the tai chi intervention.

Both interventions took place at the School of Public Health, Li Ka Shing Faculty of Medicine, the University of Hong Kong. Attendance was recorded by the instructors as a measure of treatment adherence.

Outcomes

All outcomes were assessed at baseline, after the intervention (month 3), and at 12 month follow-up (month 15).

Primary outcome

The primary outcome was perceived insomnia severity measured using the Insomnia Severity Index (ISI) at month 3 and month 15. The ISI includes seven items assessing the following: sleep onset, sleep maintenance difficulties, satisfaction with the current sleep pattern, interference with daily functioning, noticeable impairment owing to sleep problems, degree of distress, and concerns caused by sleep problems. Each item is rated on a five point Likert scale (eg, 0=no problem; 4=very severe problem), yielding a total score ranging from 0 to 28. The total score is interpreted as follows: absence of insomnia (0-7); subthreshold insomnia (8-14); moderate insomnia (15-21); and severe insomnia (22-28).[24] A score change ≥8 has been established as the minimally important difference with 60% sensitivity and 70% specificity to detect moderate improvement.[25] The Chinese version of the ISI has been shown to have a satisfactory content validity index of 0.94 and high internal consistency, with a Cronbach's alpha of 0.81.[26]

Secondary outcomes

Secondary outcomes included insomnia remission rate (defined as "no longer meeting the criteria for insomnia" according to the *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition); insomnia treatment response rate (defined as a decrease in ISI of ≥8 points[25]); subjective sleep quantity and quality measured by the Pittsburgh Sleep Quality Index; seven day actigraphy; seven day sleep diary; sleep drug use; health related quality of life measured by the Short Form (SF) 12 item version 2 (SF-12v2); body balance and lower extremity function measured by the Short Physical Performance Battery; physical activity level measured by the International Physical Activity Questionnaire Short Form; severity of symptoms of depression and anxiety measured by the Hospital Anxiety and Depression Scale; and total energy intakes measured by a three day food diary.

Statistical analysis

Sample size

We conducted sample size estimation for a two sample t test between tai chi and CBT-I interventions to detect non-inferiority using POWER in SAS OnDemand for Academics (SAS Institute). The sample size estimation was based on a primary comparison of perceived insomnia severity measured by ISI between the two groups using a 95% power and 0.05/2=0.025 maximum chance of committing false type I errors to account for multiplicity. To assess whether tai chi is non-inferior to CBT-I, we adopted an ISI threshold

of 4 points as the margin of non-inferiority, which is 50% of the minimally important difference in the ISI (reported as 8 points).[25] The margin of 4 points in the ISI has been adopted in several non-inferiority trials conducted in different populations with chronic insomnia.[23 27] Our pilot study indicated that the tai chi intervention resulted in a mean reduction of 5.05 points in the ISI.[16] Assuming that the CBT-I group would also induce a similar improvement in the ISI with standard deviation conservatively taken as 6.5,[16] we needed a total of 70 participants in each group. Expecting a 20% study dropout rate, we aimed to recruit 90 participants (rounded up from 88) for each of the tai chi and CBT-I interventions, giving an overall study sample of 180 participants. Eventually, a total of 200 participants were enrolled in this study.

Data analysis

A non-inferiority analysis was performed on the primary outcome by comparing differences in the changes in ISI scores between the two groups at month 3 and month 15. Per protocol analyses were used to provide a more conservative and stringent non-inferiority comparison.[28] A margin of 4 points in the ISI (50% of minimally important difference) was adopted to assess whether tai chi was non-inferior to CBT-I.[23 27] The per protocol approach included all the participants who completed the assessments at the specific time point (ie, month 3 or month 15). For instance, for the non-inferiority analysis at month 3, only participants who completed month 3 assessments were included. Additionally, we adopted another per protocol approach that only included those who completed both month 3 and month 15 assessments.

We used generalised estimating equations analyses to examine the treatment effects on the quantitative secondary outcomes, adjusting for baseline values.[16 17] Pairwise comparisons were performed using linear contrasts. We conducted logistic regression to analyse insomnia remission rate and treatment response rate. The intention-to-treat principle was adopted in the secondary outcomes analyses for all randomised participants, except for insomnia remission and treatment response rates because logistic regression cannot account for missing data. All statistical analyses were performed using SAS OnDemand for Academics (SAS Institute). Statistical significance was set at a P value <0.05.

Sensitivity analysis

We performed sensitivity analysis using three approaches to assess the robustness of the results of the primary outcome. The first approach was a more stringent per protocol analysis of participants who completed the assessments at all three time points. The other two approaches followed the intention-to-treat principle by replacing missing values using the last observation carried forward and multiple imputation methods, respectively. In the last observation carried forward approach, missing values were replaced by the last observed value for the same participant. In the multiple imputation approach, a total of 20 imputed datasets were generated using the fully conditional specification method. We included the following variables in the multiple imputation model: subject code, time, group, demographic factors (eg, sex), primary outcome (ie, ISI), and other secondary outcomes (eg, Pittsburgh Sleep Quality Index). Non-inferiority analysis was performed on each generated dataset and the results were then pooled according to Rubin's rules. Additionally, we conducted sensitivity analyses on the primary outcome adjusting for baseline variables that significantly differed between those who completed and those who did not complete the outcome assessments.

Subgroup analysis

We conducted generalised estimating equations analysis to examine whether the changes in primary outcome were associated with age, sex, and body mass index, all of which are strongly associated with insomnia. The differences in mean changes and 95% confidence intervals were presented for each subgroup based on age (50-59 years, 60-69 years, and 70 years and older), sex (male and female), and body mass index categories (normal weight, overweight, and obese). We applied the per protocol principle.

Patient and public involvement

Patients were not involved in formulating the research question, selecting outcome measures, or creating recruitment and implementation strategies. They were also not consulted on interpreting or reporting the results. Nevertheless, patient engagement during the trial played a crucial role in its successful completion.

Results

Baseline characteristics of participants

A total of 272 people registered for the study and underwent eligibility screening. Of these, 200 eligible participants provided written informed consent and were included in the study. They were randomly allocated in a 1:1 ratio to the tai chi (n=100) or CBT-I (n=100) group (fig 1). Table 1 shows baseline characteristics of all participants. Participants in both groups presented with moderate levels of insomnia severity, as indicated by their ISI scores. Among the 200 participants, 166 (83%; 82 in the tai chi group and 84 in the CBT-I group) completed the assessments at month 3, and 167 (83.5%; 85 in the tai chi group and 82 in the CBT-I group) completed the assessments at month 15. Baseline characteristics were compared among participants who completed the assessments at month 3 and month 15, and those who did not. We observed a statistically significant difference in the baseline physical component score in SF-12v2 between those who completed and those who did not complete the assessment at month 3. Additionally, there were statistically significant differences in the baseline sleep parameters recorded in sleep diaries—including total time in bed, wake after sleep onset, and sleep efficiency—between those who completed and

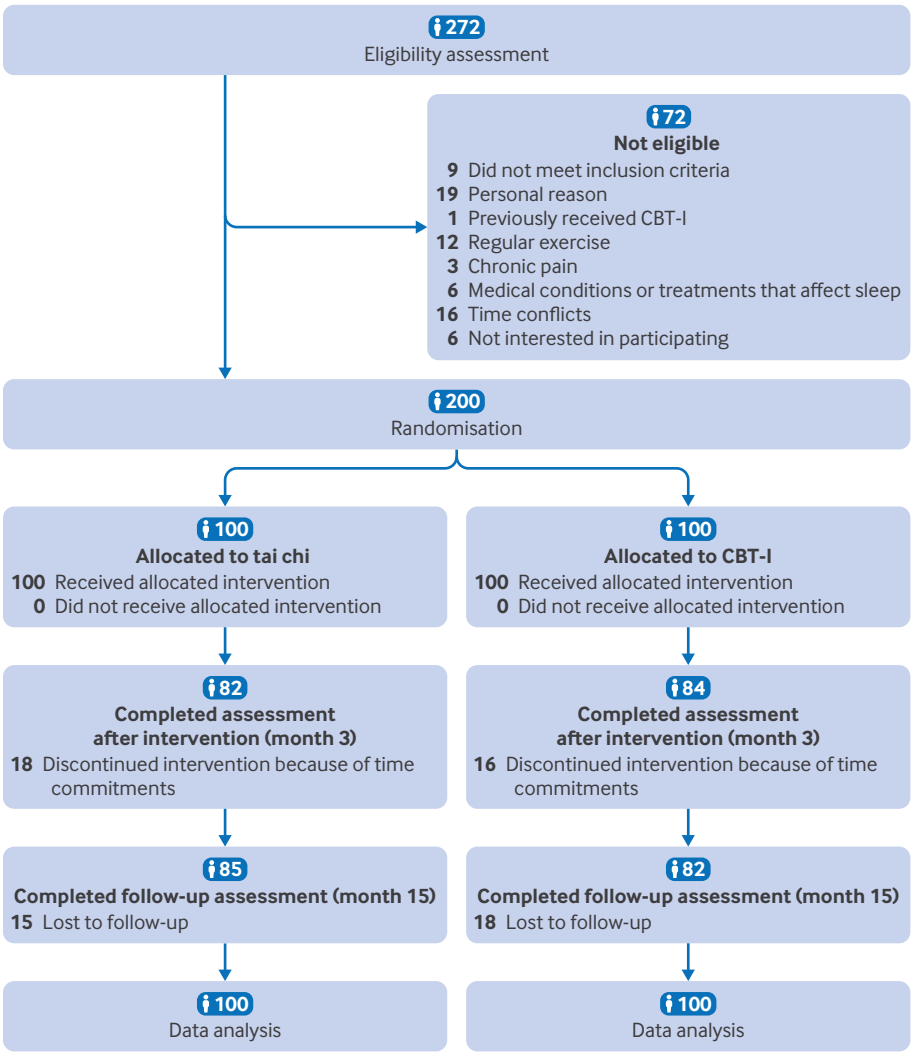

Fig 1 | Flow chart showing screening, randomisation, interventions, and follow-up of participants. CBT-I=cognitive behavioural therapy for insomnia

those who did not complete the assessment at month 15 (supplementary material IV). The adherence rates were similar for the tai chi and CBT-I groups (78.2% and 80.7%, respectively), as measured by class attendance.

Primary outcome

Figure 2 and supplementary material III present the results of the primary outcome. The per protocol analysis showed that, at month 3, the tai chi group showed a reduction of 6.67 points (95% confidence interval 5.61 to 7.73) in ISI scores, while the CBT-I group had a reduction of 11.19 (10.06 to 12.32), resulting in a between group difference of 4.52 (−∞ to 5.81). Tai chi was deemed inferior to CBT-I at month 3 because the upper confidence limit exceeded the non-inferiority margin. At month 15, the reductions for the tai chi and CBT-I groups were 9.51 (8.47 to 10.54) and 10.18 (8.97 to 11.40), respectively, with a between group difference of 0.68 (−∞ to 2.00). At this point, tai chi was considered non-inferior to CBT-I because the upper confidence limit fell within the non-inferiority margin.

Results of the intention-to-treat analysis were consistent with the per protocol findings. At month 3, the intention-to-treat analysis using the multiple imputation method showed that there was a 6.88 (95% confidence interval 5.84 to 7.90) and 10.73 (9.53 to 11.93) reduction in the ISI scores for the tai chi and CBT-I groups, respectively, with a between group difference of 3.85 (−∞ to 5.46). Tai chi was considered inferior to CBT-I at month 3 because the upper confidence limit exceeded the predefined non-inferiority margin. At month 15, there was a 9.43 (8.37 to 10.49) and 10.15 (8.94 to 11.35) reduction in the ISI scores for the tai chi and CBT-I groups, respectively, with a between group difference of 0.71 (−∞ to 2.28). Tai chi was considered non-inferior to CBT-I at month 15 because the upper confidence limit was within the predefined non-inferiority margin.

Table 1 | Baseline characteristics of participants

Characteristics	Tai chi (n=100)	CBT-I (n=100)
Female, n (%)	77 (77)	84 (84)
Age (years)	64.83 (6.31)	63.76 (6.15)
Education level, n (%)		
Below tertiary education	73 (73)	70 (70)
Tertiary education or above	27 (27)	30 (30)
Marital status, n (%)		
Single	15 (15)	21 (21)
Married	66 (66)	64 (64)
Divorced	13 (13)	8 (8)
Widowed	6 (6)	7 (7)
Monthly income ($), n (%)		
<20 000	12 (12)	10 (10)
20 000-50 000	5 (5)	5 (5)
>50 000	3 (3)	2 (2)
Retired	79 (79)	82 (82)
Undisclosed	1 (1)	1 (1)
Presented with physical comorbidities, n (%)	62 (62)	59 (59)
Presented with mental comorbidities, n (%)	13 (13)	7 (7)
Insomnia Severity Index	16.45 (3.69)	17.41 (4.42)
Pittsburgh Sleep Quality Index	13.13 (2.68)	13.79 (2.61)
Sleep diary		
Sleep onset latency (min)	45.69 (43.49)	52.49 (47.11)
Wake after sleep onset (min)	89.91 (71.76)	103.77 (92.70)
No of awakenings	2.33 (1.12)	2.46 (1.40)
Average wake-up time (min)	43.40 (40.64)	49.00 (44.47)
Total sleep time (min)	332.40 (73.37)	323.52 (94.46)
Total time in bed (min)	468.00 (79.51)	479.79 (76.32)
Sleep efficiency (%)	72.00 (16.05)	68.22 (19.00)
Actigraph		
Sleep onset latency (min)	7.55 (4.13)	7.96 (4.17)
Wake after sleep onset (min)	70.82 (34.92)	81.23 (37.28)
No of awakenings	19.92 (7.09)	20.63 (6.86)
Average wake-up time (min)	3.58 (1.04)	4.03 (2.08)
Total sleep time (min)	386.88 (63.52)	390.25 (72.19)
Sleep efficiency (%)	83.07 (7.59)	81.46 (7.53)
Hypnotic drug use*	7.38 (12.35)	8.57 (10.17)
SF-12v2		
Physical component score	44.09 (8.33)	43.47 (8.39)
Mental component score	45.19 (8.56)	43.49 (10.98)
IPAQ-SF, activity†	1974.47 (1447.02)	1603.50 (1230.41)
IPAQ-SF, sedentary behaviour†	383.85 (161.33)	390.00 (170.08)
Short Physical Performance Battery	11.02 (1.36)	11.09 (1.37)
Hospital Anxiety and Depression Scale		
Anxiety subscale	7.08 (3.55)	7.89 (4.31)
Depression subscale	6.91 (3.66)	7.45 (4.19)
Total energy intake (kcal/day)	2072.03 (856.70)	1869.30 (555.38)

£1.00=$1.32, €1.14. Data are presented as mean (standard deviation) unless specified otherwise.
Physical comorbidities mainly included hyperlipidaemia, hyperuricemia, hyperthyroidism, osteoporosis, prediabetes and diabetes, and hypertension.
Mental comorbidities included depression and anxiety.
CBT-I=cognitive behavioural therapy for insomnia; IPAQ-SF=International Physical Activity Questionnaire—Short Form; SF-12v2=Short Form 12 item, version 2.
*Thirty participants in tai chi group and 26 participants in CBT-I group were taking hypnotic drugs (lowest recommended dosage, units/week).
†Metabolic equivalent minutes per week.

Secondary outcomes

A substantial proportion of participants in the tai chi and CBT-I groups achieved remission from chronic insomnia or showed a positive treatment response. The insomnia remission rates differed between the CBT-I and tai chi groups at month 3 (83.3% *v* 56.1%, P<0.001) but were similar at month 15 (63.4% *v* 76.5%, P=0.067). The treatment response rates also differed between the CBT-I and tai chi groups at month 3 (77.4% *v* 43.9%, P<0.001) but were similar at month 15 (73.2% *v* 62.4%, P=0.137; fig 3).

No statistically significant group by time interaction effects were observed in all secondary outcomes, indicating that there were no between group differences in the changes in these outcomes over time between the tai chi and CBT-I groups (table 2, table 3).

Sensitivity analysis, subgroup analysis, and adverse events

The results of the sensitivity analyses on the primary outcome were consistent with the primary analysis (fig 2 and supplementary materials III, IV, V). The generalised estimating equations analyses revealed the changes in ISI were not associated with age and age groups, body mass index, or sex. Supplementary materials VI and VII present the differences in mean

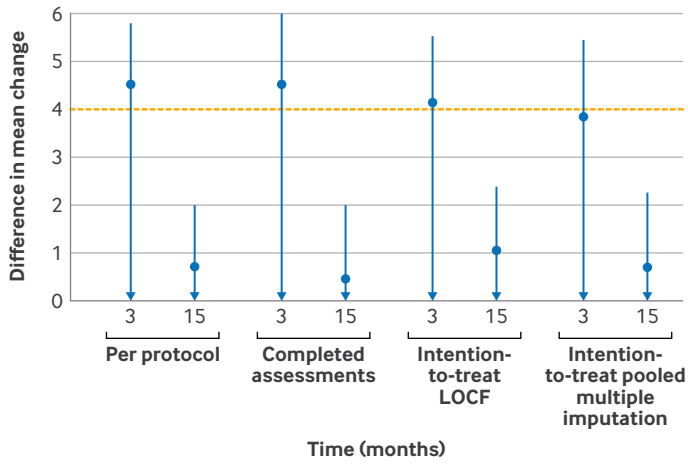

Fig 2 | Primary outcome (per protocol analysis): non-inferiority analysis for Insomnia Severity Index (ISI) at months 3 and 15 in tai chi and cognitive behavioural therapy for insomnia (CBT-I) groups. Sensitivity analyses: completed assessments, intention-to-treat last observation carried forward (LOCF), and intention-to-treat pooled multiple imputation. First approach (completed assessments) was more stringent per protocol analysis of participants who completed assessments at all time points. For LOCF, missing values replaced by last observed value for same participant. For multiple imputation, 20 imputed datasets generated using fully conditional specification method (variables were subject code, time, group, personal factors (eg, sex), primary outcome (ie, ISI), and other secondary outcomes (eg, Pittsburgh Sleep Quality Index)). Non-inferiority analysis performed on each generated dataset and results pooled according to Rubin's rules. Dots indicate differences in changes in mean ISI scores between two groups; dotted line represents non-inferiority margin of four points of ISI. Upper confidence limit not exceeding margin represents non-inferiority. Supplementary material III includes table presenting primary outcome analysis

changes in ISI and 95% confidence intervals for each subgroup. No adverse events were observed in either group during the intervention period.

Discussion

Principal findings

This randomised, non-inferiority trial compared the acute and long term efficacy of tai chi and CBT-I for treating chronic insomnia in middle aged and older adults. Our data showed that tai chi was inferior to CBT-I after the three month intervention, but became non-inferior at the 12 month follow-up (month 15).

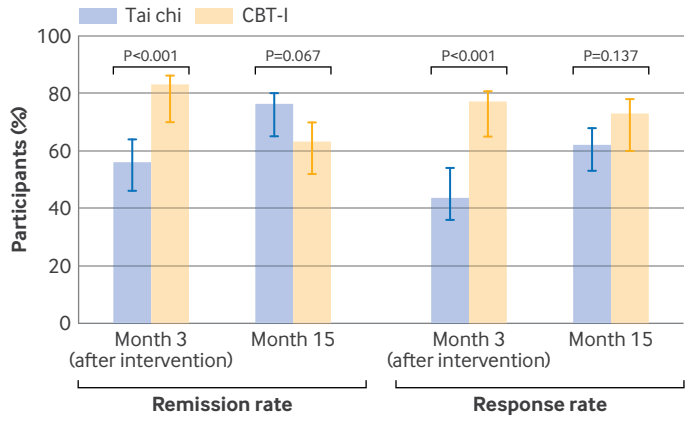

Fig 3 | Insomnia remission rate (definition of chronic insomnia from *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition) and treatment response rate (defined as decrease of ≥8 points on Insomnia Severity Index score) shown as percentage of participants. Error bars indicate range of remission or treatment response assuming that missing data all relate to participants who had remission/response or did not have remission/response. Data analysed by logistic regression. CBT-I=cognitive behavioural therapy for insomnia

Short term efficacy of tai chi

Most studies exploring tai chi as a treatment for insomnia used passive control designs or other exercise modalities as comparators, while direct comparison with first line clinical treatments is scarce.[16 19] In this study, we provide scientific evidence about the comparative efficacy of tai chi and CBT-I using a non-inferiority design with a stringent comparison margin. The results showed that tai chi was inferior to CBT-I after the three month intervention, but the lower efficacy of tai chi was mitigated during the 12 month post-intervention follow-up. Another study comparing tai chi and CBT-I found that tai chi was non-inferior to CBT-I after the three month intervention and at the 12 month post-intervention follow-up in patients with insomnia who had undergone successful treatment for breast cancer.[23] The discrepancy between the results could be attributed to differences in clinical characteristics and insomnia profiles between patients with a history of breast cancer and the participants in our study. For instance, patients with insomnia and a cancer history differ from those without cancer in terms of risk factors, such as cancer stage and history of lumpectomy and chemotherapy, and clinical characteristics, such as the number of comorbidities and increased levels of depression, anxiety, and fatigue.[29]

Our findings suggest that tai chi can lead to substantial improvements in insomnia severity after a three month intervention, while the long term efficacy of tai chi is non-inferior to that of CBT-I, the gold standard treatment for chronic insomnia. The observed effect size of the tai chi intervention on ISI was large (Cohen's d 1.50) and comparable to the effect sizes reported in previous studies investigating the efficacy of tai chi and conventional treatments (eg, hypnotic drugs and CBT-I, with Cohen's d between 0.36 and 1.13).[16 19 30] Overall, our findings support the use of tai chi as a potential treatment approach for the management of chronic insomnia.

Long term efficacy of tai chi

Current theories suggest that physiological and cognitive hyperarousal contribute to the evolution and chronicity of insomnia.[31] A longitudinal study reported that 38% of patients with insomnia presented with persistent symptoms after five years of follow-up.[32] Additionally, chronic insomnia is associated with high relapse rates because studies have shown that 27% of treated patients have a relapse after remission.[33] This finding highlights the need for treatments with long term efficacy and acceptability. Our study showed that the full benefits of tai chi do not emerge 12 months after the intervention. These findings align with previous research showing that the beneficial effects of insomnia remission on systemic and cellular

Table 2 | Primary and secondary outcomes assessed at baseline, after the intervention (month 3), and at 12 month follow-up (month 15)

Outcome	Assessment			Cohen's d†		Group effect	Time effect	Group by time interaction effect
	Baseline	Month 3	Month 15	Month 3	Month 15			
Primary outcome								
Insomnia Severity Index	—	—	—	—	—	<0.001*	<0.001*	0.74
Tai chi	16.45 (3.69)	9.66 (5.24)	7.09 (4.31)	−1.50	−2.33	—	—	—
CBT-I	17.41 (4.42)	6.14 (4.35)	7.54 (4.53)	−2.57	−2.21	—	—	—
Secondary outcomes								
Pittsburgh Sleep Quality Index	—	—	—	—	—	<0.001*	<0.001*	0.40
Tai chi	13.13 (2.68)	8.38 (3.62)	6.48 (3.54)	−1.49	−2.12	—	—	—
CBT-I	13.79 (2.61)	6.23 (2.89)	7.04 (3.46)	−2.74	−2.20	—	—	—
Sleep diary								
Sleep onset latency (min)	—	—	—	—	—	0.01*	<0.001*	0.67
Tai chi	45.69 (43.49)	35.59 (34.25)	31.64 (24.22)	−0.26	−0.40	—	—	—
CBT-I	52.49 (47.11)	22.33 (19.18)	31.16 (31.70)	−0.84	−0.53	—	—	—
Wake after sleep onset (min)	—	—	—	—	—	0.08	<0.001*	0.75
Tai chi	89.91 (71.76)	71.58 (61.50)	45.27 (39.34)	−0.27	−0.77	—	—	—
CBT-I	103.77 (92.70)	49.44 (48.40)	49.84 (53.95)	−0.73	−0.71	—	—	—
No of awakenings	—	—	—	—	—	0.64	<0.001*	0.88
Tai chi	2.33 (1.12)	1.83 (0.90)	1.70 (0.93)	−0.49	−0.61	—	—	—
CBT-I	2.46 (1.40)	1.77 (1.32)	1.73 (1.15)	−0.51	−0.57	—	—	—
Average wake-up time (min)	—	—	—	—	—	0.17	0.001*	0.91
Tai chi	43.40 (40.64)	45.88 (49.48)	30.90 (32.41)	0.05	−0.34	—	—	—
CBT-I	49.00 (44.47)	36.03 (39.73)	31.63 (35.14)	−0.31	−0.43	—	—	—
Total sleep time (min)	—	—	—	—	—	0.94	<0.001*	0.13
Tai chi	332.40 (73.37)	368.97 (68.88)	395.31 (59.35)	0.51	0.94	—	—	—
CBT-I	323.52 (94.46)	366.45 (58.79)	373.74 (65.44)	0.55	0.62	—	—	—
Total time in bed (min)	—	—	—	—	—	<0.001*	0.21	0.19
Tai chi	468.00 (79.51)	476.14 (64.97)	472.21 (54.78)	0.11	0.06	—	—	—
CBT-I	479.79 (76.32)	438.23 (62.39)	454.74 (60.22)	−0.60	−0.36	—	—	—
Sleep efficiency (%)	—	—	—	—	—	0.009*	<0.001*	0.80
Tai chi	72.00 (16.05)	77.97 (13.39)	84.02 (10.26)	0.40	0.89	—	—	—
CBT-I	68.22 (19.00)	84.15 (10.81)	82.73 (12.78)	1.03	0.90	—	—	—
Actigraph								
Sleep onset latency (min)	—	—	—	—	—	0.006*	0.03*	0.56
Tai chi	7.55 (4.13)	8.47 (4.20)	6.96 (2.68)	0.22	−0.17	—	—	—
CBT-I	7.96 (4.17)	6.59 (2.09)	6.86 (1.35)	−0.42	−0.35	—	—	—
Wake after sleep onset (min)	—	—	—	—	—	0.03*	0.36	0.36
Tai chi	70.82 (34.92)	76.29 (35.09)	74.19 (33.74)	0.16	0.10	—	—	—
CBT-I	81.23 (37.28)	61.71 (27.48)	70.12 (29.02)	−0.60	−0.33	—	—	—
No of awakenings	—	—	—	—	—	0.06	0.12	0.93
Tai chi	19.92 (7.09)	20.11 (7.25)	21.13 (7.78)	0.03	0.16	—	—	—
CBT-I	20.63 (6.86)	18.88 (6.95)	20.59 (7.18)	−0.25	−0.01	—	—	—
Average wake-up time (min)	—	—	—	—	—	0.04*	0.05	0.60
Tai chi	3.58 (1.04)	3.89 (1.82)	3.52 (0.89)	0.21	−0.06	—	—	—
CBT-I	4.03 (2.08)	3.29 (0.93)	3.47 (1.13)	−0.46	−0.33	—	—	—
Total sleep time (min)	—	—	—	—	—	0.19	0.18	0.84
Tai chi	386.88 (63.52)	386.69 (59.67)	379.22 (58.63)	−0.003	−0.13	—	—	—
CBT-I	390.25 (72.19)	372.41 (63.14)	372.21 (51.67)	−0.26	−0.29	—	—	—
Sleep efficiency (%)	—	—	—	—	—	0.07	0.61	0.68
Tai chi	83.07 (7.59)	82.16 (7.22)	82.59 (6.17)	−0.12	−0.07	—	—	—
CBT-I	81.46 (7.54)	84.51 (5.77)	82.97 (6.00)	0.45	0.22	—	—	—

Data are presented as estimated mean (standard deviation), baseline covaried. CBT-I=cognitive behavioural therapy for insomnia.
*Statistical significance.
†Effect size: change from baseline to 3 months and 15 months.

inflammation are delayed and non-significant until 12 months after the intervention.[34] The effect size on the ISI in the tai chi group at 12 month follow-up increased by 55% from levels measured immediately after the intervention. Importantly, the long term improvements after tai chi were non-inferior to those of CBT-I. This result is particularly important considering the high costs of CBT-I and its limited availability in healthcare systems worldwide.[11]

Our data revealed that 31 (36.5%) of 85 participants in the tai chi group who completed the outcome assessments at month 15 maintained their engagement in tai chi practice. The average practicing duration was 60±107 minutes, although the overall training volume decreased compared with the intervention period. However, 13 (15.9%) of 82 participants in the CBT-I group who completed the outcome assessments at month 15 reported self-practicing of the knowledge and skills learnt during the three month intervention. Therefore, the positive effects of tai chi being non-inferior to CBT-I at follow-up may be partially attributed to participants' continued practice after the end of

Table 3 | Further secondary outcomes assessed at baseline, after the intervention (month 3), and at 12 month follow-up (month 15)

Secondary outcomes	Assessment			Cohen's d†		Group effect	Time effect	Group by time interaction effect
	Baseline	Month 3	Month 15	Month 3	Month 15			
Hypnotic drug use‡	—	—	—	—	—	0.009	0.05	0.65
Tai chi (n=30)	7.38 (12.35)	1.80 (2.42)	5.79 (13.86)	−0.63	−0.12	—	—	—
CBT-I (n=26)	8.57 (10.17)	7.37 (11.20)	4.93 (7.40)	−0.11	−0.41	—	—	—
SF-12v2								
Physical component score	—	—	—	—	—	0.72	0.05	0.98
Tai chi	44.09 (8.33)	47.80 (6.70)	47.00 (9.19)	0.49	0.33	—	—	—
CBT-I	43.47 (8.39)	47.13 (8.22)	46.65 (8.80)	0.44	0.37	—	—	—
Mental component score	—	—	—	—	—	0.30	<0.001*	0.99
Tai chi	45.19 (8.56)	50.41 (7.20)	52.83 (7.71)	0.66	0.94	—	—	—
CBT-I	43.49 (10.98)	51.52 (7.84)	52.05 (8.67)	0.84	0.87	—	—	—
IPAQ-SF, activity§	—	—	—	—	—	0.06	<0.001*	0.76
Tai chi	1974.47 (1447.02)	3236.22 (2165.24)	3215.42 (2411.85)	0.69	0.62	—	—	—
CBT-I	1603.50 (1230.41)	2584.69 (2040.69)	2739.68 (1873.17)	0.58	0.72	—	—	—
IPAQ-SF, sedentary behaviour§	—	—	—	—	—	0.46	0.02*	0.09
Tai chi	383.85 (161.33)	324.09 (148.29)	367.47 (163.96)	−0.39	−0.10	—	—	—
CBT-I	390.00 (170.08)	355.36 (179.77)	418.96 (192.55)	−0.20	0.16	—	—	—
Short Physical Performance Battery	—	—	—	—	—	0.44	0.13	0.45
Tai chi	11.02 (1.36)	11.35 (1.05)	11.20 (1.42)	0.27	0.13	—	—	—
CBT-I	11.09 (1.37)	11.54 (0.77)	11.48 (0.92)	0.40	0.33	—	—	—
Hospital Anxiety and Depression Scale								
Anxiety subscale	—	—	—	—	—	0.21	<0.001*	0.48
Tai chi	7.08 (3.55)	4.09 (3.00)	2.92 (3.09)	−0.91	−1.25	—	—	—
CBT-I	7.89 (4.31)	3.39 (2.86)	3.04 (3.56)	−1.23	−1.23	—	—	—
Depression subscale	—	—	—	—	—	0.13	<0.001*	0.91
Tai chi	6.91 (3.66)	4.24 (3.20)	2.96 (3.06)	−0.78	−1.17	—	—	—
CBT-I	7.45 (4.19)	3.57 (2.78)	3.30 (3.62)	−1.09	−1.06	—	—	—
Total energy intake (kcal/day)	—	—	—	—	—	0.72	0.88	0.19
Tai chi	2072.03 (856.70)	1933.06 (628.23)	1894.03 (717.04)	−0.18	−0.22	—	—	—
CBT-I	1869.30 (555.38)	2002.39 (587.03)	1903.59 (745.69)	0.23	0.05	—	—	—

Data are presented as estimated mean (standard deviation), baseline covaried. CBT-I=cognitive behavioural therapy for insomnia; IPAQ-SF=International Physical Activity Questionnaire—Short Form; SF-12v2=Short Form 12 item, version 2.
*Statistical significance.
†Effect size: change from baseline to 3 months and 15 months.
‡The sample size for all secondary outcomes was n=100 participants in tai chi group and n=100 participants in CBT-I group; 30 participants in tai chi group and 26 participants in CBT-I group were taking hypnotic drugs (lowest recommended dosage, units/week).
§Metabolic equivalent minutes per week.

the intervention. Taken together, the large acute and long term efficacy, and the observed adherence to the intervention even after the end of the study, support the sustained benefits of tai chi, suggesting that tai chi could be used as an alternative treatment approach for the long term management of chronic insomnia.

Underlying physiological and psychological mechanisms of tai chi and CBT-I

A previous randomised controlled trial by Irwin and colleagues compared the physiological responses of tai chi and CBT-I on systemic, cellular, and genomic markers of inflammation in 90 patients with chronic insomnia and a history of breast cancer over a three month intervention and a 12 month post-intervention follow-up.[34] Both interventions statistically significantly reduced toll-like receptor 4 stimulated monocyte production of interleukin 6 and tumour necrosis factor α, and their coexpression. Additionally, they were associated with reductions in antiviral gene expression and inflammatory gene transcripts, and with increases in antiviral gene transcripts over 15 months (all P values <0.05). Interestingly, tai chi showed greater and more sustained reductions in systemic and cellular inflammation at the 12 month post-intervention follow-up, while CBT-I produced stronger increases in antiviral gene transcripts (all P values <0.05). These findings suggest distinct physiological pathways by which each intervention modulates inflammatory processes and offers therapeutic benefits, and aligns with the results of our study relating to the long term benefits of tai chi in treating insomnia.

In addition to the inflammatory profile, previous research has also examined the potential neurological mechanisms underlying the effects of these two interventions. Studies have shown that a 12 week tai chi intervention modulated resting state functional connectivity in cognitive control networks,[35] the default mode network,[36] and the hippocampus,[37] and improved fractional amplitude of low frequency fluctuations,[38] while the CBT-I intervention enhanced functional connectivity in the frontoparietal network and reduced hyperarousal by decreasing thalamic activity.[39 40] Although studies directly comparing the psychological mechanisms underlying tai chi and CBT-I are needed, existing evidence highlights notable differences. Cognitive therapy, a core component

of CBT-I, targets dysfunctional beliefs, attitudes towards sleep and insomnia, attentional biases, and cognitive arousal, addressing specific maladaptive patterns that sustain insomnia.[41] In contrast, tai chi is a holistic mind-body practice integrating physical, psychological, emotional, spiritual, and behavioural components,[14] which has been shown to reduce stress, depressive symptoms, and cognitive hyperarousal.[42-44] Importantly, only a limited number of well controlled studies have explored these underlying mechanisms, particularly in older adults with chronic insomnia. Further mechanistic research is warranted to clarify how these distinct pathways contributed to the observed sustained therapeutic effects, such as those we observed with tai chi at the 12 month post-intervention follow-up.

Study limitations

This study has several potential limitations. A large proportion (77.5%, n=155) of the study participants were older adults aged ≥60 years, which might limit the generalisability of our results when considering younger populations. However, older adults have a higher prevalence of chronic insomnia and higher risk of developing comorbid conditions such as depression and cognitive impairment.[5] Therefore, it is crucial to determine the efficacy of treatment approaches that target this vulnerable population. Additionally, this study was conducted at a single research centre, which might further limit the generalisability of the results. However, our study participants were recruited from various districts of Hong Kong, representing a diverse study population. Further studies are needed to replicate our findings and determine whether the benefits of tai chi can be applied to other countries or regions with different demographic characteristics.

Tai chi was chosen as the exercise modality in this study, which might restrict the implementation of similar interventions in "western" countries owing to cultural differences. Nevertheless, national trend surveys in the US showed that the practice of tai chi and other mind-body exercises increased from 6% to 15% from 2002 to 2012, highlighting the growing popularity of mind-body practices.[45] Additionally, the tai chi intervention was standardised and manualised to enable replication. Finally, future studies are warranted to regularly assess (eg, every three months) adherence to tai chi during the post-intervention follow-up period to capture the full tai chi practice behaviour.

Conclusion

After the three month intervention, tai chi and CBT-I improved insomnia symptoms in middle aged and older adults with chronic insomnia, although the improvements were more marked in the CBT-I group and tai chi was inferior to CBT-I in treating insomnia. At the 12 month follow-up (month 15), tai chi was non-inferior to CBT-I in improving insomnia symptoms. Additionally, tai chi and CBT-I had comparable benefits on subjective sleep parameters, quality of life, mental health, and physical activity level. Our study supports tai chi as an alternative treatment approach for the long term management of chronic insomnia in middle aged and older adults.

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Data sharing: Statistical code and dataset are available from the corresponding author at pmsiu@hku.edu.hk. The code used to analyse the data in the paper can be found in the supplementary files. The data underlying the findings in this paper are openly and publicly available and can be found here: https://doi.org/10.6084/m9.figshare.29203967.v3. If you encounter problems accessing the data, please contact the corresponding author.

Transparency: The lead author (PMS) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: The authors will circulate all study results to participants and patient organisations immediately after publication and will showcase the trial findings at pertinent national and international conferences.

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Web appendix: Supplementary material