

# BMJ Open 'Mindfulness Living with Insomnia': an mHealth intervention for individuals with insomnia in China: a study protocol of a randomised controlled trial

Chen Pan,<sup>1</sup> Bingyu Tie,<sup>1</sup> Weichao Yuwen,<sup>2</sup> Xiaoyou Su,<sup>3</sup> Yunlong Deng,<sup>1</sup> Xin Ma,<sup>1</sup> Yan Wu,<sup>1</sup> Yanhui Liao,<sup>4</sup> Luya Kong,<sup>5</sup> Yutao Zhang,<sup>6</sup> Ziwan Li,<sup>7</sup> Qinghua Pan,<sup>8</sup> Qiuping Tang<sup>1</sup>

**To cite:** Pan C, Tie B, Yuwen W, *et al.* 'Mindfulness Living with Insomnia': an mHealth intervention for individuals with insomnia in China: a study protocol of a randomised controlled trial. *BMJ Open* 2022;**12**:e053501. doi:10.1136/bmjopen-2021-053501

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-053501>).

Received 18 May 2021  
Accepted 19 January 2022



© Author(s) (or their employer(s)) 2022. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

## Correspondence to

Dr Qiuping Tang; [tt96@sina.com](mailto:tt96@sina.com)

## ABSTRACT

**Introduction** Insomnia has a remarkably negative effect on the work, quality of life and psychosomatic health of individuals, and imposes a substantial economic burden on society. Mindfulness-based interventions (MBIs) have proven beneficial in the treatment of insomnia. However, the effect of mobile or online-based (mHealth) MBIs requires further verification. This study will evaluate the effectiveness of an mHealth MBI, 'Mindful Living with Insomnia' (MLWI), relative to that of mHealth cognitive behavioural therapy for insomnia (CBT-I).

**Methods and analysis** The study is an mHealth, randomised controlled trial. Two hundred and fifty participants will be allocated randomly and equally to either the MLWI or CBT-I group. The intervention will involve 12 sessions over a 6-week course, with 2, 30 min sessions per week. The primary outcomes are sleep quality, severity of insomnia symptoms and sleep activity, according to the Pittsburgh Sleep Quality Index, Insomnia Severity Index and sleep tracker Mi Smart Band, respectively. The secondary outcomes are perceived stress, anxiety, depression and mindfulness. Outcomes will be evaluated at the baseline, end of the intervention period and at the 3-month follow-up. Data analyses will include covariance, regression analysis,  $\chi^2$ , t-test and Pearson's correlations. Participants will be recruited from January to June 2022, or until the recruitment process is complete. The follow-up will be completed in December 2022. All trial results should be available by the end of December 2022.

**Ethics and dissemination** Full approval for this study has been obtained from the Ethics Committee at The Third Xiangya Hospital, Central South University, Changsha, China (21010). Study results will be disseminated via social media and peer-reviewed publications.

**Trial registration number** NCT04806009.

## INTRODUCTION

Insomnia refers to persistent difficulty in initiating sleep, reduced sleep duration or disrupted sleep integrity or quality despite adequate sleep opportunities and environment, and can be cause of daytime functional

## Strengths and limitations of this study

- This study is the first randomised controlled trial to evaluate the efficacy of an mHealth mindfulness-based intervention (MBI) to manage insomnia in China.
- This trial involves a large sample size to explore the benefits of an mHealth MBI for insomnia.
- In addition to participant self-reports, an objective measure of sleep duration and quality and daytime activity will be assessed by an activity-based tracker.
- This study is limited, as it will not include an untreated control group.

impairment.<sup>1</sup> Based on clinical manifestations, insomnia can be classified as affecting sleep onset or maintenance, or both, or neither. The latter refers to cases that do not meet the quantitative thresholds for onset or maintenance problems.<sup>2</sup>

Insomnia can affect an individual's emotional stability and ability to focus attention; can lead to interpersonal, social and career problems; and increases the risk of accidents.<sup>3</sup> While insomnia causes distress in individuals, concomitantly it results in huge economic losses to society.<sup>4</sup> Insomnia also increases the risk of mental and physical illness, being a common comorbidity of depression, bipolar disorder, anxiety disorder, substance abuse, and other psychiatric disorders, and diabetes, coronary heart disease and other chronic physical diseases.<sup>3</sup>

Insomnia is a risk factor of oversedation, fatigue, cognitive impairment and dependence associated with pharmacotherapy. Thus, non-pharmacological therapies have attracted increasing attention from clinicians.<sup>5</sup> Non-drug treatments for insomnia include acupuncture and psychobehavioural, light and music therapies, and transcranial



magnetic stimulation and electrical stimulation.<sup>6</sup> Among the latter stimulation techniques, cognitive behavioural therapy for insomnia (CBT-I) is the most common.<sup>7</sup> CBT-I has been shown as effective as drugs for the treatment of insomnia.<sup>8</sup> Moreover, the therapeutic effects of CBT-I on insomnia in the workplace are also effective.<sup>9</sup> However, implementing CBT-I requires highly trained therapists.<sup>10</sup> Thus, having an effective, economical, and accessible intervention for insomnia is imperative, one that can be readily delivered by trained healthcare professionals and easily incorporated into existing healthcare systems.

Among non-pharmacological treatments, mindfulness-based interventions (MBIs) such as medication are particularly promising. MBIs are recommended by the National Center for Complementary and Integrative Health as a complementary psychological approach. The 2012 National Health Interview Survey reported that meditation among adults is very popular to supplement healthy activities, as the practice increased more than threefold from 4.1% in 2012 to 14.2% in 2017.<sup>11</sup>

The essence of meditation is mindfulness.<sup>12</sup> Mindfulness involves focusing attention on current experience, with attention comprising thoughts, feelings and physical sensations, and practising an attitude of openness, curiosity and acceptance.<sup>13</sup> MBIs are founded on the concepts of 'being present' and 'not judging' via a standardised and formalised mindfulness method.<sup>12</sup> The practice of mindfulness can be formal or informal. Examples of formal mindfulness practice include sitting meditation, Tai Chi and yoga, while informal mindfulness can be applied during any daily activity such as household chores or walking.<sup>14</sup> The advantage of mindfulness practice is that it can be conveniently performed at any place or time, with less dependence on therapists and venues.<sup>15</sup> This has benefited the popularisation of mindfulness practices.

Numerous studies have reported the effectiveness of MBIs toward psychosomatic health, as they better sleep, reduce stress and depression, and improve well-being.<sup>16–20</sup> A meta-analysis including 49 studies showed that MBIs are effective in treating insomnia and improving the sleep quality of healthy subjects and clinical patients.<sup>17</sup> The 49 studies explored the effects of several mindfulness practices on insomnia: Mindfulness meditation significantly reduced the severity of insomnia, sleep latency, arousal level before sleep and waking times, and prolonged total sleep time; improved sleep efficiency and quality in individuals with chronic insomnia; and ameliorated insomnia in individuals with cancer, depression, anxiety and obesity.<sup>17</sup>

However, studies on the application of MBIs for insomnia have been limited by focusing on secondary rather than primary insomnia; small population samples; and use of qualitative indicators rather than quantitative measurements. In addition, research on the effect of MBIs in patients with different types of insomnia is lacking. A new randomised clinical trial showed that MBIs are effective at improving subjective and objective sleep quality in older adults, but the generalisability to younger

people remains undecided.<sup>21</sup> Therefore, more rigorous scientific studies are needed regarding insomnia treatment through MBIs.

The development of information technologies has made possible the delivery of psychological interventions through the internet.<sup>22</sup> Online interventions reduce costs and increase accessibility.<sup>23–24</sup> The benefits of CBT-I accessed online are similar to that of in-person, group-based CBT-I,<sup>25</sup> and can be successfully offered to a wide and varied range of insomnia sufferers.<sup>26</sup> A real-world study also provided evidence that adjunctive digital CBT-I improved clinical outcomes and access to psychological therapy.<sup>27</sup> A meta-analysis in 2016 indicated that online MBIs can improve mental health stress, depression, anxiety and well-being.<sup>22</sup> Although there has been little evidence that online MBIs can improve sleep,<sup>28–30</sup> rigorous studies using an active online-based control group, a large sample size, and both subjective and objective assessments are needed to explore their effect on insomnia.

Psychological interventions via mobile technologies (mHealth), such as smartphones, handheld tablets and other wireless devices are popular and an innovative mode of treatment delivery. In China, the WeChat app and its mini-programmes have dominated the browsing time of mobile phone users.<sup>31</sup> Mobile learning using WeChat mini-programmes has become an important learning method.<sup>32</sup> Considering the extreme shortage of insomnia interventions in China, or studies on the efficacy of MBIs for insomnia and online MBIs for mental health, we propose to design a population-based, widely accessible MBI via the WeChat mini-programme in China. This randomised controlled trial (RCT) will be conducted in this population to examine the effectiveness and feasibility of a 6-week MBI termed 'mindful living with insomnia' (MLWI) via the WeChat mini-programme, focusing on sleep and mental health. This study may provide valuable insights into bridging the huge gap between need and services received for insomnia in China.

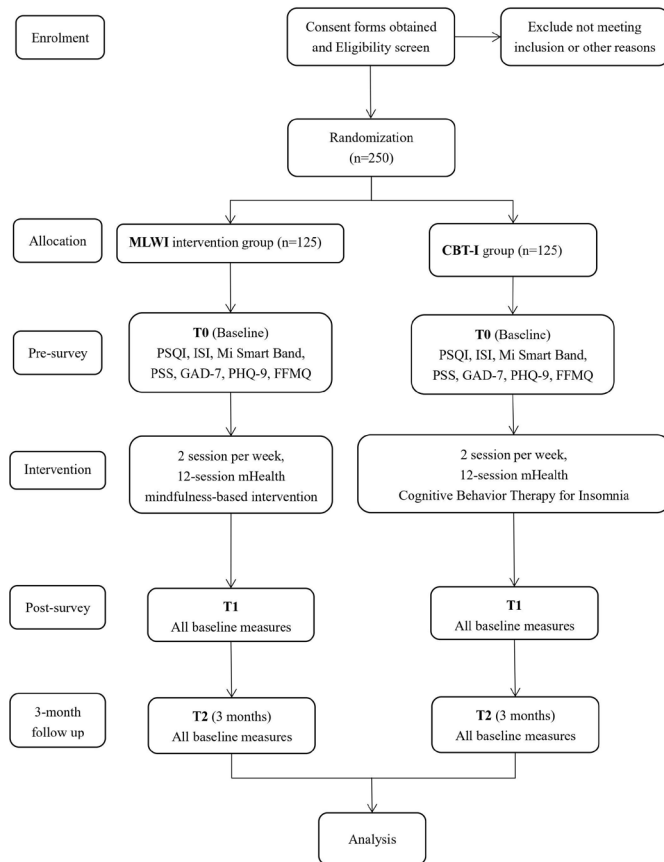
## METHODS

### Patient and public involvement

Patients and the public were not involved in the development of the research question or in the design of the study. The general results (no personal data) will be disseminated on demand.

### Study design

This study (figure 1) will be an mHealth, randomised, parallel-group, actively controlled trial. The trial will consist of a screening visit, a 1-week wash-out period and a 6-week intervention period. Two hundred and fifty participants will be randomised at a 1:1 ratio to either an intervention or control group. The intervention group will undergo a 6-week MBI via the WeChat mini-programme. The control group will receive a 6-week CBT-I via the WeChat mini-programme. Both groups will be given



**Figure 1** RCT study design and assessment timepoints (consort chart). CBT-I, cognitive-behavioural therapy for insomnia; FFMQ, Five Facets Mindfulness Questionnaire; GAD-7, Generalised anxiety disorder questionnaire; ISI, Insomnia Severity Index; MLWI, Mindful Living with Insomnia; PHQ-9, Patient Health Questionnaire; PSQI, Pittsburgh Sleep Quality Index; PSS, Perceived Stress Scale.

questionnaire surveys at three time points: 1 week before the intervention period (baseline); at the end of the respective 6-week interventions; and at the 3-month follow-up. Plans for important protocol modifications will be communicated to trial registration. Trial results will be disseminated through trial registration (ClinicalTrials.gov) or publication.

### Study objectives

The primary study objective is to evaluate the feasibility, acceptability and efficacy of the MBI via the WeChat mini-programme for insomnia and identify the insomnia phenotype(s) that are the most responsive to it, relative to the control intervention (CBT-I via the WeChat mini-programme).

The secondary study objective is to determine the effects of the MBI via the WeChat mini-programme on stress, anxiety, depression, and mindfulness in individuals with insomnia.

### Setting

The trial will be conducted at the Department of Clinical Psychology, The Third Xiangya Hospital of Central

South University, in Changsha, China. All researchers in this project are required to have an educational background in psychiatry/psychology or information management and will be trained regarding research ethics and methods. This study is planned to begin in January 2022 and to last for approximately 1 year.

### Sample size

Based on a previous study assessing the effects of online MBIs on sleep disturbances,<sup>28</sup> a priori power analysis was conducted using G\*power software. Assuming a moderate effect size ( $d=0.40$ ), results indicated that analyses with 190 participants across 3 time points would yield a power of 0.8. To account for 20% attrition, we anticipated enrolling 238 participants. However, considering that online interventions often have a much higher drop-out rate than face-to-face interventions and also a high loss to follow-up, this study will have a final target sample size of 250 participants (125 participants in each arm), which will have sufficient power to detect a significant difference among the outcomes.

### Recruitment

Participants will be recruited through advertisements posted in hospitals, universities, pharmacies and social media (ie, WeChat and internet bulletin boards) and by doctor referrals from outpatient clinics. Interested participants will be invited to attend an online screening by communicating with social media (mainly WeChat), which will be conducted by the researchers who are trained in psychiatry or psychology. Participants who fulfil the inclusion criteria will be informed about the procedures, responsibilities, benefits and possible risks of participation in the study and will be asked to sign digital informed consent forms to ensure that their participation is voluntary. Participants who enrol in this study can withdraw at any time. They will also be asked to provide contact information, and all personal information will be kept confidential on an encrypted laptop and used for research purposes only. Table 1 shows the schedule of enrolment, interventions and assessments. In addition, the researchers whose major is psychiatry or psychology will observe for severe psychological symptoms in participants by reviewing online consultation records, and will provide referral suggestions to a psychiatry clinic if necessary to ensure the safety of the participants.

### Eligibility criteria

#### Inclusion criteria

1. Aged between 18 and 59 years old.
2. Able to read and write Chinese.
3. Obtained a Pittsburgh Sleep Quality Index (PSQI) of  $>5$  at screening.
4. Able to access online services.
5. Willing to participate in the study.

#### Exclusion criteria

1. Unable to communicate.
2. With somatic disorders.

**Table 1** Schedule of enrolment, interventions, and assessments by time points ( $t_n$ )

	Enrolment	Allocation	Postallocation		Close-out
	$t_1$	$t_0$	$t_1$ , intervention period	$t_2$ , post assessment	$t_3$ follow-up
<b>Enrolment</b>					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
<b>Interventions</b>					
MBI			X		
CBT-I			X		
<b>Assessments:</b>					
<b>Primary outcome measures</b>					
PSQI	X			X	X
ISI	X			X	X
Mi Smart Band	X			X	X
<b>Secondary outcome measures</b>					
PSS	X			X	X
GAD-7	X			X	X
PHQ-9	X			X	X
FFMQ	X			X	X

CBT-I, cognitive-behavioural therapy for insomnia; FFMQ, Five Facets Mindfulness Questionnaire; GAD-7, Generalised Anxiety Disorder Questionnaire; ISI, Insomnia Severity Index; MBI, mindfulness-based interventions; PHQ-9, Patient Health Questionnaire; PSQI, Pittsburgh Sleep Quality Index; PSS, Perceived Stress Scale.

3. With mental disorders other than insomnia disorder.
4. Being treated with pharmacotherapy.
5. Already performing considerable mindfulness practices (>15 min/day).

### Randomisation and blinding

Each participant who meets the eligibility criteria will be randomly assigned (in a 1:1 ratio) to either the mHealth MBI group or the mHealth CBT control group. After participants provide digital informed consent by clicking the 'I agree to participate in this study' button on the electronic detail page of the trial, a code will pop up on the page. By scanning this code, participants will be randomly assigned to either the intervention or active control group (in a 1:1 ratio) according to computer-generated numbers. Given that the participants will be told that they will either receive the MLWI intervention or CBT-I, their blinding will not be possible. The blinding of the researchers who are directly involved in interventions will also not be possible because of the differences in these two interventions. The following researchers will be blinded to the participants' allocated groups until all data have been analysed: outcome assessors, statisticians, and data analysts. Before the trial, the researchers will be trained in the randomisation procedure and their individual responsibilities. The successful implementation and maintenance of the randomisation and blinding method will be validated.

### Interventions

#### Intervention group: MLWI via the WeChat mini-programme

Participants in the intervention group will receive the MLWI intervention after installing the WeChat mini-programme. The MLWI intervention was developed by the principal investigator, a psychiatrist who has completed the programme for Training of Mindfulness Facilitation at the Mindful Awareness Research Centre at the University of California, Los Angeles. A similar face-to-face and group-based MBI has been verified as useful in helping nurses caring for people living with the HIV to manage stress and emotions, and improve their acceptance of others and attention.<sup>33</sup>

The MLWI intervention will involve 12 sessions over a 6-week course, divided into 2, 30 min sessions per week. Two new sessions of online lessons will be updated weekly during the 6 weeks. Each session will consist of a theoretical lecture, mindfulness practices, sharing common difficulties and coping strategies during mindfulness practices, and a homework assignment in the form of a video or audio recording. Embedded in the intervention will be mindfulness exercises in breathing, body scan, thoughts and emotions, meditation, movement and daily-life. In the intervention, the participants will also receive sleep hygiene education. Participants will be asked to conduct mindfulness practices for 5–20 min daily. [Table 2](#) summarises the content of the MLWI intervention.



**Table 2** Content of MLWI by session

	Theoretical instrument	Meditation practice	Homework
1	Physiological and psychological response to stress	Mindful eating practice	Bringing mindfulness to daily life
	What is mindfulness?	Mindful breathing meditation	Mindful breathing meditation
	Mindfulness history, application and science research		
2	Brain's mode of action and existence	Mindful body scan	Bringing mindfulness to daily life
		Mindful breathing space exercise	Mindful breathing meditation
			Mindful body scan
			Mindful breathing space exercise
			Calendar of pleasant/unpleasant events
3	Interpretation of insomnia	Mindful forest meditation	Mindfulness clock
	Psychological regulation of insomnia	Mindful sleep meditation	Mindfulness meditation
4	Interpretation of thoughts	Mindful walking	Mindful walking
	Interpretation of emotions	Mindful sea meditation	Mindful listening and speaking
	Interpretation of STOP practice		Mindful meditation
5	Avoidance response	Mindful yoga practice	Mindful yoga practice
	Allow emotions	Tai chi practice	Tai chi practice
	Interpretation of RAIN practice		Mindful meditation
6	How to balance our life	Mindful voices and thoughts practices	Listing nourishing/consuming activities and balancing life
	Seven attitude of mindfulness practices	Mindful dealing with difficulties practices	How to insist on daily mindfulness practices

MLWI, Mindful Living with Insomnia; RAIN, Recognition, Acceptance, Investigation, None Identification; STOP, Stop, Take a breath, Observe, Proceed.

Push notifications from the WeChat mini-programme will be sent to participants every day to remind them about their regular attendance and mindfulness practices to enhance compliance. The participants can share their experiences and challenges during the 6-week intervention and at the 3-month follow-up in a WeChat group that includes all participants and some researchers. The outcome assessors, statisticians, and data analysts will not be in the WeChat group. The researchers will provide feedback to participants' questions about cognitive or behavioural regulation practices.

#### Control group: CBT-I via the WeChat mini-programme

Participants in the control group will receive CBT-I after installing the WeChat mini-programme. The CBT-I was developed by a researcher who is a psychiatrist/psychologist and has many years of experience in CBT. The aim of CBT-I is to reduce sleep-related physiologic and cognitive arousal so that restorative sleep function can be re-established.<sup>34</sup>

The CBT-I will involve 12 sessions over a 6-week course divided into 2, 30 min sessions per week. Two new sessions of online lessons will be updated weekly during the 6 weeks. Each session will consist of a theoretical lecture, cognitive or behavioural regulation techniques, a discussion of common difficulties and coping strategies during

mindfulness practices, and a homework assignment in the form of a video or audio recording. Participants will be asked to conduct a cognitive or behavioural regulation technique for 5–20 min daily. Table 3 summarises the content of the CBT-I.

Push notifications from the WeChat mini-programme will be sent to participants every day to remind them about their regular attendance and cognitive or behavioural regulation practices to enhance compliance. The participants can share their experiences and challenges during the 6-week intervention and at the 3-month follow-up in a WeChat group including all participants and some researchers. The outcome assessors, statisticians and data analysts will not be in the WeChat group. The researchers will provide feedback to participants' questions about cognitive or behavioural regulation practices.

#### ANALYSIS MEASURES

##### Compliance

The researchers will inform the participants about the importance of attending each MLWI/CBT-I session and completing their homework, because learning and practising mindfulness-based or CBT skills is crucial for the effect of the intervention on their insomnia. Participants

**Table 3** Content of CBT-I by session

	Theoretical instrument	Cognitive/behavioural regulation skills	Homework
1	What is cognitive model?	Distinguish ideas and facts	Calendar of thoughts
	What is CBT?	Distinguish situation, thoughts, emotion, behaviour and physiological response	Calendar of event-emotion-thinking
	History, application and science research of CBT		
2	Cognitive behaviour model of insomnia	Elicit, confirm automatic thinking	Drawing your cognitive model of insomnia
	Automatic thinking	Grasp key automatic thinking	Recording your automatic thinking
3	Interpretation of sleep and insomnia	Sleep hygiene education, stimulus control and sleep restriction	Automatic thinking categorisation and modification tool table
	Interpretation of emotions	Relaxation training for sleep	Relaxation training for sleep
4	Physiological and psychological response to stress	Emotion ruler	Recording your emotions in daily life
	Understanding depression, anxiety, anger	Imaginary exposure skill	Imaginary exposure practice
5	Identifying intermediate belief	Arrow down skill	Finding supportive or unsupportive proofs of your automatic thinking when you face challenges
	Inspection and correction of intermediate belief	Developing new belief through Socratic questions	Recording your intermediate belief
6	Identifying core belief	Rational emotion role-play	Core beliefs worksheet
	Developing new core belief	Shifting attention practice	How to use cognitive and behaviour skills to deal with future challenges

CBT-I, cognitive-behavioural therapy for insomnia.

will be provided audio-video materials related to MLWI/CBT-I to promote their adherence to daily practice. The compliance of participants will be measured in three ways: attendance rate, training time and assignment completion. The attendance rate and training time will be automatically recorded by an online intervention platform. Assignment completion will be reported by participants via the WeChat mini-programme.

### Outcome measurements

**Primary outcomes: sleep quality, severity of insomnia symptoms and sleep parameters**

#### *Pittsburgh Sleep Quality Index*

The 19-item PSQI will be used to subjectively measure sleep quality and sleep disturbances during the previous month on a 4-point Likert scale of 0 to 3. PSQI can be divided into seven components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of medication and daytime dysfunction. A low global PSQI score indicates good sleep quality.<sup>10</sup> Cronbach's  $\alpha$  for the Chinese version of the PSQI is 0.84.<sup>35</sup>

#### *Insomnia Severity Index*

The seven-item Insomnia Severity Index (ISI) is used to assess the current severity of insomnia symptoms, sleep dissatisfaction, daytime effects and distress concerning difficulties with sleep on a 5-point Likert scale (0=never;

4=always). The total scores will range from 0 to 28. The cut-offs for subthreshold, moderate and severe insomnia are 8, 15 and 22, respectively. On the ISI, response to treatment and remission are defined by a change of  $\geq 7$  points from baseline and a reduction to a score of  $< 8$ , respectively.<sup>36</sup> Cronbach's  $\alpha$  for the Chinese version of the ISI is 0.81.<sup>37</sup>

#### *Mi smart band*

The Mi Smart Band is a very popular activity-based tracker in China.<sup>38</sup> Participants will be given a Mi Smart Band as a gift for attending this study. Digital biomarker data, such as sleep duration and quality and daytime activity, will be assessed using the Mi Smart Band. The insomnia of participants will be classified into the following four types based on the monitoring data of the Mi Smart Band before the start of the respective intervention: sleep onset, sleep maintenance, combined sleep onset and maintenance, or neither sleep onset nor sleep maintenance. Sleep onset insomnia is defined as sleep onset latency (SOL)  $\geq 31$  min, and total wake time after sleep onset (WASO)  $< 31$  min. Sleep maintenance insomnia is considered SOL  $< 31$  min and WASO  $\geq 31$  min. Combined onset and maintenance insomnia is SOL  $\geq 31$  min and WASO  $\geq 31$  min. Neither sleep onset nor sleep maintenance insomnia is SOL  $< 31$  min and WASO  $< 31$  min. Data for sleep parameters including total sleep time, sleep onset, sleep offset, WASO and sleep efficiency will be measured and analysed.

## Secondary outcomes: stress, anxiety and depression

### Perceived stress

The 14-item Perceived Stress Scale (PSS) is used to assess all thoughts, feelings, and stressful situations experienced during the past month on a 5-point Likert scale (0=never; 4=always).<sup>39</sup> A high total score indicates high perceived stress.<sup>39</sup> The Chinese version of the PSS has been well validated (Cronbach's  $\alpha=0.78$ ), and a score  $\geq 25$  indicates severe stress.<sup>40</sup>

### Anxiety

Anxiety will be assessed using the Generalised Anxiety Disorder Questionnaire (GAD-7). GAD-7 comprises seven items for assessing the level of general anxiety.<sup>41</sup> All items are rated on a 4-point scale (0=never; 3=always), with high total scores indicating high levels of anxiety. A cut-off score  $>6$  indicates anxiety symptoms. The Cronbach's  $\alpha$  for the Chinese version of GAD-7 is 0.89.<sup>42</sup>

### Depression

Depression will be assessed using the Patient Health Questionnaire (PHQ-9). The PHQ-9 is used to measure depression in primary care and other medical settings.<sup>43</sup> The PHQ-9 consists of 9 items, and all items are rated on a 4-point scale (0=never; 3=always), with high total scores indicating severe depression. The cut-offs for mild, moderate, moderately severe, and severe depression are 5, 10, 15 and 20, respectively.<sup>44</sup> Cronbach's  $\alpha$  for the Chinese version of the PHQ-9 is 0.86.<sup>43</sup>

### Mindfulness

Level of mindfulness will be assessed using the Five Facets Mindfulness Questionnaire (FFMQ). The FFMQ includes five domains: observing, describing, acting with awareness, non-judgement and non-reactivity. The FFMQ comprises 39 items which range from 1 (never or very rarely true) to 5 (very often or always true). The higher the total score, the more mindful the individual is. Cronbach's  $\alpha$  values for the subscales observing, describing, acting with awareness, non-judging and non-reactivity are 0.75, 0.84, 0.79, 0.66 and 0.45, respectively.<sup>45 46</sup>

### Data collection, management and monitoring

Data will be collected online by Wenjuanxing, a Chinese online market research website that provides a professional online questionnaire survey or data collection for RCTs.<sup>47</sup> Data from the electronic questionnaires assessing sleep/stress/depression/anxiety/mindfulness and the Mi Smart Bands will be collected at three points: preintervention (1 week before the first session), post-intervention (1 week after the last session) and at the 3-month follow-up. Demographics, including age, gender, education level, employment status, marital status and other information will be collected at the baseline. The questionnaires will be required to be completed within approximately 40 min. Outcome assessors will be available to answer questions for questionnaires by WeChat and Mi Wristband data will be sent to outcome assessors.

The participants' confidentiality will be protected by storing all data in password-protected files on a designated computer and limiting access to the data to only the principal investigator and data analysts. Furthermore, once the study has been completed, all the data will be destroyed.

A data monitoring committee that is independent from the sponsor and free from competing interests will include the principal investigator, statisticians, outcome assessors and data analysts. Outcome assessors will be trained to collect good quality data, promote participant retention and complete follow-up. Data analysts will be trained on data entry, coding, security and storage. The training will be conducted by the principal investigator and statisticians.

Participants will be encouraged to report any adverse event, such as unfavourable or unintended signs or symptoms of diseases that arise during the trial. Psychiatrists in the research team will evaluate if the adverse events are associated with the intervention. If there is no association and the participants' psychosomatic statuses are suitable for attending the intervention, they will be invited to continue participating in the study. Otherwise, the research team will recommend that the participants withdraw from this study and seek help from other healthcare providers.

### Statistical analysis

All data will be collected automatically online. A user-specified Excel file will be downloaded from the database. No interim analyses will be performed. When all data have been obtained, it will be analysed using SPSS V.22.0 by the trial statistician who will be blinded to the intervention assignment. Between-group differences in numeric socio-demographic data and other measures at pretreatment will be assessed via independent t-tests and  $\chi^2$  tests. Variables that are significantly different between groups will be treated as covariant(s) in the analyses of treatment effects. Significant differences in multivariate analysis of variance (ANOVA) will be assessed with repeated-measures ANOVA to compare the participants' outcomes (ie, PSQI, ISI, Mi Smart Band, PSS, GAD-7, PHQ-9 and FFMQ). All tests will be two tailed. A two-sided  $p<0.05$  will determine statistical significance.

### DISCUSSION

Insomnia has a remarkably detrimental effect on the work, quality of life and psychosomatic health of individuals and imposes a substantial economic burden on society.<sup>3 4</sup> An estimated 33% of the general population suffer from insomnia symptoms, and 6%–10% meet the diagnostic criteria for insomnia disorder.<sup>1</sup> A meta-analysis in 2017 reported an insomnia prevalence of 15% in China.<sup>48</sup> Due to the large population of China, there are many individuals with insomnia. However, there are few qualified psychiatrists or psychologists, and innovative measures are needed to deliver mental health support with high efficiency.

CBT-I is the preferred non-drug therapy for the treatment of insomnia according to the American Academy of Sleep

Medicine,<sup>7</sup> and is recommended for the initial treatment for chronic insomnia disorder by the American College of Physicians.<sup>49</sup> However, psychotherapy that is suitable for all patients is not available, and only 26%–43% of patients who receive CBT-I achieve full remission from insomnia.<sup>50</sup> Mind-body movement practices including yoga and tai chi have also been investigated as treatments for insomnia. The most recent systematic review and meta-analysis on yoga for sleep quality and insomnia in women indicated that yoga did not significantly alter the severity of insomnia.<sup>51</sup> Several RCTs have suggested that tai chi for sleep can improve sleep quality, particularly among older adults.<sup>52</sup> However, an evaluative study showed that tai chi was less effective than CBT-I for chronic insomnia disorder.<sup>53</sup>

MBIs are particularly promising non-pharmacological treatments. Mindfulness practice focuses attention on the present and allows stressful, obsessive and intrusive thoughts, beliefs and emotions to pass.<sup>54</sup> Thus, mindfulness practice can change cognitive processes and behavioural patterns associated with insomnia and reduce the over-arousal of sympathetic nerves.<sup>55</sup> This reduces redundancy and emotional responses and promotes an unbiased reappraisal of important experiences,<sup>56</sup> resulting in better sleep. A meta-analysis in 2019 reported that MBIs are effective in treating insomnia and improving the sleep quality of healthy subjects and clinical patients.<sup>17</sup> However, highly rigorous scientific research with a large sample size and objective assessment indicators is needed to explore the efficacy of MBIs for primary insomnia.

Intervention research via online resources can increase the timeliness, convenience, and interaction of intervention training, which is more in line with the particularity of psychological intervention. This study will involve use of the WeChat app and its small programmes, which have become an integral part of daily life for a vast number of users in China.<sup>31</sup> Given the need of intervention, which can be delivered to more people suffering from insomnia in China, highly rigorous research on exploring the efficacy of mHealth MBI is crucial.

Considering the extreme shortage of insomnia interventions in China, or data on the efficacy of MBIs for insomnia, or online MBIs for mental health, we propose to design a population-based and widely accessible MBI via WeChat in China. This article described the design and methodology of a parallel group RCT to test differences in sleep between individuals receiving the MBI and CBT-I. This study should provide valuable insights into bridging the huge gap between need and services for insomnia interventions in China.

#### Author affiliations

<sup>1</sup>Department of Clinical Psychology, The Third Xiangya Hospital, Central South University, Changsha, Hunan, China

<sup>2</sup>School of Nursing and Healthcare Leadership, University of Washington Tacoma, Tacoma, Washington, USA

<sup>3</sup>School of Population Medicine and Public Health, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China

<sup>4</sup>Department of Psychiatry, Sir Run Run Shaw Hospital, School of Medicine, Zhejiang University, Hangzhou, Zhejiang, China

<sup>5</sup>Psychology of Teaching and Research Section, Ideological and Political Department, Heze Professional College on Household, Heze, Shandong, China

<sup>6</sup>Department of Student Affairs, Hunan University of Chinese Medicine, Changsha, Hunan, China

<sup>7</sup>Department of Psychology, Hunan Normal University, Changsha, Hunan, China

<sup>8</sup>Department of Ophthalmology and Otorhinolaryngology, The Second People's Hospital of Xiangtan City, Xiangtan, Hunan, China

**Contributors** CP took primary responsibility for the design of the MBI and CBT-I, developing the initial draft of this manuscript and conducting the interventions. QT provided guidance in the design of the project and implementation of interventions and revised this manuscript. WY, XS and YD provided guidance in the design of the project. XM and YL contributed to the design of the MBI and CBT-I. YW, LK, YZ, ZL and QP assisted the conduct of intervention. BT contributed to the statistical methods and data analysis.

**Funding** This study is funded by the following: Natural Science Foundation of Hunan Province (Grant No. 2020JJ4845); Changsha Science and Technology Bureau (No. kq1901127); The Innovative Engineering Program sponsored by the Chinese Academy of Medical Sciences (2020-I2M-2-015, 2019-I2M-2-005); and NIH-FIC Fogarty International Center (Grant # D43 TW009579).

**Disclaimer** The study sponsors will not participate in any study activities including study design; data collection, management, analysis, and interpretation; report writing; nor the decision to submit the report for publication; and will have no ultimate authority over any of these activities.

**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)

**Ethics approval** The trial has been approved by the Ethics Committee of The Third Xiangya Hospital, Central South University, Changsha, China (21010). All procedures involving human participants will be performed in accordance with the ethical standards of the institutional and/or national research committee, and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Findings will be published in a peer-reviewed journal.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Open access** This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

#### ORCID iDs

Yanhui Liao <http://orcid.org/0000-0003-4735-3252>

Qiuping Tang <http://orcid.org/0000-0003-0676-6835>

#### REFERENCES

- Gao H. *International classification of sleep disorders*. 3rd ed. Beijing: People's Medical Publishing, 2017.
- Pillai V, Roth T, Drake CL. The nature of stable insomnia phenotypes. *Sleep* 2015;38:127–38.
- American psychiatric publishing. *Psychiatric association : diagnostic and statistical manual of mental disorders*. 5th ed. Washington dc: American psychiatric publishing, 2013.
- Kessler RC, Berglund PA, Coulouvrat C, *et al*. Insomnia and the performance of US workers: results from the America insomnia survey. *Sleep* 2011;34:1161–71.
- Black DS, O'Reilly GA, Olmstead R, *et al*. Mindfulness meditation and improvement in sleep quality and daytime impairment among older adults with sleep disturbances: a randomized clinical trial. *JAMA Intern Med* 2015;175:494–501.
- Ding X, Geng XL. Research progress of non-pharmacological therapy to improve sleep. *Journal of Beijing Biomedical Engineering* 2016:544–8.
- Morgenthaler T, Kramer M, Alessi C, *et al*. Practice parameters for the psychological and behavioral treatment of insomnia: an update. An American Academy of sleep medicine report. *Sleep* 2006;29:1415–9.
- Wilson SJ, Nutt DJ, Alford C, *et al*. British association for psychopharmacology consensus statement on evidence-based



- treatment of insomnia, parasomnias and circadian rhythm disorders. *J Psychopharmacol* 2010;24:1577–601.
- 9 Vega-Escañó J, Porcel-Gálvez AM, Diego-Cordero Rde, et al. Insomnia interventions in the workplace: a systematic review and meta-analysis. *Int J Environ Res Public Health* 2020;17:6401.
  - 10 Black DS, O'Reilly GA, Olmstead R, et al. Mindfulness-based intervention for prodromal sleep disturbances in older adults: design and methodology of a randomized controlled trial. *Contemp Clin Trials* 2014;39:22–7.
  - 11 Complementary, alternative, or integrative health: What's in a name? Available: <https://www.nccih.nih.gov/health/complementary-alternative-or-integrative-health-whats-in-a-name>
  - 12 Xiong WR. *The lost and reversion of the theory of human nature of the mindfulness psychotherapy*. Jilin University, 2011.
  - 13 Smalley SL, London E, Winston D. *Fully present the science, art, and practice of mindfulness*. Da Capo Press, 2010.
  - 14 Haydon MD, Boyle CC, Bower JE. *Mindfulness interventions in breast cancer survivors: current findings and future directions*. Current Breast Cancer Reports, 2018: 1–7.
  - 15 Chen X, Wang KM. Effect of mindfulness meditation training on mental health and sleep quality of college students. *Chinese Journal of Health Psychology* 2017:276–81.
  - 16 Davis DM, Hayes JA. What are the benefits of mindfulness? A practice review of psychotherapy-related research. *Psychotherapy* 2011;48:198–208.
  - 17 Wang X, Li P, Pan C. The effect of Mind-body therapies on insomnia: a systematic review and meta-analysis. *Evid Based Complement Alternat Med* 2019:–1–17.
  - 18 Rash JA, Kavanagh VAJ, Garland SN. A meta-analysis of mindfulness-based therapies for insomnia and sleep disturbance: moving towards processes of change. *Sleep Med Clin* 2019;14:209–33.
  - 19 Chen T-L, Chang S-C, Hsieh H-F, et al. Effects of mindfulness-based stress reduction on sleep quality and mental health for insomnia patients: a meta-analysis. *J Psychosom Res* 2020;135:110144.
  - 20 Kim HG. *Effects and mechanisms of a mindfulness-based intervention on insomnia*. Yeungnam University Journal of Medicine, 2020.
  - 21 Perini F, Wong KF, Lin J, et al. Mindfulness-based therapy for insomnia for older adults with sleep difficulties: a randomized clinical trial. *Psychol Med* 2021:1–11.
  - 22 Spijkerman MPJ, Pots WTM, Bohlmeijer ET. Effectiveness of online mindfulness-based interventions in improving mental health. *Clinical Psychology Review* 2016;45:102–44.
  - 23 Jayewardene WP, Lohrmann DK, Erbe RG, et al. Effects of preventive online mindfulness interventions on stress and mindfulness: a meta-analysis of randomized controlled trials. *Prev Med Rep* 2017;5:150–9.
  - 24 Lancee J, van Straten A, Morina N, et al. Guided online or face-to-face cognitive behavioral treatment for insomnia: a randomized wait-list controlled trial. *Sleep* 2016;39:183–91.
  - 25 de Bruin EJ, Bögels SM, Oort FJ, et al. Efficacy of cognitive behavioral therapy for insomnia in adolescents: a randomized controlled trial with Internet therapy, group therapy and a waiting list condition. *Sleep* 2015;38:1913–26.
  - 26 van der Zweerde T, Lancee J, Ida Luik A, et al. Internet-Delivered cognitive behavioral therapy for insomnia: tailoring cognitive behavioral therapy for insomnia for patients with chronic insomnia. *Sleep Med Clin* 2019;14:301–15.
  - 27 Stott R, Pimm J, Emsley R, et al. Does adjunctive digital CBT for insomnia improve clinical outcomes in an improving access to psychological therapies service? *Behav Res Ther* 2021;144:103922.
  - 28 Querstret D, Cropley M, Fife-Schaw C. Internet-Based instructor-led mindfulness for work-related rumination, fatigue, and sleep: assessing facets of mindfulness as mechanisms of change. A randomized waitlist control trial. *J Occup Health Psychol* 2017;22:153–69.
  - 29 Low T, Conduit R, Varma P, et al. Treating subclinical and clinical symptoms of insomnia with a mindfulness-based smartphone application: a pilot study. *Internet Interv* 2020;21:100335.
  - 30 Huberty JL, Green J, Puzia ME, et al. Testing a mindfulness meditation mobile APP for the treatment of sleep-related symptoms in adults with sleep disturbance: a randomized controlled trial. *PLoS One* 2021;16:e0244717.
  - 31 Montag C, Becker B, Gan C. The multipurpose application WeChat: a review on recent research. *Front Psychol* 2018;9:2247.
  - 32 Zhang F, Wang PJ, Lin YR. Research on the construction of mobile learning activity teaching mode based on WeChat small program. *Computer Engineering&Software* 2020;41:119–24.
  - 33 Pan C, Wang H, Chen M, et al. Mindfulness-based intervention for nurses in AIDS care in China: a pilot study. *Neuropsychiatr Dis Treat* 2019;15:3131–41.
  - 34 Garland SN, Carlson LE, Stephens AJ, et al. Mindfulness-based stress reduction compared with cognitive behavioral therapy for the treatment of insomnia comorbid with cancer: a randomized, partially blinded, noninferiority trial. *J Clin Oncol* 2014;32:449–57.
  - 35 Sun Y, Yang ZJ. Analysis of sleep quality, mental health status and polysomnography of patients with insomnia. *Chinese Journal of Behavioral Medicine and Brain Science* 2006;15:498–500.
  - 36 Gross CR, Kreitzer MJ, Reilly-Spong M, et al. Mindfulness-based stress reduction versus pharmacotherapy for chronic primary insomnia: a randomized controlled clinical trial. *Explore* 2011;7:76–87.
  - 37 Yu DS. Insomnia severity index: psychometric properties with Chinese community-dwelling older people. *J Adv Nurs* 2010;66:2350–9.
  - 38 Liu DW, Cai SF. Research on influencing factors of wearable device user adoption behavior based on comparative analysis of iwatch and xiaomi band. *Journal of Productivity Research* 2016;11:68–72.
  - 39 dos Santos TM, Kozasa EH, Carmagnani IS, et al. Positive effects of a stress reduction program based on mindfulness meditation in Brazilian nursing professionals: qualitative and quantitative evaluation. *Explore* 2016;12:90–9.
  - 40 Yang T, Wu D, Zhang W, et al. Comparative stress levels among residents in three Chinese provincial capitals, 2001 and 2008. *PLoS One* 2012;7:e48971.
  - 41 Spitzer RL, Kroenke K, Williams JBW, et al. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092–7.
  - 42 Tong X, An D, McGonigal A, et al. Validation of the generalized anxiety Disorder-7 (GAD-7) among Chinese people with epilepsy. *Epilepsy Res* 2016;120:31–6.
  - 43 Bian CD, XY H, Qian J. The reliability and validity of a modified patient health questionnaire for screening depressive syndrome in general Hospital outpatients. *Journal of Tongji University* 2009;30:136–40.
  - 44 Moriarty AS, Gilbody S, McMillan D, et al. Screening and case finding for major depressive disorder using the patient health questionnaire (PHQ-9): a meta-analysis. *Gen Hosp Psychiatry* 2015;37:567–76.
  - 45 Deng Y-Q, Liu X-H, Rodriguez MA, et al. The five facet mindfulness questionnaire: psychometric properties of the Chinese version. *Mindfulness* 2011;2:123–8.
  - 46 Bohlmeijer E, ten Klooster PM, Fledderus M, et al. Psychometric properties of the five facet mindfulness questionnaire in depressed adults and development of a short form. *Assessment* 2011;18:308–20.
  - 47 Fitzpatrick T, Zhou K, Cheng Y, et al. A crowdsourced intervention to promote hepatitis B and C testing among men who have sex with men in China: study protocol for a nationwide online randomized controlled trial. *BMC Infect Dis* 2018;18:489.
  - 48 Cao X-L, Wang S-B, Zhong B-L, et al. The prevalence of insomnia in the general population in China: a meta-analysis. *PLoS One* 2017;12:e0170772.
  - 49 Qaseem A, Kansagara D, Forcica MA, et al. Management of chronic insomnia disorder in adults: a clinical practice guideline from the American College of physicians. *Ann Intern Med* 2016;165:125–33.
  - 50 Ong JC, Manber R, Segal Z, et al. A randomized controlled trial of mindfulness meditation for chronic insomnia. *Sleep* 2014;37:1553–63.
  - 51 Wang W-L, Chen K-H, Pan Y-C, et al. The effect of yoga on sleep quality and insomnia in women with sleep problems: a systematic review and meta-analysis. *BMC Psychiatry* 2020;20:195.
  - 52 Zhou ES, Gardner P, Bertisch SM. Integrative medicine for insomnia. *Med Clin North Am* 2017;101:865–79.
  - 53 Irwin MR, Olmstead R, Carrillo C, et al. Cognitive behavioral therapy vs. tai chi for late life insomnia and inflammatory risk: a randomized controlled comparative efficacy trial. *Sleep* 2014;37:1543–52.
  - 54 Kim SM, Park JM, Seo H-J. Effects of mindfulness-based stress reduction for adults with sleep disturbance: a protocol for an update of a systematic review and meta-analysis. *Syst Rev* 2016;5:51.
  - 55 Huang GP. Research status of mindfulness cognitive therapy for insomnia. *Journal of SiChuan Mental Health* 2016;29:190–2.
  - 56 Rusch HL, Rosario M, Levison LM, et al. The effect of mindfulness meditation on sleep quality: a systematic review and meta-analysis of randomized controlled trials. *Ann N Y Acad Sci* 2019;1445:5–16.