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The Efficacy of Integrated Cognitive Behavioral Therapy (CBT) and Acupressure versus CBT for Insomnia: A Three-Arm Pilot Randomized Controlled Trial

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Abstract

Objectives: This pilot study aimed to examine the efficacy of integrated cognitive behavioral therapy (CBT) and acupressure in treating insomnia and its daytime impairments in a Chinese adult population.

Methods: 40 eligible participants with insomnia were randomly assigned to either the integrated CBT and acupressure (CBTAcup) group (n = 14), the CBT group (n = 13), or the waitlist control (WL) group (n = 13). Participants in the CBTAcup group attended a 2-hour integrated CBT and self-administered acupressure group treatment once per week for six consecutive weeks, while participants in the CBT group attended six weekly 2-hour CBT for insomnia. Sleep, mood, daytime impairments, quality of life, and treatment credibility and adherence were assessed at baseline, immediate post-treatment (Week 7), and 4-week post-treatment (Week 11).

Results: Linear mixed-effects models showed that both the CBTAcup and CBT groups had significantly lower insomnia severity (d = -1.74 and d = -2.61), dysfunctional beliefs related to sleep (d = -2.17 and -2.76), and mental fatigue (d = -1.43 and -1.60) compared with the WL group at Week 7. The CBTAcup group provided additional benefits in reducing total fatigue (d = -1.43) and physical fatigue (d = -1.45). Treatment credibility was found to be improved in the CBTAcup group from baseline to Week 7.

Conclusions: Integrated CBT and acupressure demonstrated comparable efficacy to pure CBT in treating insomnia symptoms, with additional advantages to improve fatigue symptoms and acceptability in the Chinese population. Further methodologically rigorous studies on a larger scale and longer follow-up are warranted to confirm these findings.

***Keywords*:** Cognitive behavioral therapy, acupressure, randomized controlled trial, insomnia

1. Introduction

Insomnia is a significant public health concern that imposes substantial global societal burdens. Approximately 6% to 15% of the general population worldwide suffers from insomnia and its daytime consequence [1]. Insomnia is associated with an array of mental health problems and mortality risks [2]. In epidemiological studies, 30% to 60% of individuals with psychiatric disorders also reported insomnia complaints [1]. Chronic insomnia also imposes significant economic burdens on society, encompassing both direct (i.e., healthcare costs) and indirect (i.e., loss of human resources) costs [3]. Also, people with chronic insomnia encounter a significant reduction in their quality of life and impairment in their daily functioning [4].

Pharmacological interventions for insomnia are associated with potential problems such as dependence, tolerance, and adverse effects. Insomnia research therefore shows a trend toward increased use of non-pharmacological interventions such as psychotherapy and complementary and alternative medicine (CAM) [5]. Cognitive behavioral therapy (CBT), an evidence-based psychological intervention, is now recognized as a first-line option for the treatment of insomnia [6]. CBT for insomnia (CBT-I) is a multicomponent treatment package that typically integrates two core behavioral components, namely stimulus control and sleep restriction, along with sleep hygiene, cognitive restructuring, and relaxation training [7]. It aims to modify dysfunctional beliefs about sleep, manage maladaptive sleep-incompatible behaviors, and consolidate fragmented sleep. There is a consistent and growing body of literature demonstrating strong empirical support for the efficacy of CBT-I. In two recent meta-analytic reviews of the efficacy of CBT-I for insomnia, marked improvements were found in several sleep variables collected by sleep diary at post-treatment, which were maintained at short- and long-term follow-up assessments [8,9]. The efficacy of CBT-I has also been demonstrated in other delivery modalities, such as group [10] and self-help therapies [11,12].

Despite the favorable outcomes of CBT-I in alleviating insomnia symptoms, cultural adaptation of CBT-I might provide additional benefits in Chinese society. There are potential merits in advocating the culturally adapted approach over the conventional approach. A qualitative focus group study was conducted in Hong Kong to assess the experience of chronic insomnia in the Chinese adult population [13]. This study found that adults with insomnia held negative attitudes toward pharmacological interventions and showed a preference toward traditional Chinese medicine (TCM). A culture-specific treatment for insomnia, which takes the advantages of CBT-I and incorporates longstanding Chinese cultural beliefs and values, may be a feasible treatment approach to facilitate treatment acceptability and help-seeking behaviors. In addition to the qualitative study, a telephone survey was conducted on the use of CAM for insomnia among Hong Kong Chinese [14]. Among 402 respondents with insomnia, the weighted 12-month prevalence of any CAM use was estimated at 32.1%, of which acupressure is the 5th most commonly used CAM. While CBT-I is proven to be efficacious, there are critical limitations that are worthy of clinical attention. Due to the nature of sleep restriction, a core treatment component of CBT-I, patients frequently experience an acute reduction in total sleep time (TST), which is associated with adverse effects such as pronounced fatigue and excessive daytime sleepiness [15]. Furthermore, the treatment component of CBT-I places less emphasis on the physiological aspects (e.g., daytime impairments) than cognitive and behavioral aspects of insomnia. In view of converging evidence demonstrating the efficacy as well as the potential limitations of the conventional CBT approach, we believe that integrating Asian traditional healing (e.g., TCM elements) into psychological treatment (e.g., CBT) might achieve additive or synergistic effects for Chinese individuals with insomnia.

Acupressure, a non-invasive form of acupuncture in TCM, can serve as an adjunctive non-pharmacological treatment approach that is considered acceptable, approachable, safe, and cost-effective in the Chinese culture. Practitioners apply pressure stimulation over acupoints

using the fingers, palms, elbows, or specialized devices to enhance regional blood circulation. It is thought that from a TCM perspective, the vitalization of organs relies on a network of energy channels (i.e., meridians) to regulate blood circulation and increase the flow of life energy "qi". In recent years, the role of acupressure has gained neurophysiological support in Western medicine [16]. For instance, research evidence shows that acupuncture, which has a similar mechanism to acupressure, can regulate various hormonal factors (e.g., melatonin), neurotransmitters (e.g., serotonin), and higher cortical functions (e.g., hypothalamic-pituitary-adrenal axis) that are closely associated with sleep regulation [17]. In fact, acupressure has been used to treat insomnia and its associated daytime symptoms such as fatigue. Evidence suggested that acupressure could improve self-perceived sleep quality [18] in menopausal women and diverse types of patients [19] and lower the daytime consequences of insomnia such as fatigue [20,21]. A systematic review of six randomized controlled trials (RCTs) demonstrated the efficacy of acupressure in improving both sleep and fatigue symptoms in adults [20]. Due to the vast public mental health demand, researchers have advocated for the dissemination of self-acupressure, and positive effects were found in the management of sleep and fatigue symptoms [22]. A recent pilot RCT with 31 participants [23] and an RCT with 76 participants revealed that a short training in self-administered acupressure was superior to sleep hygiene in reducing insomnia symptoms (d = 0.56).

In recent years, the overemphasis and globalization of the Western mental health field have been questioned for overlooking the roles of traditional healing practices in non-Western societies [24,25]. Notably, many mental health professionals may already be integrating CAM into current clinical practice, such as meditation and progressive muscle relaxation (PMR) [26]. Considering the promising results of CBT-I in the Chinese population [11], together with its inadequacy in addressing daytime symptoms, it is relevant and innovative to integrate traditional healing practices (i.e., TCM) into CBT for future mental health services in the local

context. To the best of our knowledge, this was the first RCT to examine the efficacy of a 6-week integrated CBT and self-administered acupressure in treating insomnia and its daytime impairments in the Chinese adult population. Insomnia symptoms (primary outcome measure), dysfunction sleep-related cognitions, daytime symptoms (i.e., symptoms of anxiety, depression and fatigue), and treatment credibility and adherence toward the novel integrated CBT and acupressure for insomnia were evaluated. We hypothesized that participants with insomnia symptoms receiving integrated CBT and acupressure would show greater improvement in insomnia severity (assessed by Insomnia Severity Index; ISI) and lower fatigue symptoms (assessed by Multidimensional Fatigue Inventor; MFI) compared to the CBT and WL control groups from baseline (Week 0) to immediate post-treatment assessment (Week 7).

2. Method

2.1. Study design

This study is a randomized, assessor-blind controlled trial. Eligible participants were randomly assigned to the integrated CBT and acupressure (CBTAcup) group, the CBT group, or the waitlist control (WL) group in a ratio of 1:1:1. The study followed the Consolidating Standards of Reporting Trials (CONSORT) recommendations and was registered in ClinicalTrials.gov (NCT03291301). Ethical approval was obtained from the Survey and Behavioural Research Ethics Committee (SBREC) of the Chinese University of Hong Kong. The trial was conducted from December 2017 to May 2018.

2.2. Participants

Participants were recruited in the community through social media sites, local newspapers, posters, project websites, emails, public talks, and referrals. The inclusion criteria were: (1) Hong Kong residents; (2) Cantonese language fluency; (3) aged ≥ 18 years; (4) the Sleep Condition Indicator (SCI) score ≤ 21 indicating probable insomnia disorder based on DSM-5; (5) Insomnia Severity Index (ISI) score ≥ 8 indicating sub-clinical to clinical level of insomnia; (6) willingness to give informed consent and comply with the trial protocol, and (7) having a mobile phone with Internet access (iOS or Android system). Participants were excluded if they (1) were pregnant; (2) had suicidal ideation based on Beck Depression Inventory (BDI-II) Item 9 score ≥ 2 (referral information to professional services was provided to those who endorsed items on suicidal ideation); (3) received CBT-I, acupuncture and/or practitioner-delivered acupressure treatment within 6 months prior to baseline assessment; and (4) had taken herbal remedies, over-the-counter medication, or psychotropic drugs that target insomnia within 2 weeks prior to the baseline assessment.

2.3. Study procedure

The screening was conducted through an online platform (Qualtrics). All eligible participants were invited to complete the assessments through an in-house mobile app (*Longitudinax*). Informed consent was collected from the participants before commencing the study's procedures. Block randomization with a block size of 4 was conducted by an independent researcher using a list of computer-generated random numbers. Randomization results were announced to participants via email. Participants in both the CBTAcup and CBT groups received weekly treatment sessions for 6 consecutive weeks. Assessments were managed by an independent assessor who was blind to group allocation at baseline, immediate (Week 7), and 4-week (Week 11) post-treatment assessments. The WL group received CBT-I as compensation after 8 weeks of assessment (from baseline to Week 7). Thus, only participants from the CBTAcup and CBT groups completed the Week 11 assessment. The treatment was provided free of charge.

2.4. Intervention

Eligible participants in the CBTAcup and CBT groups attended 2-hour group treatments once per week for six consecutive weeks at the Chinese University of Hong Kong and Hong Kong Polytechnic University. Both groups were delivered by a clinical psychology trainee under the supervision of a clinical psychologist who was specialized in behavioral sleep medicine. Self-administered acupressure training was conducted by a registered TCM practitioner and acupuncturist. Only the instructors knew the treatment allocation of each participant. Data analyses were performed by an independent assessor. The treatment content of CBT-I was designed based on a clinician guide [27,28] and a systematic review [12]. The treatment protocol of self-administered acupressure was developed by two experienced acupuncturists and was based on a previous study [14]. At the beginning of each treatment session, a brief review was given in the format of group competition or discussion. After each

treatment session, a set of homework was distributed to the participants, including sleep diaries, relaxation logs, acupressure logs, and/or thought records. The instructors and research assistants reviewed the participants' homework and addressed their concerns and challenges in the next session.

2.4.1. CBT group

Session 1 consisted of an overview of the treatment, basic facts about sleep, three physiological systems that govern sleep-wake regularity (i.e., homeostatic regulation, circadian regulation, and arousal system), Spielman's 3P model (predisposing, precipitating, and perpetuating factors) of insomnia, and training on diaphragmatic breathing. Participants were asked to identify factors leading to their insomnia and practice diaphragmatic breathing daily at home. In Session 2, the participants were educated about healthy sleep behaviors and the elimination of sleep-interfering factors. Lifestyle factors (e.g., caffeine, nicotine, alcohol, diet, and exercise) and environmental conditions (e.g., noise, room temperature, and lighting) were included. The participants were invited to complete the Sleep Hygiene Practice Scale (SHPS) and Caffeine Knowledge Quiz to enhance the understanding of their sleep habits. The instructions and rationales of the stimulus control therapy were introduced to the participants as well. Session 3 covered the concept of sleep efficiency and sleep restriction. The participants were guided to calculate their sleep efficiency based on their sleep diaries. The recommended bedtime for the coming week was derived with a minimum time in bed set at 5 hours. Session 4 included an introduction of common sleep-related cognitive distortions, the CBT model of insomnia, dysfunctional beliefs and attitudes about sleep, and cognitive restructuring. Progressive muscle relaxation (PMR) was also delivered and practiced within the session. The participants were encouraged to keep a thought record to explore their automatic thoughts about sleep and practice PMR daily. Session 5 focused on cognitive therapy to replace dysfunctional thoughts about sleep with more adaptive thoughts. The use of a worry log was also covered.

Session 6 included activity scheduling, a review of all major treatment content and treatment gain, and relapse prevention.

2.4.2. CBTAcup group

The treatment content in both groups was identical except for the inclusion of self-administered acupressure in the CBTAcup group. In reference to some existing RCTs with similar study design [29-30], we did not extend the treatment programme but keep the number of sessions identical to the CBT group. We struck a balance between treatment quality and cost-effectiveness by including all core CBT-I components in the CBTAcup group and slightly shortened some non-essential sessions that were not related to core CBT-I components. Nonetheless, the sequence of the treatment sessions in this group slightly deviated from the CBT group. Self-administered acupressure was arranged in Session 2 to allow maximum practice during the treatment period. This arrangement was also designed to equip the participants with techniques to overcome insomnia and its associated daytime symptoms induced by sleep restriction such as fatigue or daytime sleepiness. During the session, an introduction to acupressure and TCM meridian theory, location of acupoints and their functions. Group training on locating acupoints and acupressure techniques was provided. The acupoints associated with insomnia were introduced, including unilateral Baihui (GV20), Zhongwan (CV12), bilateral Fengchi (GB20), Neiguan (PC6), Shenmen (HT7), and Yongquan (KD1), in a total of 10 acupoints. These acupoints were examined in our previous RCT of self-administered acupressure for insomnia [23] and were commonly used for insomnia in previous clinical trials [31]. The participants were instructed to press on each acupoint with circular motion for 1 minute to an extent of feeling soreness and numbness but not pain. The participants practiced self-administered acupressure under the supervision of a registered TCM practitioner with at least 5 years related clinical experience. They were recommended to perform self-acupressure for approximately 10 minutes every night before going to bed and

were asked to record their practice at home on an acupressure log. Sleep restriction was placed in Session 3 to optimize treatment gains as participants could adjust their sleep windows for several weeks before they completed the assessment at Week 7. Also, self-administered acupressure was reviewed and practiced in Session 3.

2.4.3. WL group

Participants in the WL group didn't receive any treatment from baseline to Week 7 assessments. However, they received CBT-I that was identical to the treatment content in the CBT group starting from Week 8.

2.5. Measures

2.5.1. Primary outcome. It was measured by the Insomnia Severity Index (ISI) [31,32], a 7-item scale designed to evaluate perceived insomnia severity, distress, and daytime impairment. Ratings on a 5-point Likert-type scale were obtained on the perceived severity of sleep onset, sleep maintenance, and early morning awakening problems, satisfaction with current sleep pattern, interference with daily functioning, noticeability of impairment attributed to the sleep problem, and the level of distress caused by the sleep problem.

2.5.2. Secondary outcomes. Secondary outcomes included: Dysfunctional Beliefs and Attitudes about Sleep Scale – 16-item version (DBAS-16) [33,34], a 16-item self-report measure designed to evaluate sleep-related cognitions (e.g., faulty beliefs and appraisals, unrealistic expectations, perceptual and attention bias); Multidimensional Fatigue Inventory (MFI) [35-37], a 20-item self-report instrument measuring various aspects of fatigue. Ratings on a 5-point Likert-type scale were obtained on the dimensions of spiritual fatigue, mental fatigue, and physical fatigue; Hospital Anxiety and Depression Scale (HADS) [38,39], a 14-item self-rating scale assessing anxiety and depression in both hospital and community

settings; and Credibility-Expectancy Questionnaire (CEQ) [40], a 6-item scale that yields ratings of treatment credibility, satisfaction, and expectations for success.

2.6. Statistical analysis

Statistics analyses were conducted using SPSS 25.0. All analyses were conducted using the intention-to-treat (ITT) approach. According to the European Medicines Agency (EMA) Guideline on adjustment for baseline covariates in clinical trials, between-group differences in baseline characteristics were not computed [41]. Linear mixed-effects models were used to examine group effects over time (from baseline to Week 7 and Week 11 assessments) on primary and secondary outcomes. Pairwise comparisons were conducted when there was a significant group by time interaction. Between and within-group effect sizes were expressed in Cohen'*d*. Clinical significance was defined as ISI score ≤ 8, following Yang and colleagues' [32] recommendation of a cutoff score of 9 in the validated Chinese version of ISI, which yielded a sensitivity of 91·8% and a specificity of 91·2%. The between-group difference in the proportion of participants who attained clinically significant improvement was performed by Fisher's exact test. Clinical significance was set at $p < \cdot 05$ (2-tailed). To examine the power achieved of this pilot study and determine the appropriate sample size for a future RCT of similar nature and design, a post-hoc power analysis was conducted using G*Power Version 3.1.9.2.

3. Results

3.1. Participant characteristics

A total of 260 potential participants completed the informed consent and online screening for eligibility. 220 of them were excluded due to various reasons (Figure 1). Forty participants who completed the baseline assessment were randomly assigned to the CBTAcup (n = 14), CBT-I (n = 13), or WL (n = 13) groups. Their baseline characteristics are presented in Table 1. The mean age was 37.9 years (SD = 13·0), and the majority of them were female (77·5%). The mean age of the onset of insomnia was 22.9 years (SD = 13·1), and the mean duration of insomnia was 12.3 years (SD = 11·4). Around one-third of the participants had sought professional help before this study, mainly from Chinese medicine practitioners (12·5%) and psychiatrists (12·5%), followed by general practitioners (7·5%). Forty percent of the participants had tried various treatments for insomnia. Chinese medication (20%) was the most common treatment attempted, followed by prescribed Western medications (15%), acupuncture, acupressure or reflexology (2·5%), and Western herbs or vitamins (2·5%). The prevalence of self-report comorbid psychiatric disorder was 12·5%, while no participants reported comorbid sleep disorders. At baseline, the mean score of ISI was 16·5 (SD = 5·0), indicating a moderate insomnia severity.

3.2. Attrition

The attrition rates of CBTAcup, CBT, and WL groups were 16.7% (n = 2), 38·5% (n = 5), and 38·5% (n = 5) respectively. Most of the dropouts did not respond to email and phone reminders (n = 7, 53·8%), while the rest withdrew due to incompatible schedule (n = 3, 23·1%) and personal reasons (n = 2, 15·4%) (Figure 1). There was no attrition in the CBTAcup and CBT groups at Week 7. Fisher's exact test indicated no significant difference in the overall attrition rates among the 3 groups.

Table 1. Demographic and clinical characteristics of participants.

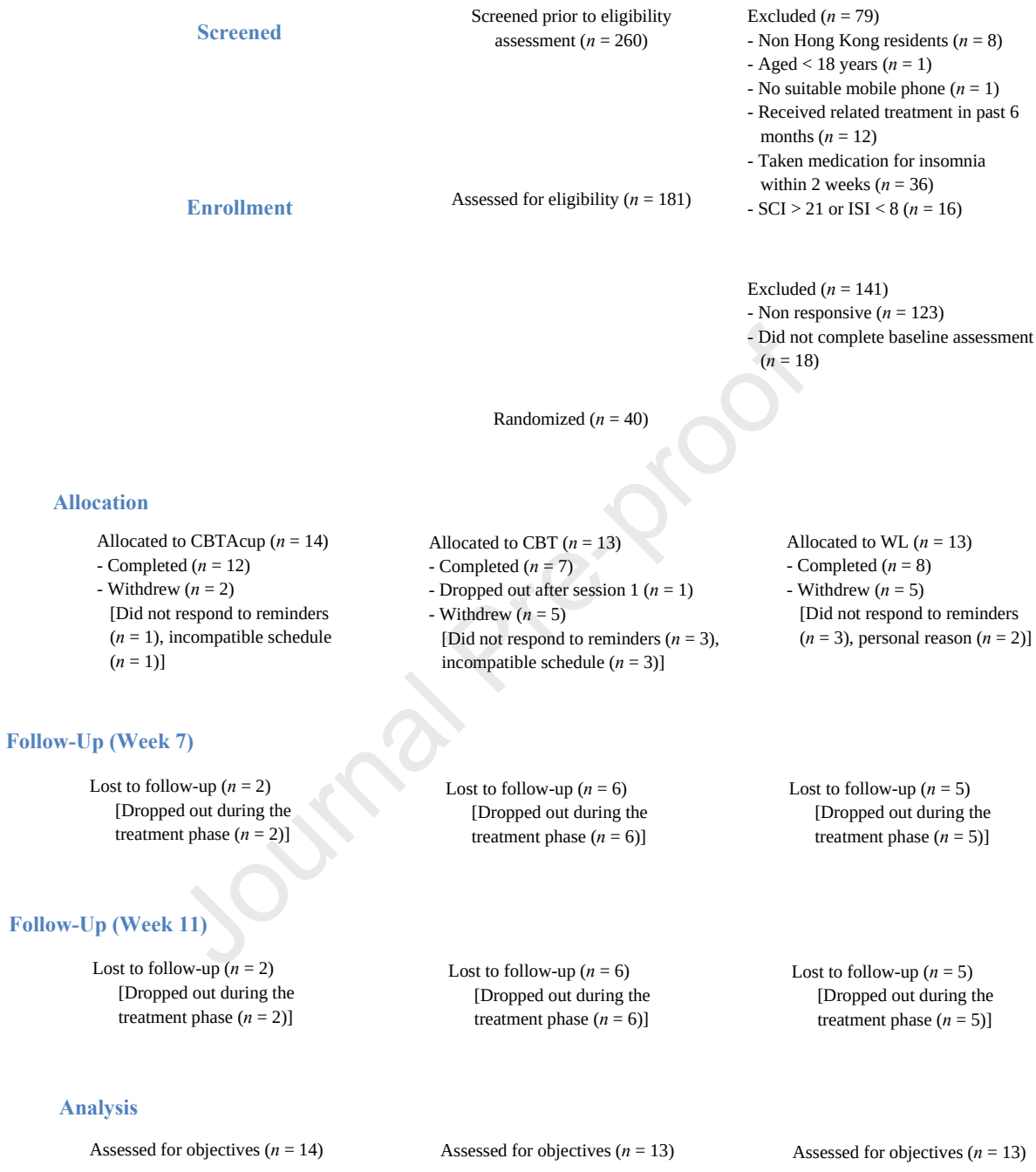
Variables	CBTAcup (*n* = 14)	CBT (*n* = 13)	WL (*n* = 13)	Total (*n* = 40)
Age, years	34·2 ± 12·1	43·1 ± 14·3	36·6 ± 11·7	37·9 ± 13·0
Sex, male/female	3/11	2/11	4/9	9/31
Full-time education, years	14·6 ± 4·7	14·0 ± 6·0	12·3 ± 7·2	13·6 ± 5·9
Marital Status				
Single	9 (64·3)	8 (61·5)	6 (46·2)	23 (57·5)
Married	4 (28·6)	4 (30·8)	7 (53·8)	15 (37·5)
Divorced	1 (7·1)	0 (0·0)	0 (0·0)	1 (2·5)
Widowed	0 (0·0)	1 (7·7)	0 (0·0)	1 (2·5)
Occupation				
Executives or professionals	3 (21·4)	4 (30·8)	5 (38·5)	12 (30·0)
Clerical, service, or sales workers	7 (50·0)	2 (15·4)	2 (15·4)	11 (27·5)
Technicians or tutors	0 (0·0)	2 (15·4)	2 (15·4)	4 (10·0)
Student	3 (21·4)	1 (7·7)	4 (30·8)	8 (20·0)
Housemakers	0 (0·0)	3 (23·1)	0 (0·0)	3 (7·5)
Retired	0 (0·0)	1 (7·7)	0 (0·0)	1 (2·5)
Unemployed/Others	1 (7·1)	0 (0·0)	0 (0·0)	1 (2·5)
Age of insomnia onset, years	22·0 ± 12·6	25·1 ± 15·9	21·7 ± 11·4	22·9 ± 13·1
Insomnia duration, years	9·7 ± 9·1	15·0 ± 12·9	12·7 ± 12·5	12·3 ± 11·4
Previous professional help				
Any	4 (28·6)	5 (38·5)	4 (30·8)	13 (32·5)
Psychiatrists	0 (0·0)	3 (23·1)	2 (15·4)	5 (12·5)
General practitioners or other doctors	3 (21·4)	0 (0·0)	0 (0·0)	3 (7·5)
Chinese medicine practitioners	1 (7·1)	2 (15·4)	2 (15·4)	5 (12·5)
Previous treatment of insomnia				
Any	5 (35·7)	8 (61·5)	3 (23·1)	16 (40·0)
Western medications	1 (7·1)	3 (23·1)	2 (15·4)	6 (15·0)
Chinese medications	4 (28·6)	3 (23·1)	1 (7·7)	8 (20·0)
Western herbs or vitamins	0 (0·0)	1 (7·7)	0 (0·0)	1 (2·5)
Acupuncture, acupressure or reflexology	0 (0·0)	1 (7·7)	0 (0·0)	1 (2·5)
Hypnotics use ≥ 1 time/week	1 (7·1)	1 (7·7)	0 (0·0)	2 (5·0)
Psychological treatment ≥ 1 time/month	0 (0·0)	0 (0·0)	1 (7·7)	1 (2·5)
Comorbid psychiatric disorder [a]				
Any	1 (7·1)	2 (15·4)	2 (15·4)	5 (12·5)
Depression	1 (7·1)	1 (7·7)	1 (7·7)	3 (7·5)
Anxiety disorder	0 (0·0)	0 (0·0)	1 (7·7)	1 (2·5)
Bipolar disorder	0 (0·0)	1 (7·7)	0 (0·0)	1 (2·5)
Comorbid physical disorder [a]				
Any	0 (0·0)	3 (23·1)	2 (15·4)	5 (12·5)
Pain disorder	0 (0·0)	1 (7·7)	0 (0·0)	1 (2·5)
Diabetes or other endocrine disorder	0 (0·0)	0 (0·0)	1 (7·7)	1 (2·5)
Respiratory disease	0 (0·0)	1 (7·7)	0 (0·0)	1 (2·5)
Others	0 (0·0)	1 (7·7)	1 (7·7)	2 (5·0)

CBTAcup, integrated cognitive behavioral therapy and acupressure; CBT, cognitive behavioral therapy; WL, waitlist control.

Values are expressed in mean ± standard deviation or *n* (%)

[a] Self-report history of clinical diagnosis

Figure 1. CONSORT flow diagram.



CBTAcup, integrated cognitive behavioral therapy and acupressure; CBT, cognitive behavioral therapy; ISI, Insomnia Severity Index; SCI, Sleep Condition Indicator; WL, waitlist control.

3.3. Treatment compliance

The attendance rate of the CBTAcup group achieved over 90%. Eleven out of 12 participants attended at least 5 sessions and one attended 4 sessions. Treatment materials were sent through email to the absent participants, and the instructors explained to them via phone, email, and in-person during the next session to make sure that they could catch up with the treatment progress. All participants submitted weekly homework such as thought records and relaxation logs. In addition, participants in the CBTAcup group learned the self-administered acupressure techniques and passed the fidelity check by the TCM practitioner and acupuncturist in Sessions 2 and 3. Their weekly practice logs showed that 10 participants complied with the treatment protocol and performed self-administered acupressure for 6·4 days per week (range: 4-7 days) and 11·7 minutes per day (range: 5 - 29 minutes) on average.

3.4. Treatment efficacy

3.4.1. Between-group comparison. Table 2 presents the statistical summary of all outcome measures from baseline to Week 7 and Week 11 assessments. Linear mixed-effects model analyses showed that there were significant differences among the CBTAcup, CBT, and WL groups in ISI, DBAS, and MFI from baseline to Week 7 assessment. No significant group by time interaction was found between the CBTAcup, CBT, and WL groups in HADS – Anxiety and Depression from baseline to Week 7 assessment (p <·05). Post-hoc pairwise comparisons revealed that the CBTAcup and CBT groups had significantly larger improvements in reducing insomnia symptoms (d = -1·74 and -2·61; p <·05), sleep-related dysfunctional beliefs (d = -2·17 and -2·76; p <·001), and mental fatigue symptoms (d = -1·43 and -1·60; p <·05) compared to the WL group at Week 7 assessment. In addition, the CBTAcup group was significantly superior to the WL group in reducing MFI - total fatigue (d = -1·41; p <·05) and physical fatigue (d = -1·45; p <·05) (Table 3). However, there was no significant difference between the CBTAcup and CBT groups in all outcome measures from baseline to Week 7 and Week 11 assessments.

Table 2. Means, standard deviations, and effect sizes across study time points and group by time interactions.

Variables[a]	CBTAcup (n = 14)	CBT (n = 13)	WL (n = 13)[b]	p-value[d]	Between-group ES (Cohen's d)		
	Mean ± SD	Mean ± SD	Mean ± SD		CBTAcup vs. WL	CBT vs. WL	CBTAcup vs. CBT
ISI							
Baseline	16·5 ± 3·2	16·2 ± 5·3	17·0 ± 6·5				
Week 7	9·9 ± 4·4	8·0 ± 2·2	18·1 ± 5·0	**·00**	-1·74	-2·61	0·55
Week 11	9·6 ± 5·0	7·4 ± 2·7	--	·80	--	--	0·54
DBAS							
Baseline	99·9 ± 18·0	90·9 ± 25·4	103·5 ± 18·0				
Week 7	58·6 ± 28·0	46·3 ± 27·7	108·1 ± 15·3	**·00**	-2·17	-2·76	0·44
Week 11	61·3 ± 18·0	50·6 ± 32·8	--	·997	--	--	0·41
MFI							
Total Score							
Baseline	65·5 ± 15·9	69·0 ± 12·1	71·1 ± 8·2				
Week 7	60·0 ± 15·4	60·4 ± 14·7	77·3 ± 7·5	**·001**	-1·41	-1·45	-0·03
Week 11	61·9 ± 16·9	60·3 ± 14·5	--	·13	--	--	0·10
Spiritual fatigue							
Baseline	21·6 ± 6·0	22·3 ± 5·3	21·4 ± 3·1				
Week 7	19·0 ± 5·4	19·6 ± 4·4	23·6 ± 3·9	**·02**	-0·97	-0·96	-0·12
Week 11	20·4 ± 6·5	19·7 ± 5·4	--	·54	--	--	0·12
Mental fatigue							
Baseline	18·4 ± 5·9	19·5 ± 3·8	21·3 ± 4·2				
Week 7	17·8 ± 5·3	17·0 ± 5·5	23·9 ± 2·7	**·01**	-1·43	-1·60	0·15
Week 11	17·9 ± 6·0	17·6 ± 4·7	--	·15	--	--	0·06
Physical fatigue							
Baseline	25·6 ± 5·4	27·2 ± 4·5	28·4 ± 3·3				
Week 7	23·2 ± 5·8	23·9 ± 6·0	29·8 ± 2·6	**·01**	-1·45	-1·28	-0·12
Week 11	23·6 ± 6·3	23·0 ± 5·9	--	·35	--	--	0·10
HADS							
Anxiety							
Baseline	8·7 ± 4·5	9·2 ± 4·3	11·5 ± 4·0				
Week 7	9·3 ± 4·2	9·1 ± 3·6	10·3 ± 4·2	·27	-0·24	0·05	0·05
Week 11	10·5 ± 4·5	8·4 ± 4·1	--	·22	--	--	0·49
Depression							
Baseline	6·4 ± 4·2	7·2 ± 3·3	8·7 ± 3·9				
Week 7	5·8 ± 3·5	6·1 ± 3·7	10·4 ± 3·8	·08	-1·26	-1·15	-0·08
Week 11	6·9 ± 3·7	5·6 ± 3·9	--	·24	--	--	0·34

CBTAcup, integrated cognitive behavioral therapy and acupressure; CBT, cognitive behavioral therapy; DBAS, Dysfunctional Beliefs and Attitudes about Sleep Scale; HADS, Hospital Anxiety and Depression Scale; ISI, Insomnia Severity Index; MFI, Multidimensional Fatigue Inventory; SD, standard deviation; SE, sleep efficiency; SOL, sleep onset latency; WASO, wake after sleep onset; WL, waitlist control.

[a] Higher score indicates greater severity.

[b] No comparison was conducted in the WL group at Week 11 due to the commencement of treatment.

[c] Cohen'*d* indicates within-group effect size from baseline Week 7 and Week 11 assessments. Positive values indicate improvement.

[d] Linear mixed-effects models were used to examine the group by time interactions. Week 7: 3 groups × 2 time points; Week 11: 2 groups × 3 time points.

Table 3. Post-hoc pairwise comparison and mean difference at immediate post-treatment for variables with significant group by time interactions.

Variables[a]	Immediate Post-treatment Assessment (Week 7)					
	CBTAcup vs. WL		CBT vs. WL		CBT vs. CBTAcup	
	p-value[c]	Between-group difference ± 95% CI)[d]	*p*-value[c]	Between-group difference ± 95% CI)[d]	*p*-value[c]	Between-group difference ± 95% CI)[d]
ISI	**·03**	-3·9 (-7·3, -0·5)	**·01**	-4·6 (-8·2, -1·1)	·67	-0·7 (-4·2, 2·7)
DBAS	**·00**	-24·3 (-40·1, -8·6)	**·00**	-33·3 (-49·7, 0·9)	·26	-9·0 (-24·9, 6·9)
MFI						
Total Score	**·047**	-9·7 (-19·3, -0·1)	·07	-9·0 (-18·8, -2·4)	·88	0·7 (-8·9, 10·3)
Spiritual fatigue	·29	-1·9 (-5·4, 1·6)	·40	-1·5 (-5·2, 2·1)	·85	0·3 (-3·2, 3·9)
Mental fatigue	**·04**	-3·8 (-7·3, -0·3)	**·03**	-4·2 (-7·8, -0·5)	·83	-0·4 (-3·9, 3·1)
Physical fatigue	**·02**	-4·2 (-7·7, -0·6)	·07	-3·3 (-6·9, 0·3)	·62	0·9 (-2·7, 4·4)

CBTAcup, integrated cognitive behavioral therapy and acupressure; CBT, cognitive behavioral therapy; CI, confidence interval; DBAS, Dysfunctional Beliefs and Attitudes about Sleep Scale; ISI, Insomnia Severity Index; MFI, Multidimensional Fatigue Inventory; WL, waitlist control.

[a] Higher score indicates greater severity.

[b] No comparison was conducted in the WL group at Week 11 due to the commencement of treatment.

[c] Linear mixed-effects models.

[d] Based on estimated marginal means.

3.5. Clinical significance

There was a marginally significant difference among the three groups in the proportion of participants who attained a clinically significant improvement in insomnia symptoms (ISI score ≤ 8) at Week 7 (p <·05; Table 4). Post-hoc Fisher's exact tests indicated that only the CBTAcup group was significantly better than the WL in reaching the clinical significance at Week 7 (p <·05). For the CBTAcup group, the number increased from none to 5 out of 12 at Week 7 and Week 11. The number of participants in the CBT group who fulfilled the criterion of clinical significance increased from none to 3 at Week 7 and further increased to 6 at Week 11. No significant difference was found between the CBTAcup and CBT groups in the proportion of achieving clinical significance in ISI at both Week 7 and Week 11 (p >·05). However, the raw data appeared to be slightly higher in the CBTAcup group at Week 7 yet slightly higher in the CBT group at Week 11.

Table 4. The number of participants fulfilled and not fulfilled the criterion of clinical significance at Week 7 and Week 11.

Variables	CBTAcup	CBT	WL[a]	*p*-value[b]
	N fulfilled / *N* not fulfilled	*N* fulfilled / *N* not fulfilled	*N* fulfilled / *N* not fulfilled	
ISI ≤ 8				
Baseline	0/14	0/13	2/11	
Week 7	5/7	3/4	0/9	< ·05
Week 11	5/7	6/1	--	·15

CBTAcup, integrated cognitive behavioral therapy and acupressure; CBT, cognitive behavioral therapy; ISI, Insomnia Severity Index; WL, waitlist control.

[a] One participant from the WL group filled in the ISI questionnaire at Week 7 before subsequent withdrawal.

[b] Fisher's exact tests.

3.6. Treatment evaluation

3.6.1. Expectancy. The CEQ revealed that, before the treatment commencement, 75% of the participants expected an improvement in insomnia symptoms by at least 50% by the end of the treatment. Treatment completers reported improvement by 56·4% on average at Week 7. Before the treatment commenced, participants of all 3 groups expressed a moderate level of expectation towards the treatment in reducing insomnia symptoms. The mean expectation score of symptom reduction before the treatment commenced was 5·7 (*SD* = 1·5) out of a 9-point scale, in which a higher score indicates greater expectation. When answering how much they really felt the therapy had helped to reduce their symptoms at Week 7, the completers of the CBT and CBTAcup groups reported a score of 5·6 and 7·2 respectively.

3.6.2. Credibility. The participants in all 3 groups considered the treatment logical to them. The mean score at baseline was 7·1 (*SD* = 1·1) out of a 9-point scale, in which a higher score indicates 'very logical'. The mean score was maintained at 7·1 (*SD* = 2·1) for the CBT group and increased to 7·9 (*SD* = 1·1) for the CBTAcup group at Week 7. Ninety percent of the participants reported at baseline that they were confident in recommending the treatment to a friend. The mean score of this confidence was 6·0 (*SD* = 1·4) out of a 9-point scale in which

a higher score indicates 'very confident'. The scores of the CBT and CBTAcup groups increased to 6·9 (*SD* = 1·2) and 7·6 (*SD* = 1·0) at Week 7 respectively.

3.7. Post-hoc power analysis

Post-hoc power analysis revealed that the power of the present sample size in determining the difference in ISI score was 99-100% at Week 7 (effect sizes for the CBT and CBTAcup were 2·61 and 1·74 respectively when compared to WL). When the comparison was made only between the CBT and CBTAcup groups, the power of the present sample size was 28% (effect size = 0·55) at Week 7. The effect size estimated in this study suggested that a sample size of 53 in each group will be needed to detect the difference in ISI scores between the CBT and CBTAcup groups at Week 7 with a power level of 80%.

4. Discussion

4.1. Discussion

This study was the first pilot RCT to examine the efficacy of integrated CBT-I and self-administered acupressure in treating insomnia. The results demonstrated that CBT-I with or without self-administered acupressure was effective in improving insomnia, dysfunctional thoughts and beliefs related to sleep, and mental fatigue when compared with the WL group at immediate post-treatment assessment (Week 7). In particular, significant improvements in overall fatigue and physical fatigue were only found in the CBTAcup group. Such improvement in fatigue symptoms brought upon by CBT-I with acupressure was consistent with our speculation that acupressure could address pronounced fatigue symptoms associated with CBT-I. Although both treatment groups obtained significantly superior findings relative to the WL group, no significant difference was detected in the comparison of CBTAcup and CBT groups at Week 7 and Week 11. The findings of the current study appeared to be superior to that of existing literature regarding the effects of CBT-I and acupressure separately on sleep quality. The effect sizes of CBTAcup and CBT (d = 1·74 and 2·61) in our study were comparable to pure CBT-I obtained in other studies, including face-to-face CBT-I (g = 0·98) [9], group CBT-I (g = 0·85) [10], and self-help CBT-I (g = 1·26) [12] relative to WL, treatment as usual, placebo, or no treatment as well as self-acupressure (d = 0·56) [23] relative to sleep hygiene in reducing insomnia symptoms.

CBT-I and acupressure have different mechanisms in treating insomnia. CBT-I aims at changing sleep-related distorted beliefs that serve to promote sleep-disruptive habits. This explains the significant reduction in dysfunctional beliefs and attitudes about sleep in both treatment groups relative to the WL group. In contrast, acupressure, in terms of the TCM theory, aims at regulating the flow of qi, vitalizing the key organs involved in insomnia and thereby reducing sympathetic hyperactivity, promoting relaxation, and improving general health [42].

In our study, a significantly higher proportion of participants in the CBTAcup group achieved an ISI score ≤ 8 compared with the WL group at Week 7. This suggested that acupressure may have brought additional short-term benefits in lowering insomnia severity as acupressure covered more of the physiological aspect of insomnia, which was less emphasized in CBT-I. Though the mechanism of how acupressure reduces insomnia severity requires further investigation, it has been theorized that improvement in sleep is attributed to the activation of the parasympathetic nervous system and reduction of psychological stress when pressure is applied to acupoints such as HT7 [19], which was included in the present study. Also, a previous study showed that acupressure on HT7 significantly improved melatonin and circadian rhythm which have been proved to play a crucial role in sleep [43]. Also, despite insignificance, the raw data showed that the CBT group had a slightly higher proportion of participants who attained clinical improvement in contrast to the CBTAcup group at Week 11. Nevertheless, the findings should be interpreted with caution due to the small sample size. Future studies on a larger scale and longer follow-up are warranted to confirm these findings.

In comparison with the WL group, both treatment groups reported a significantly lower level of mental fatigue, but the improvements in overall fatigue and physical fatigue were only found in the CBTAcup group. With respect to fatigue symptoms, a network meta-analysis showed that there was no significant effect for individual face-to-face CBT-I relative to placebo [44]. We speculated that the additional benefits in fatigue symptoms might be brought by acupressure. Some studies showed that acupressure is effective in reducing fatigue among breast cancer survivors [45], cancer patients undergoing chemotherapy [46], and hemodialysis patients [47]. A systematic review also concluded that acupressure is an effective treatment for reducing fatigue among healthy adults and those with various health problems such as end-stage renal disease [20]. While the biomedical model of acupressure is yet to be established, it was hypothesized that rhythmic stimulation of acupoints with sufficient physical pressure

affects the release of endorphins and changes in the peripheral and central nervous system and hence the level of fatigue [48]. Since short-term improvement in sleep predicted long-term improvement in fatigue [49], it is possible that acupressure improves sleep quality and hence leads to a reduction of fatigue symptoms.

Even though no significant difference was found in all outcome measures between the CBTAcup and CBT groups, the CBTAcup group reported a higher level of perceived helpfulness in symptom reduction at Week 7. Moreover, only the CBTAcup group reported an increase in the level of credibility in terms of how logical they perceived the treatment was at Week 7 and was more confident in recommending the treatment received to others than those in the CBT group. Our findings suggested that the integration of acupressure with CBT-I brought a higher treatment acceptance and credibility. It also supported the findings of a previous study which demonstrated the Chinese's preference towards TCM in treating insomnia [13] and shed light on the need for a culturally adapted therapy for insomnia.

4.2. Strengths and limitations

This study was the first to examine the efficacy of the combination of CBT-I and self-administered acupressure in treating insomnia. Despite its proven efficacy, CBT-I still faces critical obstacles to treatment acceptance and adherence, especially the adoption of sleep restriction which requires a strong willingness to change. The integration of acupressure with the conventional CBT-I has taken both evidence and preference of participants into consideration. Such integration offers an option of culturally adapted therapy for improving insomnia. While CBT-I emphasizes the cognitive and behavioral changes, acupressure covers more of the physiological aspect of insomnia. In particular, self-administered acupressure is easy to learn, cost-effective, and of high acceptance and creditability. The integration suggested in this study has given rise to a holistic approach towards the treatment of insomnia. Self-administered acupressure can potentially be an adjunctive treatment to conventional

psychotherapies and an alternative self-help intervention for patients who cannot afford regular visits to therapists.

Several limitations, apart from the small sample size that required cautious interpretations, were noted in this study. First, findings were based on self-reported assessments instead of objective data such as polysomnography. Thus, sleep state misperception or comorbid conditions which affect sleep might have included. Second, the long-term efficacy of CBT-I and acupressure in the Chinese population was still unclear as data was collected up to 4-week post-treatment only. Third, the CBT and WL control groups reported a relatively high attrition rate. Participants who dropped out might be non-responders or those experienced marked improvement in sleep; hence, results might be based on participants with higher insomnia severity or extreme outcomes remaining in the study. This might have led to under- or over-estimation of the true efficacy of the treatments. Fourth, the present study did not include a sham acupressure control group. We could not rule out the possibility that the sleep improvement was due to the non-specific effects of acupressure such as general physical touch and placebo effects. Future studies may examine the specific effects of acupressure such as the importance of pressing on precise acupoint locations. Finally, recruitment and screening were performed online and all data was collected through a mobile application. Only participants who had Internet access, in possession of a mobile phone, and with basic knowledge in the use of mobile applications could join the study. The generalizability of the study might thus be limited to well-educated individuals.

4.3. Conclusion

In conclusion, integrated CBT and acupressure demonstrated comparable efficacy to pure CBT in treating insomnia symptoms and appeared to be advantageous to improve fatigue symptoms and acceptability in the Chinese population. Although this pilot RCT showed

promising results, the evidence is still preliminary. Future RCTs with larger sample size and longer follow-up are needed to replicate these findings.

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Highlights

- This study provided the first evidence to treat insomnia using integrated CBT-I and acupressure.
- The integrative treatment approach considers both empirical support and patients' treatment preferences.
- Both CBT-I and integrated treatment were effective in reducing insomnia symptoms.
- Integrated treatment showed additional benefits on fatigue symptoms and treatment acceptability and credibility.
- Further studies with larger sample size and longer follow-up are indicated to increase scientific rigor.

CRediT Author Statement

Fiona Ho – Project coordination, study design, data collection and statistical analysis, quality assessment, and manuscript preparation

WT Choi – Treatment delivery, data collection & analysis and manuscript preparation

WF Yeung – Treatment delivery, revision of the draft paper and quality assessment

HK Lam – Data collection and manuscript preparation

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