Title: Self-administered Acupressure for Insomnia Disorder: A Randomized Controlled Trial

Running Head: Self-acupressure for Insomnia

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Author Contributions:

WFY conceived and designed the trial. LXL and ZZJ provided expert opinion to the self-acupressure protocol and training materials. WFY provided training to the self-acupressure instructors. KFC, LKPS, and YYH reviewed the sleep hygiene education training materials and provided training of instructors. BYMY conducted the assessments and drafted manuscript. YMY and LMH analyzed the data. KFC, ZZJ, LKPS, YYH and HYC revised the manuscript. All authors approved the final version accepted for publication.

Abstract

Background: Insomnia is a significant health problem in the community. Self-administered acupressure (SAA) may be an alternative strategy to alleviate insomnia.

Purpose: This study is the first to investigate the effects of SAA delivered through a training course in alleviating insomnia disorder compared with sleep hygiene education (SHE).

Methods: A randomized controlled trial was conducted on 200 participants with insomnia disorder. The eligible participants were randomized into the SAA or SHE group. Both groups attended the allocated training courses (two sessions, 2 h each) and then were followed up at weeks 4 and 8. The primary outcome was the severity of insomnia symptoms and related daytime impairment as measured by the Insomnia Severity Index (ISI). Other measures included a 7-day sleep diary and actigraphy, Hospital Anxiety and Depression Scale (HADS), and Short-Form Six-Dimension (SF6D).

Results: The SAA group showed a significantly greater improvement in ISI score than the SHE group at week 4 (mean difference: -1.89 units, 95% CI: 0.85, 2.93; Cohen's d = 0.51, P < 0.001) and week 8 (mean difference: -2.89 units, 95% CI: 1.67, 4.11; d = 0.67, P < 0.001). In addition, the SAA group showed a greater reduction in the HADS anxiety score and HADS depression score and increase in SF6D at week 8.

Conclusions: SAA taught in a short training course is a feasible and effective approach to improve sleep and related daytime impairment and mood problems in individuals with insomnia disorder.

Keywords

Sleep; acupuncture; self-help; self-acupressure; sleep hygiene.

Clinical Trial Registration: Self-administered Acupressure for Insomnia Disorder https://clinicaltrials.gov/ct2/show/NCT03623438, ClinicalTrials.gov: Identifier: NCT03623438.

Abbreviations: CTRS, Credibility of Treatment Rating Scale; HADS, Hospital Anxiety and Depression Scale; ISI, Insomnia Severity Index; RCTs, randomized control trials; SAA, self-administered acupressure; SDs, standard deviations; SE, sleep efficiency; SF6D,Short-FormSix-Dimension; SHE ,sleep hygiene education; SOL, sleep onset latency; TCM, traditional Chinese medicine; TIB ,total time in bed; TST, total sleep time duration; WASO, wake time after sleep onset.

Introduction

Insomnia is a prevalent sleep disorder, which is associated with an increased risk of depression, anxiety disorders, substance abuse, suicide, and cardiovascular diseases (Khurshid, 2018; Zheng et al., 2019). Insomnia is defined as consistent dissatisfaction about sleep and significant impairment in daytime functioning with the presence of at least one insomnia symptoms (difficulty in initiating sleep, difficulty in maintaining sleep, and difficulty in re-initiating sleep, and early-morning awakening) for at least 3 months (American Psychiatric Association, 2013). Early diagnosis and treatment of insomnia are crucial because when left untreated, this condition may lead to the development of anxiety and depressive disorders (Khurshid, 2018). Pharmacotherapies such as benzodiazepines and non-benzodiazepine hypnotics are effective against insomnia but are associated with abuse, dependence, and uncertain efficacy with long-term use (Khurshid, 2018; Misra and Sharma, 2017). Recommended first-line psychological and behavioral therapies, such as cognitive behavioral therapy for insomnia, are also effective but have remained largely underutilized possibly due to the shortage of specialists (Ng and Cunnington, 2021).

Given the limitations of conventional treatments, patients with insomnia commonly seek alternative treatment to improve their sleep. Acupressure is a non-invasive variant of acupuncture and a treatment

modality in traditional Chinese medicine (TCM). Previous systematic reviews have observed a positive effect of acupressure on sleep quality (Hmwe et al., 2016; Song et al., 2015; Waits et al., 2018; Yeung et al., 2012). Acupressure can be taught to patients to allow them to perform this practice on themselves, instead of being administered by practitioners. Self-administered acupressure (SAA) is less time-intensive, low cost, and flexible to perform. Despite the scarcity of studies investigating the effects of SAA, the latest systematic review found the positive effects of SAA on improving sleep quality on cancer patients, menopausal women, and hypertensive patients in four randomized control trials (RCTs)(Waits et al., 2018). However, these RCTs examined a rather specific population without a precise insomnia diagnosis. RCTs on insomnia disorders in general adult population are lacking. Therefore, the present RCT investigated the effects of SAA in alleviating insomnia compared with sleep hygiene education (SHE). We hypothesized that the SAA group would exhibit greater improvement in insomnia symptoms and daytime impairment compared with the SHE group at weeks 4 and 8.

Methods

Study Design

This study was a two-arm, assessor-blind, pragmatic RCT comparing SAA and SHE delivered through a short training course for insomnia disorder. All procedures involving human subjects/patients were approved by the Human Subjects Ethics Subcommittee of Hong Kong Polytechnic University (HSEARS20171121002). This study was registered at ClinicalTrials.gov (NCT03623438).

Participants

Sample size calculation was based on our pilot study(Yeung et al., 2018a). A sample size of 100 participants per group was needed to detect an effect size of 0.48 with 80% power, assuming a significance level of 0.05 and 30% attrition rate. Participants were recruited through study posters in university campuses and online advertisement through social media platform from October 2018 to

September 2020. This work was advertised as a clinical trial of SAA and SHE courses for insomnia. Participants were eligible if they met the following criteria: (1) Chinese Hong Kong residents who can communicate in Cantonese; (2) aged 18–64 years; (3) fulfilled the diagnostic criteria for insomnia disorder in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition through the Brief Insomnia Questionnaire(Chung et al., 2014). The criteria included having difficulties in falling asleep, difficulties in staying asleep, or early morning awakening with clinically significant consequences for daily life for at least 3 months; (4) Insomnia Severity Index (ISI)(Bastien et al., 2001) total score of at least 10 indicating insomnia at the clinical level(Morin and Benca, 2012); and (5) willingness to give informed consent. The exclusion criteria included: (1) receiving acupuncture or practitioner-delivered acupressure in the past 6 months; (2) pregnant; (3) exhibits cognitive impairment as indicated by a Hong Kong Montreal Cognitive Assessment score <22; (4) at significant suicidal risk as rated by the Hamilton Depression Rating Scale item on suicide (score ≥ 3); (5) experiencing comorbid sleep disorders primarily requiring other treatments, such as sleep apnea or narcolepsy; (6) taking psychotropic drugs that target insomnia within 2 weeks prior to baseline; and (7) shift-workers.

Randomization and blinding

The study was advertised as a comparison of two education courses for improving insomnia. All eligible participants were randomized into the SAA or SHE group in a 1:1 ratio. An independent researcher generated the randomization code using a computer-generated block with random block size. The group allocations were enclosed in sequentially numbered opaque envelopes. The participants opened the envelopes after having finished baseline assessment. Assessors were blinded to group allocation.

Study Intervention

The SAA and SHE courses were matched for time and practitioner contact (two sessions, 2 hours each, 1 week apart). The training materials have been reviewed by expert investigators and tested in previous

studies (Yeung et al., 2018a; Yeung et al., 2018b). The instructors for SAA were registered Chinese medicine practitioners with at least 5-year clinical experience, while the SHE courses were instructed by registered nurses who had teaching experience. The instructors were trained and inspected by the investigators.

SAA

The SAA treatment protocol (Appendix 1) included 6 acupoints, namely, Baihui (GV20) and Zhongwan (CV12) and bilateral Fenchi (GB20), Neiguan (PC6), Shenmen (HT7), and Yongquan (K11), which was developed by the team members who are experienced acupuncturists (L.X.L and Z.J.Z) based on our previous systematic review (Yeung et al., 2012) and theoretical basis of TCM (Zhang et al., 2014). In brief, during the first lesson, the participants were given an introduction to acupressure and TCM meridian theory, followed by group training and practice on locating acupoints and acupressure techniques. The functions of acupoints were also explained. In the second lesson, the participants were encouraged to raise questions regarding their self-acupressure practice at home during the past week and have a revision to refresh their memory of the first session. The participants were then asked to practice the self-acupressure again for final checking. Participants in this group would learn the knowledge and technique of self-administered acupressure using their fingers, followed by group practice.

Fidelity of self-administered acupressure

Participants' capability of performing the acupressure technique was evaluated by the instructor with a competency checklist in each lesson. The checklist included four domains: accuracy of locating acupoints, acupressure technique, strength, and frequency of acupressure at each acupoint. Any gaps identified were corrected, and instructions were given to ensure their mastery of acupressure technique. The participants then performed the acupressure every night for about 10–15 min for 4 weeks. A phone number was given to subjects to contact the student research assistant when they had any queries regarding the acupressure. The training materials were prepared, reviewed, and approved by the

research team's senior acupuncturist (LL and ZZ). The PI had trained and inspected the instructor's demonstration with random visits.

<u>SHE</u>

Participants in the SHE group were taught and reminded to follow the sleep hygiene practice daily for 4 weeks. Briefly, the first lesson included introduction of facts about sleep and insomnia and explanation of sleep hygiene items through completing the Sleep Hygiene Practice Scale (Lin et al., 2009) and Caffeine Knowledge Quiz (Anderson et al., 2009), and the influence of poor sleep hygiene on the maintenance of their sleep problems, namely, the importance of restriction of stimulants, regularity of meals and sleep—wake pattern, arrangement of a pleasant sleep environment, merits of enhancing daytime activity, and problems of taking naps. During the second lesson, the participants were encouraged to raise questions regarding their sleep hygiene practice at home during the past week, and the content in the first lesson was reviewed. Finally, the subjects completed the Sleep Hygiene Practice Scale again to reinforce their learning. The participants were provided the same amount of contact hours with the research personnel to control the normal progression of insomnia and the non-specific effects of practitioner—patient interaction in the SAA group.

Fidelity of SHE delivery by instructors

The SHE courses were instructed by a registered nurse who had teaching experience. Similar to those in the SAA group, all training materials were prepared, reviewed, and approved by the research team. The team's psychiatrist (KC), clinical psychologist (FH), and registered nurse (LS) had trained and inspected the instructor's demonstration.

All participants were phoned twice a week for the first 4 weeks to remind them to practice acupressure or sleep hygiene. The training course and the assessment schedule are shown in **Figure 1**. The participants were encouraged to continue practicing during weeks 5–8, but no telephone reminder was

performed during this follow-up period. The frequency of reminders in both groups was identical.

Outcome assessment

Major assessments were conducted at baseline, week 4, and week 8 by a research assistant who was blinded to the group allocation. The primary outcome measure was ISI (Bastien et al., 2001), a sevenitem self-rated questionnaire on perceived severity of insomnia symptoms, impairments in daytime functioning, and associated distress (Bastien et al., 2001).

Secondary measures included: the subjective 7-day daily record of sleep parameters using a standardized sleep diary (Carney et al., 2012), namely, sleep onset latency (SOL), wake time after sleep onset (WASO), total sleep time duration (TST), total time in bed (TIB), and sleep efficiency (SE); objective sleep parameter data collected by 7-day wrist actigraphy; mood symptoms assessed with the Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983); and health-related quality of life by the Short-Form Six-Dimension (SF6D) (Brazier et al., 2002). The validated Chinese versions of ISI(Chung et al., 2011), HADS(Leung et al., 1999), and SF6D(Lam et al., 2008) were used. Expectations about the effect and the credibility of treatment rationale were assessed by the Credibility of Treatment Rating Scale (CTRS) (Vincent, 1990).

At the end of training courses, the participants' acceptability toward the intervention received was assessed by using a single-item scale from 0 to 10 about their willingness to learn about SAA or SHE in accordance with the group allocation. Intervention compliance throughout the study period was assessed using the daily record of acupressure and sleep hygiene log.

Data Analysis

SPSS 26.0 was used to perform the statistical analysis. Intention-to-treat and per-protocol analysis approaches were performed. Sociodemographic information and baseline measures were presented by

descriptive statistics in means and standard deviations (SDs) or in numbers and percentages. The differences of ISI (primary outcome) and other outcome measures between the two groups were examined for the group-by-time point interaction effect (from baseline to weeks 4 and 8). Missing data were handled with multilevel modeling. Statistical significance was set at the 0.05 level for all analyses. Within- and between-group effect sizes were calculated with estimated means and pooled SDs for both groups and expressed as Cohen's *d*. Clinical significance was determined using remission (ISI score, \leq 7) (Morin et al., 2011), sleep-diary-derived SOL or WASO less than 30 min, or having SE of at least 85%. The proportion of achieving clinical significance in both groups was compared with χ^2 tests. Sensitivity analysis was performed to assess the impact of missing values on the treatment effect by multiple imputation with 10 sets of imputations; participants' expectation toward the allocation in the intervention at baseline, as measured by the CTRS, was adjusted as covariates to control the possible non-specific effect due to difference in the preference of interventions.

Results

Subject characteristics

Two hundred participants (age, mean [SD] = 48.0 [12.8] years, range = 20 to 64 years; 150 females, [75.0%]) with insomnia disorder were randomized to the SAA (n = 100) and SHE (n = 100) groups (**Figure 2**). Participant baseline characteristics are shown in **Table 1**. The participants reported a mean (SD) ISI score of 16.7 (3.7) and mean (SD) insomnia duration of 6.1 (7.7) years.

Treatment acceptability, fidelity, and compliance

Ninety-seven participants completed the two-session SAA training course and rated high in the overall rating of acceptability (mean [SD], 9.18 [0.99], range: 7–10). All participants in the SAA group passed the fidelity check of acupressure techniques at the end of training. The participants who returned their logbooks (91 and 87 at weeks 1–4 and weeks 5–8, respectively) practiced the acupressure for an average of 6.66 days during the first 4 weeks (13.40 [5.6] min per day, range: 4.9–32.9 min) and 6.52

days per week during weeks 5–8 (12.70 [5.7] min per day, range: 1.43–30.00 min). For the SHE group, 97 participants completed the course (acceptability rating, 8.32 [1.64], range: 5–10); 92 and 90 returned their logbooks at weeks 1–4 and 5–8, respectively. Among those who returned their logbooks, 75.0% and 80.5% followed at least eight out of 10 items of the recommended sleep hygiene instructions during weeks 1–4 and 5–8, respectively.

Primary outcome

From baseline to week 4, the average ISI score decreased by 4.68 points in the SAA group and 2.79 points in the SHE group; the SAA group showed significantly better improvement in ISI score compared with the SHE group (Cohen's d = 0.51, P < 0.001). The group differences were sustained at week 8 (d = 0.67, P < 0.001) by mixed-effect model (**Figure 3**). Sensitivity analyses revealed that the observed greater reduction in the ISI score in the SAA group compared with that in the SHE group was not altered with the adjustment of baseline difference (all P < 0.001), adjustment of CTRS scores (all P < 0.001), and missing value handled by multiple imputation (week 4, P = 0.001; week 8, P < 0.001).

Secondary outcomes

At week 4, the sleep-diary-derived TST in the SAA and SHE groups increased by 34.02 and 17.03 min, respectively. The sleep-diary-derived SE in the SAA and SHE groups increased by 6.61% and 3.48%, respectively. The SAA group had higher sleep-diary-derived TST (d = 0.32, P = 0.03) and SE (d = 0.30, P = 0.03) than the SHE group at week 4 but not at week 8, probably due to the increase of TST in the SHE group at week 8 (**Table 2**). No between-group difference was found in SOL or WASO at week 4 or 8.

For the objective sleep parameters by wrist actigraphy, none of the results from SOL, WASO, TST, nor SE reached statistically significant levels across all assessment time points (**Table 2**).

Table 3 shows that the SAA group had greater improvement in HADS-anxiety score (MD, 1.03 units, 95% CI: 0.21, 1.85; d = 0.35, P = 0.02), HADS-depression score (MD, 0.93 units, 95% CI: 0.01, 1.85; d = 0.28, P = 0.049), and SF6D (MD, 0.04 units, 95% CI: 0.01, 0.07; d = 0.40, P = 0.02) than the SHE group at week 8 but not at week 4. In the model adjusted with baseline scores, the significant between-group difference in HADS-anxiety and SF6D score at week 8 was not altered, but the difference in HADS-depression score became insignificant (P = 0.05).

Clinical significance

The proportion of participants in the SAA group with ISI score <8 (24.7% vs 5.3%, P < 0.001, **Table** 4) at week 8 was significantly higher than that in the SHE group. However, no differences in the percentage of other clinically significant criteria using sleep parameters were found between the two groups.

Adverse events

The adverse events reported in the SAA group included bloating (n = 4, 4%), stomach ache (n = 2, 2%), painful feeling at acupoints (n = 2, 2%), bruise at the acupoint (n = 1, 1%), and dizziness after pressing (n = 1, 1%). All adverse events were mild in severity and self-resolved.

Discussion

This RCT is the first to demonstrate that SAA taught by a short training course was more effective than SHE in improving insomnia severity in individuals with insomnia disorder using both subjective and objective sleep measures. Compared with the SHE group, the SAA group showed longer TST and higher SE at week 4, although the between-group differences were not significant at week 8, probably due to the delayed improvement in the SHE group. The SAA group also showed greater improvement in depression, anxiety, and quality of life at week 8 than the SHE group. Most of the subjects in the

SAA group had learnt the acupressure technique and showed high compliance in home practice.

Our findings showed that acupressure administered by participants produced a moderate effect size in the improvement of ISI score (d = 0.51-0.67), which was in line with our pilot study (d = 0.56). Previous RCTs of self-acupressure on sleep adopted sham acupressure or waiting list as a control and studied a relatively specific population, such as menopausal women, people with hypertension, and lung cancer patients undergoing chemotherapy (Abedian et al., 2015; Tang et al., 2014; Zheng et al., 2014), which makes direct comparison with the present study not plausible. Similar to our comparison group design, the study by Zeng et al. adopted sleep health instructions as a control group to examine the effects of SAA on the elderly with poor sleep (Zeng et al., 2016). In contrast to the present study, they found a significantly large effect size (d = 1.54) on improving the sleep questionnaire score (Zeng et al., 2016). Such difference may be attributed to the longer treatment duration (12 months), higher treatment intensity (30 min, twice per day), and additional home visits in their research compared with the present work. Further studies are warranted to explore the optimal dose for SAA.

A great diversity exists in sham acupressure controls being adopted in previous clinical studies. In a systematic review of sham design in acupressure trials, "non-acupoint" stimulation was found to be the most frequently used sham design. However, the location of inert non-acupoints are difficult to define (Tan et al., 2015). In the present study, SHE was used as a comparison group. SHE has been commonly adopted as a comparison group in the RCTs of self-help and psychological interventions for insomnia (Chung et al., 2018). This practice provided the subjects the same amount of contact hours with the healthcare professional to control the non-specific effect of practitioner–patient interaction in the SAA group and the normal progression of insomnia, but not the placebo effects. However, designing an adequate placebo for a complex non-pharmacological intervention such as acupuncture or acupressure is difficult because the treatment characteristics may also contribute to the non-specific effects of the treatment (Chen et al., 2016; Paterson and Dieppe, 2005). Although the

present study did not examine the specific effects of precise acupoint stimulation, our findings showed that the participants still benefited from the SAA intervention compared with SHE, a commonly used self-help strategy in individuals with insomnia. Such a comparison will provide more clinically relevant information to clinicians, practitioners, and patients.

This study has several limitations. First, a formal polysomnography screening was not adopted although we excluded patients diagnosed with other sleep disorders such as sleep apnea and narcolepsy. This situation reflects that the SAA training course can be performed in a community in which polysomnography screening is not always available. Second, the participants were relatively well educated with more than 50% having tertiary education. The impact of education on the outcome should be assessed in future studies. Finally, this study did not examine the specific effects of precise acupoint stimulation, and further sham-controlled studies are needed to control the placebo effect and non-specific effect of physical pressure on the body.

Conclusions

SAA taught in a short training course is a feasible and effective approach to improve sleep and related daytime impairment and mood problems in individuals with insomnia disorder. This strategy is a feasible and easy-to-learn self-help intervention that can help insomnia sufferers in the community.

Author contributions: YWF conceived and designed the trial, and supervised the conduct of the trial. YYM monitored the recruitment and acquisition of data. CKF, ZZJ, LLX, HYY, and SKP advised on the treatment procedure and other theoretical aspects. YYM analyzed the data with the advice provided by HLM on statistical analysis. YWF and YYM drafted the final manuscript and were involved in the interpretation of the results. All co-authors contributed to reviewing the manuscript. All data were generated in-house, and no paper mill was used. All authors agreed to be accountable for all aspects of the work ensuring integrity and accuracy.

Declaration of interest: The authors declared no relationships with any organizations that might have an interest in this study or might have influenced this study.

Ethics approval and consent to participate

The trial protocol was approved by the Human Subjects Ethics Subcommittee of Hong Kong Polytechnic University (HSEARS20171121002), and this study was registered at ClinicalTrials.gov (NCT03623438). All subjects provided written informed consent to participate in this study and publish their data.

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Conclusions and Relevance: SAA taught in a short training course is a feasible and effective approach to improve sleep and related daytime impairment and mood problems in individuals with insomnia disorder. The SAA course and training materials can be disseminated by healthcare providers in the community and clinical setting. Owing to its non-invasive and less time-intensive nature, this therapy will be an acceptable first step to care for patients with insomnia who are reluctant to take hypnotics or seek formal medical consultations.

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8		5	1	
Variables ^a	All sample	SAA	SHE	Standardized
	(<i>N</i> =200)	(<i>n</i> =100)	(<i>n</i> =100)	difference
Age, years	48.0 (12.8)	47.6(12.7)	48.5((12.9)	0.07
Female	150 (75.0)	74 (74.0)	76 (76.0)	0.05
BMI, kg/m ²	22.3 (3.5)	22.4 (3.5)	22.3 (3.6)	0.05
Marital status				0.07
Single	59 (29.5)	31 (31.0)	28 (28.0)	
Cohabitation/Married	123 (61.5)	60 (60.0)	63 (63.0)	
Widowed/divorced	18 (9.0)	9 (9.0)	9 (9.0)	
Education level				0.25
Secondary education or below	82 (41.0)	35 (35.0)	47 (47.0)	
Tertiary education	118 (59.0)	65 (65.0)	53 (53.0)	
Occupation				0.37
Employed	102 (51.0)	54 (54.0)	48 (48.0)	
Economically inactive	80 (40.0)	34 (34.0)	46 (46.0)	
Unemployed	4 (2.0)	4 (4.0)	0 (0.0)	
Self-employed ^b	14 (7.0)	8 (8.0)	6 (6.0)	
Insomnia duration, years	6.1 (7.7)	5.4 (7.1)	6.8 (8.1)	0.19
With chronic disease ^c	41 (20.5)	22 (22.0)	19 (19.0)	0.07
History of psychiatric comorbidities	12 (6.0)	4 (4.0)	8 (8.0)	0.17

Table 1. Socio-demographic and Clinical Characteristics of the Study Participants

Abbreviations: BMI, Body Mass Index; SAA, Self-administered Acupressure; SHE,

Sleep Hygiene Education.

^a Data are presented as mean (standard deviation) or number (%).

^b Self-employment included freelancers, post-natal care workers, coaches, merchants, and investors.

^c Chronic disease referred to chronic medication conditions required current

treatment/medication, such as chronic pain, anemia, hypertension, gastritis, knee osteoarthritis and asthma.

Outcomes	SAA (n=100)		SHE (<i>n</i> =100)		P-value ^b	Cohen's d
	Mean (SD) ^a	Change from baseline,	Mean (SD) ^a	Change from baseline,		(95% CI) ^c
		mean (SD)		mean (SD)		
<u>ISI, ranged 0–28</u>						
Baseline	16.00 (36.70)		17.38 (4.47)			
Week 4	11.32 (37.30)	-4.68 (34.00)	14.59 (4.54)	-2.79 (4.03)	< 0.001	0.51 (0.22 to 0.79)
Week 8	10.41 (37.70)	-5.59 (41.10)	14.68 (4.55)	-2.70 (4.55)	< 0.001	0.67 (0.38 to 0.95)
<u>Sleep Diary</u>						
Sleep Onset Latency, min						
Baseline	44.06 (31.91)		48.49 (36.85)			
Week 4	31.84 (33.14)	-12.23 (31.98)	39.54 (37.84)	-8.95 (32.41)	0.47	0.10 (-0.18 to 0.38)
Week 8	34.05 (33.42)	-10.01 (31.05)	35.62 (38.32)	-12.87 (35.23)	0.55	-0.09 (-0.36 to 0.19)
Wake After Sleep Onset, min						
Baseline	42.84 (27.38)		45.43 (38.46)			
Week 4	29.91 (28.43)	-12.93 (27.60)	34.36 (39.29)	-11.07 (29.98)	0.67	0.06 (-0.21 to 0.34)
Week 8	22.56 (29.02)	-20.28 (32.89)	33.78 (39.78)	-11.65 (33.93)	0.08	0.26 (-0.02 to 0.54)
Total Sleep Time, min						
Baseline	332.41 (63.93)		327.19 (74.03)			
Week 4	366.43 (65.74)	34.02 (52.80)	344.22 (75.49)	17.03 (54.08)	0.03	0.32 (0.04 to 0.60)
Week 8	369.60 (66.48)	37.19 (56.82)	353.12 (76.06)	25.93 (56.30)	0.16	0.20 (-0.08 to 0.48)
Sleep Efficiency, %						
Baseline	73.32 (12.60)		71.66 (15.74)			
Week 4	79.93 (12.92)	6.61 (9.79)	75.14 (15.98)	3.48 (9.91)	0.03	0.30 (0.02 to 0.58)
Week 8	80.27 (13.09)	6.95 (11.06)	77.32 (16.13)	5.67 (11.61)	0.42	0.11 (-0.16 to 0.39)
<u>Actigraphy</u>						
Sleep Onset Latency, min						
Baseline	20.79 (16.39)		19.66 (15.10)			
Week 4	20.08 (17.88)	-0.71 (18.04)	18.03 (16.20)	-1.63 (14.50)	0.68	-0.06 (-0.33 to 0.22)
Week 8	18.37 (18.38)	-2.42 (18.97)	19.66 (16.72)	-0.69 (14.62)	0.50	0.10 (-0.18 to 0.38)

Table 2. Insomnia Severity Index, Subjective and Objective Sleep Parameters across Timepoints

Wake After Sleep Onset, min						
Baseline	32.96 (20.22)		35.10 (25.62)			
Week 4	30.72 (21.97)	-2.24 (21.33)	34.34 (26.71)	0.76 (18.68)	0.59	0.07 (-0.20 to 0.35)
Week 8	31.64 (22.33)	-1.32 (20.89)	38.25 (27.75	3.15 (22.57)	0.15	0.21 (-0.07 to 0.48)
Total Sleep Time, min						
Baseline	394.69 (52.22)		395.25 (53.50)			
Week 4	401.19 (55.15)	6.50 (42.62)	397.69 (57.17)	2.44 (50.48)	0.55	0.09 (-0.19 to 0.36)
Week 8	398.00 (55.98)	3.31 (43.68)	391.69 (59.97)	-3.56 (57.64)	0.34	0.13 (-0.14 to 0.41)
Sleep Efficiency, %						
Baseline	85.45 (6.81)		85.18 (7.18)			
Week 4	86.30 (7.25)	0.84 (6.07)	85.95 (7.56)	0.77 (5.88)	0.93	0.01 (-0.27 to 0.29)
Week 8	86.56 (7.45)	1.11 (6.76)	84.89 (7.91)	-0.29 (7.09)	0.16	0.20 (-0.08 to 0.48)

Abbreviations: CI, Confidence Interval; ES, Effect Size; ISI, Insomnia Severity Index; SE, Standard Error; SAA, Self-administered Acupressure; SHE, Sleep Hygiene Education.

^a Mean and standard error from linear mixed-effects model.

^b P-value for group by time interaction by linear mixed-effects models.

^c Cohen's *d* effect sizes calculated as the between-group difference in the mean changes from baseline divided by a pooled standard deviation. A positive sign was used to denote a superior effect in the SAA group to the SHE group.

Outcomes	SAA (<i>n</i> =100)		SHE (<i>n</i> =100)		<i>P</i> -value ^b	Cohen's d
	Mean (SD) ^a	Change from baseline, mean (SD)	Mean (SD) ^a	Change from baseline, mean (SD)	-	(95% CI) ^c
HADS Anxiety subscore, re	anged 0–21					
Baseline	8.21 (3.69)		8.93 (3.70)			
Week 4	7.42 (3.75)	-0.79 (2.94)	8.24 (3.74)	-0.70 (2.71)	0.80	0.03 (-0.24 to 0.31)
Week 8	6.57 (3.75)	-1.65 (3.00)	8.31 (3.74)	-0.62 (2.89)	0.02	0.35 (0.07 to 0.63)
HADS Depression subscor	re, ranged 0–21					
Baseline	6.73 (3.57)		7.79 (3.80)			
Week 4	5.71 (3.64)	-1.02 (3.10)	7.20 (3.85)	-0.59 (3.10)	0.33	0.14 (-0.14 to 0.41)
Week 8	5.22 (3.65)	-1.51 (3.44)	7.21 (3.86)	-0.58 (3.20)	0.049	0.28 (0.00 to 0.56)
SF6D, ranged 0–1						
Baseline	0.70 (0.12)		0.66 (0.12)			
Week 4	0.74 (0.12)	0.04 (0.10)	0.70 (0.13)	0.05 (0.12)	0.56	-0.08 (-0.36 to 0.20)
Week 8	0.78 (0.12)	0.08 (0.11)	0.69 (0.13)	0.04 (0.13)	0.02	0.40 (0.12 to 0.68)

Table 3. Anxiety and Depressive Symptoms, and Health-related Quality of Life across Timepoints

Abbreviations: CI, Confidence Interval; ES, Effect Size; HADS, Hospital Anxiety and Depression Scale; SE, Standard Error; SAA, Selfadministered Acupressure; SF6D, Short-Form Six-Dimension Health Survey; SHE, Sleep Hygiene Education.

^a Mean and standard error from linear mixed-effects model.

^b P-value for group by time interaction by linear mixed-effects models.

^c Cohen's *d* effect sizes calculated as the between-group difference in the mean changes from baseline divided by a pooled standard deviation. A positive sign was used to denote a superior effect in the SAA group to the SHE group.

Assessment Point	SAA	SHE	<i>P</i> -value ^b
	<i>n</i> /N (%) ^a	<i>n</i> /N (%) ^a	
<u>ISI score < 8</u>			
Week 4	15/95 (15.8)	7/95 (7.4)	0.07
Week 8	23/93 (24.7)	5/95 (5.3)	< 0.001
Sleep onset Latency < 30 min			
Week 4	54/90 (60.0)	55/91 (60.4)	0.95
Week 8	54/87 (62.1)	48/88 (54.5)	0.31
Wake after Sleep onset < 30 min			
Week 4	54/90 (60.0)	51/91 (56.0)	0.59
Week 8	63/87 (72.4)	56/88 (63.6)	0.21
<u>Sleep Efficiency ≥ 85%</u>			
Week 4	34/90 (37.8)	32/91 (35.2)	0.72
Week 8	39/87 (44.8)	36/88 (40.9)	0.60

 Table 4. Group Comparison of Participants who Achieved Clinically

 Significant Criteria

Abbreviations: ISI, Insomnia Severity Index; SAA, Self-administered Acupressure; SHE, Sleep Hygiene Education.

^a Number of participants meeting criterion from total number of participants analyzed.

^b Group differences were compared with Chi-square test.