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## **Title: Self-administered Acupressure for Insomnia Disorder: A Pilot Randomised Controlled**

### **Trial**

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## ABSTRACT

Self-administered acupressure has potential as a low-cost alternative treatment for insomnia. To evaluate the short-term effects of self-administered acupressure for alleviating insomnia, a pilot randomised controlled trial was conducted. Thirty-one subjects (mean age: 53.2 years old; 77.4% female) with insomnia disorder were recruited from a community. The participants were randomised to receive two lessons on either self-administered acupressure or sleep hygiene education. The subjects in the self-administered acupressure group ( $n = 15$ ) were taught to practice self-administered acupressure daily for four weeks. The subjects in the comparison group ( $n = 16$ ) were advised to follow sleep hygiene education. The primary outcome was the Insomnia Severity Index (ISI). Other measures included a sleep diary, Hospital Anxiety and Depression Scale and Short-form Six-Dimension. The subjects in the self-administered acupressure group had a significantly lower ISI score than the subjects in the sleep hygiene education group at week 8 (effect size = 0.56,  $P = 0.03$ ). However, this observed group difference did not reach a statistically significant level after Bonferroni correction. As for the secondary outcomes, moderate between-group effect sizes were observed in sleep onset latency and wake after sleep onset based on the sleep diary, although the differences were not significant. The adherence to self-administered acupressure practice was satisfactory, with 92.3% of the subjects who completed the lessons still practicing acupressure at week 8. In conclusion, self-administered acupressure taught in a short training course may be a feasible approach to improve insomnia. Further fully-powered confirmatory trials are warranted.

**Trial registration number** ClinicalTrials.gov, #NCT03053648

**Keywords:** Acupressure; self-acupressure; sleep; TCM; self-help; RCT

## INTRODUCTION

Insomnia is a common sleep disorder that is associated with fatigue irritability, impaired daytime functioning, disturbed mood and even suicide (Buysse, 2013, Perlis et al., 2016) (Taylor et al., 2007). The prevalence of insomnia accompanied by daytime consequences among the general population worldwide is around 9% to 15% (Ohayon and Reynolds, 2009). In Hong Kong, 10.8% of the general population fulfilled the insomnia disorder diagnosis according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) (Chung et al., 2015a).

Conventional pharmacological and psychological treatments for insomnia are effective, but these therapies have their limitations. Pharmacotherapies, such as benzodiazepines and non-benzodiazepine hypnotics, are associated with abuse and dependence, and they have uncertain efficacy with long-term use (Buysse, 2013). Cognitive behavioural therapy (CBT) is supported by a large body of evidence that it is efficacious in various delivery modalities, including in individual (Hofmann et al., 2012), in group (Koffel et al., 2015), and as a self-help intervention (Ho et al., 2015). CBT for insomnia assists patients to identify and modify perpetuating factors that maintain insomnia, including cognitive factors (e.g., dysfunctional beliefs and unrealistic expectations), behavioural factors (e.g., irregular sleep-wake patterns and poor sleep habits), and physiological factors (e.g., arousal and tension) (Morin and Benca, 2012). Nonetheless, CBT requires extensive behavioural changes and patients' time for effective implementation (Morin and Benca, 2012).

Given the limitations of conventional treatments, patients with insomnia commonly seek complementary health approaches (CHAs) to improve their sleep, but these CHAs usually lack rigorous evidence to support their use (Leach and Page, 2015, Sarris and Byrne, 2011). CHA, as defined by National Institute of Health, are medical and health care systems, practices, and products that derived from outside the mainstream medicine (National Institute of Health, 2016). A previous survey on the use of therapies for insomnia within previous 12 months revealed that 17.6% of the subjects with insomnia and daytime consequences had taken prescribed medication to improve their sleep, whereas 32.1% had used at least one CHA, and 3.9% had tried acupressure (the fifth most commonly used CHA) (Yeung et al., 2014). Acupressure is a treatment modality in traditional Chinese medicine (TCM) and a non-invasive variant of acupuncture, in which the

practitioner stimulates the patient's acupoints with the use of fingers, hands or elbows to facilitate the flow of *qi* (vital energy) along the meridian. However, the mechanisms for the action of acupressure in improving sleep have not been fully investigated. While CBT targets dysfunctional beliefs and attitudes about sleep as well as two-process model of sleep-wake regulation involving circadian rhythm and sleep-wake homeostasis (Morin and Benca, 2012, Borbely, 1982), the effects of acupressure on sleep are proposed to involve the activation of the parasympathetic nervous system, increases in autonomous responses and reduction of psychological stress (Waits et al., 2016). An RCT indicated that giving physical pressure to HT7 with a wrist acupressure band improved the patients' sleep quality and increased melatonin levels (Nordio and Romanelli, 2008). An fMRI study found that needling at CV12 in healthy subjects could modulate the limbic–prefrontal functional network, which is overlapped with the functional circuits associated with emotional and cognitive regulation (Fang et al., 2012). Needling at PC6 could reduce heart rate and systolic blood pressure in healthy subjects, suggesting a sympatho-inhibitory effect (Abad-Alegria et al., 2001). However, more research is needed to explore the mechanism of physical pressure on acupoints which will allow a more in-depth comparison of acupressure and other conventional treatments for insomnia.

Acupressure may not be the most popularly used CHA, but previous studies suggested that it has obvious effects on improving sleep, which can be a potential treatment alternative. According to previous systematic reviews on acupressure for improving sleep (Yeung et al., 2012, Hmwe et al., 2016, Song et al., 2015, Waits et al., 2016), most of the included randomised controlled trials (RCTs) investigated practitioner-administrated acupressure. The latest meta-analysis identified 13 RCTs (Waits et al., 2016), and self-administered acupressure was examined in only four RCTs involving cancer patients undergoing chemotherapy, menopausal women and patients with hypertension. These four studies revealed the positive effects of self-administered acupressure on improving sleep quality, and the pooled-analysis suggested that self-administered acupressure improved the Pittsburgh Sleep Quality Index score (PSQI) score in comparison with the sham and no treatment control (standardized mean difference =1.21,  $P<0.001$ ) (Waits et al., 2016). A recent RCT not included in the previous systematic reviews examined self-administrated acupressure in the elderly with complaints of sleep quality and revealed that the subjects who received self-acupressure training achieved greater improvement in PSQI scores in comparison with those who

received sleep health education (effect size = 1.53) (Zeng et al., 2016).

Although previous studies seemingly suggested that self-administered acupressure may improve sleep quality, their conclusion about the efficacy of self-administered acupressure for insomnia was limited because of imprecise diagnostic methods and lack of assessment of sleep parameters. The previous studies were rated as having high or unclear risks of bias because of problems in allocation concealment, blinding of outcome assessor and participant compliance (Waits et al., 2016). In addition, none of the previous studies examined the effects of self-administered acupressure on general adults with insomnia disorder. Given the limitation of previous RCTs and seemingly large effect sizes observed in the previous systematic reviews, it is warranted to examine the effects and feasibility of self-administered acupressure using a more rigorously designed RCT. Therefore, we proposed to conduct a pilot RCT of self-administered acupressure for adults with insomnia disorder. The specific aims of this study are: (1) to test the feasibility and acceptability of training subjects to perform self-administered acupressure through a short course; and (2) to evaluate the short-term effects of self-acupressure for alleviating insomnia in comparison with sleep hygiene education. This exploratory pilot study was not powered for formal hypothesis testing. Nonetheless, the results and participants' feedback obtained from this pilot study will inform the design and sample size calculation for future fully-powered trials.

## **METHODS**

### **Study design**

A pilot randomised parallel-group controlled trial was performed in this study. Potential subjects were randomly assigned to either the self-administered acupressure training group or the sleep hygiene education group, with the ratio being 1:1. A computer-generalised number list was used in the block randomisation with a random block size of 4 to 6, and the group allocation was enclosed in sealed, sequentially numbered, opaque envelopes. Research ethic approval for all the study procedures was obtained from the local institution review board, and the study was registered in the ClinicalTrials.gov (ClinicalTrials.gov identifier: NCT03053648). This trial followed the CONSORT (Moher et al., 2012) and STRICTA (MacPherson et al., 2010) recommendations for designing and reporting. Recommendations on future trials would be based on the subjects'

feedback (acceptability), feasibility of the short training course (subjects' fidelity and adherence), and effects of self-administered acupressure for insomnia (effect sizes in the treatment outcome).

## **Subjects**

Thirty-one participants were recruited from the community through posters disseminated around the university and through magazine advertisements from December 2016 to February 2017. Eligible participants were identified on the basis of the criteria: (1) 18–65 years old; (2) Chinese Hong Kong residents with proficiency in Cantonese or Putonghua; (3) fulfilling the diagnostic criteria of DSM-5 insomnia disorder (difficulty in falling asleep and staying asleep or early morning awake for at least three months, along with significant daytime consequences) using the Brief Insomnia Questionnaire (sensitivity: 0.55; specificity: 0.87; area under the receiver operating characteristic curve: 0.76; test-retest reliability: Pearson's  $r = 0.4$ – $0.7$ ) (Chung et al., 2014); (4) a clinical insomnia level with a score of at least 10 points in the Insomnia Severity Index (ISI) (Morin, 2011); (5) willingness to give consent and comply with the protocol. The exclusion criteria included the following: pregnancy; score of  $\leq 23$  (indicative of cognitive impairment) in the Mini Mental State Examination; significant suicidal risk determined with the rating of  $\geq 3$  points in the Hamilton Depression Rating Scale (suicide item) (Hamilton, 1960); sleep disorders requiring treatment (e.g., sleep apnea); consumption of over-the-counter medication, herbal remedies or psychotropic drugs for insomnia within 2 weeks; and receipt of acupuncture or practitioner-delivered acupressure in previous six months.

## **Therapists' background**

Self-acupressure training was provided by a registered Chinese medicine practitioner with at least 5 years' worth of clinical experience in providing acupuncture and acupressure. The instructor for sleep hygiene education was a registered nurse who had been engaged in sleep research and trained by a clinical psychologist. The clinical psychologist's research postgraduate studies were specialized in sleep research. The nurse had demonstrated the teaching to the clinical psychologist and principal investigator before the commencement of the study.

## **Interventions**

Both groups were provided two 120-min training courses (240 min in total) on a weekly basis.

The group size was small at 4–6 participants to enhance interaction and quality of teaching. The subjects in both groups received the same assessment procedures and the same number of contact hours with the research personnel. The subjects were not paid for participation.

### *Self-administered acupressure training course*

The protocol of self-administered acupressure was developed on the basis of previous systematic reviews (Hmwe et al., 2016, Song et al., 2015, Waits et al., 2016, Yeung et al., 2012) and the experience in acupuncture of the senior authors (LL and ZJZ). In the first lesson, introduction to acupressure, therapeutic actions and functions of each acupoint according to TCM theory were explained. A hand out with a step-by-step guide and pictures providing information about administering self-administered acupressure was provided to each participant. The details of the acupoints and self-administered acupressure procedure are listed in Table 1. Afterward, the participants received training in locating acupoints and performing acupressure techniques, followed by a group practice. The instructor inspected their practice and provided feedback or correction when necessary. Finally, the instructor presented a brief summary of the course and answered questions regarding the mastery of self-acupressure techniques. The participants were told to perform self-administered acupressure (around 12–20 min) every night for 30 min prior to sleep for 4 weeks. The duration was based on previous systematic reviews that beneficial effects were observed after 4-week of treatment (Waits et al., 2016, Yeung et al., 2012). In the second lesson, the instructor answered the subjects' specific queries during home practice, reviewed course contents and inspected the participants' self-acupressure techniques. The instructor checked the participants' mastery of self-acupressure techniques using a competency checklist before the end of each lesson.

### *Sleep hygiene education*

The subjects in the comparison group were given sleep hygiene education (Harsora and Kessmann, 2009, Morin and Espie, 2003). At the beginning of the first lesson, a sharing session was conducted to allow the participants to share and discuss their sleep problems. A training hand out covering activity schedules and sleep hygiene instructions was delivered to each subject. These instructions included a dark and quiet sleep environment, and separate from other activities; encourage the increase of daytime activity, regular meal and bedtime routine and avoidance of nap

taking and looking at the clock when waking at night. The rationale for each instruction and a discussion about possible solutions were included. The subjects' understanding of their sleep habits was enhanced by completing the Sleep Hygiene Practice Scale (SHPS) (Lin et al., 2009) and Caffeine Knowledge Quiz (Anderson et al., 2009). The SHPS covered four dimensions - sleep schedule and timing (e.g. regular bedtime and avoid emotional activities before bed time), arousal-related behaviors (e.g. timing of exercise and nap), drinking and eating habits (e.g. regular meal, problems of smoking, caffeine and alcohol), and sleep environment (e.g. bedroom setting and bed partner). The items in SHPS and Caffeine Knowledge Quiz will be discussed with the subjects and explained by the course instructor. Subjects would be told to follow the 10 items of sleep hygiene, which included (1) avoid napping; (2) no smoking within 2 hours before bedtime; (3) avoid eating heavy near the bedtime; (4) avoid performing vigorous physical activities within 2 hours before sleep; (5) avoid going to be hungry or thirsty; (6) avoid thinking about day's events and worries in bed; (7) avoid engaging with highly demanded activities near to bedtime; (8) no activities in bed other than sleep; (9) prepare the bedroom to be comfortable in terms of temperature, light, and noise; (10) sleep and wake at a regular time (Yazdi et al., 2016). During the second lesson, the subjects' questions about the home practice of sleep hygiene instructions were answered and discussed in class. Thereafter, the subjects completed the SHPS again, along with a 'true or false' test regarding some facts about insomnia, to reinforce their learning. Finally, the instructor reviewed the course contents and checked the participants' understanding of the sleep hygiene instructions. The training session would be adjourned when all the subjects had expressed understanding to the instructions.

Sleep hygiene education has been commonly used as a comparison group in RCTs of self-help and psychological interventions for insomnia. Sleep hygiene education will provide subjects the same amount of contact hours with the healthcare professional (instructor) to control the non-specific effect of practitioner-patient interaction in the self-administered acupressure group.

#### *Telephone reminder*

During the first 4 weeks, the instructors made a telephone follow-up for both groups twice a week to remind the participants about their practice at home and to answer subjects' queries. The subjects in the self-administered acupressure group were told to perform acupressure daily for four



consecutive weeks (weeks 1–4) and complete an acupressure log to record their home practice. Continuous practice was encouraged, but it was not made mandatory during weeks 5–8. The subjects in the sleep hygiene education group were asked to check whether they had followed the sleep hygiene education and recorded entries in the sleep hygiene log. The subjects in the sleep hygiene education group received the same self-administered acupressure training after the study period as compensation. The course schedule is presented in figure 1.

### **Fidelity check of self-acupressure**

To ensure the subjects' performance of self-administered acupressure, the course instructor evaluated every participant's mastery of self-acupressure with a competency checklist in each lesson. The checklist included items on the accuracy of locating acupoints, acupressure techniques and strength and duration of acupressure for each acupoint. Any identified discrepancy in treatment fidelity was corrected, and extra practice time and specific instructions were given by the instructor as necessary.

### **Outcome measures**

The primary outcome was the ISI (Bastien et al., 2001), a validated measure of perceived severity of insomnia and daytime impairments (score ranged from 0 to 28, Cronbach's alpha = 0.74). The Chinese versions of ISI was validated with good internal consistency (Cronbach's alpha of = 0.83) and test-retest reliability (Pearson's  $r = 0.79$ ) (Chung et al., 2011). The secondary outcomes included a seven-day sleep diary, which is a daily record capturing the bed and wake information for the estimation of sleep onset latency (SOL), wake after sleep onset (WASO), total sleep time (TST) and sleep efficiency (SE) (Carney et al., 2012); the Hospital Anxiety and Depression Scale (HADS), which is a self-rated questionnaire for measuring the severity of depressive and anxiety symptoms (Zigmond and Snaith, 1983); the Chinese versions of HADS showed a Cronbach's alpha of 0.86 (Leung et al., 1999). The Short-form Six-Dimension (SF-6D) is a multi-level evaluation of quality of life (Brazier et al., 2002); the Chinese version SF-6D was evaluated in a Chinese population, showing an intraclass correlation of 0.79 and with a mean absolute error of 0.054 in fitting into the econometric model (Lam et al., 2008). The Credibility of Treatment Rating Scale (CTRS, Cronbach's alpha = 0.73; test-retest reliability, Pearson's  $r = 0.82$ ), which assesses subjects' expectations regarding the effects of intervention for their complaints

(Vincent, 1990). The adapted Chinese version of the sleep diary has been used in previous RCTs (Chung et al., 2016, Chung et al., 2015b, Yeung et al., 2011). The calculation of SE was based on the TST and time in bed (TIB) derived from the recorded time of lights out and getting out of bed sleep diary with the following equation:  $SE = TST/TIB \times 100\%$ .

The primary outcome ISI and the sleep diary were evaluated after completion of training (week 2), the end of treatment period (week 4) and the four-week post-treatment follow-up (week 8). Other secondary outcome assessments were assessed at baseline, week 4 and week 8. Adverse events were recorded during each visit, and the subjects' acceptability towards self-administered acupressure was assessed using a 10-point single item scale (ranges from 1 to 10) after completion of the training course. The specific assessment regarding the course such as acceptability, acupressure and sleep hygiene log, and record of adverse events were conducted and analysed by the course instructors. The research assistant who performed the outcome assessment and data analysis was blinded to the treatment allocation.

## **Statistical analysis**

We used SPSS version 23.0 (IBM Corp) for all the statistical analyses. The primary analysis was conducted using a linear mixed effects model to examine the groups (self-administered acupressure vs. sleep hygiene education) by time (baseline to week 8) interactions on the primary outcome ISI score and other secondary outcomes, including sleep parameters and other questionnaires. Missing data were dealt with using the mixed effects model, assuming missing at random. Both completers and intention-to-treat analyses were conducted. Completers analysis only included the subjects who had completed the training courses and complied with the intervention protocol, defined as having self-administered acupressure practice at home or following the sleep hygiene instruction for at least 4 days per week as recorded by the acupressure or sleep hygiene log during the treatment period (up to week 4). Between-group effect sizes were computed by dividing the difference between group means by the pooled standard deviation. Within-group effect sizes were computed by dividing the mean difference between baseline and post-treatment assessment by the pooled standard deviation. We used a positive sign to denote that the treatment group was superior to the comparison group for between-group effect sizes and post-treatment assessment was superior to the baseline assessment for within-group effect sizes. We used Bonferroni correction to adjust multiple time points in comparison with conservative

thresholds of  $P < 0.017$  and  $P < 0.025$  in sleep outcomes (three time points) and other secondary outcome measures (two time points), respectively. A post-hoc power analysis was conducted to determine the appropriate sample size for this study by G\*Power 3.1.9.2.

## RESULTS

### Subject characteristics

A total of 31 participants were finally recruited (Figure 2). The subjects' characteristics and baseline assessment are presented in Table 1. The recruited participants had an average age of 53.2 years ( $SD = 9.0$ ). They were mainly female (77.4%), and most of them had previously tried alternative treatments for insomnia (87.1%). About 12.9% of the subjects had a history of mental illness, and 41.9% of them were on regular medications for their medical illnesses. At baseline, the mean scores of ISI was 17.0 ( $SD = 3.8$ ), indicating a moderate severity of insomnia. Fifteen participants were allocated to the self-acupressure group, and 16 participants were allocated to the sleep hygiene education group. No significant between-group differences were observed in their demographic factors and baseline assessments (all  $P > 0.05$ , Table 2).

### Treatment acceptability, fidelity, and compliance

The overall mean rating for acceptability of the self-administered acupressure training course was 9.0 ( $SD = 1.0$ , range = 7 to 10), indicating a high acceptability among the subjects to learn and perform self-administered acupressure. The compliance was good; 86.7% of the subjects attended all lessons of the self-administered acupressure training. In the self-administered acupressure group, all the subjects learned the self-acupressure techniques and passed the fidelity check after the course. During the 28-day treatment period, all 13 subjects who had completed the self-administered acupressure training course practiced acupressure for 25.2 days (range: 22–28 days) and 14.8 min per day (range: 5–50 min) on average. At week 8, 12 subjects (92.3% of those who had completed the course) still practiced acupressure with an average of 6.1 days per week and 12.9 min per day (range: 5–38 min). For the subjects in the sleep hygiene education group, all subjects had attended all lessons and 14 had returned their sleep hygiene log; 85.7% of them had followed at least 8 sleep hygiene instruction items during the 28-day treatment period and at week 8.

### **Primary outcome**

The differences in the ISI scores of the self-administered acupressure group and sleep hygiene education group across study time points were compared using mixed effects model analysis (Table 3). No significant group difference was observed in the ISI scores at weeks 2 and 4. The subjects in the self-administered acupressure group had significantly lower ISI scores than those who received sleep hygiene education at week 8 (Effect size = 0.56,  $P = 0.03$ ). However, this observed group difference did not reach a statistically significant level after Bonferroni correction for assessing multiple endpoints. The result was not altered in the completers analysis.

### **Secondary outcomes**

The SOL, WASO, TST, and SE derived from the sleep diary did not significantly differ between the two groups at none of the time points (Table 3). In addition, no between-group difference was found in SF-6D, HADS anxiety scores and HADS depression scores across all assessment time points (Table 4).

Although the item of ‘confidence in recommending to others’ in the CTRS showed a significant between-group difference ( $P = 0.046$ ), the difference was not significant after Bonferroni correction (Table 5). A completers analysis showed consistent findings on the secondary outcomes.

### **Adverse events**

In the self-administered acupressure group, one subject exerted acupressure too strong with his nail, leading to mild bleeding; two subjects experienced a stomach ache after performing acupressure on the abdomen. The adverse events experienced by these subjects were mild, and no treatment was needed. However, one subject complained of worsened insomnia symptoms and dropped out during the second week. In the sleep hygiene education group, one subject complained of low back pain and withdrew from the study during the week 4.

### **Post-hoc power analysis**

The post-hoc power analysis revealed that the powers of present sample size in determining the difference in ISI at week 4 (Effect size = 0.33) and week 8 (Effect size = 0.56) were 15% and 33%,

respectively. The effect size estimated in this study suggested that a sample size of 56 in each group was needed to detect between-group differences in ISI scores at week 8 with a power level of 80%.

## **DISCUSSION**

The present study is the first RCT that examined the effects of self-administered acupressure on adults with insomnia disorder. This pilot trial was aimed at examining the feasibility of training participants to perform self-administered acupressure through a two-session training course and at generating estimates of effect sizes for future fully powered studies. The effects of self-administered acupressure were most pronounced in the ISI score at week 8, although it did not reach a significant level after correction for multiple comparisons. Moderate effect sizes were observed in the sleep diary-derived SOL at week 4 and week 8, and a large effect size was observed in WASO at week 4. These differences were not significant due to the small sample size of this pilot trial.

The adherence to at-home self-administered acupressure practice was satisfactory, with a completion rate of 86.7% for the training course. After the training course, all participants were successfully trained to perform self-administered acupressure and passed the fidelity check. This study showed that our training course is feasible for the training of participants to perform self-administered acupressure at home. Future studies should include a fidelity check at the end of the follow-up period to assess subjects' learning of the acupressure technique.

Our results showed that unlike sleep hygiene education, self-administered acupressure produced a moderate effect size in the improvement of ISI score. The previous studies used a sham or waitlist as a control and studied a rather specific population, such as lung cancer patients undergoing chemotherapy (Tang et al., 2014), menopausal women (Abedian et al., 2015) and patients with hypertension (Zheng et al., 2014). Therefore, the effect sizes of the pilot trial cannot be directly compared with those of existing studies. Similar to our comparison group design, Zeng et al. adopted sleep health instructions to examine the effects of self-administered acupressure on the elderly with poor sleep (Zeng et al., 2016). In the study, a significantly large effect size (1.54) on improving the sleep questionnaire score was found (Zeng et al., 2016), in contrast to the moderate effect size (0.56) found in this study. This difference is probably due to the longer treatment duration (12 months), higher treatment intensity (30 min, twice per day), and additional

home visits in their study in comparison with the current one. Further studies can be carried out to investigate the optimal treatment duration and intensity of performing self-administered acupressure.

In the present study, the subjects in sleep hygiene education group appeared to have a longer WASO, lower SE, and lower confidence toward the intervention, although the differences were not statistically insignificant. A previous secondary analysis found that baseline insomnia severity was a predictive factor for treatment response in acupuncture (Yeung et al., 2017). These factors can be controlled as covariates to increase the power in future studies. In addition, subjects' confidence toward the intervention may associate with their motivation and readiness to change. Interim assessment of the confidence and acceptability toward the intervention can be examined as a moderator or mediator to explain the effectiveness.

## **LIMITATION**

Our study had several limitations apart from the small sample size. First, no objective sleep measures, such as polysomnography or actigraphy, were used as outcome measures due to limited resources. Nevertheless, we adopted essential subjective sleep assessment (Buysse et al., 2006), including validated sleep questionnaire and seven-day prospectively recorded sleep diary, which had not been included in the previous studies (Waits et al., 2016). Future studies should include objective sleep measures to substantiate the effects of self-administered acupressure. Second, we did not use polysomnography to exclude those with sleep apnea and other possible sleep disorders such as periodic limb movement disorder, delayed sleep phase disorder and circadian rhythm sleep disorder which may also present with insomnia complaint. As we expected self-administered acupressure to be applicable in the community, we decided to use a loose inclusion and exclusion criteria to enhance the generalizability of the findings. Third, the clinical psychologist who trained the course instructor of sleep hygiene education was not a specialist in sleep medicine, although her postgraduate research focus was in sleep medicine. In order to ensure the quality and a comprehensive coverage of sleep hygiene instruction of the course, the instructor can be trained by a clinician or psychologist formal sleep medicine training. Finally, despite the fact that the self-administered acupressure technique is not complicated and all subjects could learn the acupressure

technique after the training course and after passing the fidelity check by the instructor in our pilot study, we cannot rule out the possibility that a few participants did not fully follow the instructions, when they practiced the technique at home. Nevertheless, our results reflected real-world practice and presented important information about the implementation of the training course in the community.

In summary, our short training course showed a high acceptability and subjects' adherence. In addition, several medium-to-large effect sizes favoured the intervention group, suggesting that self-administered acupressure taught through a short training course may be a feasible approach to improve insomnia. Given the low cost and convenient nature of self-administered acupressure, further fully-powered confirmatory trials are warranted.

**Author Contribution**

WFY conceived and designed the trial. LXL, ZZJ and HYC provided experts' opinion to the self-acupressure protocol. KPS and YYH reviewed the sleep hygiene education instructions and provided training of personnel. WFY and YTC performed the self-acupressure and sleep hygiene education training courses, respectively. YMY conducted the assessments. WFY and YMY analysed the data and drafted the manuscript. KFC, ZZJ, KPS, YYH and HYC revised the manuscript. All authors approved the final version accepted for publication.



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**Table 1.** Selected Self-Acupressure Acupoints for Relieving Insomnia

Acupoint	Location (Zhang et al. 2014)	Acupressure technique	Frequency and duration
<i>Baihui</i> (GV20, 百會)	On the vertex of the head at the sagittal midline of the scalp at the midpoint of the line connection the apexes of both ears	Using 4 finger pads gently tap the area of this acupoint on the scalp	60/min for 1 min
<i>Fengchi</i> (GB20, 風池)	on the nape, in a depression between the upper portion of the sternocleidomastoid muscle and the trapezius	Using two thumbs press on the points bilaterally while the other four fingers should hold the back of the head naturally	60/min for 1 min (both sides at the same time)
<i>Neguan</i> (PC6, 內關)	On the medial aspect of the forearm between the palmaris longus and flexor carpi medial tendons, 2 <i>cun</i> proximal to the palmar wrist crease	Using thumb pad firmly massage the surrounding area of this acupoint on the medial side of the wrist unilaterally	60/min for 1 min (bilateral, 2 mins in total)
<i>Shenmen</i> (HT7, 神門)	On the posteromedial aspect of the wrist radial to the flexor carpi ulnaris tendon at the palmar wrist crease	Using thumb pad firmly massage the surrounding area of this acupoint on the ulnar side of the wrist unilaterally	60/min for 1 min (bilateral, 2 mins in total)
<i>Zhongwan</i> (CV12, 中脘)	On the upper abdomen and on the anterior midline, 4 <i>cun</i> above the centre of the umbilicus.	Using finger pads in clockwise circle genially massage the upper abdomen area, 4 <i>cun</i> above the umbilicus	100/min for 2 min
<i>Yongquan</i> (KD1, 涌泉)	On sole, in depression with foot in plantar flexion, at the junction of the anterior 1/3 and posterior 2/3 of line connecting base of the 2nd and 3rd toes with the heel	Using thumb pad firmly massage the area bilaterally on each sole, in depression with foot in plantar flexion	40/min for at least 2 min (bilateral, 4 mins in total)

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**Table 2.** Sociodemographic, clinical and baseline characteristics of the sample

Variable <sup>a</sup>	All participants (n = 31)	Self-acupressure (n = 15)	Sleep hygiene (n = 16)	<i>P</i> value t-test/ chi-square
Age, y	53.2 ± 9.0	50.4 ± 11.0	55.8 ± 6.0	0.10
Female gender (%) <sup>c</sup>	24 (77.4)	12 (80)	12 (75)	1.00
Educational level, y	13.0 ± 4.7	14.5 ± 4.3	11.5 ± 4.8	0.08
Marital status (%) <sup>c</sup>				0.20
Never married	13 (41.9)	8 (53.3)	5 (31.3)	
Married/cohabiting	15 (48.4)	7 (46.7)	8 (50.0)	
Divorced/widowed	3 (9.7)	0 (0)	3 (18.7)	
Employment status (%)				0.59
Employed	15 (48.4)	8 (53.3)	7 (43.7)	
Unemployed/retired/housework	16 (51.6)	7 (46.7)	9 (56.3)	
Income, HK\$ (%) <sup>c</sup>				0.83
No income	8 (26.7)	4 (26.7)	4 (25.0)	
Below \$10,000	3 (10.0)	1 (6.6)	2 (12.5)	
\$10,000-\$50,000	13 (43.3)	6 (40.0)	7 (43.8)	
Above \$50,000	6 (20.0)	4 (26.7)	2 (12.5)	
BMI	22.4 ± 3.4	23.1 ± 3.6	21.9 ± 3.3	0.35
Chronic medical illnesses (%) <sup>b</sup>	13 (41.9)	5 (33.3)	8 (50.0)	0.35
History of mental illness (%) <sup>c</sup>	4 (12.9)	2 (13.3)	2 (12.5)	1.00
Insomnia duration, y	7.6 ± 10.1	6.9 ± 9.9	8.3 ± 10.6	0.71
History of hypnotics use (%) <sup>c</sup>	8 (25.8)	2 (13.3)	6 (37.5)	0.22
Alternatives treatment for insomnia (%) <sup>d</sup>	27 (87.1)	12 (80.0)	15 (93.8)	0.25
ISI	17.0 ± 3.8	17.1 ± 4.4	16.8 ± 3.4	0.82
Sleep diary				
Sleep onset latency	41.5 ± 27.5	38.8 ± 16.5	44.5 ± 35.3	0.60
Wake after sleep onset	52.0 ± 39.1	41.0 ± 27.5	62.3 ± 46.0	0.13
Total sleep time	331.9 ± 65.2	340.3 ± 49.7	324.1 ± 77.8	0.49
Sleep efficiency	69.7 ± 14.3	73.5 ± 11.6	66.2 ± 16.1	0.16
Sleep Quality	2.4 ± 0.5	2.4 ± 0.5	2.4 ± 0.6	0.80
HADS				
Anxiety	10.0 ± 3.8	10.3 ± 3.5	9.8 ± 4.3	0.75
Depression	7.5 ± 3.7	7.1 ± 3.4	7.9 ± 4.0	0.58
SF-6D utility score	0.639 ± 0.115	0.641 ± 0.107	0.637 ± 0.125	0.92
CTRS				
Confidence in effectiveness	4.19 ± 1.08	4.40 ± 1.06	4.00 ± 1.10	0.31
Confidence in recommending to others	4.19 ± 1.20	4.40 ± 1.18	4.00 ± 1.21	0.36
Perceived logic	4.45 ± 0.96	4.60 ± 1.12	4.31 ± 0.79	0.41
Likelihood of relieving other complaints	4.16 ± 1.00	4.40 ± 0.91	3.94 ± 1.06	0.21

BMI, Body Mass Index; ISI, Insomnia Severity Index; HADS, Hospital Anxiety and Depression Scale; SF-6D, Short-Form Six-Dimension.

<sup>a</sup> Data are presented as mean ± SD or number (%).

<sup>b</sup> Participants were on regular medications for their medical illnesses.

<sup>c</sup> Fisher exact test was performed.

<sup>d</sup> Experience of alternative treatment other than hypnotics included herbal medicine, acupuncture/acupressure, exercise, massage, alcohol, aromatherapy, relaxation therapy, and Tai Chi.

**Table 3.** Insomnia Severity Index (ISI) and Sleep Parameters Derived from the 7-days Sleep Diary across Study Time Points

	Self-administered acupressure (n = 15)			Sleep hygiene education (n = 16)			Between-group effect size <sup>c</sup>	P-value <sup>d</sup>
	Estimated Mean (SE) <sup>a</sup>	Change from baseline Mean (SE) <sup>a</sup>	Within-group effect size <sup>b</sup>	Estimated Mean (SE) <sup>a</sup>	Change from baseline Mean (SE) <sup>a</sup>	Within-group effect size <sup>b</sup>		
<u>ISI</u>								
Baseline	17.13 (1.32)			16.81 (1.28)				
Week 2	12.79 (1.37)	-4.39 (1.19)	0.83	15.02 (1.31)	-1.82 (1.13)	0.35	0.42	0.08
Week 4	12.88 (1.37)	-4.31 (1.19)	0.82	14.63 (1.30)	-2.20 (1.11)	0.42	0.33	0.17
Week 8	10.88 (1.37)	-6.31 (1.19)	1.20	13.87 (1.32)	-2.97 (1.13)	0.57	0.56	0.03
<u>SOL, min</u>								
Baseline	38.79 (7.26)			44.12 (7.03)				
Week 2	23.68 (7.54)	-14.08 (6.38)	0.53	34.82 (7.28)	-9.78 (6.15)	0.32	0.38	0.49
Week 4	26.10 (7.51)	-11.80 (6.38)	0.44	44.51 (7.26)	-0.02 (6.15)	-0.01	0.63	0.10
Week 8	17.76 (7.93)	-20.51 (6.61)	0.71	35.14 (7.26)	-9.40 (6.15)	0.31	0.58	0.15
<u>WASO, min</u>								
Baseline	41.00 (10.47)			62.32 (10.14)				
Week 2	27.70 (10.88)	-13.13 (7.80)	0.32	55.80 (10.50)	-7.69 (7.52)	0.16	0.67	0.575
Week 4	24.53 (10.76)	-16.36 (7.80)	0.40	59.57 (10.40)	-3.52 (7.52)	0.07	0.84	0.167
Week 8	22.85 (11.27)	-18.16 (8.59)	0.43	38.64 (10.43)	-24.58 (7.52)	0.58	0.37	0.620
<u>TST, min</u>								
Baseline	340.28 (17.53)			324.06 (16.98)				
Week 2	350.45 (17.90)	9.63 (12.52)	0.15	332.83 (17.31)	10.31 (12.06)	0.13	0.25	0.92
Week 4	350.23 (17.97)	9.29 (12.52)	0.14	317.90 (17.37)	-4.29 (12.06)	-0.09	0.46	0.31
Week 8	363.62 (18.65)	20.15 (13.20)	0.33	341.25 (17.38)	19.13 (12.06)	0.25	0.32	0.72
<u>SE, %</u>								
Baseline	73.46 (4.08)			66.17 (3.95)				
Week 2	78.44 (4.17)	4.83 (2.88)	0.31	71.47 (4.03)	5.52 (2.77)	0.33	0.43	0.92
Week 4	76.90 (4.17)	3.30 (2.88)	0.22	68.30 (4.03)	2.35 (2.77)	0.13	0.53	0.69
Week 8	81.40 (4.30)	6.62 (2.98)	0.49	72.88 (4.03)	6.93 (2.77)	0.42	0.52	0.72

SOL, Sleep Onset Latency; WASO, Wake After Sleep Onset; TST, Total Sleep Time; SE, Sleep Efficiency.

<sup>a</sup> Estimated mean and standard error from linear mixed-effects model.<sup>b</sup> Effect size calculation was based on the difference of estimated mean and standard deviation comparing each time point and baseline.<sup>c</sup> Effect size calculation was based on the between-group difference in total scores divided by pooled standard deviation.<sup>d</sup> P-value for group by time interaction of mean score using linear mixed-effects models.

**Table 4.** Hospital Anxiety and Depression Scale (HADS), Short-Form Six-Dimension (SF-6D) and Credibility of Treatment Rating Scale (CTRS) scores across Study Time Points

	Self- administered acupressure (n = 15)		Sleep hygiene education (n = 16)		Between-group effect size <sup>c</sup>	P-value <sup>d</sup>
	Estimated Mean (SE) <sup>a</sup>	Within-group effect size <sup>b</sup>	Estimated Mean (SE) <sup>a</sup>	Within-group effect size <sup>b</sup>		
<u>HADS-Anxiety</u>						
Baseline	10.27 (0.88)		9.81 (0.86)			
Week 4	8.26 (0.96)	0.56	8.79 (0.90)	0.29	0.14	0.43
Week 8	8.71 (1.06)	0.41	8.30 (0.90)	0.43	-0.11	0.97
<u>HADS-Depression</u>						
Baseline	7.13 (0.86)		7.88 (0.83)			
Week 4	6.35 (0.91)	0.23	7.34 (0.86)	0.16	0.28	0.81
Week 8	6.44 (1.02)	0.19	6.79 (0.88)	0.32	0.09	0.78
<u>SF-6D, 0-1</u>						
Baseline	0.641 (0.030)		0.637 (0.029)			
Week 4	0.672 (0.032)	0.26	0.635 (0.030)	-0.02	0.30	0.43
Week 8	0.649 (0.036)	0.06	0.658 (0.031)	0.17	-0.07	0.78

<sup>a</sup> Estimated mean and standard error from linear mixed-effects model.

<sup>b</sup> Effect size calculation was based on the difference of estimated mean and standard deviation comparing each time point and baseline.

<sup>c</sup> Effect size calculation was based on the between-group difference in total scores divided by pooled standard deviation.

<sup>d</sup> P-value for group by time interaction of mean score using linear mixed-effects models.

**Table 5.** Credibility of Treatment Rating Scale (CTRS) across Study Time Points

	Self- administered acupressure (n = 15)	Sleep hygiene education (n = 16)	P-value <sup>b</sup>
	Estimated Mean (SE) <sup>a</sup>	Estimated Mean (SE) <sup>a</sup>	
<u>CTRS-Confidence in effectiveness</u>			
Baseline	4.40 (0.27)	4.00 (0.26)	
Week 4	4.12 (0.28)	3.38 (0.27)	0.28
Week 8	4.06 (0.32)	3.45 (0.27)	0.58
<u>CTRS-Confidence in recommending to others</u>			
Baseline	4.40 (0.28)	4.00 (0.27)	
Week 4	4.63 (0.30)	3.52 (0.28)	0.046
Week 8	4.48 (0.35)	3.60 (0.29)	0.27
<u>CTRS-Perceived logic</u>			
Baseline	4.60 (0.25)	4.31 (0.24)	
Week 4	4.61 (0.27)	4.12 (0.25)	0.54
Week 8	4.40 (0.31)	3.69 (0.25)	0.28
<u>CTRS-Likelihood of relieving other complaints</u>			
Baseline	4.40 (0.28)	3.94 (0.27)	
Week 4	4.09 (0.30)	3.36 (0.28)	0.55
Week 8	3.93 (0.36)	3.43 (0.28)	0.95

<sup>a</sup> Estimated mean and standard error from linear mixed-effects model.

<sup>b</sup> P-value for group by time interaction using linear mixed-effects models.



Figure 1. Schedule of Self-administered Acupressure Training Course and Sleep Hygiene Education (SHE) Course

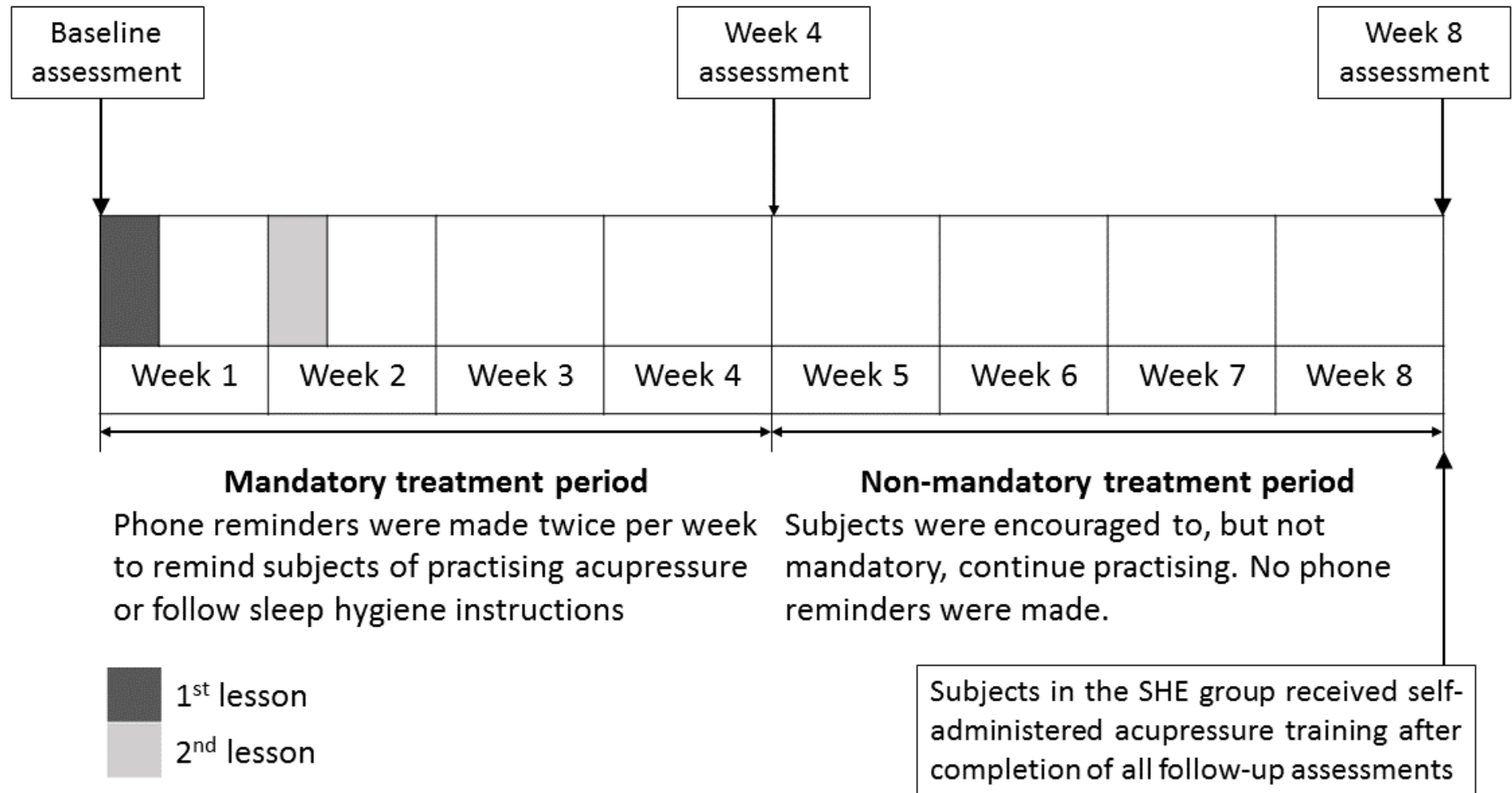


Figure 2. CONSORT study flow diagram

