Effectiveness and safety of auricular acupoint bloodletting in treatment of insomnia: an assessor-blinded pilot randomized controlled trial

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METHODS: Participants (n = 60) with insomnia were randomized into two groups to receive treatment of auricular acupoint bloodletting: low frequency group, 1 times/week for five weeks (n = 30); high frequency group, 2 times/week for two weeks (n = 30). The following outcomes were measured blindly at baseline, after first treatment, 4 weeks, and 8 weeks: Pittsburgh sleep quality index scale (PSQI).

RESULTS: The groups were balanced at baseline for insomnia and demographic characteristics. There were no significant differences between the groups in terms of any of the outcomes, at the first follow-up time point. However, the therapeutic effect of LFG (once per week) is obviously lower than that of HFG (twice per week). In addition, there was no significant difference in the side effects between the two groups.

CONCLUSION: The treatment of insomnia with different frequencies of auricular acupoint bloodletting is effective and has less side effects. More reasonable treatment frequencies are worth further study.

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Keywords: insomnia; Auricular acupoint bloodletting; Randomized controlled trials; Frequency

INTRODUCTION
Insomnia is the most common sleep-related complaint and the second most common overall complaint (after pain) reported in primary care settings. The symptoms...
of insomnia are variable, thus make it difficult to define other dimensions of the condition, such as incidence and remission rates, as a uniform characterization of episode lengths is lacking. Insomnia not only increases the patient’s pain and mental burden, seriously, it also affects the physical and mental health, quality of life and work efficiency. According to the epidemiological survey, a variety of factors are closely related with insomnia, including gender, age, genetic quality and other self factors, economic status, education, occupation, marriage, living environment and other external factors, as well as physical and mental illness and drug use. The clinical manifestations of insomnia are: firstly, prolongation of sleep latency: time of falling asleep is more than 30 min; secondly, sleep maintenance disorder: nocturnal awakening ≥ 2 times or early morning wake; thirdly, sleep quality decline: shallow sleep, dreaminess; fourthly, the total sleep time is shortened: usually less than 6 h; fifthly, daytime residual effect: dizziness, lack of energy, lethargy, fatigue in the next morning.  

Insomnia can be treated with medications, herbal therapy and psychological or physical therapy. The commonly used medications include benzodiazepine, non-benzodiazepine, melatonin drugs and antidepressants. However, long-term use of them are easily to induce fatigue, dizziness, drowsiness and other adverse reactions, leading to mental disorders, memory disorders, drug addiction and rebound insomnia after withdrawal.  

Non-drug treatment includes cognitive behavioral therapy, sleep hygiene education, and relaxation therapy. Acupuncture treatment of insomnia is considered to be an effective. The clinical selection of acupoints involves symptom pattern identification in terms of the theory of Traditional Chinese Medicine.  

Auricular acupoint bloodletting has a long history in our country. It is an important part of acupuncture and moxibustion. It is widely applied in various clinical departments, such as department of dermatology disease, department of orthopedics disease, neuropsychiatric disease and so on.  

Acupoint pricking blood refers to using a three-edged needle to let blood bleedat auricular acupoints and at the ear apex. Shenmen, and oral drugs, the results show that this method for the treatment of intractable insomnia has obvious curative effect, and can improve the anxiety and depression.  

According to a system review for the treatment frequency of auricular acupoint bloodletting is deferent from 1 times a day to 1 times a week or even every two weeks 1 times a month. In clinical practice, the frequency of insomnia treated by ear acupuncture is mostly 2 times a week, but occasionally 1 time a week. Although it may be assumed that more frequent treatment may have a greater impact, this often leads to greater side effects, such as: syncope, local infection, hematoma et al. Due to the lack of trials addressing the question of how often auricular acupoint bloodletting should be conducted, the current pilot study has examined the feasibility of conducting a trial to explore two frequencies (2 times/week versus 1 time/week) of auricular acupoint bloodletting for insomnia. The purpose of this study was to evaluate the effectiveness and safety of auricular acupoint bloodletting on insomnia, and how often it should be conducted.

**MATERIALS AND METHODS**

**Selection of participants**

The study protocol was approved by the Review Board on Clinical Research of Fuxing Hospital Affiliated to Capital Medical University (Beijing, China). Participants with insomnia were recruited through the poster advertisements in the hospital, and screened using an insomnia Examination Form and Participant History Sheet, based on the strict inclusion and exclusion criteria listed below. The nature of the treatment was explained in the Participant Information Sheet before each participant was required to give written informed consent.

**Inclusion criteria**

(a) Aged between 18-60 years, male or female ; (b) Meeting the criteria for ICD-10, Idiopathic insomnia (F51.0); (c) PQSI score > 6; (d) Voluntary participation and comprehension of informed consent.

**Exclusion criteria**

(a) Insomnia caused by systemic or external disturbances; (b) suffering from infectious diseases, serious heart disease, organic diseases and mental illness; (c) previous history of diabetes mellitus and suboptimal glycemic control; (d) patients who have been treated for insomnia in the last week; (e) received medicine treatment within the past 1 week; (f) patients with coagulation disorders; (g) ear is injured or infected or ulcerated or scarred; (h) pregnancy; (h) patients with depression anxiety and other emotional disorders (Hamilton Depression Scale (HAMD) score >20, Hamilton Anxiety Scale (HAMA) score more than 21 points).

**Sample size**

This study was considered a preliminary study in preparation for a main RCT, therefore a sample size of 60 participants was considered appropriate and achievable on the basis of the time allocated for participant recruitment, treatment and follow-up.

**Randomization**

Randomization of patients to treatment is carried out into two groups, using a computer-generated random allocation sequence and sealed opaque envelopes which were opened by the acupuncturist before treatment started.
Categorical variables were summarized with frequencies and percentages. Their distributions were assessed with Fisher exact test. Continuous variables were reported as means with standard deviations or medians with interquartile ranges. To simplify presentation, group means using the t test were presented because the large sample size ensured the robustness of the t test. Data messines will be investigated and if deemed necessary, generally when messiness is not completely at random, a suitable multiple imputation method will be used. All analyses were conducted using SPSS 15.0 (SPSS Inc. Released 2006. SPSS for Windows, Version 15.0. Chicago, IL, USA). Two-sided P < .05 indicated statistical significance.

RESULTS
Participant flow is shown in Fig. 2. From October 2015 to February 2016, a total of 60 (20 male, 40 female) participants were recruited in the acupuncture clinic, of them, 5 (2 in HFG, 3 in LFG) were ineligible for various reasons and 55 were randomized into two groups: LFG, 1 time/week (n = 28; 8 male, 19 female; age, 48 ± 13 years); HFG, 2 times/week (n = 27; 12 male, 16 female; age, 49 ± 14 years) (Table 1). The mean disease course was 94 ± 23 months for the LFG, and 89 ± 27 months for the High Frequency Group. There were no significant differences in gender, age, disease course, PQSI scores and total score before inclusion in both groups with different treatment frequencies, and the baseline characteristics of both groups had no statistically differences (P > 0.05), which suggested the comparability in both groups. The baseline demographic, clinical characteristics (Table 1) and outcome measure scores (Table 2) of the participants were well balanced between groups.

Outcomes comparison of both groups at each period of time
PQSI scores were significantly lower in both high frequency and low frequency groups at each stage after treatment than before treatment (P < 0.05, Table 3). At the end of the first treatment, the PQSI scores in the HFG (6.5 ± 3.4) and the LFG (6.1 ± 2.5) decreased significantly compared with that before treatment (13.2 ± 2.9 in HFG, 12.7 ± 2.1 in LFG, P < 0.05, Table 3). Seven evaluation indexes, including sleep quality, time for falling asleep, sleep time, sleep efficiency, sleep disorders, daytime dysfunction, were decreased in both groups after treatments, the differences were statistically significant (P < 0.05, Table 3). However, there was no significant difference between the HFG and the LFG after treatment in immediate effect. At the end of 4-week treatment, the PQSI total score, sleep quality, sleep time, sleep efficiency score of both groups was lower than that before treatment, and has the statistical significance. And the HFG in the PQSI score is higher than the LFG, and has the statistical sig-
After treatment, the sleeping time, sleep disorders, hypnotic drugs and daytime dysfunction scores in the two groups were significantly lower than those before treatment, and the difference was statistically significant. However, there was no significant difference between the two groups ($P > 0.05$).

At the 8-week follow-up, the PQSI total score, sleep quality, sleep time, sleep efficiency score of both groups was lower than that before treatment, and has the statistical significance. And the HFG in the PQSI score is higher than the LFG, and has the statistical significance.

**Adverse effects**

Only some minor incidences were reported throughout the duration of the trial. There was no adverse event in the LFG. In the HFG, 2 participants reported minor subcutaneous hematoma and vanished after several days. All these were slight adverse reaction (Table 4).
Discussion

In treatment of insomnia, we choose the ear, heart, coracoid, liver, gallbladder, spleen and stomach are located in the ear, and we mainly focus on their main effect on direct nerve. In our clinical practice, we choose more compatible options and less effective for a prolonged period. Acupuncture has been widely used to treat insomnia. Acupuncture stimulates the body’s neuroendocrine system to induce CNS inhibition. The mechanism of how acupuncture affects the brain is not fully understood, but it is believed that acupuncture may affect the hypothalamic-pituitary-adrenal axis, the reward system, and the sleep-wake cycle. It is suggested that acupuncture might help regulate the sleep-wake cycle by promoting sleep quality and reducing insomnia symptoms. However, there is no significant difference between the HFG and the LFG (P > 0.05). However, there was no significant difference between the HFG and the LFG (P > 0.05). However, there was no