The efficacy of acupuncture in decreasing *The Pittsburgh Sleep Quality Index* scores of depressive patients with insomnia

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**Abstract.** Insomnia is a common side effect of depression that often persists despite the availability of effective antidepressants that considerably improve other symptoms of the disease. This single-blinded randomized controlled clinical trial aimed to examine the effects of acupuncture on the symptoms of insomnia in patients with depression using the Pittsburgh Sleep Quality Index (PSQI). The study included 48 patients with depression who were randomly allocated into one of two groups (acupuncture and sham acupuncture groups). Both groups received antidepressant (fluoxetine 1 × 1 10–20 mg capsule/day) therapy throughout the study period. Additionally, acupuncture or sham acupuncture was administered five times a week for 2 weeks, and the self-evaluation questionnaire (PSQI) scores were used to measure the research output. The acupuncture and control groups exhibited a significant decrease and increase in the mean PSQI scores (from 14.50 ± 2.14 to 5.70 ± 2.25 and from 13.62 ± 1.43 to 16.66 ± 1.83, respectively) between baseline and after completion of the 10th acupuncture session, respectively (*p* < 0.05). Two weeks after completion of acupuncture therapy, the PSQI scores were seen to improve in the acupuncture group [from 14.50 ± 2.14 to 5.58 ± 3.37 (*p* < 0.05)], but not in the control group [scores increased from 13.62 ± 1.43 to 17.25 ± 2.09 (*p* < 0.05)]. In conclusion, the findings of this study show that acupuncture, when combined with antidepressants, can decrease the PSQI scores of patients with depression.

**1. Introduction**

Insomnia is a common complaint of depression that often persists despite the availability of effective antidepressants [1,2].

Adequate treatment of insomnia in patients with depression is important as its persistence is correlated with an increased risk of recurrence or relapse of the condition, thus leading to further deterioration of the psychosocial condition of the patient. A previous study reported that depressed patients with insomnia who did not receive adequate therapy exhibited three-to-six times higher risk of relapse compared with those with perfect remission [3]. The severity of depression is also associated with impairment of the ability to function, making insomnia therapy critical for avoiding relapse and improving the psychosocial functions of the patient [4].
In 2002, the World Health Organization issued an official declaration consisting of 29 medical conditions that could be effectively treated with acupuncture, one of which was insomnia [5]. When performed by a competent operator, acupuncture is a safe procedure with few contraindications or complications. However, there is limited evidence on the efficacy of this procedure in the treatment of insomnia.

The aim of this questionnaire-based study was to examine the effectiveness of acupuncture in treating insomnia in patients with depression using the Pittsburgh Sleep Quality Index (PSQI).

2. Methods
This single-blinded randomized controlled clinical trial included 48 patients aged between 18 and 65 years who had experienced insomnia within the last month. The patients were diagnosed with depression using the Mini International Neuropsychiatric Interview (MINI). The initial scoring of PSQI is >10.

Patients who fulfilled the inclusion criteria and were willing to participate were asked to provide informed consent. The PSQI and MINI scoring questionnaires were completed prior to commencement of acupuncture therapy. Pregnant women and patients with other psychiatric disorders (screened using MINI), tumors, infections at the acupuncture points, diabetes (blood sugar >200 mg/dL, diagnosed using screening with glucometer), and fever >38 °C or receiving benzodiazepine therapy were excluded from this study. Additionally, participants who did not receive acupuncture therapy twice in a row, those who conceived during the study, and those who consumed psychopharmacological drugs and/or other drugs that had sedative or hypnotic effects were also excluded. The materials used in this study included 0.25 × 30 mm Dongbang disposable acupuncture needles, 70% alcohol swabs, a timer, an Accu-Chek Active glucometer, Micropore medical tape, and a needle disposal container.

Antidepressant therapy consisting of 1 × 1 capsule of 10–20 mg of fluoxetine per day was initiated among the study participants 3 months prior to commencement of this study and was continued until 2 weeks after completion of the acupuncture therapy sessions. The antidepressant dosage was maintained at the same level throughout the study period. The acupuncture therapy sessions lasted for 10 days (Monday to Friday for 2 weeks), and the patients were followed up for a period of 2 weeks thereafter. Acupuncture therapy was carried out with the patients in a supine position, and aseptic and antiseptic measures were taken in both groups (the acupuncture group with antidepressant and sham acupuncture group with antidepressant). In the acupuncture group, the needles were inserted in the acupoints (GV20 Baihui, Ex-HN1 Sishencong, Ex-HN3 Hintang, bilateral NH54 Anmian, and bilateral MA-TF1 Shenmen) until a feeling of stiffness, soreness, and tingling was felt. Thereafter, the needles were kept in position for 20 min, before being removed and discarded in the medical needle disposal container. In the control group, the needles were taped to the same acupuncture points using Micropore tape instead of being inserted. Once again, the needles were retained in position for a period of 20 min in the control group and were then removed and discarded in the medical needle disposal container. The PSQI scores were recorded upon completion of the 10th session of acupuncture.

Data of this study was analyzed using a numerical independent comparative hypotheses test, using General Liner Model and post hoc Bonferroni if the data distribution is normal. If the distribution is not normal, a transformation is performed. Analyses are conducted on the basis of the distribution and the variant of the transformation results. If the data were not normally distributed, the Mann–Whitney test was used for analysis. The level of statistical significance was set at \( p < 0.05 \).

The study protocol was approved by the Health Research Ethics Committee, Faculty of Medicine, Universitas Indonesia-Cipto Mangunkusumo Hospital (Number: 287/H2.F1/ETIK/2014). The identity of the study participants were kept confidential and will not be included in any publications or disclosed to any parties without the participant's consent.

3. Results
This study included 48 patients diagnosed with depression and insomnia who were randomly allocated into two groups, the acupuncture group (\( n = 21 \)) and the sham acupuncture group (\( n = 21 \)). The dropout rate was 0% throughout the course of this study. A significant difference in results was observed between the two groups upon completion of the 10th acupuncture therapy session (\( p < 0.05 \)). The mean
PSQI scores were seen to decrease from $14.50 \pm 2.14$ to $5.70 \pm 2.25$ in the treatment group (patients receiving antidepressants and acupuncture), and this difference was statistically significant ($p < 0.05$). Conversely, the mean PSQI scores increased from $13.62 \pm 1.43$ to $16.66 \pm 1.83$ in the control group (sham acupuncture + antidepressants), and this difference was also statistically significant ($p < 0.05$). These findings suggest that acupuncture positively affected insomnia in patients receiving antidepressant therapy to a greater extent than sham acupuncture.

The PSQI scores also decreased from $14.50 \pm 2.14$ before treatment to $5.58 \pm 3.37$ 2 weeks after treatment in the acupuncture group, and this difference was statistically significant ($p < 0.05$). Conversely, the scores were seen to significantly increase ($p < 0.05$) from $13.62 \pm 1.43$ before treatment to $17.25 \pm 2.09$ 2 weeks after treatment in the control group. These differences suggest that the effects of acupuncture were still observed 2 weeks after completion of the therapy sessions.

**Table 1. Patient demographics by group**

|                | Case          | Control       |
|----------------|---------------|---------------|
| **Sex**        |               |               |
| Male           | 7 (29.2)      | 10 (41.7)     |
| Female         | 17 (70.8)     | 14 (58.3)     |
| **Education**  |               |               |
| Elementary–Middle School | 2 (8.3) | 2 (8.3) |
| High School or equal | 14 (58.3) | 12 (50.0) |
| Associate/Bachelor degree | 8 (33.3) | 10 (41.7) |
| **Marital Status** |           |               |
| Married        | 19 (50.0)     | 19 (50.0)     |
| Single         | 1 (33.3)      | 2 (66.7)      |
| Divorced       | 4 (57.1)      | 3 (42.9)      |
| **Age (years)**| 53.08±10.02   | 52.67±10.97   |
| **Total**      | 24 (100.0)    | 24 (100.0)    |

Table 1 shows the differences in demographics between the groups ($p > 0.005$).

**Table 2. Comparison of PSQI scores between groups**

|                                | Case   | Control  | Value |
|--------------------------------|--------|----------|-------|
|                                | Mean   | SD       | Mean  | SD    | p*     |
| **Initial PSQI Score**         | 14.50  | 2.14     | 13.62 | 1.43  | 0.104  |
| **PSQI score after the tenth session** | 5.70   | 2.25     | 16.66 | 1.83  | <0.001 |
| **PSQI score two weeks after the tenth session** | 5.58   | 3.37     | 17.25 | 2.09  | <0.001 |

*General linear model test, $p < 0.001$; $p$ value shown in the table is the post hoc Bonferroni analysis between groups.*

No differences in initial PSQI scores were observed between the groups (Table 2). However, a statistically significant difference in PSQI scores was observed between the groups upon completion of the 10th session ($p < 0.05$) and at the end of the 2 week follow-up period ($p < 0.05$) (Figure 1).
Figure 1. Comparison of PSQI scores between groups

4. Discussion
This study included 48 patients with depression and insomnia. The PSQI scores of all patients were recorded at the time of commencement of the study, after the 10th session of acupuncture therapy, and 2 weeks after completion of the therapy sessions. The MINI questionnaire was completed at the start of the study prior to administration of treatment. The acupuncture points used in this study included GV20 Baihui and Ex-HN3 Yintang as they regulate the expression of mRNA glucocorticoid receptors in the hippocampus and increase the gamma-Aminobutyric acid (GABA) levels in the brain. Evidence-based medicine has previously shown that the acupuncture point Ex-HN1 Sishencong regulates the brain by parasympathetic facilitation and hindrance of the sympathetic autonomic central nervous system [6]. N-HN52 Anmian stimulation can influence the sleep circadian rhythm modulation by affecting the rapid eye movement phase, and previous studies have demonstrated that it affects on mouse brain sleeping wave through vagal activity and muscarinic receptor modulation at the nucleus caudatus solitary tract [7]. Stimulation of the MA-TF1 Shenmen acupuncture point in the ears may affect the central nervous system by releasing endogen opioid peptides that decrease pain and exert sedative effects. Additionally, stimulation of this point may also regulate the autonomic nervous system and improve the functioning of the cortical–hypothalamus–pituitary–adrenal axis [6,8].

Acupuncture may have a synergistic effect with antidepressants, which mainly affect the serotonin which are selective serotonin reuptake inhibitors fluoxetine drug category, and the results of this research is in accordance with a literature which found that acupuncture stimulates serotonin production from accumben nucleus of mice [9], while fluoxetine is known to selectively inhibit the reuptake of serotonin. Acupuncture has been shown to influence the release of dopamine in the limbic system and the GABA receptor type B in the brain.

Additionally, acupuncture also increases met-enkephaline levels in the cerebrospinal fluid and influences the human psychological condition by exerting an antidepressant, antianxiety, and anticonvulsant effect, thus making it suitable for the treatment of sleeping disorders [10]. It can also inhibit sympathetic tonus, resulting in a decrease in the heart rate, blood pressure, and amplitude of electric conduction at a cellular level [11] and also stimulate nocturnal melatonin secretion. Other effects include improvement in the polysomnographic onset sleep latency, sleep efficiency, a significant
decrease in anxiety test scores [12], and an increase in melatonin levels in the pineal gland, hippocampus, and blood serum [13, 14].

5. Conclusion
The findings of this study show that acupuncture, when combined with antidepressants, can decrease the PSQI scores of patients with depression.

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