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## Efficacy and safety of acupuncture treatment on primary insomnia: A randomized controlled trial

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**Objectives:** The objective of the study is to evaluate the efficacy and safety of acupuncture treatment for primary insomnia.

**Methods:** We conducted a single-center, single-blinded, and randomized controlled clinical trial. 72 patients with primary insomnia were randomly assigned into two groups – the acupuncture group, which received acupuncture treatment, and the control group, which received sham acupuncture treatment. The treatment was given 3 times a week for 4 weeks. Patients were asked to wear sleep monitors and complete questionnaires every 2 weeks for a total of 8 weeks. The primary outcome was the insomnia severity index (ISI). The secondary outcomes were sleep parameters including sleep efficiency (SE), sleep awakenings (SA) and total sleep time (TST) recorded in the actigraphy, as week as scores of self-rating anxiety scale (SAS) and self-rating depression scale (SDS).

**Results:** Compared with pretreatment baseline, patients in both groups had varying degrees of improvements in their sleep conditions. Paired *t*-test showed that there was a significant difference in all indicators in the acupuncture group before and after acupuncture treatment. One-way analysis of covariance adjusted for baseline scores indicated that the ISI improved dramatically in the acupuncture group at 2 weeks post-treatment (F=11.3, P=0.001), 4 weeks post-treatment (F=33.6, P<0.001), 2 weeks follow-up (F=39.4, P<0.001) and 4 weeks follow-up (F=34.1, P<0.001). Similar significant improvements can also be observed in the SE, TST and SDS scores. Although no differences in SA and SAS were shown between the two groups until the end of the treatment, remarkable decrements in SA and SAS were found in the acupuncture treatment group after the 2 week and 4 week follow-ups.

**Conclusion:** Acupuncture treatment is more effective than sham acupuncture treatment on increasing insomnia patients' sleep quality and improving their psychological health.

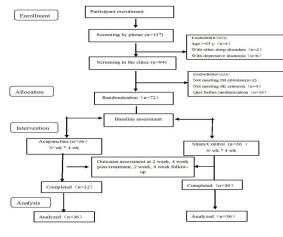


Figure 1. Participant flowchar

## Biography

Shifen Xu, PhD, has her expertise in long-term clinical and basic research of acupuncture on depression, insomnia, and anxiety, unique skills in acupuncture treatment of stroke, facial paralysis, epilepsy, pains and sub health status. She is a Professor and Director of Acupuncture Department in Shanghai Municipal Hospital of Traditional Chinese Medicine in China.

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