Acupuncture improves sleep in postmenopause in a randomized, double-blind, placebo-controlled study


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ABSTRACT

Background Insomnia increases in frequency as women approach and pass through menopause. Studies have not shown acupuncture efficacy for insomnia in postmenopausal women.

Objectives The aim of this study was to evaluate the effectiveness of acupuncture therapy on sleep parameters, depression symptoms and quality of life in postmenopausal women with insomnia.

Methods This study included 18 postmenopausal women aged 50–67 years old. Participants had a body mass index of ≤ 30 kg/m², presented a diagnosis of insomnia according to the DSM-IV criteria, had experienced at least 1 year of amenorrhea and had a follicle stimulating hormone level ≥ 30 mIU/ml. Participants were not using antidepressants, hypnotics or hormonal therapy. This study was randomized, double-blind and placebo-controlled. The sample was divided into two groups: acupuncture and ‘sham’ acupuncture. We performed ten sessions of acupuncture and ‘sham’ acupuncture during a period of 5 weeks. A polysomnography exam (PSG) and questionnaires (WHOQOL-BREF, Beck Depression Inventory and Pittsburgh Sleep Quality Index) were completed by all patients before and after the treatment period.

Results Anthropometric, polysomnographic, and questionnaire data were similar among the groups at baseline. Comparison of baseline and post-treatment data of the acupuncture group showed that treatment resulted in significantly lower scores on the Pittsburgh Questionnaire and an improvement in psychological WHOQOL. The acupuncture group had a higher percentage of the N3 stage than the sham group in PSG findings.

Conclusion Acupuncture was effective in improving reported sleep quality and quality of life in postmenopausal women with insomnia.

INTRODUCTION

Sleep disturbances increase in frequency as women approach and pass through menopause. These sleep disturbances include complaints of insomnia, poor sleep efficiency and breathing irregularity. Sleep complaints increase with age and are more common in women than in men. A number of studies highlight an incidence of insomnia of 28–63% in postmenopausal women. The incidence of sleep disturbance has been found to be higher in postmenopause, and over 60% of postmenopausal women suffer from insomnia. Insomnia is defined as problems in sleep onset, sleep maintenance and early awakening in the presence of adequate opportunity and circumstance for sleep, lasting for at least 1 month with daytime repercussions. Consequences reported in the cognitive sphere include irritability, attention deficit, memory deficit and others. Insomnia has been treated with pharmacological interventions such as hypnotics and non-pharmacological interventions such as relation-based treatment, stimulus control therapy, sleep restriction and a variety of cognitive and educational strategies. The close relationship between sleep problems and decreased levels of reproductive hormones in...
menopausal women suggests hormone therapy (HT) for relief,
with good results, especially in reducing hot flashes.11

We have previously observed the effects of HT on sleep
patterns.12 To avoid the possible collateral effects of HT,
alternatives for treatment are sought. Isoflavones have been
investigated and found to improve both sleep quality and
memory.13,14 We have good preliminary results using massage
to treat insomnia in postmenopause.15

Due to limitations and concerns with currently available
insomnia treatments, a sizeable proportion of the population,
especially in Europe and China, has turned to complementary
alternative medicine, including acupuncture, in the search for
a treatment with potential efficacy and few side-effects.16

Acupuncture is a clinical treatment modality in an indepen-
dent medical system of Traditional Chinese Medicine, which
was developed over 2000 years ago under the influence of
Oriental philosophical theories, such as Yin-Yang, Five Ele-
ments and Dialectical Unity. The basic acupuncture technique
is to insert acupuncture needles into select acupoints along
meridians, which are the channels believed to guide the flow
of bio-energy in human bodies.17 Acupuncture has been used
as a complement to estrogen therapy, placebos and relaxation
therapies to treat hot flushes in postmenopausal women.18
Electro-acupuncture has also been considered an efficient
and safe therapy to treat perimenopausal syndrome.16

Considering the efficacy of acupuncture in many areas
and the lack of research on this therapy in postmenopausal
women, the objective of this study was to verify the effects of
acupuncture on subjective and objective sleep parameters and
on quality of life in postmenopausal women with insomnia.

METHODS

The inclusion criteria were as follows: age from 50 to 67 years
old, postmenopausal status (at least 1 year of amenorrhea
before enrollment and a follicle stimulating hormone level
equal to or greater than 30 mIU/ml), body mass index (BMI,
calculated as weight in kilograms divided by the square of
height in meters) less than 30 kg/m², no previous exposure to
exogenous hormones and a diagnosis of insomnia according
to the DSM-IV.17 The volunteers underwent a routine climac-
teric check-up. Patients with severe and/or uncontrolled clin-
cal disease, a reported history or suspicion of carcinoma of
the endometrium and/or breast cancer, antidepressant or hyp-
notic drug use, apnea/hypopnea index (AHI) > 15 events/h,
or illiteracy were excluded. This study was approved by the
institutional ethics committee (Approval n.° 0229/08).

In the first phase of the study, patients received instructions
about the survey and signed the consent form. Patients
answered the brief form of the World Health Organization
Quality of Life (WHOQOL-BREF)19,20, Beck Depression
Inventory21 and Pittsburgh Sleep Quality Index (PSQI)
questionnaires.22 The patients then underwent a basal poly-
somnography (PSG) recording.

Sleep stages were determined according to Rechtschaffen
and Kales criteria.23 Respiratory events24, periodic leg
movements25 and arousals26 were scored using standardized
criteria. The sleep parameters analyzed were: sleep latency,
rapid eye movement (REM) sleep latency, sleep efficiency,
stages 3 and 4, REM sleep, AHI (number/h); periodic leg
movements (PLM, number/h).

The patients were randomly assigned to one of two groups:
an acupuncture group and a sham acupuncture group (pla-
cepto). The acupuncture group underwent two applications
per week for 5 weeks for a total of ten sessions. The sessions
consisted of the insertion of very fine metal needles into the
skin at specific points on the body (acupoints). A similar tech-
nique was used for the acupuncture sham group, but at
different acupoints.18 Patients remained in a comfortable
position for 30 min with disposable 0.25 mm × 40 mm acu-
puncture needles in place, following basic hygiene standards.
Five weeks after beginning the sessions, the patients were
re-evaluated. At this time, they underwent a second PSG
recording at Instituto do Sono/AFIP. On the next day, they
again answered the questionnaires described above. Neither
the researchers nor the participants knew which patients
had received the sham acupuncture and which had received
the actual acupuncture, to prevent bias on the part of the
researchers and the volunteers.

Statistical analysis

Statistical analysis was performed using SPSS (version 13).
Descriptive analysis (means ± standard errors) was used to
categorize the groups. A Mann–Whitney test was used to
compare the variables between the two groups (acupuncture
and sham), and a Wilcoxon test was performed for repeated
measures between both groups for PSG parameters and ques-
tionnaires. Statistical significance was set at 5% (p < 0.05).

RESULTS

This double-blind, placebo-controlled study interviewed 102
postmenopausal women. Eighteen patients met the initial cri-
tera of insomnia (DSM-IV) and were included in the study.
All patients gave written informed consent and completed
the study protocol.

At baseline, the two groups were not significantly different
in anthropometric characteristics such as BMI and age.
There were no differences between the variables of age and
BMI when comparing the two groups, showing comparative
viability between the acupuncture (age 58 ± 4.85 years;
BMI 25.78 ± 3.62 kg/m²) and sham (age 59.8 ± 5.86 years;
BMI 25.43 ± 2.9 kg/m²) groups (p = 0.82, p = 0.45 for BMI
and age, respectively).

The PSG features showed differences between the two
groups in the final evaluation. The acupuncture group had
a higher percentage of the N3 + 4 stage than the sham
group (16 ± 1.4 vs. 8.64 ± 2.6, respectively; p = 0.02; effect
size = 0.51), and the sham group had a higher PLM index than
the acupuncture group (11.68 ± 6 vs. 1.47 ± 1.5, respectively;
DISCUSSION

Acupuncture intervention produced a significant improvement in subjective sleep quality, as evaluated by the psychological WHOQOL and sleep quality indicated by the PSQI at the final evaluation. This finding suggests that the acupuncture treatment was effective for treating insomnia, as suggested in other studies that showed an improvement in sleep quality through acupuncture by different types of evaluations, such as melatonin secretion and nocturnal hot flushes. The improvements detected in the scores of the PSQI questionnaire regarding baseline and final evaluations of the acupuncture group were similar to the findings of Zhou and colleagues, who studied the effect of scalp point penetration needling on the sleep quality of insomnia patients. However, the target population in their study was not only women of a specific age range, as in our study. A systematic review of randomized, controlled trials using meta-analyses to study acupuncture for the treatment of insomnia showed a beneficial effect of acupuncture compared to no treatment and of real acupressure compared with sham acupressure on total PSQI scores. However, these results were also not specific to menopausal women.

Lunny and Fraser showed that more than 50% of women use complementary and alternative medicine (CAM) during menopause. Our previous studies showed improvements in sleep quality in postmenopausal women with insomnia under physical therapy and isoflavone. Llanas and colleagues used treatment consisting of segmental and global stretching exercises, strengthening exercises, massage therapy and relaxation techniques. They found an increase in REM sleep and in total sleep efficiency in patient I and a reduction in sleep latency and an increase in

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Polysomnographic results before and after 5 weeks of treatment in the Acupuncture and Sham groups. Data are given as mean ± standard error</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Acupuncture</td>
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<tr>
<td></td>
<td>Baseline</td>
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<tr>
<td>Sleep latency</td>
<td>17.79 ± 3.6</td>
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<tr>
<td>Sleep efficiency</td>
<td>77.37 ± 2.9</td>
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<td>N3 + 4 stage (%)</td>
<td>20.14 ± 2.9</td>
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<tr>
<td>Rapid eye movement stage (%)</td>
<td>17.41 ± 1.7</td>
</tr>
<tr>
<td>Apnea-hypopnea index/h</td>
<td>4.92 ± 0.7</td>
</tr>
<tr>
<td>Blood oxygen saturation &lt; 90% O2 (%)</td>
<td>0.61 ± 0.2</td>
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<tr>
<td>Arousal/h</td>
<td>14.1 ± 1.7</td>
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<tr>
<td>Periodic leg movements/h</td>
<td>1.23 ± 1.2</td>
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* Comparison between the pre- and post-treatment moments of each group; † comparison of the groups in the post-intervention moment, p < 0.05
the percentage of slow wave sleep in patient 2. The use of isoflavone led to an increase in sleep efficiency compared to the placebo group.14

In previous studies, we used a combination of relaxation training, physiotherapy, yoga, massage, postures, and cognitive-behavioral therapy to improve sleep quality and to reduce menopausal symptoms, with good results.17

Most studies on acupuncture in the literature have focused on menopausal symptoms, especially hot flushes, with positive outcomes. However, these studies have not established conclusions about the efficacy of acupuncture.18,19

Previous studies have presented data on the association between insomnia, and acupuncture may be an effective intervention for the relief of insomnia.20 Ruan and colleagues demonstrated that electro-acupuncture improved sleep quality by increasing the percentage of slow wave sleep and REM sleep in chronic insomniacs.40 However, Zhou and colleagues found that scalp point penetration needling produced a more significant improvement in the sleep quality and sleep structure of insomnia patients than routine needling.30

The diagnostic criteria for insomnia are essentially clinical and based on subjective evaluation.17 The acupuncture group reported an improvement in sleep quality (Table 2). These data suggest an improvement in subjective insomnia, a self-reported complaint of non-restorative sleep, difficulty falling asleep, frequent awakenings or waking too early in the morning.41 The same results were demonstrated by Zhou and colleagues,30 who found an improvement in sleep latency, total sleep time and the percentage of slow wave sleep after acupuncture treatment in insomnia patients. As shown in previous studies, an improvement in subjective sleep quality is commonly observed in postmenopausal women even when PSG is not altered or is altered only slightly.12

The sham group showed a decrease of NREM 3 + 4 between the baseline and final evaluations but it was not clinically relevant. Additionally, this study found an augmentation of the Periodic Leg Movements index, which could be related to the high prevalence of night-to-night variability in periodic leg movements.42

CONCLUSION

Despite the large number of women suffering from climacteric syndrome and the high frequency of sleep disturbances in postmenopausal women, there is a lack of studies addressing the treatment of sleep difficulties, especially concerning complementary and/or alternative therapies. This scarcity of information led our group to use polysomnographic examinations to investigate sleep disorders in postmenopausal women with complaints of insomnia and to examine the effects of acupuncture in this population.

Based on the results of this randomized, controlled-trial study, we conclude that acupuncture is effective in improving the quality of sleep and the psychological domain of quality of life in postmenopausal women with insomnia. Furthermore, we observed an important decrease in subjective insomnia supported by a high effect size.

Conflict of interest This was not an industry-supported study. The authors have indicated no financial conflicts of interest.

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Acupuncture in postmenopausal women with insomnia

Hachul et al.