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Auricular Acupuncture Versus Sham Acupuncture in the Treatment of Women Who Have Insomnia

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ABSTRACT

Background: Improvement in sleep parameters in relation to acupuncture treatment is often found and referred to as being a positive side-effect in the treatment of other illnesses. There is a lack of randomized studies, which primarily study the direct effect of acupuncture on sleep.

Objectives: To investigate whether or not auricular acupuncture has an effect on sleep parameters among people with insomnia.

Design: A single-blind, randomized pilot study where the treatment group received auricular acupuncture treatment (AAT) on active points and the control group received AAT on sham points during a 6-week treatment period.

Setting: Participants were recruited from the psychiatric outpatient clinics in the geographical area connected to a local hospital in central Sweden.

Subjects: In all, 28 women were included in the study, with 14 in each group. Their mean and median age was 53 years.

Outcome Measures: Sleep parameters were obtained by using the Karolinska Sleep Diary.

Results: No statistically significant differences were observed between the groups relating to parameters associated with the definition of insomnia. The treatment group experienced that it was easier to wake up in the morning compared with the control group (repeated-measures analysis of variance, $p = 0.04$). Both groups showed a statistically significant recovery in subjective sleep parameters during the study period (weeks 1–6) compared with baseline values (week 0).

Conclusions: Only modest evidence was found supporting the hypothesis that AAT may have an effect on insomnia. Least improvements were found in *total sleep time* and *number of awakenings*, 2 parameters directly associated with the definition of insomnia. AAT may have a role in the treatment of insomnia, especially in combination with other treatments such as cognitive behavioral therapy. This study provides an example of how to perform studies using alternative therapies for sleep disorders.

INTRODUCTION

The definition of insomnia as defined by the Diagnostic and Statistical Manual of Mental Disorders DSM-IV-TR[1] includes having problems of initiating and/or maintaining sleep, with accompanying daytime tiredness causing significant suffering and a lower ability in cognitive activities. Sleep problems, including insomnia, are a common problem. In a worldwide study from 2005 ($n = 35{,}327$), about 25% of study participants reported "disturbed sleep."[2]

Due to its influence on the central nervous system and the immunologic system, sleep plays an important role in keeping a homeostasis between sickness and health.[3,4] Insufficient restitution after stressful events or strains may lead to exhaustion and burnout.[5–6,*] Spiegel et al.[7] state that sleep debt may increase the severity of age-related chronic disor-

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ders, due to the fact that disturbed sleep affects metabolic function, hormone levels, functional ability, as well as individuals' subjective well-being negatively.

The cause of insomnia is multifactorial.[8] Anxiety and depression may be the major psychologic causes of poor sleep,[9] but anxiety and depression may also be caused by insomnia.[10] Ekstedt* suggests that stress can be a common denominator of sleep disturbances, because it affects sleep both physiologically and psychologically.

Stress and difficulties in dealing with stress may lead to sleeping disorders* as well as depression.[11] Permanent or repeated exposure to stress can result in abnormal elevations of circulating glucocorticoids such as cortisol, which has been observed to result in negative effects on neural structures, especially in the hippocampus, an area in the brain responsible for memory functions.[12] Apart from the psychologic effects, insomnia also leads to an alteration of the immunological, neuroendocrine, and thermal functions of the body, and contributes to pathological processes such as infectious diseases.[4]

Sleep disorders can be treated with a variety of methods, including pharmacological treatment with hypnotics and behavioral therapy.[10,11,13] Pharmacological treatment can be effective for short-term treatment of insomnia, but there are substantial risks for a recurrence of insomnia when the treatment is discontinued.[10,14]

Jacobs et al.[15] have shown that behavioral therapy has a better effect than pharmacological treatment, in short-term as well as in long-term treatment of insomnia, which is supported by others.[16,17] In a review paper, Benca[13] concludes that there is no definite evidence that any of the 2 forms of treatment (behavioral/pharmacological) can be preferred before the other. However, there are higher risks of experiencing adverse effects, such as daytime drowsiness, with pharmacological treatment.

Acupuncture and sleep disorders

It is suggested that acupuncture affects the central nervous system through structures in the spinal cord and the brain that regulate transmitter substances such as dopamine, norepinephrine, and acetylcholine.[18] Spence et al.[19] have found evidence that acupuncture may increase the nocturnal endogenous melatonin, an important transmitter substance with regard to the regulation of the circadian cycle.

Indications exist that both traditional Chinese and European auricular acupuncture affect insomnia by increasing subjective sleep quality, total sleep time, sleep efficacy, and sleep onset latency.[18–22] Prison inmates who receive auricular acupuncture according to the National Acupuncture Detoxification Association protocol, in order to alleviate symptoms of psychological and physical discomfort related to drug use, report that they feel more relaxed and calmer after the treatment.[23] They also experience the acupuncture as generating better sleep quality.[24]

Improvement in sleep parameters in relation to acupuncture treatment is often found and referred to as being a positive side-effect in the treatment of other illnesses, but there is a lack of randomized studies, which primarily study the direct effect of acupuncture on sleep.[21,22]

The objective of this study was to investigate whether or not auricular acupuncture has an effect on sleep parameters among people with insomnia.

Research hypothesis

The hypotheses of the study were that auricular acupuncture therapy given to a treatment group on active points results in the following:

- reduction of sleep onset latency
- reduction of the number of awakenings during nighttime sleep
- increased total sleep time

This was in comparison with baseline data as well as a control group (sham acupuncture), receiving auricular acupuncture therapy on inactive points.

METHODS

This pilot study with a single-blind randomization procedure followed an experimental prospective design with 2 parallel groups of equal size—a treatment group, and a control group, with a total of $n = 28$. The intervention consisted of auricular acupuncture treatment (AAT) on active points in the treatment group and AAT on inactive sham points in the control group.

The Ethics Committee at Umeå University approved the study.

Outcome measures

The Karolinska Sleep Diary (KSD) was used in order to obtain data referring to the purpose of the study. KSD consists of items referring to initiation and maintenance of sleep as well as a global appreciation of sleep. The diary has been validated against polysomnography, shows good correlations with objective sleep measures,[25,26] and has been used in several studies.[27–29,*] Items in KSD relating to insomnia were primarily investigated in line with the objective of this study.

The primary efficacy measures to determine differences in sleep parameters between the 2 groups, and comparing with baseline data were as follows:

- Sleep onset latency: the time in bed until falling asleep ($<$ 30 minutes is defined as normal)
- Number of awakenings during nighttime sleep

- Total sleep time
- Sleep efficacy expressed in percent of time asleep while in bed (>85% is defined as normal)
- Sleep quality—phrased "How did you sleep?"—very well (5), very badly (1)
- Sleep Quality Index: formed by 4 of the items in KSD (sleep quality, calmness of sleep, easy to fall asleep, and slept throughout the allotted time)

The participants in the study filled out the sleep diary upon awakening each morning during 5 days of pretreatment, in order to obtain baseline data. The day after AAT treatment, both groups began the recording of subjective sleep (KSD). This recording was carried out daily during the study period of 6 weeks.

Treatment procedure

The treatment protocol followed Nogier's ear reflex theory as described by Oleson.[30] The treatment group received AAT on 5 reflex points relating to treatment of insomnia (*Shen Men*, Sympathetic autonomic, Kidney, Insomnia 1, and Insomnia 2). The control group received sham acupuncture treatment, in Helix (HX) points, between landmarks 2 and 3 (HX 8–10) clearly remote from the inner ear area.[30] In Figure 1, the different AAT points are illustrated.

Stainless steel disposable needles (0.30 × 13 mm, VIVA®; Helio, San Jose, CA) were inserted according to standard procedure in each of the 5 points bilaterally.

Study procedure. Study participants were treated in groups of 3 (belonging to the same group: treatment/control) in a secluded room. During the treatment they were recommended to stay silent, sitting in comfortable recliner chairs, and were also offered soft music to listen to. Each treatment session lasted 45 minutes and was performed 3 times/week during the first 3 weeks and during the following 3 weeks they underwent 2 sessions/week, which resulted in a total of 15 treatments over 6 weeks. In the start-up phase of the study, an independent person observed the acupuncturist to assert that her personal behavior did not differ between the treatment and control groups. The acupuncturist (M.R.) is trained in auricular acupuncture and has 3 years' experience of providing this treatment (approximately 500 treatments).

Material

Inclusion of participants. A decision was made to include a small number of participants, resulting in 14 persons in each group, in all $n = 28$. Participation in the study followed a systematic sampling procedure in which the first participant was randomized to the control group and each subsequent following participant was alternatively allocated to 1 or the other group.[31]

Inclusion criteria

- Insomnia according to DSM-IV-TR[1]
- Informed consent
- Female
- Age 40–65 years

Exclusion criteria

- Pregnancy
- Substance abuse
- Medicated with neuroleptics, hypnotics, or antiepileptics
- Affective bipolar disorders

Study participants were recruited by a referral procedure from the psychiatric outpatient clinics in the geographical area connected to a local hospital in central Sweden. A psychiatrist confirmed that the diagnosis of insomnia conformed with *DSM-IV-TR*.[1] After receiving the letter of referral, each potential study participant was contacted by telephone

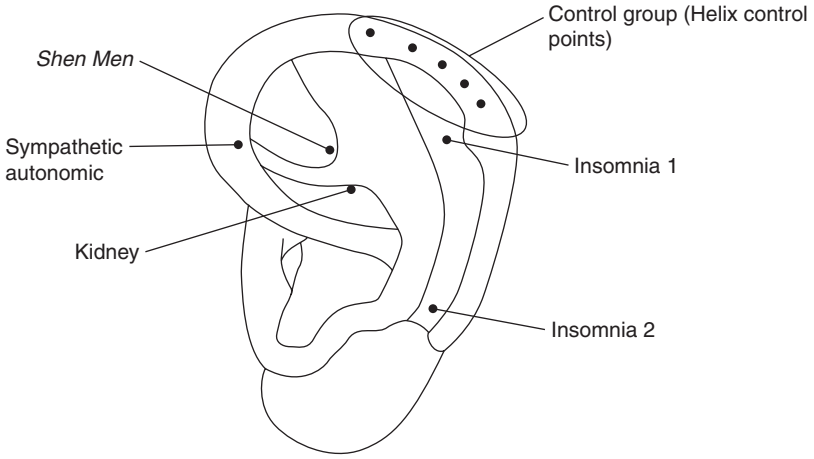

FIG. 1. Auricular acupuncture points used in the treatment versus the control group.

Table 1. Characteristics of the Two Groups

	Treatment group (n = 14)	*Control group (n = 14)*	p *value**
Age (mean/SD)	54/7	52/5	0.2
Duration of insomnia (years mean/SD)	5.6/5.5	9.7/10.7	0.3

*Student's *t*-test.

and informed of the general nature of the study. No one declined participation. During 5 days before the first treatment, each participant was instructed to fill out the KSD in order to obtain baseline data. Immediately prior to the first treatment session, the participant was once again informed of the study and verbal as well as written informed consent was obtained. Participants were included from October 2003 until April 2005. One participant chose to discontinue treatment during the ongoing study and subsequently her data were excluded from analysis. No adverse effects due to the acupuncture treatment were reported by the participants.

In all, 28 women completed the full study, their mean and median age was 53 years (range 40–61, SD ±6). There were no statistical significant differences between the 2 groups regarding age and duration of insomnia. Participants were included consistently during the entire study period.

In Table 1, the characteristics of the participants are shown for each group.

Statistical methods

We conducted Student's *t* test when appropriate,[32] and a 2-factor repeated-measures analysis of variance (R-ANOVA)[33] in order to explore the differences in sleep parameters between the treatment and the control group. For the purpose of data reduction, mean values of sleep parameters were computed before being entered in the R-ANOVA.

Daily values for each item in the KSD were calculated into mean values covering the 7 days of the week (weeks 1–6), 5 days for baseline values (week 0). The weekly value (week 1–6) has been used in order to test for differences *between* the 2 groups. Similarly, the mean week values were used in the "within group" analysis to calculate a contrast, where values from weeks 1–6 were compared with the baseline value (week 0).

A test with a *p*-value less than 0.05 was considered statistically significant. Statistical analysis was made using SPSS (version 13 SPSS Inc., Chicago, IL).

Sample size. Since there was a lack of reliable data to use as a basis for calculation of sample size, no power analysis was made. The sample size was determined from what was reasonable to perform due to the high treatment intensity and the strict inclusion criteria, in combination with the resources provided for the study.

RESULTS

Both the treatment and the control group attained statistically significant improvements in most sleep parameters during the study period, compared with baseline values (R-ANOVA *within-groups analysis*). Tested parameters are illustrated in Table 2.

Sleep-onset latency. In the entire group, 11 participants (39%) fell asleep within 30 minutes from bedtime, during baseline measurements (week 0). The corresponding number for the last study week (week 6) was 13 participants (46%). There were no statistically significant differences between the treatment and control groups regarding the pro-

Table 2. Between-Group Analysis of Subjective Sleep Variables Tested in the Study (The Karolinska Sleep Diary)

		Treatment						*Control*					
	Week	*1*	*2*	*3*	*4*	*5*	*6*	*1*	*2*	*3*	*4*	*5*	*6*
Total sleep time													
Sleep efficacy						+	+			+		+	
Sleep-onset latency						+	+						
Sleep quality index		+	+	+	+	+	+		+	+	+	+	+
Sleep quality *(How did you sleep?)*			+	+	+	+	+			+	+	+	+
Feeling refreshed after awakening			+	+	+	+	+			+	+	+	+
Easy to fall asleep			+	+	+	+	+					+	
Calmness of sleep		+	+	+	+	+	+		+	+	+	+	+
Slept throughout the allotted time						+	+			+		+	
Number of awakenings								+	+	+	+	+	+
Slept enough?			+	+	+	+	+		+	+	+	+	
Easy awakening										+		+	

Comparisons are made *within* the treatment group and the control group using repeated-measures analysis of variance. Comparisons of values at baseline (week 0) and values from weeks 1–6 define the contrast. Every plus sign (+) indicates a statistically significant difference ($p < 0.05$) (a positive improvement of the variable) between baseline values and a weekly value during the study period.

TABLE 3. WITHIN-GROUP ANALYSIS OF SUBJECTIVE SLEEP VARIABLES TESTED IN THE STUDY (THE KAROLINSKA SLEEP DIARY)

	F *value*	p *value*
Total sleep time	0.35	0.3
Sleep efficacy	0.01	0.9
Sleep-onset latency	0.0	1.0
Sleep quality index	0.3	0.6
Sleep quality *(How did you sleep?)*	0.01	0.8
Feeling refreshed after awakening	1.5	0.2
Easy to fall asleep	0.4	0.6
Calmness of sleep	0.3	0.6
Slept throughout the allotted time	0.2	0.7
Number of awakenings	0.2	0.7
Slept enough?	0.004	1.0
Easy awakening	4.9	0.04*

*$p < 0.05$.

Comparisons are made between the treatment group and the control group using a 2-factor analysis of variance (ANOVA) for repeated measurements (R-ANOVA). The values tested are mean values from weeks 1–6.

portion of participants with prolonged *sleep-onset latency* (>30 minutes) at the end of the study (Fisher's exact test).

Easy awakening in the morning. In the *between-groups analysis*, we have observed a statistical significant difference regarding *easy awakening in the morning,* $p = 0.04$ (R-ANOVA); the result is presented in Figure 2. In Table 3, the remaining sleep variables from the KSD are presented. There are no other statistically significant differences between the 2 groups.

Number of awakenings. An important result to notice is that the control group shows a reduction of *number of awakenings* in all 6 measurements compared with baseline, and the treatment group in none (Table 2).

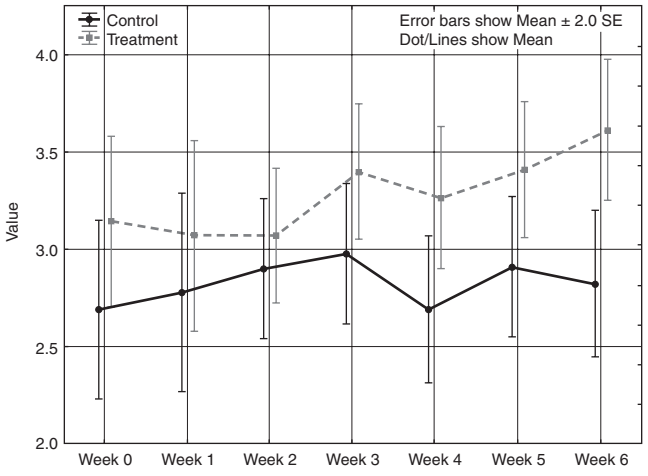

FIG. 2. This line chart illustrates a statistically significant difference between the 2 groups regarding easy awakening ($p < 0.05$). The treatment group can more easily wake up in the morning than the control group.

Total sleep time. At baseline, the participants ($n = 28$) slept on average 5 hours and 15 minutes (SD ±121 minutes), and in the 6th week they slept on average 6 hours and 15 minutes (SD ± 88 minutes). There are no statistically significant differences between either the treatment and control group or within the separate groups or in the total sample.

Sleep efficacy. At baseline, the participants had a sleep efficacy corresponding to 67% (SD ±18%), and in the 6th week it had increased to 76% (SD ±16%). Figure 3 illustrates the participants' sleep efficacy compared with baseline values. The treatment group has attained a statistically significant improvement ($p < 0.05$) in sleep efficacy compared with baseline, especially in weeks 4–6, and the control group in week 5, compared with baseline.

Sleep quality and sleep quality index. Both groups have obtained statistically significant improvements in *sleep quality* during the study period compared with baseline values ($p < 0.05$. R-ANOVA *within-groups analysis,* illustrated in Table 2). Figure 4 illustrates the statistically significant improvement for both groups ($p < 0.05$) regarding *sleep quality index*. No statistically significant differences are observed between the 2 groups ($p > 0.05$. R-ANOVA *between-groups analysis*).

DISCUSSION

The research hypotheses of the study were that auricular acupuncture therapy given to a treatment group on active points would result in a reduction of sleep onset latency, a reduction of the number of awakenings during nighttime sleep, and increased total sleep time. The findings of the study are inconclusive, and we are unable to confirm or reject the research hypotheses.

There are results indicating that AAT may have an effect on sleep parameters. In this study, we have only observed 1 statistically significant difference *between* the 2 groups. The treatment group experienced that it was easier to wake up in the morning.

As noted above, both the treatment and control groups showed a remarkable recovery in subjective sleep parameters during the study period. We have observed statistically significant improvements on almost all sleep parameters when testing for differences within the groups compared with baseline values. There are tendencies as shown in the figures and the tables that the treatment group obtained more benefit from the acupuncture than the control group did. These differences were not statistically significant when the study was terminated. Had we been able to perform a long-term follow-up, the differences might have been more pronounced. We aimed to have a long-term follow-up at 3 months post-treatment, but the response rate was too low

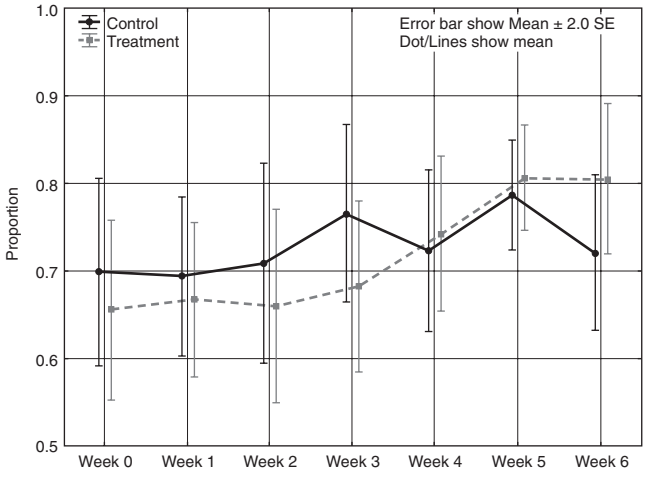

FIG. 3. Sleep efficacy (percent of time asleep while in bed) from baseline (week 0) throughout study period (weeks 1–6). A higher value indicates a positive improvement of the measure. The treatment group has attained a statistically significant improvement in sleep efficacy compared with baseline, especially in weeks 4–6 ($p < 0.05$), and the control group in week 5 ($p < 0.05$), compared with baseline.

(<50%). As a result, the data from long-term follow-up cannot be analyzed.

As noted in the introduction, there are indications that both traditional Chinese acupuncture and European auricular acupuncture affect insomnia by increasing subjective sleep quality, total sleep time, sleep efficacy, and decreasing sleep-onset latency.[18–22] Results from previous research are inconclusive and do not give evidence that acupuncture is a treatment to recommend on a larger scale in the treatment of insomnia.[34] On the basis of the present study, we cannot draw any general conclusions about the effect of AAT on sleep parameters. The conclusions are limited due to the small sample size and the lack of a third control group without needle insertion. AAT may have an effect on the sleep variables under observation, but from our study it seems rather irrelevant where the needles are inserted in the ear, as the control group has benefited from the treatment as well. A possible explanation may be that the needle insertion itself produces a physiological response regardless of the localization of the point of insertion. A recent review studied the effect of acupuncture on anxiety, and the authors conclude that especially auricular acupuncture seems to have a relieving effect on anxiety[35] and the mechanisms of stress, an important aspect of insomnia.* The issue relating to how "inactive" control points are has previously been discussed. It has been shown that endogenous melatonin responds to acupuncture treatment,[19] but not concluded that the secretion of melatonin responds to specific acupuncture points only. The relevance of "active" points versus "inactive" points has also been raised in other studies.[24,36] The effect may quite well be a placebo effect (for both groups), or may be affected by treatment-related factors such as soft music and a calm relaxing environment, and the attitude of the treatment provider may also play an important role. It is also possible that the participants' sleeping difficulties have decreased during the course of time. We should therefore bear in mind that the participants have suffered from insomnia/sleeping difficulties over a long period of time. It is interesting to observe that neither total sleep time nor sleep-onset latency was affected by the AAT, leading to the conclusion that only a few of the participants would be diagnosed as noninsomniacs at the end of the study.

In this study, sleep diaries have been used as the method of data collection. Sleep diaries do not comprise an objective measure of an individual's sleep such as, for example, electroencephalography-polysomnography would have provided. People with insomnia tend to overestimate their sleep-onset latency and underestimate their total sleep time compared with polysomnography.[37] However, sleep diaries are considered to be reliable and to correspond to data obtained from polysomnography, regarding changes in sleeping patterns, but most importantly they illustrate a person's subjective apprehension of sleep.[15,17] During the stage of designing this pilot study, a decision was made to include a limited number of women ($n = 28$). As mentioned, this was due to the high treatment intensity, the strict inclusion criteria, and limited staff resources. The small sample size is a major limitation of this study, which may have contributed to the modest differences between the two groups. In order to overcome the limitations, future research needs to include more participants, and as a suggestion an additional true control group, not given any form of active treatment (i.e., no needle insertion). A recommendation would also be to have a short- and long-term follow-up in order to have a better possibility to study treatment effects.

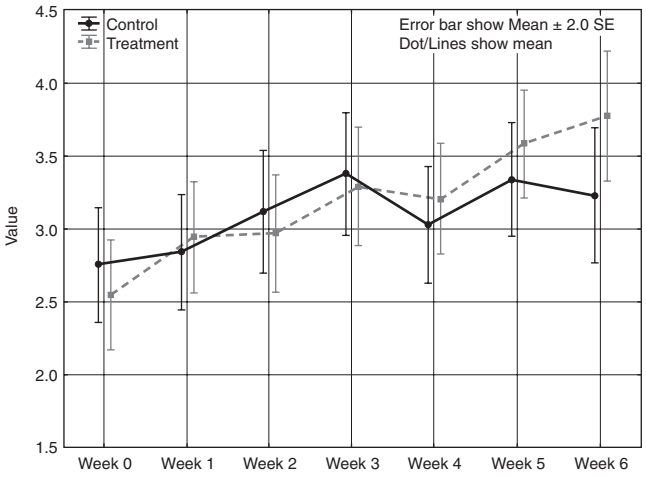

FIG. 4. Sleep quality index at baseline (week 0) throughout the study period (weeks 1–6). A higher value indicates a positive improvement of the index.

CONCLUSIONS

We have not found any strong support for the specific study hypothesis, that auricular acupuncture treatment has an effect on parameters related to insomnia; on the contrary, we have found the least improvements in *total sleep time* and *number of awakenings* to be two important parameters directly associated with the definition of insomnia. From the results of this study, we conclude that AAT may have a positive effect on sleep parameters, regardless of where the needle is inserted, because the treatment group and the sham acupuncture group had similar improvements in most variables. Conclusions drawn from the results of this study are limited due to the small sample size, and there is a need to perform more studies with a larger sample size. AAT may have a role in the treatment of insomnia (as indicated in the study), perhaps in combination with other treatments such as cognitive behavioral therapy. This study may provide an example on how to perform studies using alternative therapies for sleep disorders.

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