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Sleep patterns in a randomized controlled trial of auricular acupuncture and cognitive behavioral therapy for insomnia

Lena Bergdahl [a, *], Jan-Erik Broman [a, b], Anne H. Berman [c], Kristina Haglund [a], Lars von Knorring [a], Agneta Markström [b]

[a] Department of Neuroscience, Psychiatry, Uppsala University, SE-751 85 Uppsala, Sweden
[b] Department of Medical Sciences, Lung, Allergy and Sleep Research, Uppsala University, SE-751 85 Uppsala, Sweden
[c] Department of Clinical Neuroscience, Center for Psychiatry Research, Karolinska Institutet, Norra Stationsgatan 69, SE-113 64 Stockholm, Sweden

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ABSTRACT

The aim of the study was to objectively examine how sleep patterns were affected in a short- and long-term perspective after auricular acupuncture (AA) and cognitive behavioral therapy for insomnia (CBT-i). Sixty participants with insomnia disorders (men/women 9/51; mean age of 60.5 years, (SD 9.4)), were randomized to group treatment with AA or CBT-i. Actigraphy recordings were made at baseline, post-treatment and 6-month follow-up. The CBT-i group reduced their time in bed, their actual sleeping time, their sleep latency and their actual time awake. The AA group slept longer, increased their time in bed and decreased their sleep latency post-treatment. The between-groups results differed in wake-up time, rising, time in bed, actual sleep time and actual wake time. The differences were not maintained six months later. In accordance with previous findings the results support the notion that the objective sleep time does not necessarily affect the subjective perception of insomnia.

1. Introduction

Insomnia is a common problem in the general population (e.g [1]) and is known to be associated with psychiatric and somatic comorbidities [2–5]. The diagnosis is characterised by difficulties initiating and/or maintaining sleep as well as residual daytime symptoms three times a week or more often during a period of 3 months or more [6]. The perception of good or bad sleep is also related to age and gender [7–9]. Insomnia may influence different aspects of life, and in a review by Kyle et al. [10] it was concluded that insomnia has a negative influence on different aspects of health-related quality of life (HRQoL), adequate treatment of insomnia can, however, lead to significant improvements.

Insomnia can be measured in various ways, objective as well as subjective (e.g. [11]). When it comes to objective measurements, polysomnography (PSG) is considered to be the golden standard of sleep assessment [12]. PSG can be performed in the laboratory or at home. Despite the fact that PSG can be used to determine the different sleep stages and the total sleep time, it is not primarily used to diagnose insomnia, but rather other sleep disorders such as narcolepsy, sleep disordered breathing disorders and parasomnia [12]. Actigraphy is another objective method to measure physical activity, and it is also, indirectly, used to study sleep-wake patterns by assessing movement [13]. The actigraph is a portable device, measuring movements by being attached to the non-dominant wrist. One of the advantages of actigraphy is that, in comparison to PSG, it is possible to record many days and nights without a significant intrusion in a person's everyday life. It also allows the patient to sleep in the natural sleep environment. According to a review by Ancoli-Israel et al. [13] the majority of the literature shows that the reliability and validity of actigraphy is moderate to high in differentiating sleep from wake in a healthy population. Vallières et al. [14] performed a study where actigraphy was compared to PSG and sleep diary. The results confirmed actigraphy as a reliable method for assessing insomnia disorder. In a population with fragmented sleep, the reliability of actigraphy was questioned by Paquet et al. [15], who performed a study using actigraphy and PSG during one nocturnal sleep episode and two daytime recovery sleep episodes. The results, in accordance with previous research by Sivertsen et al. [16], demonstrated that

* Corresponding author.
E-mail addresses: lena.bergdahl@neuro.uu.se (L. Bergdahl), jan-erik.broman@neuro.uu.se (J.-E. Broman), anne.h.berman@ki.se (A.H. Berman), kristina.haglund@neuro.uu.se (K. Haglund), lars.von_knorring@neuro.uu.se (L. von Knorring), agneta.markstrom@akademiska.se (A. Markström).

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Abbrevations

AA	Auricular acupuncture
CBT-i	Cognitive behavioural therapy for insomnia
DSM-5	Diagnostic and statistical manual of mental disorders, fifth edition
HRQoL	Health-related quality of life
ISI	Insomnia Severity Index
MCS	Mental component summary
NADA	National Acupuncture Detoxification Association
PCS	Physical component summary
PSG	Polysomnography
RCT	Randomized controlled study
SF-12	Short Form 12
SD	Standard deviation
SE	Standard error

actigraphy was less reliable than PSG for detecting wakefulness [15]. Rowe et al. [17] however found that a minimum measurement period of seven days was required to obtain reliable information regarding sleep parameters. To establish insomnia diagnosis, subjective methods such as a clinical interview according to the diagnostic and statistical manual of mental disorders, fifth edition (DSM-5) criteria [6], combined with self-report questionnaires, is standard procedure. A sleep diary or sleep log can also be used to monitor the sleep-wake pattern. Insomnia symptoms are subjective [18] and the experience of the symptoms, measured with subjective measurements, does not necessarily correlate with the objective measurements since persons with insomnia tend to underestimate their total sleep time as well as overestimating time spent awake in bed [19]. While objective measurements can show an improved actual sleep time after an intervention, subjective measurements may not necessarily reflect the improvement [19–22].

There are various ways to treat insomnia. Over the last two decades interest has increased in developing non-pharmacological insomnia treatments, an effort that enables reduction of hypnotic drug dosages as well as side effects [23]. The most effective non-pharmacological treatment is cognitive behavioral therapy for insomnia (CBT-i) [24]. The components of CBT-i include cognitive techniques addressing common insomnia-related features such as rumination and dysfunctional beliefs and attitudes towards sleep, and behavioral techniques addressing practical aspects such as sleep restriction (e.g [25]). Another non-pharmacological treatment that has been tested to treat insomnia is acupuncture [26]. Acupuncture is a complementary treatment method, which to some extent is used in the health care system, for example within maternity care and pain management [27]. Auricular acupuncture (AA) is a branch of traditional acupuncture and has also been used to treat insomnia [22,28–30]. Given that objective measurements do not always correlate with subjective measurements and that there are very few studies of AA for insomnia where objective measurements of the sleep patterns are used [22,31,32], we found it important to report the effects of CBT-i and AA with an objective sleep measurement. In a recent study we compared the treatment effects of AA and CBT-i regarding the subjective symptoms of insomnia severity [33], using the Insomnia Severity Index (ISI) [34] as the primary outcome. The results showed that CBT-i significantly improved subjective insomnia symptoms compared to AA.

In the present report our aim was to use an objective measurement method, actigraphy, to examine how sleep patterns were affected in a short- and long-term perspective after AA- and CBT-i, as well as to compare sleep parameters related to these patterns between the two treatment forms.

2. Materials and methods

This was a prospective randomized controlled study (RCT) using actigraphy to examine sleep patterns and evaluate treatment effects of AA and CBT-i in a short- and long-term perspective.

2.1. Participants

The participants and the inclusion- and exclusion criteria and the procedure are described in detail in Bergdahl et al. [33]. To briefly summarize, participants in the study sample, 51 women and 9 men (N = 60), with a mean age of 60.5 (SD 9.4) years, had experienced insomnia symptoms for more than six months. All had used non-bensodiazepine hypnotics for a mean of 7.3 years (SD 5.6), but even with the pharmacological treatment the insomnia symptoms persisted and the participants wanted to end their medication. All participants were instructed to end their hypnotic drug treatment three to five days before the treatment start.

2.2. Procedure

Participants were recruited by advertisement in the local newspaper and from an outpatient sleep clinic. All subjects were informed that participation was voluntary and that they could withdraw from the study at any time without any negative consequences. In total 204 persons were assessed for eligibility. The 67 participants who fulfilled the inclusion criteria met with an experienced medical sleep specialist (senior author AM) who assessed all subjects before inclusion. After signing the informed consent form, the participants were given an actigraph to wear on their non-dominant wrist. Instructions on how to use it were given verbally and in writing; participants were instructed to wear the actigraph during seven days and nights in order to register 24-h activity patterns, where the focus was the sleep periods. To indicate when they went to bed at night and when they rose in the morning they were instructed to press the actigraphy event marker. During the inclusion session the participants also completed the SF-12. Follow-up actigraphy recordings and SF-12 was performed directly post-treatment and six months after the end of the treatment.

Randomization to group treatment with AA (n = 32) or CBT-i (n = 35) was carried out after the inclusion session. The randomization procedure is described in detail in Bergdahl et al. [33]. For participant flow during the study, see Fig. 1.

2.3. The treatments

Extended treatment descriptions are given in Bergdahl et al. [33], and only summarized briefly below (see Fig. 2). Both treatments were performed in hospital facilities for outpatients.

2.3.1. AA

The AA group (n = 27) was scheduled for treatment sessions twice a week during four weeks. The standardised National Acupuncture Detoxification Association (NADA) protocol, according to the Nogier's European ear map, was used. The acupuncture points used in the NADA protocol are Shen Men, Sympathetic, Kidney, Liver and Lung. In a previous study it was shown that this point selection might have contributed to an improved sleep [35]. It has not however, except for the study by Bergdahl et al. [33], previously been tested as a stand-alone treatment for insomnia