JAMSAT
Journal of Advanced Medical Sciences and Applied Technologies
December 2022, Volume 7, Issue 1

Short Communication: The use of eye pillow (aroma hot-pack) as an alternative non-pharmacological approach in remediating chronic psychophysiological insomnia symptoms; a subjective and polysomnography-informed evaluation

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Citation Kamali AM, Mousavi Baigi SR, Kazemiha M, Yahyavi S, Chakrabarti P, Nami M, Kateb B. TThe use of eye pillow (aroma hot-pack) as an alternative non-pharmacological approach in remediating chronic psychophysiological insomnia symptoms; a subjective and polysomnography-informed evaluation. JAMSAT. 2022; 7(1):20-24.

https://doi.org/10.30476/jamsat.2021.92479.1024

Article info:
Received: 22 January 2022
Accepted: 30 February 2022

Keywords:
Psychophysiological insomnia, Alternative treatment, Sleep quality, Eye Pillow, Aroma hot-pack

ABSTRACT

Introduction: Sleep is among the pivotal biological functions which serve the overall health as well as neurological, psychobehavioral and cognitive performance. Psychophysiological insomnia (PPI) is a prevalent condition with much of its treatment solutions revolving around medication therapy. Despite that, many patients prefer nonpharmacological therapies for PPI. We were therefore prompted to report our clinical observations in a cohort of PPI cases who used the eye-pillow (aroma hot-pack or AHP) for 3 months as an alternative solution to mitigate insomnia symptoms.

Methods: This single arm quasi-experimental cohort study comprised 52 sequentially and conveniently recruited PPI patients who received bedtime AHP plus sleep hygiene recommendations for 77±6 nights with no concurrent pharmacological treatment. The Petersburg's sleep quality index (PSQI) and Petersburg's Insomnia Rating Scale (PIRS) scores were documented at baseline and following 12 weeks of AHP use. Objectively, standard overnight polysomnography (PSG) tests were done at baseline and week 12 in an accredited sleep disorders laboratory. Paired t-test, Spearman and Pearson's correlation coefficient were employed to comparatively analyze changes in the outcome measures pre- and post-treatment.

Results: The primary outcome measures in this single arm observational study was subjective sleep quality parameters as well as changes in polysomnographic sleep biomarameters following a roughly 12 weeks of nightly use of aroma hot-pack (AHP) at bedtime. Patients' mean adherence to therapy was 84.7±3.5%. The PSQI and PIRS scores were significantly decreased after intervention (4.89±1.88, and 16.5±2.1) from baseline (10.67±4.09, and 38.7±3.3) ($p<0.0001$). The PSG data also revealed significantly improved N1 sleep latency, number of wakes after sleep onset (WASO) and sleep efficiency at week 12 as compared to the baseline.

Conclusion: It appears that the use of AHP can be considered as a low-cost and easily applicable alternative treatment to medication therapy in uncomplicated PPI cases.

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Behavioral sleep disturbances are diversely classified into several types of insomnia, excessive daytime somnolence (EDS), sleep phase disorders and various parasomnias potentially rooting in psychophysiological, cognitive, emotional and behavioral abnormalities associated with impaired sleep efficiency, disintegrated sleep cycles and/or arousal instability (1, 2). Along these lines, insomnias are characterized by poor subjective sleep quality, difficulty falling and maintaining asleep at bedtime, wakes after sleep onset (WASO) or unprompted early morning awakening. The consequent diurnal symptoms may then include improper cognitive functions, fatigue, declined cognitive aptitude, hampered productivity, depression or irritability, impaired decision-making, low motivation as well as mood dysregulation (3-5).

Despite the burden of insomnia, studies have shown that even physicians do not tend to explore insomnia features, hence prescription of sleep-aid medications (which bear potential adverse effects in many instances) often remains to be the mainstay of treatment. Insomniacs then start to show tolerance or dependance to hypnotic medications and their symptoms get even more complex by time. As such, there has been a growing tendency to use non-pharmacological approaches to alleviate insomnia over recent years (6).

Beside mindfulness-based cognitive training (MBCT), cognitive behavioral therapy for insomnia (CBT-I), meditation and bineural acoustic beats(7, 8); the use of aroma therapy and more specifically, aroma hot-packs (AHPs) or eye pillows, have gained public interest recently (9).

Similar to other non-pharmacological therapies for insomnia, we need to have compelling evidence-based insight on the efficacy and tolerability of AHPs before recommending such available and affordable remedy to patients with insomnia (10).

Based on the above the present single-arm open label study was planned to investigate the objective and subjective impacts of applying AHPs in insomniacs using questionnaire-based (Pittsburg Sleep Quality Index-PSQI) and pre-/post-treatment polysomnographic assessments in a cohort of patients with psychophysiological insomnia (PPI).

1. Method

This single arm quasi-experimental cohort study comprised 52 sequentially and conveniently recruited PPI patients who received bedtime AHP plus sleep hygiene recommendations for 77±6 nights with no concurrent pharmacological treatment. The Petersburg's sleep quality index (PSQI) and Petersburg's Insomnia Rating Scale (PIRS) scores were documented at baseline and following 12 weeks of AHP use. Objectively, standard overnight polysomnography (PSG) tests were done at baseline and week 12 in an accredited sleep disorders laboratory. Paired t-test, Spearman and Pearson's correlation coefficient were employed to comparatively analyze changes in the outcome measures pre- and post-treatment.

Using Altman's nomogram and considering the earlier studies as samples, the sample size for pre/post cross-comparison of sleep bioparameters using PSG was 57 with power = 90%, $\beta = 10\%$ and $\alpha = 5\%$ and the by calculation of 10% sample loss, we selected 52 subjects in a single-arm prospective observational approach. The inclusive criteria in this study according to the selected studies included: minimum age of 18 years, awareness of time and place, lack of implementing surgery, ejection fraction of over 40%, lack of receiving narcotics 5-6 hours before night sleep, lack of taking psychiatric drugs, lack of a clear and known co-morbid sleep disorder, lack of brain disorder, lack of visual and auditory disorders, lack of dependency on narcotic drugs, no history and dependency of using AHP, no history of underlying diseases affecting sleep, such as rheumatoid arthritis, migraine and etcetera, and no dependency on any substance or procedure influencing sleep.

The samples were selected according to the inclusive criteria and those without the inclusive criteria were excluded from the study. The exclusive criteria of the study were: incidence of acute problems during admission and/or prescription or consumption of narcotics during the night, which were excluded from the study. Data collection tools in this study included Petersburg's Sleep Quality Index (PSQI) and PSG. PSQI is a self-report questionnaire which has been designed by Buysse et al. (11) in order to measure the quality of sleep and help the diagnosis of those who have good or poor sleep. This index has been widely used in clinical and non-clinical researches in order to review sleep quality during the previous month (4 weeks) and consisted of 19 questions in seven parts (subjective sleep quality C1,

sleep latency C2, sleep duration C3, habitual sleep efficiency C4, sleep disturbance C5, use of sedative medications C6, and daytime dysfunction C7) which are briefly given in a table. Each part scores from 0-3. The scores 0, 1, 2 and 3 in each scale indicate normal, minor problem, average problem and severe problem respectively. Most of the test articles are based on multi-choice questions and short answers and are easily fathomable. In this index, high scores indicate lower sleep quality (12). This index had 90% sensitivity and 87% specificity. Buysse et al. in their study also reported sensitivity and specificity of 89.6% and 86% respectively and internal consistency $\alpha = 0.83$ and its validity in test re-test was $r = 0.85$ (11).

AHPs were lightly scented with homegrown lavender, lavender essential oils, and filled with natural botanical plant matter (cotton seed). The pack was made from silk velvet making them easy to use on delicate eyes. The AHPs measured 4x8 inches fabric and machine-sewed (Arnica Group).

Participants were instructed to heat the AHPs microwaved in 30 second increments and place them over their low forehead covering the eyes and nose bridge.

Polygraphic Sleep Study (Polysomnography-PSG)

Full-night video-polysomnographic sleep study was performed at the sleep Health Unit (Dana Brain Health Institute) at baseline and after the mean of 12 weeks compliant use of AHP in all participants (80% of the bedtime usage was considered as compliance). A technician was present during the entire recordings. The following data were documented to a special sleep recording computer (SSC plus PSG+AASM) and scored according to the latest AASM manual for sleep scoring and analysis: electroencephalography-EEG (F3-A2, F4-A1, C3-A2, C4-A1, O1-A2 and O1-A2), EOG (right), electro-oculography-EOG (left), electromyograpgyEMG (submental), EMG (right and left anterior tibialis), breathing effort (chest and abdomen), air intake (mouth/nose air flow), snoring sounds, oxygen saturation, plethysmogram, ECG, heart rate and sleeping position (13, 14).

2. Results

In this cohort, the total score of sleep quality (PSQI) before the intervention was 10.46 ± 4.09 and after the intervention it was reduced to 4.86 ± 1.88 and paired t-test showed a significant difference in this regard ($p < 0.000$) (Table 1)

In comparison of the scores for all the sleep quality domains before the intervention, there was a significant difference in all the domains except sleep latency and sleep disturbance ($p < 0.05$). In our cohort, the maximum score of the domains before and after the intervention were related to good sleep duration (1.66 ± 0.75) and subjective sleep quality respectively (0.8 ± 0.48). Furthermore, the minimum score of the domains before the intervention was related to sleep disturbance (1.33 ± 0.08) and after the intervention to use of sleeping medication (0.6 ± 0.62). Moreover, the maximum score of the domains before and after the intervention was related to daytime dysfunction

Table 1. Histopathological findings of colon in experimental groups. The results were expressed as the median score.

Domains	Pre-intervention mean (SD)	Post-intervention mean (SD)	P*
Subjective sleep quality	1.46 (0.77)	0.8 (0.48)	0.000
Sleep latency	1.46 (0.77)	0.66 (0.6)	0.000
Sleep duration	1.66 (0.75)	0.76 (0.5)	0.000
Habitual sleep efficiency	1.53 (0.86)	0.73 (0.52)	0.000
Sleep disturbance	1.33 (0.8)	0.63 (0.49)	0.001
Use of sleeping medications	1.4 (0.8)	0.6 (0.62)	0.000
Daytime dysfunction	1.63 (0.7)	0.66 (0.47)	0.000

***Paired t-test**

(1.3 and 1.56 respectively) and the minimum score before the intervention was related to subjective sleep quality (0.83) and after the intervention was relate to subjective sleep quality and sleep duration adequacy (1.03). After the intervention, there was a significant difference in other domains of sleep ($p<0.0001$). No significant correlation was seen between the demographic variables and score of sleep quality (Spearman and Pearson; $p > 0.05$).

The baseline PSG studies of all participants were uneventful with findings favoring arousal instability and psychophysiological insomnia (PPI). The analysis revealed no significant sleep-disordered breathing with normal apnea-hypopnea index of 3.54±1.2 (Normal<5). No Cheyne–Stokes respirations were noted. The patients' baseline oxygen saturation was 95±3%; SaO2 dropped 11±4 times to more than 3%. The minimal O2 saturation (91±2%) was recorded in N2 sleep in all participants at baseline. Post intervention PSG studies were similarly uneventful and not indicating PPI in 73% of the cases.

The patients' average heart rate in sleep was 76±15 bpm (baseline) and 63±5 bpm (post-intervention), $P<0.05$. There were infrequent narrow-complex accelerations in HR with a no significant ectopic beats in the electrocardiography recording of 23% and 6% of participants pre- and post-intervention, respectively ($P<0.01$).

Secondary to rapid sleep stage changes and maintenance insomnia at baseline PSG, the patient's sleep efficiency was poor. However, this has been resolved by 68% for rapid sleep stage transition index after the intervention. During 475±36 minutes of recording time, patients slept for 298±38 minutes after 85 minutes of Stage-1 (N1) sleep latency in their pre-intervention PSG. Meanwhile, post-intervention PSGs revealed that During 525±44 minutes of recording time, patients slept for 335±39 minutes after 22±12 minutes of (N1) sleep latency ($P<0.01$). The pre- and post-intervention PSG-informed Sleep efficacy was 63.1±12% and 86±7% , respectively (normal ≥ 90%); $P<0.05$.

At baseline, the patients had normal amount of light sleep (stage N1=6.9±5%), normal percentage of stage 2 sleep (N2=55.8±8.5%), decreased percentage of REM sleep (R=19.4±3.2%) and decreased deep sleep (N3=8.9±4%). Delta-wave progression was poor at baseline.

While post-intervention PSG suggested equivalent mean proportion of N1 and N2 sleep as compared to the baseline, post-intervention PSGs revealed an increased percentage of REM sleep (R=25.4±6.8%) and deep sleep (N3=18±5.7%), $P<0.05$. Delta-wave progression was improved by 35.4% based on the delta progression degree score.

There were 19±5 and 7±3 awakenings lasting for more than 60 seconds ($P<0.05$) as well as 98±11 and 33±15 micro-arousals ($P<0.01$) in pre- and post-intervention PSG recordings. In both pre- and post-intervention PSGs, the arousals were largely (>70%) spontaneous with beta-2 intrusions in fronto-central brain regions. While sleep EEGs were significantly suggestive for Spindling-Excessive Beta (SEB) in baseline evaluations, this has not been the case in post-intervention studies. Inboth pre- and post-intervention PSGs, leg electromyograms did not indicate periodic limb movement during sleep and Video recording did not suggest any sleep behavioral disorders.

Conclusive Remarks

The obtained results before the intervention showed that 65% of the study subjects had both subjectively and objectively undesirable sleep quality while this has been shown to be significantly improved after 12 weeks of compliant AHP use. Our findings have been in agreement with the study results of Chaudhary A et al., Williams PC et al., Richardson A et al., and Greco V et al (15-18). There was a significant difference in all the domains and total score of PSQI before and after the intervention.

Sleep is one of the important elements in human life which is associated with reconstruction of physical and emotional power. Maintaining regular sleep cycles is absolutely necessary in order to preserve fitness and health. AHP is a cost-effective and uncomplicated method that is shown to improve both subjective and objective sleep efficiency measures and seems to be a proper alternative or add-on method to pharmacological and other non-pharmacological therapies in patients with primary insomnias, namely PPI.

Conflict of Interest

The authors declare no conflict of interest in this study.

References

1. Perlis ML, Jungquist C, Smith MT, Posner D. Cognitive behavioral treatment of insomnia: A session-by-session guide: Springer Science & Business Media; 2005.
2. Van Dongen HP, Vitellaro KM, Dinges DF. Individual differences in adult human sleep and wakefulness: Leitmotif for a research agenda. Sleep. 2005;28(4):479-98.
3. Riemann D, Spiegelhalder K, Feige B, Voderholzer U, Berger M, Perlis M, et al. The hyperarousal model of insomnia: a review of the concept and its evidence. Sleep medicine reviews. 2010;14(1):19-31.
4. Nami M. Chronic insomnia, pharmacotherapy and the cognitive behavioural approaches. J Sleep Disorders Ther. 2014;3(1):1-4.
5. Mai E, Buysse DJ. Insomnia: prevalence, impact, pathogenesis, differential diagnosis, and evaluation. Sleep medicine clinics. 2008;3(2):167-74.
6. Khachatryan SG. Insomnia burden and future perspectives. Sleep Medicine Clinics. 2021;16(3):513-21.
7. Yoon H, Baek HJ. External Auditory Stimulation as a Non-Pharmacological Sleep Aid. Sensors. 2022;22(3):1264.
8. De Fazio R, Mattei V, Al-Naami B, De Vittorio M, Visconti P. Methodologies and Wearable Devices to Monitor Biophysical Parameters Related to Sleep Dysfunctions: An Overview. Micromachines. 2022;13(8):1335.
9. Tang Y, Gong M, Qin X, Su H, Wang Z, Dong H. The therapeutic effect of aromatherapy on insomnia: a meta-analysis. Journal of Affective Disorders. 2021;288:1-9.
10. dos Reis Lucena L, dos Santos-Junior JG, Tufik S, Hachul H. Lavender essential oil on postmenopausal women with insomnia: Double-blind randomized trial. Complementary Therapies in Medicine. 2021;59:102726.
11. Buysse DJ, Reynolds III CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry research. 1989;28(2):193-213.
12. Khademian F, Aslani A, Ravangard R, Bastani P, Nami M, Jafari P. Efficacy of a web application for stress management among Iranian college students during COVID-19 outbreak: a study protocol for randomized controlled trials. Trials. 2020;21(1):1-7.
13. Karimzadeh F, Nami M, Boostani R. Sleep microstructure dynamics and neurocognitive performance in obstructive sleep apnea syndrome patients. Journal of integrative neuroscience. 2017;16(2):127-42.
14. Boostani R, Karimzadeh F, Nami M. A comparative review on sleep stage classification methods in patients and healthy individuals. Computer methods and programs in biomedicine. 2017;140:77-91.
15. Chaudhary A, Kumari V, Neetu N. Sleep promotion among critically ill patients: earplugs/eye mask versus ocean sound—a randomized controlled trial study. Critical Care Research and Practice. 2020;2020.
16. Williams PC, Alhasan DM, Krafty R, Coutts C, Miles-Richardson S, Jackson CL. A mixed methods approach to understand greenspace redevelopment in relation to objectively-and subjectively-measured sleep health among Black adults in Southwest Atlanta. Health & Place. 2022;76:102812.
17. Richardson A, Allsop M, Coghill E, Turnock C. Earplugs and eye masks: do they improve critical care patients' sleep? Nursing in critical care. 2007;12(6):278-86.
18. Greco V, Bergamo D, Cuoccio P, Konkoly KR, Lombardo KM, Lewis PA. Wearing an Eye Mask During Overnight Sleep Improves Episodic Learning and Alertness. bioRxiv. 2022.