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Open-Loop Neurofeedback Audiovisual Stimulation: A Pilot Study of Its Potential for Sleep Induction in Older Adults

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Abstract

This pilot study tested the efficacy of a 30-min audio-visual stimulation (AVS) program for the treatment of chronic insomnia in older adults. Chronic insomnia has been conceptualized as entailing increased cortical high frequency EEG activity at sleep onset and during NREM sleep. We hypothesized that an AVS program gradually descending from 8 to 1 Hz would potentially reduce the excessive cortical activation that is thought to contribute to difficulties with initiating and maintaining sleep. Accordingly, we conducted an intervention study of AVS using a pre-post design. Eight older adults (88 ± 8.7 years) complaining of chronic insomnia self-administered a 30-min AVS program nightly at bedtime for one month. Sleep was assessed at baseline and throughout the 4-week intervention. After using AVS for 4 weeks, significant improvement was reported in insomnia symptoms (ISI, $p = 0.002$) and sleep quality (PSQI, $p = 0.004$); with moderate to large effect sizes (Partial Eta2: 0.20-0.55)(Cohen's d: 0.7-2.3). The training effect (self-reported sleep improvement) was observed at the end of week one and persisted through the 1-month intervention. The results from this pilot study suggest that further exploration of AVS as a treatment for insomnia is warranted.

Keywords

Acoustic Stimulation, Aged, Aged, 80 and over, Brain Waves, Female, Humans, Male, Neurofeedback, Photic Stimulation, Pilot Projects, Sleep Initiation and Maintenance Disorders, Treatment Outcome

Disciplines

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Keywords

Aging; audio-visual stimulation; light-sound stimulation; insomnia; sleep

Introduction

Sleep disturbance is a common health concern in older adults, affecting up to 50% of people aged 50 years old and above (Ancoli-Israel & Cooke, 2005; Crowley, 2011). Insomnia, one type of sleep disturbance, is characterized by self-reported problems with initiating and/or maintaining sleep. When such difficulties occur 3 or more times per week for 3 or more months and are associated with diminished daytime function, this form of sleep disturbance may be diagnosed as chronic insomnia (Insomnia Disorder)(APA, 2013; Buysse, 2013; Roth, 2007). Prior studies have shown that people with insomnia have higher incidences of hypertension, coronary heart disease, metabolic syndrome, immunosuppression, cognitive impairment, chronic pain, depression, and substance abuse (Paudel et al., 2013; Taylor et al., 2007).

While the factors contributing to disturbed sleep may be medical, environmental or psychological in nature, chronic insomnia has long been conceptualized as a hyper-arousal disorder that occurs during both sleep and wakefulness (M. L. Perlis, Giles, Mendelson, Bootzin, & Wyatt, 1997; M. Perlis, Shaw, Cano, & Espie, 2011; Riemann et al., 2010). In

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recent years, this conceptualization has given way to a more specific point of view: chronic insomnia occurs in association with a conditioned form of increased central nervous system (CNS) activity that is either elicited by sleep-related cues or occurs in association with a failure of sleep related down-regulation in CNS activity. In either case, the resultant heightened level of cortical arousal is thought to produce a hybrid state (part wake and part sleep) and that is not conducive to sleep initiation or maintenance and/or is deleterious to the perception of sleep quality and quantity (Espie, Broomfield, MacMahon, Macphee, & Taylor, 2006; M. L. Perlis et al., 1997; M. Perlis et al., 2011). Consistent with this perspective is the finding that persons with chronic insomnia exhibit signs of autonomic nervous system (ANS) dysregulation such as abnormal hormone secretion, increased metabolic activation, elevated heart rate, and increased cortical high frequency EEG activity (Beta/Gamma frequencies) at sleep onset and during NREM sleep (Bonnet & Arand, 2010; M. Perlis et al., 2011).

Standard treatment options for insomnia include medication and cognitive behavioral therapy for insomnia (CBT-I) (Mitchell, Gehrman, Perlis, & Umscheid, 2012; Wang, Wang, & Tsai, 2005). Prescription medication treatment has good short term efficacy (Nowell et al., 1997), however the untoward side effects (e.g., dependence, rebound insomnia, cognitive impairment, and fall risk in older adults) often outweigh the clinical benefit (Roth, Walsh, Krystal, Wessel, & Roehrs, 2005). CBT-I is widely considered the gold standard intervention for insomnia, with treatment effects comparable to or exceeding, those observed for medications (Jungquist et al., 2010). While CBT-I has been shown to be effective for older adults (Irwin, Cole, & Nicassio, 2006), there are several factors that limit its regular use in this segment of the population. First, the sleep restriction component of CBT-I can be difficult to implement in individuals that do not have required “wake-time”. Second, if implemented, the acute sleep loss may be difficult for older adults to tolerate and/or it may put them at increased risk (in the short term) for accidents and injuries. Third, and perhaps the biggest obstacle to the regular use of CBT-I by any segment of society, is that there are very few credentialed providers (Smith & Perlis, 2006). The first two issues suggest that older individuals would benefit from the availability of an effective non-medical and non-CBT-I option. The last issue suggests that there is a need for widely available self-administered treatment option. One promising alternative approach to the treatment of insomnia is open-loop neurofeedback audio-visual stimulation (AVS), a self-care approach using light and sound patterns to potentiate sleep-related EEG activity (delta-theta; 1–8 Hz) (Budzynski, Budzynski, Sherlin, & Tang, 2011; Collura & Siever, 2008; Teplan, Krakovska, & Stolc, 2006). The purpose of this article is to describe potential AVS effectiveness in a pilot study of older adults with insomnia.

The term AVS is often used interchangeably with “light-sound stimulation”, and “audio-photic stimulation” in the literature. This process of central nervous system stimulation is called “brainwave entrainment”. AVS for brainwave entrainment refers to the use of synchronized flashing light and pulsing sound to elicit predominant brainwaves that are manifest during a given mental state; for example, 10–12 Hz for peak mental performance and 1–4 Hz for deep relaxation and/or sleep (Budzynski et al., 2011).

There are two types of brainwave entrainment: closed-loop and open-loop. The closed-loop method requires electroencephalographic (EEG) data. EEG activity is monitored and modulates the light and sound stimulation provided by the AVS device. Thus, this approach provides concurrent real-time EEG training/entrainment. The application of this form of treatment often requires a clinician for electrode placement and stimulating frequency setting (Collura & Siever, 2008).

The open-loop method of AVS is a self-care approach that is relatively simple. In the open-loop method, entrainment occurs in response to synchronized light and audio pulses of particular frequencies that are delivered in a pre-programmed manner through goggles and headphones. The stimulation is thought to evoke sensory potentials at the programmed frequencies, which are then transmitted through sensory neural pathways to the thalamus where audio and visual sensory information is processed. This synchronized neural activity is then propagated to the cerebral cortex through the thalamo-cortico-thalamic circuits (Collura & Siever, 2008). Key in this process, the frequency of brainwave activity tends to assume the frequency of the audiovisual stimulus (Adrian & Matthews, 1934; Bartley, 1937; Jasper, 1936). In general, the average length of an AVS session, whether closed-loop or open-loop, is usually 20–60 minutes. Sessions are typically delivered while the person is seated or lying in a resting position with the eyes are closed (Huang & Charyton, 2008).

The beneficial effects of AVS have been shown in several clinical studies for outcomes such as cognitive functioning, headache/migraines, and premenstrual syndrome (Huang & Charyton, 2008; H. Y. Tang, 2004; H. Y. Tang & Riegel, 2013; Hsin Yi Tang, 1998). However, AVS has not been well-tested as a method of promoting sleep. In this study, theorizing that cortical activation plays an important role in insomnia (i.e., that persistent 20 Hz and above EEG activity and the inability to achieve EEG synchronized activity at 4Hz and below promotes insomnia), we pilot tested a 30-minute AVS program that gradually descends from 8 Hz (alpha/theta brainwave range – an alert but calm mental state) to 1 Hz (delta brainwave range – deep sleep) to facilitate a state that is conducive to sleep in a group of older adults with self-reported insomnia.

Methods

Using a pre- and post- design, we recruited participants from three retirement communities in the northwestern US. The inclusion criteria were age greater than 65 years, evidence of insomnia with a score 8 or higher on the Insomnia Severity Index (ISI), sleep problems >=3 times per week for >=3 months. English speaking, normal hearing with or without the hearing aids, and sufficiently intact cognitively to participate (Mini Mental Status Examination [MMSE] score 25 or above). The exclusion criteria were night shift worker, sleep disorder diagnosis (e.g., sleep apnea, restless leg syndrome), known photosensitivity, seizure disorder, dementia, other significant chronic illness, and severe psychiatric disorders. This pilot study was approved by the University of Pennsylvania and Seattle University Institutional Review Boards. Informed consent was obtained prior to data collection.

Screening

Multivariable Apnea Prediction Index (MAP)—The MAP is a 13 items survey that screens for prediction of sleep apnea. The survey assesses common symptoms of sleep apnea such as loud snoring, gasping during sleep, breathing difficulty, and excessive daytime sleepiness. Participants were asked to rate the frequency of these identified symptoms on a numeric scale (0 = never; 4 = always, 5–7 times/week; and do not know). The score is then entered into a formula along with covariates (age, gender, and body mass index) for further computation. A MPA score higher than 0.5 suggests likelihood of sleep apnea (Maislin et al., 1995). In this study, the MPA was assessed at the initial interview. People who scored higher than 0.5 on MPA were excluded from participating in this study.

International Restless Legs Syndrome scale (IRLS)—The IRLS (short form) was used as a screening tool in this study. The IRLS short form is a 4 item questionnaire that indexes typical symptoms of restless leg syndrome during the day and sleep (e.g., discomfort sensation in legs, urgency to move or rub legs to relieve discomfort, symptoms worsen when resting). The response option for each item is yes or no (Walters et al., 2003). If a participant answered yes to all 4 questions, then they were not eligible to participate in this study.

Measurement

Insomnia Severity Index (ISI)—The ISI is a validated 7-item (0–4) scale that measures insomnia severity. Norms are: 0–7 = no clinically significant insomnia; 8–14 = mild insomnia; 15–21 = clinical insomnia (moderate severity); 21–28 = clinical insomnia (severe). The ISI has internal consistency (alpha =0.90), sensitivity (86%) and specificity (87%); the scale is well-established and sensitive to changes with intervention (Bastien, Vallieres, & Morin, 2001; Morin, Belleville, Belanger, & Ivers, 2011).

Sleep Diary—The diary is a two-page brief log with questions about the quantity and quality of the previous night of sleep, including time to bed, Sleep Latency (SL), and Numbers of Awakenings during the night (NWAK), and time out of bed. The diary also includes questions about the causes of sleep difficulties if any, caffeine and alcohol consumption, daytime napping, exercise, health issues, and the hypnotic use. The sleep diary was completed during the 1-week baseline and throughout the 4 weeks of the intervention.

Pittsburgh Sleep Quality Index (PSQI) is a well-established tool to assess self-reported sleep quality and disturbances over 1-month interval. The PSQI consists of 19 self-rated questions that measure seven domains of sleep: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medications, and daytime dysfunction. Each domain is weighted equally on a 0–3 scale, contributing to a total PSQI score that ranges between 0–21; higher scores indicate worse sleep quality. The scale takes 5–10 minutes to complete. The internal consistency coefficient alpha reliability was (r=0.83) for the global score. The test-retest reliability with the interval of 28 days was (r=0.85). The validity of PSQI scale was reported in its effectiveness of distinguishing people with sleep disorders from the control group with a sensitivity of 89.6% and a specificity of 86.5%

(Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). The PSQI scale was administered once at baseline and again at the end of the 1-month intervention.

Patient Health Questionnaire (PHQ-9)—The PHQ-9 is a well-established scale measuring mood state. The items ask how often in the past 2 weeks the individual has been bothered by symptoms of depression. Scores on the PHQ-9 range from 0 to 27 (1–4 minimal depression; 5–9 mild depression; 10–14 moderate depression; 15–19 moderately severe depression; and 20–27 severe depression (Kroenke, Spitzer, & Williams, 2001).

Other Measures—Demographic data, brief health history (i.e., smoking, alcohol, drug use) and medication data (name, dosage, frequency, duration, indication, and medication changes) were also collected and used to describe the sample.

Procedures

In this study, the 30-minutes open-loop AVS intervention was delivered through a Walkman-sized device [Procyon by MindPlace] that produces flickering light (goggles) and pulsing tones (headphones) gradually ramping from 8Hz down to 1Hz to entrain brainwaves to a deep relaxation and sleep state.

During the baseline week, participants completed ISI, PSQI, PHQ-9 and 1-week sleep diary. After baseline, participants were trained to self-administer the 30-minutes AVS program (turn on the device, wearing goggles and headphones) at bedtime (as they are ready to sleep) for 1-month, and record their sleep pattern in a sleep diary. The ISI, PSQI and PHQ-9 were measured again upon conclusion of the intervention.

Data Analysis

The raw data were screened for accuracy, missing values, outliers, and distributional properties prior to analysis (SPSS V21). The sample was described using descriptive statistics of demographic and baseline variables. Repeated paired sample T tests with the Bonferroni correction were used to examine pre- and post-intervention differences. One-way repeated measures ANOVA was performed to explore the change scores across 5 time points. Effect sizes were examined using both ANOVA partial η_2 and Cohen's d.

Results

A total of 8 community dwelling older adults (mean age 88±8.7, 88% female, 75% White, 12.5% African American, 12.5% Asian) participated and completed the study. Participants were cognitively intact (mean MMSE 29 ± 1.4), moderately overweight (BMI 25.7 ±3.9), and moderately depressed (PHQ-9 14.5 ± 4.8). The baseline severity of insomnia was moderate (ISI 15.6 ± 4.8, PSQI 9.9 ± 3.9). During the 1-week baseline, mean self-reported sleep diary variables were as follows: Sleep Latency = 105 ± 37 minutes, and Numbers of awakenings = 3.0 ± 0.8.

Pre and post outcome measures are reported in Table 1. In brief, after 1-month of AVS intervention, the insomnia severity declined to the sub-threshold insomnia range; 63% of participants no longer met the criteria for having insomnia (ISI ≤ 7). The mean pre-post

scores were 15.6 ± 4.8 and 8.0 ± 6.4 respectively (p = 0.002). The pre-post PSQI mean total scores were not significantly different, however, significant changes were observed on the PSQI subscales measuring Daytime Dysfunction (p = .048) and Sleep Quality (p = .004). In the 5 of 8 subjects whose baseline PHQ-9 score was greater than 5 (indicative of at least mild depression), their scores were reduced from a baseline of 16.2 ± 1.2 (moderate to severe depression) to 8 ± 2.6 (mild depression) (p=.004). Overall, the findings suggest large effect sizes for sleep related variables (ISI, PSQI-Daytime Dysfunction, PSQI-Sleep Quality) (Partial η_2, range 0.18 – 0.55) (Cohen's d, range 0.7 – 2.3) and the mood variable (PHQ-9 in 5 subjects whose score was > 5 at baseline) (Partial η_2, 1.0) (Cohen's d, 1.8). When Bonferroni correction was performed, ISI and PSQI - Sleep Quality remained statistically significant (Table 1).

The sleep diary variables (sleep latency, numbers of awakenings, reported in Table 2) were not significantly different in the within-subject comparison across the 5 time points. However, the week to week trends suggest training effects occurred early in training, typically in the first week. There was a reduction in mean sleep latency from 105 minutes at the baseline week to 37 minutes of the intervention week 1. The trend then stabilized and was sustained throughout the remaining 3 weeks of the intervention (Table 2).

Discussion

Over the years, AVS has been demonstrated to improve performance (attention, cognition, intellectual achievement) and symptoms (anxiety, stress, pain, headache, mood and premenstrual syndrome)(Huang & Charyton, 2008), but little is known about the efficacy of AVS for sleep promotion. In this pilot study, we tested an in-home self-administered AVS program for sleep promotion in a group of older adults. After 1-month of the AVS intervention, participants' levels of insomnia severity significant decreased, from clinically moderate severity to sub-threshold (mild) insomnia. Participants' self-reported sleep quality and daytime functioning also significantly improved. In addition, those participants who were depressed at baseline, had significant improvement in mood after 1-month of intervention. The intervention effect was also observed in sleep diary data (sleep latency and numbers of awakening), as early as at end of the first week of intervention, with changes then effectively stabilizing over the remaining 3 weeks of intervention.

Findings from this pilot study provide preliminary evidence that an open-loop neurofeedback AVS program may be efficacious in promoting sleep in older adults. These findings are consistent with our other preliminary work testing AVS for comorbid insomnia and chronic pain. (H. Y. Tang, Vitiello, Perlis, Mao, & Riegel, 2014). Taken together, these two pilot studies are the first to examine the efficacy of a 30-minutes AVS program for sleep induction and maintenance; demonstrating effect sizes comparable to Cognitive Behavioral Therapy for Insomnia (CBT-I)(Siebern & Manber, 2011), the standard non-pharmacological approach for insomnia.

The interpretation of the study results is limited by the small sample size, the lack of both a control group, a randomization design, and the lack of adherence rate measure. Future studies should consider including an objective measure of sleep such as actigraphy or

polysomnography in addition to the self-reported data. Although the potential efficacy of the 30-minutes open-loop AVS program was observed in preliminary studies with adults and older adults, the mechanism of AVS and neurological responses and the manner in which the neurological response relates to the outcome measures (i.e. sleep) remains to be fully demonstrated. Future studies should consider using quantitative EEG or neuroimaging to describe the concurrent brain activity changes in responding to the AVS.

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Table 1

Mean Scores at Baseline Compared with Mean Scores at Post-Testing 4 Weeks Later in Older Adults (N=8)

	Pre-test	Post-test	Significance	Partial Eta^2	Cohen's d
Insomnia Severity Index	15.6 ± 4.8	8.0 ± 6.4	0.002*Δ	.55	1.34
PSQI – Total Score	9.9 ± 3.9	9.5 ± 3.7	.740	1.0	0.11
PSQI – Sleep Duration	0.5 ± 0.9	1.1 ± 0.8	.217	.22	0.7
PSQI – Sleep Disturbance	1.3 ± 4.6	1.3 ± 4.6	1.0	.11	0.02
PSQI – Sleep Latency	1.6 ± 0.7	1.8 ± 0.9	.732	.55	0.25
PSQI – Daytime Dysfunction	1.3 ± 0.9	0.5 ± 0.8	.048*	.18	0.94
PSQI – Sleep Efficiency	1.4 ± 1.4	1.9 ± 1.1	.381	.39	0.4
PSQI – Sleep Quality	2.4 ± 0.7	1.0 ± 0.5	.004*Δ	.27	2.3
PSQI – Needs for Sleep Medication	1.5 ± 1.4	2.0 ± 1.4	.227	.51	0.36
PHQ-9 Depression	14.5 ± 4.8	7.8 ± 5.1	0.058	.78	1.4
PHQ-9 Depression (baseline>5) (N=5)	16.0 ± 2.6	8.0 ± 5.7	0.040*	1.0	1.8

*p value

ΔSignificance after Bonferroni adjustment, p value at 0.05/10 items: 0.005

Cohen's d, large effect size > 0.8

Partial Eta^2 large effect size > 0.14

Table 2

Weekly Sleep Diary Mean Score at Baseline and During Intervention in Older Adults (N=8)

	Baseline	Intervention Week 1	Intervention Week 2	Intervention Week 3	Intervention Week 4
Sleep Latency (SL) – minutes	105 ± 37	37 ± 2	55 ± 18	47 ± 17	60 ± 16
Numbers of Awakenings (NWAK)	3.0 ± 0.8	2.0 ± 0.8	2 ± 0.4	2 ± 0.3	1 ± 0.6

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