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ALIVE Biofeedback HRV training for Treating Insomnia: A Pilot Randomized Controlled Study.

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Abstract

Background: Insomnia is a common sleep disorder that affects a large portion of the population. While several treatments are available, such as medication and cognitive-behavioral therapy, some individuals may not respond well to these treatments. Biofeedback, a technique that provides individuals with real-time feedback on their physiological responses, has shown promise in treating insomnia. This study aimed to investigate the effectiveness of ALIVE biofeedback HRV training in treating insomnia.

Methodology: This pilot study utilized a randomized controlled trial design to investigate the efficacy of ALIVE biofeedback intervention in individuals diagnosed with insomnia. A total of 60 participants with insomnia were randomly assigned to either the ALIVE biofeedback or control group. The ALIVE biofeedback group received a six-week intervention involving relaxation techniques, deep breathing exercises, and mindfulness meditation using the ALIVE Pioneer system for heart rate variability (HRV) biofeedback training. The control group received standard care for insomnia. Outcome measures included HRV parameters, blood pressure, the Pittsburgh Sleep Quality Index Japanese version (PSQI-J), and the Insomnia Severity Index (ISI).

Results: The ALIVE biofeedback group showed significant improvements in heart rate variability (HRV) parameters, including increased SDNN and RMSSD and high-frequency power (HF) after the 6-week intervention. The control group did not display significant changes in HRV. Additionally, the ALIVE biofeedback group significantly decreased diastolic blood pressure. Regarding sleep outcomes, the ALIVE biofeedback group reported increased sleep duration and decreased sleep disturbances, as indicated by the PSQI-J scores. Furthermore, participants in the ALIVE biofeedback group significantly improved their ISI scores. These findings suggest that the ALIVE biofeedback intervention can potentially improve HRV, blood pressure, sleep quality, and insomnia severity in individuals with insomnia.

Conclusion: It is concluded from the study results that the ALIVE biofeedback training is a non-invasive and effective treatment for insomnia.

Keywords

Alive Biofeedback, Heart Rate Variability, Insomnia

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Introduction

Sleep disorders have numerous negative consequences, including increased stress, somatic pain, reduced quality of life, emotional stress, mood disorders, cognitive deficits, memory problems, and performance issues[1]. Additionally, the emergence of significant medical illnesses such as arterial hypertension, cardiovascular disease, metabolic syndrome, and type 2 diabetes mellitus has been linked to persistent sleep disorders[2-5]. Unfortunately, many adults turn to hypnotics or sedatives to treat their sleep problems; according to a survey conducted in the United States, 4% of adults utilize prescription sleep medicine within a month[6]. However, these drugs frequently have severe side effects[7] and may even make people more likely to die[8]. As a result, non-pharmacological approaches to treating sleep disturbances, such as cognitive behavioral therapy, have drawn attention[9].

By detecting physiological signals that people may not normally be aware of and providing them with visual feedback, biofeedback (BF), a behavioral therapy, helps people regulate their minds and bodies[10,11]. The development of these skills and greater awareness can help people better manage their symptoms. Resonant frequency breathing (RFB) is a technique used in one particular protocol called heart rate variability (HRV) biofeedback (HRV-BF) to obtain desired results[12]. The autonomic nervous system is active when the time between heartbeats varies, as measured by HRV. By creating resonance between breathing and the baroreceptor reflex, the RFB breathing technique specifically maximizes HRV. RFB may be helpful for people with fibromyalgia, mood problems, and overactive autonomic nerve function, according to research[13–15]. RFB has also been observed to improve baroreflex sensitivity in people with chronic heart failure[16].

Physical processes like breathing and heart rate naturally slow down while we sleep. To boost HRV, which is a measure of autonomic nerve activity, HRV-BF with RFB makes use of respiratory sinus arrhythmia[12]. An innate feature of the cardiopulmonary system, respiratory sinus arrhythmia is amplified during non-rapid eye movement sleep in healthy individuals[17]. It's thought that HRV-BF and RFB can affect the resting function while you're asleep[18]. Prior research has shown that HRV-BF before bed can increase healthy people's respiratory sinus arrhythmia during sleep, resulting in improved sleep quality[19]. Only a small amount of research, however, has looked at the medium- to short-term effects of RFB use or HRV-BF before night on sleep. Four weeks after the intervention, HRV-BF using a portable device before night significantly decreased the Insomnia Severity Index in a controlled before-and-after experiment involving individuals with posttraumatic stress disorder[20]. The objective of this study was to assess the effectiveness of ALIVE Biofeedback in improving sleep quality and reducing symptoms of insomnia.

Methodology

Trial Design

This pilot study utilized a randomized controlled trial design to evaluate the feasibility and potential efficacy of the ALIVE biofeedback intervention in individuals diagnosed with insomnia.

Participants

A total of 60 participants aged 18 years or older who had been diagnosed with insomnia were enrolled. Recruitment for the study involved diverse sources such as local clinics and hospitals. In order to meet the inclusion criteria, participants needed to have a confirmed diagnosis of insomnia according to the criteria outlined in the DSM-5, as well as a PSQI-J score of five or higher. Exclusion criteria consisted of individuals with a history of cardiovascular disease, pregnancy, usage of beta-blockers, presence of acute or chronic medical illnesses, mental disorders, intake of medications affecting heart rate or the central nervous system, illicit drug abuse, or recent exposure to significant stressful life events within the past six months.

Randomization

Using a computer-generated randomization sequence, participants were randomly assigned to either the ALIVE biofeedback or control group. The randomization process was performed by an

independent researcher not involved in participant recruitment or assessment. Allocation concealment was ensured using sealed envelopes containing group assignments.

Interventions

- **ALIVE (HRV) biofeedback group**

Biofeedback techniques include relaxation training, deep breathing exercises, and mindfulness meditation, and have been used to treat various conditions. In insomnia, biofeedback can improve sleep quality and reduce symptoms by regulating breathing patterns and reducing stress levels. ALIVE Pioneer was used for HRV-BF training for six weeks; it specifically focuses on regulating breathing patterns and heart rate variability (HRV) to promote relaxation and improve overall health. Participants were taught relaxation techniques, including deep breathing and progressive muscle relaxation, and received immediate feedback on their physiological responses.

- **Control group**

The control group received standard care for their insomnia, which may have included medication or cognitive-behavioral therapy.

Outcome Measures

These measures were collected at baseline and after the six-week intervention.

- **Heart rate variability (HRV)**

HRV was assessed using several metrics, including root mean square successive differences (rMSSD), standard deviation of all NN-intervals (SDNN), total power (TP), power in the low-frequency band (LF) ranging from 0.04 to 0.15 Hz, and absolute power in the high-frequency range (HF) between 0.15 and 0.4 Hz.

- **Blood pressure**

Both systolic and diastolic blood pressure were measured in millimeters of mercury (mmHg) at two time points: before the intervention (pre) and after the 6-week intervention (post).

- **The Japanese version of the Pittsburgh Sleep Quality Index (PSQI-J)**

The PSQI-J's overall score is made up of seven component scores: daytime dysfunction, habitual sleep efficiency, sleep quality, sleep latency, and duration. Each component has a score between 0 and 3.

- **Insomnia Severity Index**

The Iranian version of the insomnia severity index was used to assess the severity among the participants. This index comprises seven questions rated on a Likert scale ranging from 0 (not at all) to 5 (all the time). The total score on this scale ranges from 0 to 28, and it is categorized into four levels: 0-7 indicating no insomnia, 8-14 indicating mild insomnia, 15-21 indicating moderate insomnia, and 22-28 indicating severe insomnia.

Sample Size Calculation

The sample size of 60 participants was determined based on power analysis to detect trends and generate preliminary data on the effectiveness of the ALIVE biofeedback intervention in improving sleep quality, following CONSORT guidelines for pilot studies.

Data Analysis

Descriptive statistics were used to summarize the data. Changes in HRV parameters, sleep quality, and other sleep parameters between the ALIVE biofeedback and control groups were compared using appropriate statistical methods, such as the independent sample T-test, where a p-value < 0.05 was considered significant.

Ethical Considerations

The study adhered to ethical principles outlined by the Declaration of Helsinki. Participants provided written informed consent before their inclusion in the study. The study protocol was reviewed and approved by the AEIRC ethics committee (Ref # ERC/S20/P-027). Participants' confidentiality and anonymity were ensured throughout the study.

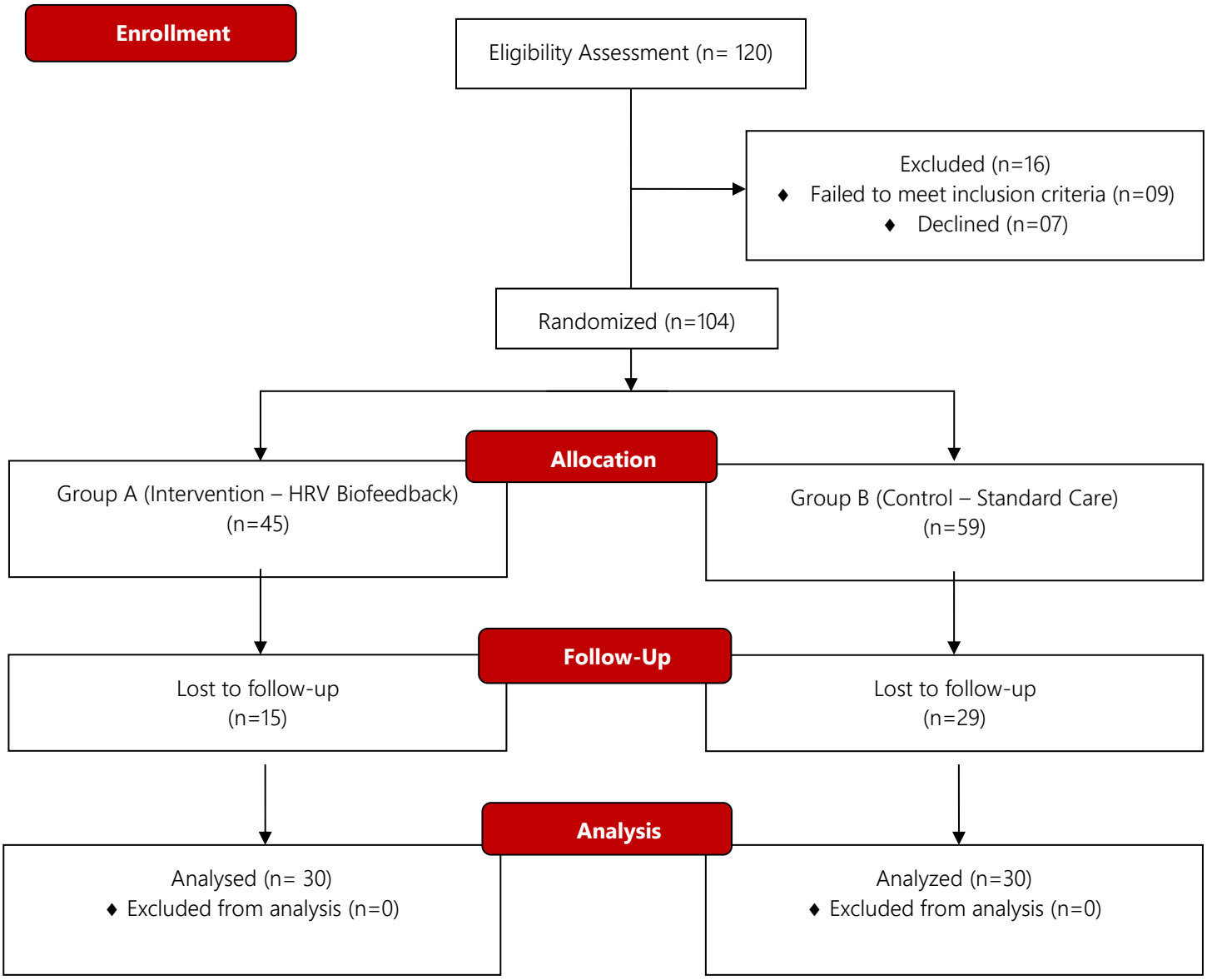

Figure 1: CONSORT Study flow.

Results

Baseline Characteristics

In this pilot study, a total of 60 participants were included. They were randomly assigned to the HRV Biofeedback (BF) group and the Control group. Each group consisted of 30 participants (Figure 1). The participants had a mean age of 35.7 years, with a standard deviation of 12.3 years. Among the participants, 33 (55.0%) were male, and 27 (45.0%) were female.

Heart Rate Variability (HRV)

In the HRV BF group, the SDNN exhibited a significant increase (p=0.04). However, in the Control group, the change was insignificant, with pre and post-values (p=0.68). Regarding RMSSD, the HRV BF group significantly improved from 45.51 ms to 48.80 ms (p<0.01).

In contrast, the Control group did not display a significant change, with pre and post-values (p=0.54). For LF, both HRV BF and the Control group had a non-significant change. In terms of HF, the HRV BF group showed a significant improvement from 410.02 ms^2 to 440.00 ms^2 (p<0.01), while the Control group had a non-significant change (p=0.07).

Table 1: Changes in the HRV Parameters after the 6-week intervention.

Variables	HRV BF Group		P-Value	Control Group		P-Value
	Pre M(SD)	Post M(SD)		Pre M(SD)	Post M(SD)	
Heart rate; bpm	82.10(10.97)	81.90(13.15)	0.93	81.50(10.70)	81.80(13.00)	0.95
SDNN (ms)	62.00(19.30)	70.50(27.32)	0.04*	73.80(23.50)	77.20(12.80)	0.68
RMSSD (ms)	45.51(19.81)	48.80(24.45)	<0.01*	67.90(23.10)	65.90(15.10)	0.54
TP (ms^2)	1350.07(840.01)	2150.00(2050.01)	0.03*	1420.50(730.80)	1500.20(890.10)	0.06
LF (ms^2)	540.20(480.03)	1300.00(1660.00)	0.06	650.00(540.00)	680.50(620.00)	0.79
HF (ms^2)	410.02(390.11)	440.00(730.10)	<0.01*	410.50(370.90)	420.00(480.30)	0.07

*p<0.05 was considered statistically significant

Blood pressure

Table 2 presents the changes in blood pressure after a 6-week intervention in the HRV Biofeedback (BF) and Control groups. In the HRV BF group, there was a significant decrease in diastolic blood pressure after the intervention, while systolic blood pressure did not significantly change. Diastolic and systolic blood pressure in the Control group remained relatively stable, with no significant differences observed before and after the intervention.

Table 2: Changes in the blood pressure after 6-week intervention.

Variables	HRV BF Group		P-Value	Control Group		P-Value
	Pre M(SD)	Post M(SD)		Pre M(SD)	Post M(SD)	
Diastolic Blood pressure (mmHg)	76.20(10.98)	74.60(0.27)	0.05*	75.50(10.85)	74.90(0.25)	0.06
Systolic Blood pressure (mmHg)	120.90(15.82)	121.80(17.92)	0.59	121.00(15.60)	121.50(17.80)	0.63

*p<0.05 was considered statistically significant

The individuals in the ALIVE biofeedback group (HRV BF 6-week intervention) reported longer sleep durations and fewer instances of sleep disturbances including nighttime awakenings. At the start and end of the trial, participants in the control group described identical sleep habits and quality.

Table 3: Changes in the PSQI-J score after 6 weeks of intervention.

PSQI-J		HRV BF Group		P-Value	Control Group		P-Value
		Pre M(SD)	Post M(SD)		Pre M(SD)	Post M(SD)	
Total score		9.42(2.06)	4.39(1.89)	≤0.01*	11.50(3.70)	11.30(3.60)	0.80
Sub scores	Sleep Quality	1.64(0.43)	0.83(0.25)	≤0.01*	1.92(0.78)	1.90(0.80)	0.95
	Sleep latency	1.18(0.47)	1.09(0.51)	0.06	1.30(1.00)	1.30(0.90)	0.78
	Sleep duration	1.08(0.28)	2.89(0.51)	≤0.01*	2.33(0.68)	1.8(0.74)	0.04*
	Habitual sleep efficiency	1.40(0.98)	1.32(0.63)	0.92	1.32(1.20)	1.2(0.90)	0.72
	Sleep disturbances	1.96(0.35)	1.78(0.45)	0.08	1.35(0.49)	1.34(0.50)	0.96
	Use of sleeping medication	1.16(0.37)	1.04(0.20)	0.07	1.20(0.30)	1.2(0.46)	0.62
	Daytime dysfunction	2.00(1.08)	0.36(0.50)	≤0.01*	1.90(1.10)	1.1(0.90)	0.03*

*p<0.05 was considered statistically significant

The participants in the ALIVE biofeedback group (Alive BF 6-week intervention) reported a significant improvement in the Insomnia Severity Index (ISI) score. In the Control group, there were no significant changes in the ISI total score or most sub-scores.

Table 4: Changes in the ISI score after the 6-week intervention.

ISI		HRV BF Group		P-Value	Control Group		P-Value
		Pre M(SD)	Post M(SD)		Pre M(SD)	Post M(SD)	
Total Score		16.3(3.7)	7.07(3.05)	≤0.01*	13.5(3.5)	13.8(6.0)	0.06
Subscore	Difficulty falling asleep	2.09(1.00)	1.05(0.70)	≤0.01*	2.1(0.8)	2.1(1.0)	0.76
	Difficulty staying asleep	1.54(0.92)	0.73(0.34)	0.001*	1.4(1.0)	1.4(1.0)	0.53
	Problem waking up too early	1.03(0.76)	0.39(0.59)	0.015*	1.2(1.0)	1.4(0.9)	0.08
	Satisfaction with the current sleep pattern	2.69(0.09)	1.29(0.68)	≤0.01*	2.5(1.1)	2.2(1.0)	0.67
	Interfering with daily function	2.50(0.96)	1.40(1.20)	≤0.01*	2.3(1.0)	2.7(1.2)	0.05*
	Noticeable for others in terms of impairing the quality of life	1.39(1.10)	0.69(0.79)	≤0.01*	1.8(1.1)	2.0(1.3)	0.34
	Worried/distressed about a current sleep problem	1.98(0.09)	0.90(1.0)	≤0.01*	1.7(1.0)	2.0(1.4)	0.08

*p<0.05 was considered statistically significant

Discussion

To the best of our knowledge, this is the first local study to investigate the effect of HRV-BF training on sleep quality and HRV in healthy adults. HRV-BF training demonstrated an improvement in sleep quality, as indicated by the PSQI-J and ISI scores, as well as an increase in the time and frequency of HRV parameters.

Several studies have provided evidence for the beneficial effects of HRV-BF (Heart Rate Variability Biofeedback) training on sleep quality across various populations. For instance, research conducted by Lin et al. (2019)[21], Burch et al. (2020)[22], Park et al. (2019)[23], and Hasuo et al. (2020)[24] demonstrated improvements in sleep quality among individuals with depression, cancer, overactive bladder syndrome, and caregivers with sleep disturbances, respectively, following HRV-BF training. Sakakibara et al. (2013) found that HRV-BF training increased HF components during two-night recordings in studies involving healthy adults[25]. However, in self-reported good sleepers, Tsai et al. (2015)[26] reported no significant effect of paced breathing before sleep on polysomnography data. In the present study, a six-week intervention of HRV-BF training was conducted with healthy adults, which revealed positive outcomes on sleep quality and vagal activity. Significant improvements were observed in the PSQI-J total score and the sub-scores related to sleep duration, sleep quality, and daytime dysfunction. Moreover, the ALIVE biofeedback group participants showed a significant improvement in the Insomnia Severity Index score. Conversely, no significant changes were observed in the ISI total score or most of the sub-scores in the Control group.

The present study showed significant improvements in all HRV parameters following the HRV BF training intervention. The HRV BF group demonstrated a significant increase in SDNN ($p=0.04$). Additionally, there was a significant improvement in RMSSD from 45.51 ms to 48.80 ms ($p<0.01$). Furthermore, the HRV BF group exhibited a significant increase in HF from 410.02 ms^2 to 440.00 ms^2 ($p<0.01$). Consistent with our findings, numerous studies have consistently reported positive effects of HRV biofeedback training on improving HRV parameters[27-28]. These collective findings provide robust evidence supporting the efficacy of HRV biofeedback training in enhancing HRV parameters, including SDNN, RMSSD, HF, and LF. These improvements reflect positive physiological changes, such as increased autonomic adaptability, enhanced vagal tone, and improved balance between sympathetic and parasympathetic activities. The positive changes observed in HRV parameters following HRV biofeedback training indicate improved autonomic nervous system function and regulation. The increase in SDNN suggests greater overall HRV and cardiac variability, indicative of a more adaptable and resilient autonomic system. The improvement in RMSSD is due to improved vagal tone and parasympathetic modulation, which suggests an improved ability for relaxation and recovery[27]. The marked improvement in HF power reflects enhanced cardiac vagal regulation and parasympathetic activity. According to the combined results of these investigations, HRV biofeedback training is a promising non-invasive strategy for enhancing autonomic function and general wellbeing[28]. People may enjoy improved physiological and psychological states, such as less stress, more relaxation, and greater resilience, by improving HRV values.

The current research provides insight into how ALIVE Biofeedback (HRV-BF) training may help people with insomnia have better quality sleep. According to the findings, ALIVE Biofeedback training has a chance to improve a number of sleep-related factors for people with insomnia, including duration, quality, daytime functioning, and general well-being. To better understand the underlying mechanisms and to examine the long-term impact of ALIVE Biofeedback training on sleep outcomes, more research is required. Investigating the underlying mechanisms by which ALIVE Biofeedback training influences sleep quality may offer insightful information on its effects on the autonomic nerve system, emotional control, and sleep-related cognitive activities.

Self-reported sleep outcomes, which were one of the key limitations, should be supplemented with objective measurements, such as actigraphy or polysomnography, to strengthen the current findings. As a result, the architecture and stages of sleep may be evaluated in greater detail, improving the data's correctness and dependability. Furthermore, to distinguish the unique effects of ALIVE Biofeedback training from non-specific factors or placebo effects, future studies should take into account including a group receiving an alternative intervention or a placebo control group. It's also crucial to take into account any possible confounding factors that could affect sleep outcomes, like the use of medications or comorbid conditions. Future research should account for these variables to more accurately assess how ALIVE Biofeedback training affects insomniacs' ability to sleep.

Conclusion

In conclusion, the pilot randomized controlled study on ALIVE Biofeedback HRV training for treating insomnia highlights its potential as a promising intervention for improving sleep quality. However, due to the pilot nature of the study, further research with larger sample sizes and randomized controlled trials is warranted to validate these preliminary findings. Nonetheless, this study contributes to the development of non-invasive and potentially effective treatments for insomnia.

Conflicts of Interest

The authors have declared that no competing interests exist.

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