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A prospective polysomnographic study of weighted-blankets in patients with psychophysiological insomnia

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Abstract:	Introduction: Options in pharmacological therapies in chronic insomnia are scarce and bear risks for side-effects and addiction. Non-pharmacological integrative therapies are increasingly being demanded by the patients. We designed a prospective polysomnographic (PSG) study in patients with chronic insomnia to investigate the effects of weighted-blankets on sleep parameters and heart rate variability. Method: Patients with primary psychophysiological insomnia used weighted-blankets (equal to about 10% of the patients' body weight) at home for 10 consecutive nights. All had clinical evaluation and full-night video-PSG before and after the use of weighted-blankets. Turkish Version of Basic Scale on Insomnia Complaints and Quality of Sleep (BaSIQS) and Pittsburgh sleep quality index (PSQI) were filled in. Results: Of twenty-six patients (18 males, 69.2%; mean age 48.7+9.4 years), 16

	patients (69.2%) stated a benefit from weighted-blanket. Total scores of BaSIQS (p=0.005) and PSQI (p=0.003) decreased significantly. Sleep latency was shortened (p=0.040) and the percentage of N3 sleep was increased (p=0.034) at the second PSG in compared to the first PSG. It was observed that the obstructive apnea-hypopnea index was increased (p=0.038). In HRV analysis, mean average RR duration, mean LF band and LF/HF ratio showed a trend to decrease at second PSG, but the difference didn't reach to the statistically significant level. Discussion: Weighted-blankets are becoming a promising option for the occupational practical therapy for chronic insomnia. An increase in obstructive apneas/hypopneas necessities a screening for sleep apnea. A trend for decreased sympathetic activity in HRV analysis, which was not statistically significant, requires further studies.

A prospective polysomnographic study of weighted-blankets in patients with psychophysiological insomnia

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Key words: Chronic insomnia, psychophysiological insomnia, integrative therapy, weighted blanket.

Abstract

Introduction: Options in pharmacological therapies in chronic insomnia are scarce and bear risks for side-effects and addiction. Non-pharmacological integrative therapies are increasingly being demanded by the patients. We designed a prospective polysomnographic (PSG) study in patients with chronic insomnia to investigate the effects of weighted-blankets on sleep parameters and heart rate variability.

Method: Patients with primary psychophysiological insomnia used weighted-blankets (equal to about 10% of the patients' body weight) at home for 10 consecutive nights. All had clinical evaluation and full-night video-PSG before and after the use of weighted-blankets. Turkish Version of Basic Scale on Insomnia Complaints and Quality of Sleep (BaSIQS) and Pittsburgh sleep quality index (PSQI) were filled in.

Results: Of twenty-six patients (18 males, 69.2%; mean age 48.7±9.4 years), 16 patients (69.2%) stated a benefit from weighted-blanket. Total scores of BaSIQS (p=0.005) and PSQI (p=0.003) decreased significantly. Sleep latency was shortened (p=0.040) and the percentage of N3 sleep was increased (p=0.034) at the second PSG in compared to the first PSG. It was observed that the obstructive apnea-hypopnea index was increased (p=0.038). In HRV analysis, mean average RR duration, mean LF band and LF/HF ratio showed a trend to decrease at second PSG, but the difference didn't reach to the statistically significant level.

Discussion: Weighted-blankets are becoming a promising option for the occupational practical therapy for chronic insomnia. An increase in obstructive apneas/hypopneas necessities a screening for sleep apnea. A trend for decreased sympathetic activity in HRV analysis, which was not statistically significant, requires further studies.

What this Article Adds: Our study demonstrates the efficacy of weighted-blankets in chronic psychophysiological insomnia, especially on shortening the sleep latency and quality. Heart rate variability was tested for the first time in the literature, but results are not conclusive and should be tested in larger population. Last, but not least, weighted-blankets should cautiously be used in patients with obstructive sleep apnea.

Introduction

Insomnia is a growing health problem due to social stress, increasing demands, industrialization, and increased stressor factors associated with modern lifestyles. Although the prevalence of chronic insomnia varies in a wide range across different countries, the overall prevalence of insomnia symptoms was found as 51% in Turkey in a prospective survey of 4758 participants, with a prevalence of 12.2% for chronic insomnia (Benbir et al., 2015). Chronic insomnia is associated with a variety of daytime consequences (such as impaired school/work performances, loss in productivity, and work/traffic accidents) as well as with serious health problems (such as psychosomatic disorders, addictions, and cardiovascular diseases) (Riemann et al., 2015). It is therefore of crucial importance to efficiently treat chronic insomnia.

Both pharmacological and non-pharmacological, behavioral therapies are used in the treatment of insomnia (Sateia et al., 2017). However, the number of the drugs approved by the Food and Drug Administration (FDA) is scarce, and FDA-approved drugs usually have addiction potentials, in addition to other side effects. Cognitive and behavioral methods are being strongly recommended in these patients, but they require long treatment sessions to achieve satisfactory results (Edinger et al., 2021). Integrative therapies are therefore being increasingly used as an alternative therapy to stabilize sleep in adult patients with chronic insomnia.

Weighted-blankets have recently introduced in the treatment on insomnia (Mullen et al., 2008). While the exact mechanisms underlying the possible sleep-improving effects of weighted-blankets are not known, decreased electrodermal activity via deep pressure stimulation (Eron et al., 2020) decreased physiological reactions to stressors via oxytocinergic activation (Case et al., 2021), and increased melatonin release at bedtime (Meth et al., 2023) have been hypothesized. There is still a need for systematic polysomnographic studies to demonstrate the potential benefits of weighted-blankets in patients with chronic insomnia. We designed a prospective, in-laboratory polysomnographic study in patients with primary psychophysiological insomnia, and aimed to investigate the effects of weighted-blankets on sleep parameters and heart rate variability.

Method

Patients admitting to our Sleep and Disorders Unit were prospectively and consecutively evaluated during one-year of study period. Those diagnosed as having chronic insomnia were enrolled into the study, and patients with any other associated sleep disorder (such as restless legs syndrome, sleep apnea syndromes), neurologic and/or psychiatric comorbidity, or using drugs/substances that interfere with sleep were excluded. For this reason, all patients had a through clinical examination with psychiatric consultation. Patients, who were eligible for the study, and who gave their written informed consent to participate into the study had a full-night video-polysomnography (PSG) in our laboratory. In case a sleep disorder other than insomnia was detected in PSG examination, they were excluded from the study. Patients diagnosed with primary psychophysiological insomnia on the basis of clinical and PSG evaluation were given weighted-blankets to use at their homes. A weighted-blanket equal to about 10% of the patients' body weight (Mullen et al., 2008) was used by the patients for 10 consecutive nights for familiarization to the therapy. At the end of this period, all patients had a second full-night video-PSG in our laboratory with weighted-blanket on. The Turkish Version of Basic Scale on Insomnia Complaints and Quality of Sleep (BaSIQS) (Mıhçıoğlu et al., 2021) and the Turkish version of the Pittsburgh sleep quality index (PSQI) (Agargun et al., 1996) were fulfilled by the patients in the morning following the first and second PSG investigations. Our study was approved by the Local Ethics Committee for Clinical Researches (ID: E-83045809-604.01.01-362616).

The recording and the evaluation of PSG were performed based on the AASM Manual for the Scoring of Sleep and Associated Events (Berry et al., 2020), and the 3rd edition of the International Classification of Sleep Disorders was used for the diagnosis of sleep-related disorders (AASM, 2014.). Total recording time, total sleep time, wakefulness after sleep onset (WASO), sleep efficiency, sleep latency, rapid eye movements (REM) sleep latency, percentages of wakefulness and sleep stages, apnea–hypopnea index (AHI), mean and minimum oxygen saturations, and the index of periodic leg movements in sleep (PLMSI) were calculated.

A single modified electrocardiography (ECG) Lead II was used for the analysis of heart rate variability (HRV). ECG signal was processed to capture beat-to-beat intervals (R-R interval) between 300-1600 millis, and abnormal R-R intervals related to cardiac rhythm disturbances or artifacts were removed. In the time domain,

the average R-R interval (avRR) and the proportion of adjacent normal-to-normal intervals differing by more than 50 millis (pNN50) were calculated. In the frequency domain, the spectral power of the low-frequency (LF), high-frequency (HF) bands, and LF to HF ratio (LF/HF) were computed by using the Fast Fourier transformation (FFT) (Heart rate variability, 1996)

Statistics

Data were analyzed by using SPSS (Statistical Package for the Social Sciences) software (version 21.0; SPSS Inc., Chicago, IL, USA). Nominal parameters between two groups were tested by Chi-square test. Test of normality was evaluated by using the Shapiro-Wilk test. Among ordinal and/or continuous data, AHI in the first and second PSGs, and PLMSI in the first PSG did not have normal distribution, while all the other parameters had normal distribution. In BASIQS, all questions at first test and all except question 2 at second test did not have a normal distribution. Total points of two tests showed a normal distribution. In PSQI, all questions at first and second test did not have a normal distribution; total point of the first test also failed to show a normal distribution, but only total PSQI score at second test had a normal distribution. Parameters of HRV at first and second night were all normally-distributes, except for avRR and pNN50 at first night and LF/HF at second night. The dependent parameters on the benefit (present or absent) were analyzed by using the independent-samples T test for the parameters with normal distribution, and by using the Mann-Whitney U test for those without a normal distribution. The changes between the first and the second night were analyzed by using the paired-samples T test or Wilcoxon test, depending on the normality. Spearman correlation analysis was used in correlation analysis of the parameters that may play a role on the benefits from therapy. Multiple comparisons were corrected by using the Benjamine-Hochberg procedure, with a false discovery rate of $q = 0.05$.

Results

Twenty-six patients (18 males, 69.2%; mean age 48.7±9.4 years) completed the study. Sixteen patients (69.2%) stated a benefit from weighted-blanket, and six of them (6/26, 23%) stated a substantial benefit. The analysis of BaSIQS and PSQI results are given in Table 1. Here it was seen that the total scores of both tests were significantly decreased (p=0.005 and p=0.003, respectively). Questions 1 and 2 in BaSIQS (related to sleep latency), and questions 3, 6 and 7 (related to sleep latency, overall sleep quality and need for medications to sleep, correspondingly) in PSQI showed significant changes following therapy (see Table 1).

PSG parameters at first and second nights are given in Table 2. It was observed that sleep latency was shortened (p=0.040) and the percentage of N3 sleep was increased (p=0.034). Nevertheless, we also observed that the obstructive AHI was increased at the second night with weighted-blanket (p=0.038). Age, sex, or PSG parameters of the first night did not show any association with the patients stating therapeutic benefit. Correlation analysis between age, sex, PSG parameters and BaSIQS and PSQI also failed to reveal significant determinants of the benefit from weighted-blanket.

HRV analysis showed that the mean average RR duration, mean LF band and LF/HF ratio showed a trend to decrease at second night with weighted-blankets, though the difference did not reach to the statistically significant level (see Table 3).

Discussion

Weighted-blankets are increasingly drawing attention as an occupational practical therapy for chronic insomnia. In our prospective PSG-based study, we demonstrated that the use of weighted-blankets resulted in improvements in symptomatology in about 70% of the patients with chronic psychophysiological insomnia, and decreased sleep latency with an increased percentage of N3 sleep was objectively shown even after 10 days of therapy. Correlation analyses, on the other hand, failed to show the determinant factors that which subgroup of patients will benefit from weighted-blanket the most. In addition, although a trend for a decreased sympathetic activity after the use of weighted-blanket was observed in HRV analysis, it was not statistically significant. Last but not least, it should be emphasized that the use of weighted-blanket may result in an increase in obstructive hypopneas/apneas, which necessitates a screening for sleep apnea in candidate patients.

The beneficial effects of weighted-blankets have been previously demonstrated in small number of studies (Ackerley et al., 2015; Eron et al., 2020; Ekholm et al., 2020). The most common effect of weighted-blankets was reported as an increase in the sleep quality in these studies. While the use of different scales in subjective evaluation and the lack of PSG in some of these studies make it difficult to compare the results adequately, in our study, we observed that the most prominent effect of weighted-blankets was on the sleep latency. Both in subjective measures including BaSIQS and PSQI and in objective PSG examinations, we observed that sleep latency was shortened significantly after the use of weighted-blankets. This finding is quite important to guide physicians in selecting the patients for this specific therapy. Also, we observed that the duration of the deep slow wave sleep was increased after the use of weighted-blankets, which may explain the high rate of subjective satisfaction and increased sleep quality, as shown by the decreased total scores in both questionnaires.

Weighted-blankets were also shown to be effective in decreasing the anxiety in insomnia associated with psychiatric disorders (Mullen et al., 2008; Ekholm et al., 2020; Steingrímsson et al., 2022). This calming and relaxation effects of weighted-blankets was hypothesized to be linked to the presence of a tactile input, which may decrease the activity of sympathetic nervous activation and sympathetic arousals during sleep (Ackerley et al., 2015; Reynolds et al., 2015). This hypothesis may also be one of the underlying mechanisms

to explain the beneficial of weighted-blankets on sleep quality. In this regard, we performed HRV analysis in our patients before and after the therapy, which shows the activity of sympathetic nervous system via measuring the variability of heart beats during sleep. Although we failed to demonstrate a statistically significant difference before and after the use of weighted-blankets, there was a trend for decreased sympathetic activation as shown by decreased average RR duration, LF band and LF/HF ratio. HRV analysis was not used in the literature before, but our results are promising to conduct a larger and longer study on this parameter.

Another original finding of our study was increased obstructive AHI by the use of weighted-blankets. In the initial study of weighted-blankets, vital signs of the participants, including pulse oximetry, pulse rate and blood pressure, were traced and showed the safety of the treatment (Mullen et al., 2008). However, our results implicate that patients who are candidate for a treatment with weighted-blankets should be screened for sleep apnea by questionnaires, or should be tested by PSG to exclude sleep apnea before implementing this therapy. Nevertheless, our results need to be replicated in larger cohorts, and the use of weighted-blankets in specific patient groups, such as those with sleep apnea, deserves further attention.

Besides original and promising results of our study, it also includes some important limitations. There was no control group because of the inability to provide a placebo weighted-blanket. The use of different weights of weighted-blankets was unclear, as the perceived heaviness of the blankets may also vary considerably among subjects (due to different levels of interoceptive and sensory awareness). Only short-term effects of weighted-blankets were interpreted in the current study, and long-term results should be performed.

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References

Ackerley R, Badre G, Olausson H. Positive Effects of a Weighted Blanket on Insomnia. J Sleep Med Disord 2015;2(3): 1022.

Agargun YM, Kara H, Anlar O. The reliability and validity the Pittsburgh sleep quality index. Turkish Journal of Psychiatry. 1996;7:107-111.

American Academy of Sleep Medicine (AASM). International classification of sleep disorders. 3rd ed. Darien: American Academy of Sleep Medicine, 2014.

Benbir G, Demir AU, Aksu M, Ardic S, Firat H, Itil O, Ozgen F, Yılmaz H, Karadeniz D. Prevalence of insomnia and its clinical correlates in a general population in Turkey. Psychiatry Clin Neurosci. 2015 Sep;69(9):543-52. doi: 10.1111/pcn.12252.

Berry RB, Quan SF, Abreu AR, et al; for the American Academy of Sleep Medicine. The AASM manual for the scoring of sleep and associated events: rules, terminology and technical specifications. Version 2.6. Darien: American Academy of Sleep Medicine, 2020.

Case LK, Liljencrantz J, McCall MV, Bradson M, Necaise A, Tubbs J, Olausson H, Wang B, Bushnell MC. Pleasant Deep Pressure: Expanding the Social Touch Hypothesis. Neuroscience. 2021 Jun 1;464:3-11. doi: 10.1016/j.neuroscience.2020.07.050.

Edinger JD, Arnedt JT, Bertisch SM, Carney CE, Harrington JJ, Lichstein KL, Sateia MJ, Troxel WM, Zhou ES, Kazmi U, Heald JL, Martin JL. Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(2):255-262. doi: 10.5664/jcsm.8986.

Ekholm B, Spulber S, Adler M. A randomized controlled study of weighted chain blankets for insomnia in psychiatric disorders. J Clin Sleep Med. 2020; 16(9): 1567–1577. https://doi.org/10.5664/jcsm.8636.

Eron K, Kohnert L, Watters A, Logan C, Weisner-Rose M, Mehler PS. Weighted blanket use: A systematic review. Am J Occupat Ther. 2020;74(2):7402205010p1–7402205010p14. https://doi.org/10.5014/ajot.2020.037358.

Heart rate variability: standards of measurement, physiological interpretation and clinical use. Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology. Circulation. 1996;93(5):1043-65.

Meth EMS, Brandão LEM, van Egmond LT, Xue P, Grip A, Wu J, Adan A, Andersson F, Pacheco AP, Uvnäs-Moberg K, Cedernaes J, Benedict C. A weighted blanket increases pre-sleep salivary concentrations of melatonin in young, healthy adults. J Sleep Res. 2023 Apr;32(2):e13743. doi: 10.1111/jsr.13743.

Mıhçıoğlu İ, Malakçıoğlu C, Mutlu HH. Uykusuzluk Şikayetleri ve Uyku Kalitesi Temel Ölçeğinin Türkçe Geçerlilik ve Güvenirliği. TJFMPC. 2021;15(4): 846-852. doi: 10.21763/tjfmpc.971532.

Mullen B, Champagne T, Krishnamurty S, Dickson D, Gao RX. Exploring the safety and therapeutic effects of deep pressure stimulation using a weighted blanket. Occupat Ther Ment Health. 2008;24:65-89. doi: org/10.1300/J004v24n01_05.

Reynolds S, Lane SJ, Mullen B. Effects of deep pressure stimulation on physiological arousal. Am J Occup Ther. 2015 May-Jun;69(3):6903350010p1-5. doi: 10.5014/ajot.2015.015560.

Riemann D, Nissen C, Palagini L, Otte A, Perlis ML, Spiegel Alder K. The neurobiology, investigation, and treatment of chronic insomnia. Lancet Neurol. 2015; 14: 547-558. doi: 10.1016/S1474-4422(15)00021-6.

Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017 Feb 15;13(2):307-349. doi: 10.5664/jcsm.6470.

Steingrímsson S, Odéus E, Cederlund M, Franzén S, Helgesson C, Nyström K, Sondell J, Opheim A.Weighted blanket and sleep medication use among adults with psychiatric diagnosis – a population-based register study. Nordic J Psychiatr. 2022;76(1):29-36. doi: 10.1080/08039488.2021.1931713.

Tables

Table 1. BaSIQS and PSQI parameters before and after the use of weighted-blankets in whole study population.

Questionnaires	Pre-treatment (mean+s.d.) [Median {95% CI}]	Post-treatment (mean+s.d.) [Median {95% CI}]	Difference	t (z) (Test statistics)	p value
BaSIQS					
Q1	2.0±1.5 [1.0 {1.3-2.8}]	1.6±1.5 [1.0 {0.8-2.3}]	0.4-0.8	2.651	0.016*
Q2	2.5±0.8 [3.0 {2.2-2.9}]	1.8±1.0 [2.0 {1.3-2.2}]	0.8-0.8	3.943	0.001*
Q3	2.0±0.6 [2.0 {1.7-2.4}]	1.8±0.8 [2.0 {1.4-2.2}]	0.2-0.6	1.285	0.214
Q4	2.0±0.8 [2.0 {1.6-2.3}]	1.7±0.8 [2.0 {1.2-2.1}]	0.2-0.9	1.228	0.234
Q5	2.2±0.9 [2.0 {1.7-2.6}]	1.9±0.7 [2.0 {1.5-2.2}]	0.4-0.7	1.561	0.135
Q6	3.0±1.1 [1.0 {0.6-1.6}]	4.0±0.7 [1.0 {0.6-1.6}]	0.4-0.8	1.789	0.090
Q7	1.3±0.7 [1.0 {1.0-1.6}]	1.0±0.8 [1.0 {0.6-1.4}]	0.2-0.7	1.561	0.135
BaSIQS-total	13.1±3.0 [13.0 {11.7-14.5}]	10.6±4.5 [11.0 {8.5-12.8}]	2.5-3.5	3.193	0.005*
PSQI					
Q1	1.7±1.0 [2.0 {1.2-2.2}]	1.4±0.8 [1.0 {1.0-1.8}]	0.3-0.6	2.042	0.055
Q2	1.7±0.7 [2.0 {1.4-2.0}]	1.5±0.5 [1.5 {1.2-1.7}]	0.6-0.2	1.453	0.163
Q3	1.8±1.0 [2.0 {1.4-2.2}]	1.4±0.8 [1.0 {1.0-1.8}]	0.4-0.8	2.179	0.042*

Q4	1.7±0.9 [1.5 {1.2-2.1}]	1.5±0.9 [1.0 {1.1-2.9}]	0.2-0.4	1.371	0.186
Q5	0.8±1.2 [0 {0.2-1.4}]	0.8±1.0 [0.5 {0.2-1.2}]	0.1-0.6	0.698	0.494
Q6	2.0±1.4 [2.0 {1.3-2.6}]	1.5±1.0 [2.0 {1.0-2.0}]	0.5-0.8	2.703	0.014*
Q7	1.9±1.2 [2.0 {1.4-2.4}]	1.3±0.8 [1.0 {0.8-1.7}]	0.6-0.9	2.854	0.010*
PSQI-total	11.6±3.7 [12.5 {9.9-13.4}]	9.2±2.8 [9.0 {7.8-10.4}]	2.5-3.3	3.339	0.003*

BaSIQS: Basic Scale on Insomnia complaints and Quality of Sleep; PSQI: Pittsburgh sleep quality index.

*statistically significant.

Table 2. PSG parameters at first and second nights in whole study population.

PSG parameters	Pre-treatment (mean+s.d.) [Median {95% CI}]	Post-treatment (mean+s.d.) [Median {95% CI}]	Difference	r (Correlation coefficient)	t (z) (Test statistics)	p value
Total recording time (min.)	492.2±97.4	478.2±36.3	14.1-102.4	0.046	0.704	0.488
Total sleep time (min.)	383.2±83.0	384.1±36.3	1.7-92.6	0.357	0.094	0.926
Sleep efficiency (%)	78.1±13.4	80.2±14.2	-2.2-18.0	0.158	-0.619	0.542
Sleep latency (min.)	42.6±59.5	14.3±9.0	-27.6-62.4	0.022	-2.175	0.040*
REM sleep latency (min.)	171.6±93.8	164.9±104.5	9.2-110.0	0.393	0.417	0.680
WASO (min.)	108.0±80.0	93.2±67.8	-14.8-103.0	0.035	-0.730	0.472
Percentage of N1 sleep (min.)	11.0±7.3	9.9±4.8	1.0-8.8	-0.029	0.589	0.561
Percentage of N2 sleep (min.)	50.3±12.7	45.7±10.4	-4.6-13.8	0.305	-1.692	0.103
Percentage of N3 sleep (min.)	9.4±5.6	13.5±4.4	-3.0-6.1	0.217	-2.269	0.034*
Percentage of R sleep (min.)	14.9±7.2	14.8±7.7	-0.07-9.2	0.242	0.041	0.968
Obstructive AHI (/hour) [Median {95% CI}]	4.4±4.4 [3.0 {2.6-6.2}]	8.3±9.9 [5.0 {4.2-12.3}]	-3.9-9.0	-	-2.196	0.038*
Central AHI (/hour)	0.2±0.4	0.2±0.5	0.06-0.6	0.003	0.424	0.675
Mean O2 saturation (%)	95.3±1.8	94.8±1.7	0.5-1.6	0.566	1.526	0.140
Minimum O2 saturation (%)	89.6±4.6	87.5±6.6	-1.8-6.8	0.306	-1.299	0.207
PLMSI (/hour) [Median {95% CI}]	10.4±15.2 [5.0 {4.2-16.5}]	10.0±12.2 [6.5 {5.0-14.9}]	0.4-10.0	-	0.199	0.844

PSG: polysomnography; REM: rapid eye movement; WASO: wakefulness after sleep onset; N1: non-REM (NREM) stage 1; N2: non-REM (NREM) stage 2; N3: non-REM (NREM) stage 3; AHI: apnea-hypopnea index; PLMSI: index of periodic leg movements in sleep.

*statistically significant.

Table 3. Heart rate variability analysis before and after the use of weighted-blankets in whole study population.

Parameters	Pre-treatment (mean+s.d.) [Median {95% CI}]	Post-treatment (mean+s.d.) [Median {95% CI}]	Difference	r (Correlation coefficient)	t (z) (Test statistics)	p value
avRR	1455.5±1973.4 [1695.3 {988.2-1859.7}]	971.5±187.7 [1049.0 {635.2-1216.9}]	-531.8-379.8	-	-0.531	0.632
pNN50	19.6±36.4 [13.4 {7.5-35.3}]	21.2±19.2 [15.2 {8.2-38.4}]	-25.5-62.4	-	1.334	0.274
LF	14732.4±15646.2	10084.8±8607.6	-22971.8-42190.4	0.282	0.939	0.417
HF	4322.0±3824.3	3571.3±2731.8	-10283.4-7908.4	-0.345	-0.415	0.706
LF/HF	5.0±5.2 [4.1 {2.9-14.7}]	3.9±4.4 [2.5 {0.8-12.4}]	-14.2-15.7	-	0.164	0.380

avRR: average R-R interval; pNN50: proportion of adjacent normal-to-normal intervals differing by more than 50 millis; LF: low-frequency band; HF: high-frequency band; LF/HF: LF to HF ratio.