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A Preliminary Study on the Effectiveness of Far-Infrared Emitting Ceramic Mattresses in Improving Sleep Quality

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ABSTRACT

Objectives : Far-infrared (FIR) lights have been investigated for sleep quality intervention. We sought to measure the advantageous effects of FIR in sleep using polysomnographic data as the objective outcomes.

Methods : The ten healthy volunteers were enrolled in a single-center, prospective, patient-blind, single-arm trial. Individuals slept on a sham mattress and a FIR emitting mattress with polysomnography for one night each.

Results : Sleep efficiency showed an increasing trend but was not statistically significant. PSQI-K significantly decreased (p=0.013). The latency to REM of the baseline was shorter than that of the intervention (p=0.008). Though there was no statistical significance, Stage N1 and N2 were shortened, and Stage N3 was prolonged after the intervention compared to the baseline.

Conclusions : The FIR-emitting mattresses improved sleep quality on self-reported insomnia. We suggested the candidate for the markers altered by the FIR therapy, such as the normalization of REM latency and increased N3 sleep.

KEYWORDS : Far-infrared; Sleep; Ceramic mattress.

INTRODUCTION

Individuals visiting sleep clinics frequently encounter the problem of suboptimal sleep quality.[1,2] Although sleep quality can be reduced by specific sleep disorders, such as sleep apnea and periodic limb movement disorder,[3] people may also complain of poor sleep quality without specific, diagnosed sleep disorders. Recent research suggests that poor sleep quality could lead to various pathologic conditions, including neurodegenerative disorders, cardiovascular diseases, and psychiatric disorders.[3] Nonetheless, the attention to the reduction in sleep quality appears to be comparatively lower than that of other sleep disorders in both sleep clinics and research.

The efficacy of infrared (IR) emitting devices has been assessed as a potential intervention for improving sleep quality.[4-6] IR is classified into near-IR (NIR, 0.78−3.0 μm), mid-IR (MIR, 3.0−50.0 μm), and far-IR (FIR, 50.0−1000.0 μm).[7] These light spectrums could transfer the energy to subcutaneous tissue without heating injury and induce various biological responses with non-thermal and thermal effects.[8] Though the integration of multiple biological activities seems to contribute to sleep modulation, the tissue-warming activity may be considered the possible common mechanism by which peripheral blood circulation is accelerated, the metabolism state is improved, and the chemical messenger transfer is enhanced.[9] Consequently, IR has been implemented across various domains of healthcare owing to these distinctive features. IR therapy methods encompass wearable devices, sauna cabins, and mattresses that

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emit IR light.[8,10]

The sleep-regulating impact of FIR on rats was demonstrated by Honda et al.[9] in their study. Several pilot studies were conducted to investigate the potential benefits of FIR therapy in improving sleep quality. The results of these studies showed the positive effects of FIR therapy on sleep quality.[4-6] However, those trials were constrained due to the application of subjective metrics, such as questionnaires, for the outcome assessment and the absence of polysomnography (PSG). Therefore, it was suggested that PSG data, which provides objective outcomes, and self-reported questionnaires, which provide subjective consequences, could be utilized to assess the beneficial impact of FIR on sleep. This study aims to investigate the FIR effect on sleep quality with both objective and subjective metrics.

METHODS

1. Study population

The experimental group consisted of ten healthy volunteers who were recruited from the Catholic Kwandong University (CKU) met the following eligibility criteria: being above 19 years old, having the ability to walk independently without any physical activity limitations, completing the necessary inquiries and evaluations, and providing written informed consent to participate in the pilot study. Subjects who were illiterate had medical conditions that resulted in a reduction of melatonin, such as diabetes mellitus and beta-blocker administration, suffered from sleep disorders such as sleep apnea, narcolepsy, chronic severe insomnia with medical treatment, and circadian rhythm disorders, including shift workers, had psychiatric disorders that limited their daily life activities, or were deemed unable to participate based on the judgment of the principal investigator, were excluded from the study.

2. Trial design and protocol

This trial was a single-center, prospective, patient-blind, single-arm trial. The protocol was conducted for a week. The CKU institutional review board approved the trial protocol (HDT 2022-08-011-001). The volunteers visited sleep center three times. The screening processes were conducted on the first visit, within five days of the second visit. Written informed consent was acquired from the enrolled volunteers. Throughout the screening process, we investigated the demographic, including gender, age, alcohol/caffeine consumption and smoking, past medical history, drug list, a history of sleep disorders treatment, depression/stress assessment with Patient Health Questionnaire (PHQ-9),[11] Goldberg Anxiety Scale,[12] Depression Anxiety Stress Scale (DASS)[13] and Hospital Anxiety & Depression Scale (HADS),[14] pain/fatigue/somatization assessment with Short-form McGill Pain Questionnaire (SF-MPQ-2),[15] Korean-symptom Checklist 95 (KSCL95)[16] and Fatigue Severity Scale (FSS),[17] health perception survey with 36-Item Short Form Survey (SF-36)[18] and Perceived Stress Scale (PSS),[19] and sleep-related survey including the Korean version of Pittsburgh Sleep Quality Index (PSQI-K),[20] Insomnia Severity Index (ISI),[21] Epworth Sleepiness Scale (ESS),[22] Stanford Sleepiness Scale (SSS),[23] presence of restless leg syndrome (RLS), Global Sleep Assessment Questionnaire (GSAQ), STOP-Bang questionnaire and Berlin Questionnaire.[24] Physical examination and the check of vital signs were performed each visit.

1) Baseline

The baseline state of the participants was assessed through the use of polysomnography (PSG) during the second visit. The study evaluated the salivary melatonin level as a reliable measure of sleep quality.[25] The assessment was conducted two hours before the participants' usual bedtime. The participants lay on a sham mattress constructed from plywood. We did not inform the order, in which they would sleep on the sham and FIR mattresses. Furthermore, the sham mattress was overlaid with a mattress topper, which served to prevent the participants from distinguishing between the sham and experimental mattresses.

2) Intervention

On the third visit, which occurred on the day after the second visit, the participants were subjected to an intervention involving the application of a FIR ceramic mattress. The FIR ceramic mattress was additionally covered with toppers intended for blinding. On the third visit, the participants underwent PSG, which was followed by a reevaluation of the questionnaires study for depression/stress assessment, the pain/fatigue/somatization assessment, and the sleep-related issues. Concomitantly with the baseline assessment, we assessed the salivary melatonin level to ascertain the comparability of sleep quality immediately prior to the intervention and that of the baseline. Additionally, the intervention's negative outcomes were assessed.

3. FIR black ceramic mattress

The ceramic material (TSJ Co. Ltd) comprises alumina (aluminum oxide) and FIR emitting germanium. The material emits 3 to 20 μm wavelengths of FIR light with 6.31×10^3 W/m^2 of the emission energy, 0.878 of the emissivity, and 0.02 μSv/hr of the dose rate. The above-mentioned substance underwent a

manufacturing procedure resulting in a final dimension of 2.5 cm, which was used as a constituent of a bedding item known as a mattress. A 2 cm topper of processed cotton was placed on top of both the control and experimental groups' mattresses to prevent potential sleep disturbances caused by the hard material of the processed mattresses. The rationale behind this decision was a pair of ways firstly, to minimize the firmness of the mattresses, and secondly, to make the difficulty for subjects to differentiate between the control and experimental cohorts.

4. Polysomnography

We record electroencephalography with F3, F4, C3, C4, O1, and O2, electrooculography, and electromyogram using Nox A1 PSG system (Nox Medical Reykjavik, Iceland). Total sleep time (TST), sleep efficiency, the proportions of N1, N2, N3 and rapid eye movement (REM) sleep, wakefulness after sleep onset (WASO), latency to sleep onset, latency to REM sleep, apnea-hypopnea index (AHI), respiratory distress index (RDI), and O2 saturation were retrieved from the data of PSG.

5. Salivary melatonin

We use the salivary melatonin enzyme immunoassay kit (Category number 1-3402, Salimetrics, USA). The salivary melatonin (pg/mL) was analyzed using SpectraMax 190 Reader (USA). The participants were given instructions to abstain from consuming food or beverages, as well as avoiding from brushing their teeth, for a duration of 30 minutes prior to the collection of saliva. This protocol was also to be followed for a period of 2 hours preceding their bedtime. The participants were instructed to retain their saliva while exposing it to running water for a duration of 2−3 minutes, in order to procure an adequate quantity of saliva for analysis.

6. Measurement of outcomes

The primary endpoint is the sleep efficiency calculated by PSG. The secondary endpoints include sleep variables, including TST, WASO, RDI, and mean change in PSQI-K scoring, SSS and ESS. The safety outcomes are dropout and any complaints associated with using the mattress.

7. Statistical analysis

Because this was a pilot study, we did not perform a sample size calculation and arbitrarily estimated the sample size as ten.[26] The epidemiological information is summarized as the percentage or the means, standard deviations, minimum and maximum. The differences in the psychological and PSG-related variables between baseline and post-intervention and the salivary melatonin levels between baseline and pre-intervention were analyzed using the Wilcoxon signed-rank test. We used SPSS 22.0 (SPSS for Windows, IBM Corp., Armonk, NY, USA) for statistical analyses and considered a p-value< 0.05 statistically significant. To visualize the comparison of salivary melatonin, we used RStudio software.

RESULTS

1. Characteristics of the volunteers

The mean age was 35.00 years old (standard deviation, SD 5.54, min to max 28.00−44.00). The sex ratio (male to female) was 4.00 (8/2). The mean height and weight were 168.6 (SD 9.0) cm and 78.70 (SD 14.77) kg, respectively. In addition, the mean body mass index (BMI) was 27.55 (SD 4.17) kg/m^2.

2. Sleep quality results and safety outcome

Sleep efficiency showed an increasing trend but was not statistically significant. (Table 2) Despite no statistical significance, there was a trend toward improved sleep quality, increased TST, and decreased WASO (Table 2). Moreover, there was a tendency to decrease RDI without statistical significance. In contrast, PSQI-K significantly decreased (difference -1.30, SD 1.16, p=0.013), suggesting perceived improvements in insomnia (Table 3). Although the differences in SSS and ESS between baseline and intervention were not statistically significant, both variables also exhibited a decreasing trend. The salivary melatonin levels of the baseline were not different from those just before the intervention (p-value=0.8127) (Supplementary Fig. 1 in the online-only Data Supplement). There was neither the dropout of the volunteer nor the complaint associated with the mattress use.

3. Exploratory analyses

We also conducted exploratory analyses to investigate whether FIR light affected sleep architectures and sleep-related variables. The latency to REM of the baseline was shorter than that of the intervention (164.61 [SD 56.94] vs. 108.17 [SD 55.67], p=0.008). Though there was no statistical significance,

Table 1. General characteristics of the participants (n=10)

	n (%)/mean±SD	Min	Max
Age (year)	35.00±5.54	28.00	44.00
Sex (female/male)	8/2 (80.0/20.0)		
Height (cm)	168.60±9.02	155.0	185.0
Weight (kg)	78.70±14.77	47.0	96.0
BMI (cm/kg^2)	27.55±4.17	19.6	34.0

BMI, body mass index

Table 2. Changes of the PSG related variables of the participants (n=10)

	Sham mattress	Ceramic mattress	Diff (post-pre)	Z	p
TST (min)	356.29±35.92	346.08±32.36	-10.21±38.19	-0.97	0.333
Sleep efficiency (%)	**88.57±11.70**	**90.22±9.54**	**1.65±11.21**	**-0.36**	**0.721**
N1 (%)	20.14±18.02	17.07±11.86	-3.07±8.58	-0.87	0.386
N2 (%)	58.45±13.14	52.31±11.03	-6.14±12.35	-1.38	0.169
N3 (%)	**10.29±7.32**	**16.99±9.30**	**9.96±6.70**	**-1.68**	**0.093**
REM (%)	11.16±5.40	13.66±6.03	6.37±2.50	-1.27	0.203
WASO (min)	43.24±59.24	30.42±37.57	-12.82±51.71	0.71	0.475
Latency to onset (%)	7.62±4.78	8.10±6.76	-0.48±9.31	-0.56	0.575
Latency to REM (%)	164.61±56.94	108.17±55.67	-56.44±44.04	-2.67	0.008
AHI (events/hour)	19.51±34.18	16.76±26.33	-2.75±8.81	-0.87	0.386
RDI (events/hour)	21.36±33.66	18.29±26.03	-3.07±8.70	-0.77	0.441
O2 Saturation (%)	85.05±6.14	84.20±7.39	-0.85±4.84	-0.54	0.593

N1, non REM1; N2, non REM2; N3, non REM2; REM, rapid eye movement

Table 3. Changes of the psychological variables of the participants (n=10)

	Baseline	Intervention	Diff (post-pre)	Z	p
GSAQ	5.30±2.95	4.00±2.91	-1.30±2.50	-1.43	.153
PSQI-K	**5.40±1.17**	**4.10±1.66**	**-1.30±1.16**	**-2.49**	**.013**
ISI	6.40±3.63	5.00±3.09	-1.40±3.59	-1.20	.231
SSS	2.60±1.35	2.30±0.67	-0.40±4.33	-0.45	.655
ESS	6.40±3.13	6.00±4.62	-0.30±1.34	-0.24	.812
Presence of RLS	0.20±0.42	0.20±0.42	0.00	0.000	1.000
HADS	9.50±6.32	7.60±5.40	-1.90±5.22	-1.02	.307
PSS	12.40±7.47	11.80±6.03	-0.60±8.40	-0.10	.919
SF-36	19.50±15.19	20.60±14.25	1.10±10.15	-0.07	.944
Goldberg anxiety	1.70±1.77	1.60±1.65	-0.10±1.91	-0.21	.832
FSS	32.90±9.89	30.50±11.87	-2.40±9.09	-0.77	.444
PHQ-9	3.70±3.20	2.20±1.99	0.53±0.11	-1.61	.107
KSCL95	3.00±3.09	3.10±2.64	0.10±3.00	-0.09	.932
DASS	6.00±6.83	4.40±4.90	-1.60±5.44	-0.72	.473
SF-MPQ-2	9.20±6.48	9.30±8.07	0.25±0.49	-0.42	.673

PSQI, Pittsburgh Sleep Quality Index-Korean; ISI, Insomnia Severity Index; SSS, Stanford Sleepiness Scale; ESS, Epworth Sleepiness Scale; RLS, restless leg syndrome; HADS, Hospital Anxiety and Depression Scale; PSS, Perceived Stress Scale; KSCL95, Korean-Symptom Checklist 95; FSS, Fatigue Severity Scale; SF-MPQ-2, short-form McGill Pain Questionnaire

Stage N1 and N2 were shortened, and Stage N3 was prolonged after the intervention compared to the baseline. Furthermore, the post-intervention other sleep problems scales, such as GSAQ, ISI, HADS, PSS, Goldberg anxiety, FSS, and DASS, were lower than the baseline despite no statistical significance. There was a trend toward an increase in the scale associated with quality of life, SF-36.

DISCUSSION

This study's primary outcome was sleep efficacy, a precise and objective parameter obtained from PSG. Despite no statistical significance, the sleep efficacy increased after sleeping on the FIR-emitting mattress. Meanwhile, the PSQI, with a higher score indicating poorer sleep quality, was only improved by FIR therapy among the secondary outcomes. Like our study, McCall et al.[6] sought to enhance sleep quality with the FIR-emitting mattress and discovered that the therapy lowered ISI scores and reduced nap rates. The study was using actigraphy as a means of evaluating alterations in objective sleep parameters. However, no statistically significant differences were observed. Nonetheless, the research did not employ PSG, a technique that could potentially yield imprecise results when assessing sleep parameters. The measurement of sleep latency was not feasible due to the inadequate accuracy of the recording. In contrast, Kotorii et al.[27] employed PSG to examine the effects of FIR therapy on objective sleep metrics and found no significant changes. A clinical trial with FIR-emitting pajamas

was conducted by Chen et al.,[4] but the results were not statistically significant.

In the exploratory analyses, REM latency significantly decreased after sleeping on the FIR-emitting mattress. Even though the reduced REM latency is linked to various conditions, such as depression and the use of certain medications, we interpreted that the REM latency was normalized after FIR therapy. The proportion of N3 increased after the FIR therapy despite no statistical significance. This finding is consistent with the study of Kotorii et al., in which the FIR therapy for patients with insomnia increases slow wave sleep (SWS), as well as the relief of subjective symptoms.[27] Hence, it is imperative to conduct further research to examine the impact of FIR treatment on the sleep architecture of insomniacs, particularly with regard to SWS.

Kennedy et al. recently confirmed improved sleep quality by NIR light using a cervical NIR emitting collar device.[5] In the study, sleep parameters were measured by actigraphy alone without PSG, like in the previous studies. While the NIR treatment did not affect the sleep parameters, subjective sleep quality variables improved with the NIR therapy. NIR light induces similar biological responses as FIR light.[5,7] However, additional investigation is required to ascertain whether there exist any variations in the therapeutic outcomes of NIR and FIR for sleep. Furthermore, it is required to investigate the impact of various factors such as the method of IR irradiation, the site and extent of IR exposure, and other associated variables on the efficacy of IR therapy.

1. Limitations

There were some limitations of this study. First, the sample size needed to be bigger to draw a conclusion. A future study with a larger sample size is warranted. Second, there was the possibility of the 'first night effect (FNE),' in which sleep architectures of the first PSG night are altered because the patients do not adapt to the PSG and sleep with unusual patterns. Third, the absence of researcher blinding could lead to performance bias throughout the protocol. Lastly, the mean AHI for both the ceraminc and sham mattress met the criteria for moderate sleep apnea even though the patients with sleep apnea were excluded in advance. This could potentially influence the results.

2. Conclusion

The utilization of FIR-emitting mattresses has been observed to enhance the quality of sleep among individuals who self-report experiencing insomnia. Furthermore, our objective was to assess the enhancement in objective sleep parameters through the utilization of PSG. Despite the observed improvement in sleep efficacy, which was the primary outcome, statistical significance was not achieved. However, our findings indicate that the FIR therapy may have an impact on certain indicators, including the normalization of REM latency and an increase in N3 sleep. Anticipated are further investigations that employ suitable objective sleep parameters to evaluate the results of the FIR trial.

Supplementary Materials

The online-only Data Supplement is available with this article at https://doi.org/10.22722/KJPM.2023.31.2.149.

Ethical Publication Statement

We confirm that we have read the journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

Data Availability Statement

Additional data are available from the corresponding author upon reasonable request.

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None

Conflicts of Interest

The authors have no financial conflicts of interest.

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