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ORIGINAL RESEARCH

The Subjective and Objective Improvement of Non-Invasive Treatment of Schumann Resonance in Insomnia—A Randomized and Double-Blinded Study

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Purpose: Accumulated studies revealed that electromagnetic field can affect human brain and sleep, and the extremely low-frequency electromagnetic field, Schumann resonance, may have the potential to reduce insomnia symptoms. The purpose of this study was to investigate the responses of patients with insomnia to a non-invasive treatment, Schumann resonance (SR), and to evaluate its effectiveness by subjective and objective sleep assessments.

Patients and Methods: We adopted a double-blinded and randomized design and 40 participants (70% female; 50.00 ± 13.38 year) with insomnia completed the entire study. These participants were divided into the SR-sleep-device group and the placebo-device group and were followed up for four weeks. The study used polysomnography (PSG) to measure objective sleep and used sleep diaries, Pittsburgh Sleep Quality Inventory (PSQI), Epworth Sleepiness Scale (ESS), and visual analogy of sleep satisfaction to measure subjective sleep. The 36-Item Short-Form Health Survey (SF-36) was used to evaluate quality of life. Chi-square test, Mann–Whitney *U*-test, and Wilcoxon test were used to analyze the data.

Results: About 70% of the subjects were women, with an average age of 50±13.38 years and an average history of insomnia of 9.68±8.86 years. We found that in the SR-sleep-device group, objective sleep measurements (sleep-onset-latency, SOL, and total-sleep-time, TST) and subjective sleep questionnaires (SOL, TST, sleep-efficiency, sleep-quality, daytime-sleepiness, and sleep-satisfaction) were significantly improved after using the SR-sleep-device; in the placebo-device group, only such subjective sleep improvements as PSQI and sleep-satisfaction were observed.

Conclusion: This study demonstrates that the SR-sleep-device can reduce the insomnia symptoms through both objective and subjective tests, with minimal adverse effects. Future studies can explore the possible mechanism of SR and health effects and, with a longer tracking time, verify the effectiveness and side effects.

Keywords: insomnia, Schumann resonance, effectiveness, polysomnography, questionnaire

Introduction

Insomnia is the most common sleep disorder in the world and affects as much as 10% of the general population and approximately 15% of adults.[1] According to the International Classification of Sleep Disorders, third edition (ICSD-3), insomnia is defined as (1) difficulty initiating sleep, maintaining sleep, or waking up earlier than desired; (2) sleep disturbance resulting in marked personal distress or interference with daily living; and (3) sleep disturbances and associated daytime symptoms occurring at least three times per week for at least three months.[2] Insomnia not only includes sleep disturbance at night but also a decline in daytime functions such as fatigue, impairment in attention and

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memory; impaired social, academic, or occupational performance; and mood disturbance.[2] In addition, many studies have shown that people with insomnia have a higher risk of cardiovascular disease,[3] chronic pain,[4] and type II diabetes.[5] Furthermore, the comorbidity rate of insomnia and other mental disorders is as high as 41–53%,[6,7] After cognitive behavioral therapy for insomnia (CBTi), patients with comorbid mental illness not only have improved symptoms of insomnia but have improved symptoms of the comorbidities as well.[8,9]

Although the pathophysiologic features of insomnia remain largely unknown, increasing evidence has shown that insomnia is a persistent condition and a complex disease. One cohort study of 3073 adults followed up annually for 5 years confirmed that 41.6% of the participants had persistent insomnia. This finding suggests that early intervention could prevent the development of insomnia chronicity and reduce its associated morbidity on sedatives and sleeping pills.[10] Previous studies have indicated that up to 13% of US adults have reported benzodiazepine use in the last year.[11] The outpatient use of benzodiazepines has also increased significantly.[12] The long-term use and overdoses of sleeping pills may cause side effects.[13,14] Although the insomnia treatment guidelines provide established clinical practice recommendations for CBTi as a first-line treatment, such treatment has not been popularized in many countries so far. Moreover, the inconvenience of and patient compliance with CBTi are still key issues in the implementation of this treatment. Therefore, exploring the effectiveness of other and more emerging non-pharmaceutical treatments of insomnia is important.[15]

In recent years, research has been done on the developments of various noninvasive treatments for insomnia, including mindfulness therapy,[16,17] acupressure,[18,19] acupuncture therapies,[20,21] cranial electrotherapy stimulation (CES)[22] or repetitive transcranial magnetic stimulation (rTMS),[23] etc. Another special discovery found in past 20 years is that ambient electromagnetic fluctuations, such as geomagnetic activity, may affect our physiology, psychology, and behavior.[24] Previous physics research showed "an electroencephalographic power revealed particular associations with the right parietal lobe for theta activity and the right frontal region for gamma activity," and some studies have shown moderate strength correlations between increases in geomagnetic activity and various behavioral inferences of cerebral activity.[25]

Wang et al (2019) used an electroencephalogram (EEG) study and reported a strong, specific human brain response to ecologically relevant rotations of Earth-strength magnetic fields. Following geomagnetic stimulation, a drop in amplitude of EEG alpha oscillations (8–13 Hz) occurred in a repeatable manner.[26] In 1954, Winfried Otto Schumann reported on the existence of a natural extremely low-frequency field of about 7.83 Hz called the Schumann resonance (SR) frequency in earth's atmosphere that globally propagates electromagnetic field (EMF) waves.[27] Its peak intensity can be detected at ~8 Hz, along with its harmonics with a lower intensity at 14, 20, 26, 33, 39, and 45 Hz due to frequency-related, ionospheric propagation loss.[28] The Schumann resonances found within both global human quantitative electroencephalographic activity and earth-ionosphere activity may suggest a causal relationship.[29] Moreover, Ghione et al found significant positive associations between geomagnetic activity and (daytime and 24-h) systolic and (daytime, nighttime, and 24-h) diastolic blood pressure.[30] Burch et al also found that increasing geomagnetic activity combined with elevated 60 Hz MF is associated with reduced nocturnal excretion of a melatonin metabolite in humans, meaning that EMF will affect human brain and sleep.[31]

With these accumulated evidence, extremely low-frequency EMF-Schumann resonance may improve human sleep. In this study, we use a sleep device with "Schumann resonance" function that outputs the low frequency of "Schumann resonance frequency (7.83 Hz) wave" in an attempt to resonate the user's brain waves to make it easier to fall asleep, reach deep sleep, and maintain sleep. Since the effectiveness and side effects of the "Schumann waves" in treating insomnia are still unclear, this study was aimed to examine the effects of the Schumann resonance on insomnia symptoms through both subjective and objective sleep assessments.

Materials and Methods

Participants

In this study, patients with insomnia were recruited through hospital outpatient clinics, and 46 participants met the inclusion criteria and entered the study after providing their informed consent. Of those, four withdrew as they were unable to attend the follow-up visit time, and two participants experienced headache and dizziness after randomization and stopped from the follow-up visit. A total of 40 participants completed the study. The study was approved by Chang

Gung Hospital IRB: No. 201701063A3 and No. 202101267B0 (clinical trial ID: NCT05053919, study period: 2021/7/27~2022/1/19) and complied with the Declaration of Helsinki.

Inclusion Criteria

The inclusion criteria include (1) participants are between 20 and 70 years old; (2) participants must meet the DSM-5 diagnostic criteria for insomnia and have been diagnosed for more than three months; (3) participants must be willing to sign an informed consent form; and (4) participants who took sleep aiding pills must cooperate not to change any medication and dosage during the study.

Exclusion Criteria

Exclusion criteria include (1) participants using pacemakers or cardiac monitors; (2) participants with severe physical illness or after surgery, such as heart disease, metabolic diseases, or cancer; (3) participants with severe mental disorders, such as schizophrenia, severe major depression, severe anxiety, bipolar disorder, dementia, substance use disorder; or severe neurological diseases such as a seizure, stroke or Parkinson's disease; (4) participants with other serious sleep disorders, such as severe sleep obstructive apnea, severe periodic limb movement syndrome or narcolepsy; (5) participants who are unable to attend regular follow-up evaluations; and (6) participants who are unable to keep good sleep hygiene and cannot stop using electronic products before going to bed.

Experimental Design

Randomization

This study is a randomized double-blinded and case–control study. All participants who met the inclusion criteria were randomly assigned to the "SR-sleep-device group" or "placebo-device group". There were no significant differences between the two groups in terms of background variables such as gender ratio, age, and years of insomnia.

Procedure

All participants were randomly assigned to two groups and used the "sleep device" for 4 weeks.

Outcome Measure

The primary outcome measure is the changes in polysomnography, and the secondary outcome measures are changes in the subjective questionnaires including the Pittsburgh Sleep Quality Inventory (PSQI) and the Epworth Sleepiness Scale (ESS), the sleep diaries, the visual analogy of sleep satisfaction scale and the 36-Item Short-Form Health Survey (SF-36).

Schumann Resonance Sleep Device/Placebo Device

The SR device is designed by Professor Ling-Sheng Zhang from National Cheng Kung University, Taiwan (Figure 1: "Enerkey Kingdom SR Sleep device"). The sleep instrument was capable of generating the "low frequency of the

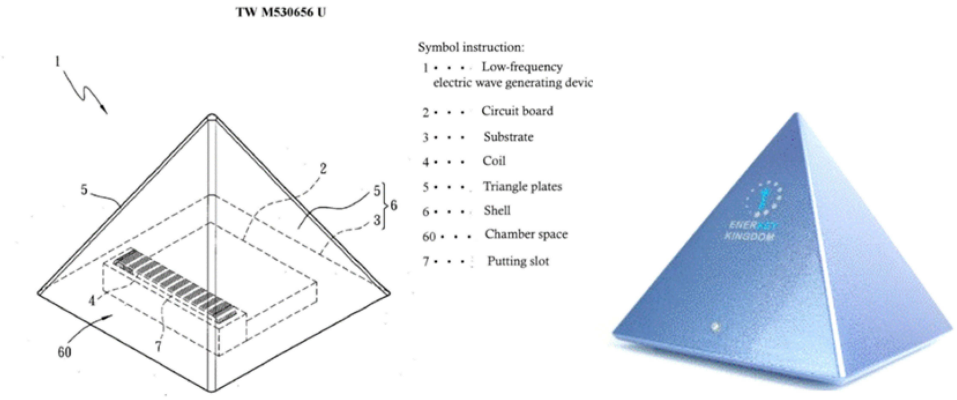

Figure 1 SR sleep device.

Schumann resonance frequency (7.83 Hz) wave" and obtained the Taiwan Patent (No. TW M530656U) on May 4, 2016. After the sleep device is turned on, it stably outputs the composite frequency of "the Schumann resonance frequency (7.83 Hz) wave, theta wave, and delta wave". A placebo-device is an instrument with the same appearance and operation as the SR-sleep-device but does not output any frequency wave. The subjects were asked to use the device (place it next to the bed facing the subject's head, turn it on about one hour before going to bed every night, and turn it off after getting up the next day) every night for four weeks and keep recording sleep by sleep logs.

Objective Sleep Measurements

Polysomnography (PSG)

Standard overnight PSG was performed to document sleep in all participants before the SR-sleep-device/placebo-device was used and for four weeks after use. Participants were asked to attend at 9 pm, guided by a sleep technician to the examination room and wear a sensor device, and lie down on the bed at 10 pm. The examination finished around 6 am the next morning. Standard overnight polysomnographic evaluation involved systematic monitoring of the following variables: 4 EEG leads, 2 electro-oculogram (EOG) leads, chin and leg electromyogram (EMG) leads, and 1 electrocardiogram (ECG) lead; respiration was monitored with a nasal cannula pressure transducer, a mouth thermistor, thoracic and abdominal inductive plethysmography bands, a finger oxygen saturation (MasimoTM) oximeter with derivation of oximetry and finger plethysmography signals, a neck microphone, diaphragmatic-intercostal, abdominal muscle EMGs, and a transcutaneous CO2 electrode; leg EMGs were also monitored. Subjects were continuously video monitored during the recording. Recordings were performed following the recommendation of the American-Academy of Sleep-Medicine-AASM and PSG scoring was also done following AASM recommendations with hypopnea scored for either a 3% oxygen saturation drop or an arousal response.[2,32]

Subjective Sleep Measurements

Sleep Diaries

Participants completed the sleep diaries every day for two weeks before using the SR-sleep-device/placebo-device and for four weeks during use of the device to record their sleep. From the diaries, an estimate was computed for an average of SOL, TST, SE, and WASO.

Pittsburgh Sleep Quality Inventory (PSQI)

The PSQI is a self-rated questionnaire for assessing the subjective sleep quality, which consists of 19 items and can be calculated and combined into 7 clinically derived component score (0–3), with higher scores indicating worse sleep quality.[33,34] Participants completed the PSQI before use, two weeks after use, and four weeks after use, of the SR-sleep-device/placebo-device.

Epworth Sleepiness Scale (ESS)

The ESS consists of 8 items (each scored from 0 to 3) and was used to assess the individual's daytime sleepiness.[35] Participants completed the ESS before use, two weeks after use, and four weeks after use, of the SR-sleep-device/placebo-device.

Visual Analogy of Sleep Satisfaction Scale

Subjects were also asked to use a seven-point scale before use and four weeks after use to evaluate their degree of satisfaction with their sleep in the past week (a higher score represents a higher degree of satisfaction with sleep).

Quality of Life: 36-Item Short-Form Health Survey (SF-36)

SF-36 includes 11 major questions that evaluate eight components. These components include physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional wellbeing, social functioning, pain, and general health. The scale can be used to estimate a patient's general quality of life status. Higher scores mean better physical or mental functions.[36]

Statistical Analysis

We used SPSS 22.0 to analyze our data. Data were presented as number, mean, percentage, and standard deviation. We used chi-square test for group comparisons of percentage and Mann–Whitney *U*-test to analyze the differences in objective and subjective measurements between SR sleep device group and placebo group. We used Wilcoxon test to analyze the differences before and after using the device. A p-value of less than 0.05 was considered significant.

Results

Differences of Background Variables Between Groups

About 70% of the 40 subjects were women, with an average age of 50±13.38 years and an average history of insomnia of 9.68±8.86 years. Table 1 lists the characteristics of participants at baseline. No significant differences were observed in gender, age, years of insomnia history, education status, marital status, socioeconomic status, or comorbidity between the two groups.

Differences of the Objective Sleep Measurements in the SR-Sleep-Device/Placebo-Device Groups

PSG Results

Comparisons of objective sleep measurements between, before, and four weeks after using the SR-sleep-device/placebo-device are presented in Table 2. A significant reduction in SOL (p = 0.012) and a significant increase in TST (p = 0.037) were observed in the SR-sleep-device group. No significant difference was observed in the placebo-device group. Although there was no significant difference between the two groups before and after treatment via Mann–Whitney *U*-test, there was a trend that many parameters of the SR-sleep-device group were improved, especially SOL (p = 0.055).

Table 1 Demographic Data of the SR-Sleep-Device Group and Placebo-Device Group

	SR-Sleep-Device Group (n = 20)	Placebo-Device Group (n = 20)	p value
Gender (male) n (%)	8 (40%)	4 (20%)	0.301
Age (year) M (SD)	50.90 (12.97)	49.10 (14.06)	0.676
Years of insomnia history (year) M (SD)	9.83 (7.18)	9.53 (6.71)	0.892
Education status, n (%)			0.562
Junior high	1 (5%)	3 (15%)	
Senior high	5 (25%)	5 (25%)	
University or above	14 (70%)	12 (60%)	
Marital status, n (%)			0.348
Single	3 (15%)	4 (20%)	
Married	12 (60%)	14 (70%)	
Divorce	3 (15%)	0 (0%)	
Widowed	2 (10%)	2 (10%)	
Socioeconomic status, n (%)			0.749
High	11 (55%)	12 (60%)	
Middle	9 (45%)	8 (40%)	
Low	0 (0%)	0 (0%)	
Comorbidity			
Hypertension, n (%)	1 (5%)	1 (5%)	1.000
Diabetes, n (%)	0 (0%)	0 (0%)	-
Thyroid disorders, n (%)	0 (0%)	0 (0%)	-

Table 2 Differences of the Objective PSG Findings in the SR-Sleep-Device/Placebo-Device Groups

(M ± SD)	SR-Sleep-Device Group (N = 20)			Placebo-Device Group (N = 20)			p2
	Pre	Post	p1	Pre	Post	p1	
BMI	23.91 ± 4.19	24.12 ± 4.23	0.272	21.56 ± 2.79	21.42 ± 2.96	0.248	0.253
SOL	26.37 ± 36.67	17.31 ± 19.27	0.012*	23.61 ± 30.92	24.84 ± 27.89	0.520	0.055
SWS	3.5 ± 5.92	3.66 ± 7.09	0.851	4.61 ± 7.88	6.29 ± 9.7	0.208	0.820
TIB	415.19 ± 27.77	428.26 ± 21.03	0.351	411.49 ± 51.86	423.44 ± 41.50	0.198	0.799
TST	295.59 ± 87.84	322.1 ± 75.31	0.037*	306.53 ± 76.32	307.53 ± 90.64	0.444	0.495
Efficiency	71.06 ± 20.03	75.2 ± 17.08	0.121	74.65 ± 16.3	71.47 ± 20.18	0.687	0.231
WASO	96.87 ± 71.99	90.03 ± 66.33	0.629	81.87 ± 63.68	94.62 ± 73.53	0.546	0.444
Arousal index (events/hr)	22.99 ± 16.47	24.9 ± 18.14	0.247	19.95 ± 11.14	25.55 ± 23.14	0.586	0.989
AHI (events/hr)	16.58 ± 19.97	19.76 ± 23.13	0.108	6.48 ± 9.01	9.97 ± 17.67	0.856	0.327
AI (events/hr)	5.96 ± 10.78	7.6 ± 12.25	0.554	1.12 ± 2.41	0.78 ± 1.46	0.275	0.627
HI (events/hr)	11.16 ± 11.54	12.17 ± 13.55	0.586	5.36 ± 7.39	5.2 ± 5.62	0.698	0.792
DI (events/hr)	13.24 ± 17.14	15.65 ± 19.34	0.108	3.46 ± 3.46	4.2 ± 4.93	0.420	0.314
Awake (%)	27.44 ± 20.9	24.79 ± 17	0.370	23.94 ± 16.73	27.2 ± 19.66	0.421	0.341
Stage N1 (%)	22.33 ± 17.76	21.83 ± 18.1	0.970	21.71 ± 14.88	21.58 ± 14.14	0.872	0.565
Stage N2 (%)	52.71 ± 18.79	58.73 ± 18.34	0.086	57.76 ± 13.75	55.36 ± 12.2	0.409	0.086
REM sleep (%)	17.83 ± 7.2	15.77 ± 7.6	0.191	15.93 ± 8.14	16.78 ± 7.21	0.215	0.053
PLMI	1.93 ± 2.97	0.71 ± 2.12	0.173	3.63 ± 7.32	3.48 ± 6.39	0.807	0.496
Snore index (events/hr)	188.24 ± 301.89	206.54 ± 292.6	0.826	115.15 ± 153.52	193.46 ± 308.9	0.469	0.968
Mean O_2 (%)	95.45 ± 1.08	95.5 ± 1.5	0.831	96.45 ± 1.15	96.35 ± 0.99	0.617	0.698

Note: *p < 0.05.

Abbreviations: p1, Wilcoxon test; p2, Mann–Whitney *U*-test (comparison of the difference between the two groups before and after); SOL, sleep onset latency; SWS, slow wave sleep; TIB, time in bed; TST, total sleep time; WASO, wake after sleep onset; BMI, body mass index; AHI, apnea-hypopnea index; AI, apnea index; REM, rapid eye movement; HI, hypopnea index; DI, O_2 desaturation index; PLMI, Periodic Limb Movement Index; Mean SaO_2, mean oxygen saturation; hr, hour.

Differences of the Subjective Sleep Measurements in the SR-Sleep-Device/Placebo-Device Groups

Comparisons of subjective sleep measurements between before, 2 weeks after, and 4 weeks after using the SR-sleep-device/placebo-device are presented in Table 3.

Sleep Diaries

A significant reduction in SOL (p = 0.004) and a significant increase in TST (p = 0.047) and SE (p = 0.017) were observed in the SR-sleep-device group (all the differences were between pre and week 4). No significant difference was observed in the placebo-device group.

PSQI and ESS

A significant reduction in sleep latency index (p = 0.003, the significance was between "pre, week 2" and "week 4") was observed in the SR-sleep-device group but not in the placebo-device group. Significant improvements in subjective sleep quality index (p_{SR} = 0.001 (pre > week 2, week 4); $p_{placebo}$ = 0.042 (pre > week 2)), sleep duration index (p_{SR} = 0.021 (pre > week 2); $p_{placebo}$ = 0.009 (pre > week 2, week 4)), global score index (p_{SR} = 0.034 (pre > week 2, week 4); $p_{placebo}$ = 0.044 (pre > week 2, week 4)), and ESS (p_{SR} = 0.019 (pre > week 4, p = 0.055)) were observed in both groups. Furthermore, the "Sleep Quality" parameter of the SR-sleep-device group improved significantly (p = 0.046).

Differences of Quality of Life (SF-36) and Visual Analogy of Sleep Satisfaction in the SR-Sleep-Device/Placebo-Device Groups

Comparisons of subjective quality of life (SF-36) between before, 2 weeks after, and 4 weeks after using the SR-sleep-device/placebo-device are presented in Table 4. Significant improvements in energy/fatigue (p = 0.008) and bodily pain

Table 3 Differences of the Subjective Sleep Measurements in the SR-Sleep-Device/Placebo-Device Groups

(M ± SD)	SR-Sleep-Device Group (N = 20)				Placebo-Device Group (N=20)				p2
	Pre (1)	After 2 Weeks (2)	After 4 Weeks (3)	p1	Pre (1)	After 2 Weeks (2)	After 4 Weeks (3)	p1	
Sleep diary									
SOL	50.74 ± 22.48	41.41 ± 17.79	36.06 ± 15.48	0.004** (1 > 3)	52.12 ± 43.52	38.16 ± 30.02	40.15 ± 39.02	0.638	0.175
TIB	511.77 ± 84.44	503.38 ± 103.51	503.04 ± 50.51	0.756	494.03 ± 66.08	515.91 ± 70.94	505.50 ± 82.46	0.064	0.204
TST	380.79 ± 84.92	389.42 ± 113.39	402.44 ± 67.99	0.047* (3 > 1)	368.49 ± 86.95	410.53 ± 51.49	396.07 ± 68.84	0.074	0.923
SE	0.74 ± 0.11	0.77 ± 0.12	0.8 ± 0.1	0.017* (3 > 1)	0.74 ± 0.14	0.8 ± 0.1	0.79 ± 0.11	0.259	0.184
WASO	29.42 ± 36.73	24.38 ± 38.26	28.48 ± 39.52	0.646	18.97 ± 21.17	23.4 ± 21.63	19.46 ± 24.34	0.471	0.945
PSQI									
Subjective sleep quality	1.95 ± 0.51	1.5 ± 0.51	1.3 ± 0.57	0.001** (1 > 2, 3)	2.1 ± 0.64	1.75 ± 0.64	1.85 ± 0.67	0.042* (1 > 2)	0.046*
Sleep latency	2.1 ± 0.79	1.9 ± 0.72	1.6 ± 0.75	0.003** (1, 2 > 3)	2.2 ± 0.95	2 ± 0.86	2.05 ± 0.83	0.485	0.142
Sleep duration	1.7 ± 0.73	1.4 ± 0.88	1.45 ± 0.89	0.021* (1 > 2)	2.05 ± 0.89	1.7 ± 0.86	1.55 ± 1.00	0.009** (1 > 2, 3)	0.398
Habitual sleep efficiency	1.65 ± 0.88	1.75 ± 0.79	1.55 ± 0.76	0.646	2.45 ± 0.89	1.9 ± 0.97	1.95 ± 1.1	0.070	0.301
Sleep disturbance	1.6 ± 0.68	1.4 ± 0.6	1.5 ± 0.69	0.336	1.8 ± 0.52	1.7 ± 0.47	1.55 ± 0.51	0.093	0.583
Use of sleep medicine	1.7 ± 1.45	1.6 ± 1.5	1.4 ± 1.57	0.223	2.1 ± 1.41	2.1 ± 1.41	2.15 ± 1.35	0.368	0.445
Daytime dysfunction	1.3 ± 0.86	1.05 ± 0.6	1.15 ± 0.67	0.301	1.3 ± 0.86	0.95 ± 0.76	1.05 ± 0.76	0.186	0.547
Global score	12 ± 2.43	10.6 ± 2.23	9.95 ± 2.06	0.034* (1 >2, 3)	14 ± 3.03	12.1 ± 3.84	12.15 ± 4.06	0.044* (1 > 2, 3)	0.445
ESS	8.6 ± 4.26	7.55 ± 3.89	7.15 ± 3.59	0.019* (1 > 3; p = 0.055)	6.55 ± 5.09	6.4 ± 5.12	6.2 ± 4.84	0.430	0.289

Notes: *p < 0.05, **p < 0.01. (**1**): pre, (**2**): after 2 weeks, (**3**): after 4 weeks.

Abbreviations: p1, Friedman test; post hoc, Wilcoxon test; p2, Mann–Whitney *U*-test (comparison of the difference between the two groups before and after 4 weeks); SOL, sleep onset latency; TIB, time in bed; TST, total sleep time; SE, sleep efficiency; WASO, wake after sleep onset; PSQI, Pittsburgh Sleep Quality Inventory; ESS, Epworth Sleepiness Scale.

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Table 4 Differences of the Health Survey (SF-36) and Sleep-Satisfaction in the SR-Sleep-Device/Placebo-Device Groups

(M ± SD)	SR-Sleep-Device Group (N = 20)				Placebo-Device Group (N=20)				p2
	Pre (1)	After 2 Weeks (2)	After 4 Weeks (3)	p1	Pre (1)	After 2 Weeks (2)	After 4 Weeks (3)	p1	
The 36-Item Short-Form Health Survey (SF-36)									
Physical function	87.00 ± 12.81	82.25 ± 14.00	85.00 ± 14.96	0.156	81.50 ± 17.18	80.50 ± 21.02	81.00 ± 20.94	0.982	0.398
Role limitations due to physical health	70.00 ± 40.23	65.00 ± 40.88	65.00 ± 41.68	0.773	56.25 ± 45.07	71.25 ± 43.89	76.25 ± 36.70	0.358	0.192
Role limitations due to emotional problems	45.00 ± 47.48	56.67 ± 49.68	61.67 ± 42.27	0.301	61.67 ± 39.40	71.67 ± 39.40	65.00 ± 41.15	0.598	0.314
Energy/fatigue	46.50 ± 22.07	55.00 ± 21.52	53.00 ± 23.25	0.008* (2, 3 > 1)	46.00 ± 16.59	51.00 ± 19.84	51.50 ± 21.40	0.054	0.738
Mental health	56.60 ± 18.27	61.20 ± 18.59	63.60 ± 18.67	0.005** (2, 3 > 1)	48.80 ± 17.63	55.40 ± 19.13	58.40 ± 19.18	0.023* (2, 3 > 1)	0.640
Social functioning	71.88 ± 17.62	73.75 ± 19.83	73.13 ± 19.57	0.442	71.88 ± 21.41	75.00 ± 24.33	76.25 ± 23.61	0.487	0.779
Bodily pain	77.13 ± 15.52	82.25 ± 15.75	84.38 ± 13.03	0.031* (3 > 1)	74.38 ± 16.16	80.00 ± 15.35	81.13 ± 13.94	0.098	0.968
General health	60.00 ± 22.77	61.50 ± 22.66	60.75 ± 22.84	0.867	50.25 ± 23.14	58.25 ± 20.28	59.75 ± 25.31	0.072	0.174
Sleep satisfaction	2.95 ± 1.21	-	4.75 ± 1.20	0.000***	2.20 ± 1.24	-	3.18 ± 1.85	0.004**	0.046*

Notes: *p < 0.05, **p < 0.01, ***p < 0.001. (**1**): pre, (**2**): after 2 weeks, (**3**): after 4 weeks.
Abbreviations: p1, Friedman test; p2, Mann–Whitney *U*-test (comparison of the difference between the two groups before and after).

($p = 0.031$) were observed in the SR-sleep-device group but not in the placebo-device group. We observed significant improvements in mental health ($p_{SR} = 0.005$; $p_{placebo} = 0.023$) in the two groups. Sleep satisfaction in both groups was significantly improved ($p_{SR} < 0.001$; $p_{placebo} = 0.004$). In addition, the change from baseline in sleep satisfaction score ($p = 0.046$) was greater in the SR-sleep-device group than in the placebo-device group.

Adverse Events

Among the 46 participants, two participants experienced headache and dizziness when using the device (1 was in SR-sleep-device group and 1 was in placebo-device group) and stopped following. There is no other adverse event.

Discussion

This study examines whether 40 participants with insomnia can experience improvements in subjective and objective sleep measurements after using an SR-sleep-device/placebo-device for four weeks. Only two participants experienced side effects of headache and dizziness (study group n = 1; placebo group n = 1) and left the study. This study is the first to investigate whether SR affects sleep and insomnia.

In the SR-sleep-device group, objective PSG measurements (SOL and TST but not SWS) and subjective sleep measurements (SOL, TST, SE, sleep quality, daytime sleepiness, sleep satisfaction) were both significantly improved after using the SR-sleep-device. However, in the placebo-device group, objective sleep measurements were not showed any differences after using the device, and there was only subjective sleep improvement in sleep satisfaction and some components of PSQI. This finding indicates that the SR can reduce the symptoms of insomnia symptoms, especially in the "sleep onset" and "total sleep time." Another important finding is that fifty-five percent of the placebo group had improvement shown by PSQI and Sleep satisfaction scale, and it may be explained by the common placebo effect in treating insomnia.[37]

Currently, we do not fully understand the mechanism of the SR in improving insomnia and sleep. Previous studies have shown that changes in geomagnetic activity have been linked to epileptic seizures,[38] myocardial infarction,[39] stroke,[40] and depression.[41] Biogenic magnetite provides a molecular mechanism for geomagnetic sensing,[42] which has been found in the human brain.[43] Cherry (2002) suspected SR, which globally propagates extremely low frequency (ELF) waves, to be "the possible biological mechanism" that explains biological and human health effects of geomagnetic activity. The peak SR frequencies undergo a moderate diurnal variation of approximately ± 0.5 Hz. Interestingly, the first four SR modes happen to be within the frequency range of the first four EEG bands (ie, delta 0.5–3.5 Hz, theta 4–7 Hz, alpha 8–13 Hz, and beta 14 to 30 Hz).[28] Some studies have also found that human brain waves and SR share the same frequency range. The human body detects, absorbs, and responds to natural EMF by the process of resonance matching of frequency. With this matching, natural EMF can influence biological communication phenomena in cell-to-cell communication in the human body.[44] Pall (2013) also reported that exposure to EMF would promote Ca2+ influx via the voltage-gate Ca2+ channel, which can increase Ca2+ concentration in the cytosol and then cause biological effects.[45] Wang (2019) also indicated that extremely low-frequency magnetic stimulation can induce low-frequency activities and lead to resonance effects in the human brain.[26] The "biophysical mechanism" for the human health effect mechanism may explain biological and human health effects of geomagnetic activity.[28] An increasing number of psychiatrists have been integrating electrophysiotherapy treatments into their clinical practice because they are noninvasive, have few side effects, and can treat anxiety, depression, and insomnia simultaneously.

From our results of improving SOL, it can be inferred that SR can make participants' brain waves resonate to 7.83 Hz waves and relax their body so that people can fall asleep easily and increase total sleep time. Another hypothesis is that EMF is related to human melatonin metabolites,[30] which could also explain the improvement of participants' total sleep time and sleep quality after 4 weeks of treatment. However, this study did not show a significant increase in the deep sleep ratio (SWS %). It may relate to the small sample size or the first night effect of PSG. The 4-week treatment period may be too short or does not affect melatonin yet. Therefore, these findings and hypotheses require more rigorous and long-term research.

A recent systematic review and meta-analysis of CBTi showed significant effects on daytime symptoms including daytime sleepiness, although the effect size is only small to moderate. By improving nighttime symptoms, CBTi can

have a positive effect on daytime symptoms indirectly.[46] Similarly, the SR-sleep-device group in this study has a significant effect on the level of daytime sleepiness, which means that the SR may improve insomnia patients' daytime quality of life (such as energy/fatigue, bodily pain, and mental health). Furthermore, Kay reported that SR improves depression.[41] Besides the possible benefits of sleep shown by this study, other therapeutic effects of SR such as improved daytime sleepiness and depression and the role of SR in these correlated conditions require further investigation.

Though with a randomized, double-blinded design, it still has limitations. First, the sample size was very small (N = 40) although we did reach the estimated sample size (N = 38). Second, several patients had received hypnotics and could not stop hypnotics, but they kept the same drugs and same dose during the study. There can be sampling errors if we only included drug naive participants. Third, the "first night effect" should be considered when performing PSG and can possibly explain the improvement in PSG. However, only the SR-sleep-device group had significant improvement in PSG, and the finding supported the effects of SR on sleep. Furthermore, we cannot truly verify compliance, but we supervised our participants to turn on the machine every night during the study period.

Conclusion

This study shows that the SR can reduce the insomnia symptoms, supported by both objective and subjective measurements, although the sample size is small. Future studies should explore the possible mental and physical effects of Schumann resonance with larger sample sizes, as well as use a longer tracking time to verify the effectiveness and side effects, and explore possible mechanism.

Data Sharing Statement

The data that support the findings of this study are available from the first author or corresponding author upon reasonable request after getting the permission of Chang Gung Hospital IRB. Additionally, the individual deidentified participant data are available after contacting the first author or corresponding author via email. The data will be available immediately following publication without an end date.

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Disclosure

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