Investigating the Efficacy of SleepGift Blanket on Sleep Quality and Heart Health

by

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List of Abbreviations

WHO – World Health Organization

RF – Radio Frequency

ORP – Odds Ratio Product

EEG – Electro encephalography

ECG – Electro Cardiography

PSG – Polysomnography

EMF / EMFs – Electromagnetic Field/s

ELF – Extremely Low Frequency

SAR – Specific Absorption Rate

REM – Rapid Eye Movement

TRT – Total Recording Time

HRV – Heart Rate Variability

HR – Heart Rate

nm – Nanometer

Hz – Hertz

kHz – Kilohertz

GHz – Gigahertz

ELF – Extremely Low Frequency

ICNIRP – Internation Commission on Non-ionizing Radiation Protection

NREM – Non-Rapid Eye Movement

PNS – Parasympathetic Nervous system

FDA – Food and Drug Administration

EOG – Electrooculography

WASO – Wake After Sleep Onset

AHI – Apnea Hypopnea Index

SL – Sleep Latency

TST – Total Sleep Time

FD – Fractal Dimension

ULF – Ultra Low Frequency

VLF – Very Low Frequency

SE – Standard Error

FIR – Far Infrared Radiation

Dedication:

To my grandma Harjinder Kaur, the one who looked at me with belief even when I couldn’t.

To my parents, who gave me every opportunity possible to succeed in life.

To my best friends, who are always there to hear me out even when I am talking senseless.

And

To all the women, who became inspiration for a small-town girl like me.

Abstract

Sleep quality and heart health may be affected negatively by electromagnetic fields (EMF) emitted by telecommunication devices, and a decline in sleep quality may lead to neurological disorders such as anxiety and depression. There are multiple products that claim to improve sleep quality by blocking exposure to EMF. This study aims to investigate the efficacy of one such product called “SleepGift” blanket on sleep quality and heart health. This single-blind cross-over study analyzes the sleep study data collected from healthy participants (13 to date). Participants were provided with real and sham SleepGift blankets during two blocks of the study, and their sleep quality data were recorded. Participants slept at the Sleep Research Lab using the assigned (real/sham) blanket for block 1 pre-intervention. They committed to using the blanket at home for the next 10 consecutive nights’ then, using the same blanket, slept at the lab for post-intervention recording. The same procedure was repeated for block 2 after the washout period with the other reversed (sham/real) blanket. The collected data were analyzed. The changes observed from the Wilcoxon-rank sum test in sleep quality, heart rate variability, and Katz fractal dimension of the EEG data over night have shown to be insignificant so far. The inconclusive results of the data could be due to small sample size of the study; however, one participant showed improvement and claimed to be EMF sensitive. Ideally, recruiting such participants could be extremely challenging. A larger data set is recommended to achieve robust conclusion about the efficacy of SleepGift blanket.

Chapter 1: Introduction

Electromagnetic fields (EMF) are ubiquitous in the current society with exponential growth of human exposure due to advancement in technology and rise in wireless communication. The effects of EMFs on human health have gained extensive attention over the recent decades [1]. Based on World Health Organisation (WHO) the intensity of spatial EMF has been expanded enormously due to increase of wireless communication and technologies; therefore, even a minor health consequence may lead to a major public health impact [2].

Radio frequency (RF) waves are emitted from various devices used in telecommunications, industry, medicines, and military, such as wireless broadcast devices (e.g., radios, cell phones, television etc.) and many other devices used in daily life such as remote controls, door openers, surveillance devices, microwave ovens, monitors, computers etc. A detailed list can be found in the report issued by WHO [2][3]. Exposure to EMFs related to wireless communication devices is widespread with number of mobile phone subscriptions currently estimated at 3.9 billion globally [4]. The increase in residential and industrial generation, transmission, and use of electricity for power, heating, and lighting over the past 130 years has inadvertently led to associated increase in human exposure to extremely low frequency EMFs [4].

Increase in exposure to EMFs have made scientists and people question the health consequences of the waves in society. Generally, it was thought that the exposure levels were lower than the level causing any health concern for individuals as concluded in 2007 report of WHO[2]. However, the increase in exposure to EMF has led to numerous studies investigating the effect of EMF on human health [5-15]. Also, EMFs used by wireless communication have the pulsed character and may pose an additional risk even if the EMF exposure occurring is below the limits set by International Commission on Non-Ionizing Radiation Protection ICNIRP[4][16][17].

The most recent guidelines issued by ICNIRP in 2020 are based on their older evaluations with no new or further evaluation by ICNIRP [18][19]. The WHO project is also in principle synonym with ICNIRP as the personnel acting as experts for the both the organisations are the same. In March 2017, WHO stated that ICNIRP is a non-government organization with an official relationship with WHO and helps WHO with their analyses as well as ICNIRP members' work as WHO experts [18].

By January 2021, 255 scientists from 44 nations and 15 supporting scientists from 11 nations concluded that the effects of EMF exposure occur below most of the national and international guidelines recommended by ICNIRP [18][19]. On the other hand, studies have shown direct or indirect effects of EMF exposure such as poor sleep quality, increased heart rate variability, electromagnetic hypersensitivity, decline in cognitive functioning, neuropsychiatric disorders, and disruption of circadian rhythm. Various studies have concluded that EMF exposure may cause subjective symptoms of headache, lack of concentration, excessive irritability, forgetfulness, slowing of reflexes, inflammation of the eyes, tearing, whistling in the ears etcetera[20].

According to centres for Disease Control and Prevention, about 50 to 70 million people in United States have chronic or ongoing sleeping disorders [21]. According to a poll conducted in 2020, about 35 percent Canadians suffer from sleep disorders such as staying awake or falling asleep [22]. Negative effects of poor sleep produce ripple effects spreading to a wide range of health issues such as heart problems resulting in an overall reduced quality of life and increased mortality rate [23]. Due to rapid development of new technical advancements and installations, even a small risk or consequence may cause epidemic public health consequences [4]. Therefore, in this thesis manuscript, the efficacy of a new technology, called “SleepGift blanket”, is investigated on sleep quality and heart health.

1.1: Objective

As sleep deprivation has become epidemic public health problem for modern society due to constantly increasing EMF exposure, it was the objective of this thesis to investigate the efficacy of SleepGift blanket on sleep quality and heart health by pursuing a placebo-controlled single-blind crossover study. Two main objectives of this study were as follows:

1. The general objective was to have an unbiased quantitative investigation on the efficacy of SleepGift blanket on improving the sleep quality measured by Prodigy device and it’s sleep quality algorithm known as Odds Ratio Product (ORP) of sleep EEG.
2. The secondary objective was to investigate the efficacy of SleepGift blanket on heart health by calculating heart rate variability using the ECG measured by CleveMed PSG device.

1.2: Thesis Organization

This thesis consists of 5 chapters. Chapter 1 provides the brief about EMF and its’ exposure as well as the objectives of this research study. Chapter 2 describes the background of EMF exposure effects on human health mainly focussing on sleep quality and cardiac health. It also provides information about existing EMF blocking technologies and SleepGift blanket used for this research study. Furthermore, the elaboration of sleep deprivation, sleep quality architecture, and HRV is provided. Chapter 3 enlightens the methodology of the study including design, participant recruitment and analysis of the data. Chapter 4 discusses the results of the research study. Chapter 5 completes this thesis with limitations, conclusion and future recommendations.

Chapter 2: Background

Electromagnetic fields (EMFs) are consisting of two components - the electric field and the magnetic field, which vary in time and propagate together in space [12][24]. Static electric fields are generated by still electric charges and static magnetic fields are generated by direct and constant electric currents. The frequency of emitted EMF is same as the frequency of its oscillating fields and oscillating charges which generate them. Oscillating electric and magnetic fields could create each other to coexist and reproduce as well as propagate themselves in the surrounding space even during the absence of material medium [12]. These quantities are vectors having both magnitude and direction. EMFs are classified based on their wavelength and frequency [24].

In nature, all the electric charges oscillate in all possible directions generating randomly polarized EMFs; however, these fields are not polarized apart from specific instances when these are locally or partially polarized. Also, these fields do not oscillate with a unique frequency and phase [12]. On the other hand, man-made EMFs are completely polarized and coherent as they oscillate in unique directions determined by the geometry of metallic conductors and coordinated by the phase and frequency [25]. All anthropogenic EMFs differ significantly from the natural EMFs as they are polarized and coherent [12]. Man made radiation used in modern telecommunication may not cause significant temperature rise in biological tissues; therefore, Specific Absorption Rate (SAR) may not be the best metric for bioactivity as per suggested by health agencies because it only accounts for thermal effects and the only reliable way to estimate SAR is by measuring temperature change [26].

High voltage power transmission and transformers operating at ELF, radars and various analog transmitters working at RF or MW were the most powerful man-made EMF sources, which first raised concerns of physicians and scientists for potential biological and health effects [12].

EMFs are classified into ionizing and non-ionizing radiations with further classification into ultra-low frequency, extremely low frequency, very low frequency, low frequency, and high frequency such as radio frequency waves, millimeter waves, infrared, x-rays, and gamma rays [27]. The significant differences of unpredictable oscillations and variations between man-made and natural EMFs explain their corresponding differences in the induced biological or health effects. Therefore, living organisms are not expected to have natural defenses against anthropogenic EMFs [12].

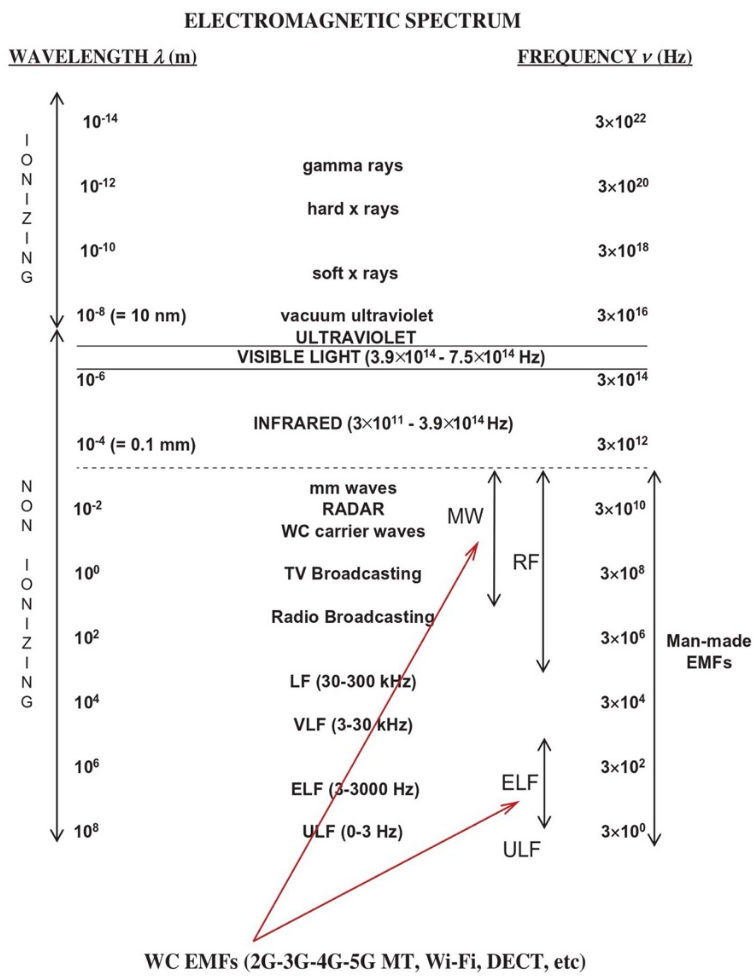

Figure 1: Electromagnetic Spectrum with ionizing, visible, infrared, and sub-infrared parts

2.1: EMF effects on health

The discussion about possible health effects of EMF exposure started in 1960s. The electromagnetic fields emitted by the technologies may affect the homeostatic systems that is nervous, endocrine, and immune system [12][14]. The consequences of EMF exposure can be divided into two distinct categories based on the frequency ranges and corresponding wavelength. The first category produces ionizing radiation with a wavelength range of 10 to 10^{-4} nm and frequency range of 10^{16} to 10^{24} Hz. This radiation is strong enough to release electrons, expelling them from the atoms and resulting in ionization. This may result in adverse health effects by causing molecular disturbances leading to tissue damage [14][27].

Second category, split into radio waves, microwaves and infra-red waves, produces non-ionizing radiations which have wavelength between 1 mm and 100 km and a frequency range from 3kHz to 300 GHz, where radiated energy is too weak to cause electron release from their orbits. Energy state of electrons is changed in non-ionizing case as well, but they remain in their atoms and avoid ion formation [27]. Non-ionizing radiation are further divided into four main categories based on the frequency range: static fields (0 Hz), extremely low frequency EMFs (0 to ~300 Hz), intermediate frequency EMFs (300 Hz to ~100 kHz), and radio frequency EMFs or microwaves (up to 300 GHz) [4].

Non-ionizing EMF exposure effects may include increased cancer risk, cellular stress, increase in harmful free radicals, genetic damages, structural and functional changes of reproductive system, learning and memory deficits, neurological disorders, and negative impacts on general well-being of humankind [5][24].

Sleep quality could be affected by EMFs emitted from human modern technologies as EMF exposure at night has been speculated to have more severe impact on overall health as compared to EMF radiation exposure during daytime. Also, nocturnal sleep has homeostatic role of being necessary for efficient functioning of cognitive, metabolic, and immune systems [14][28]. Cross sectional study including 854 participants have concluded that poor sleep quality may have been positively associated with daily occupational EMF exposure [29]. According to the study conducted in Amsterdam including 2361 children, long term regular mobile phone usage may cause less favorable sleep duration and night wakening in children as young as 7-year-old based on data provided by parents and EMF measured in school over the period of 2 years [30].

Several reports indicated that continued exposure to EMFs may affect the free radical metabolism in various tissues such as heart, kidney and brain, increasing production of reactive oxygen species and causing cell degeneration [10][31][32]. During conditions of oxidative stress, the brain may end up producing excessive Nitric Oxide causing changes in hypothalamic-pituitary-adrenal axis causing depression and anxiety [9]. A review was conducted in 2016 of papers published in between 2000 and 2015 on studying the effect of EMF exposure on sleep, circadian rhythm, and cognition in humans and result was found to be equivocal [15]. Some studies have shown that the exposure of EMF may lead to increase the EEG power in spindle frequency ranges and affects both delta, theta, alpha, beta activities [33-38]. A report resulting from three double blind studies including 77 participants concluded that exposure to magnetic field indicated intermittent decrease in HRV in spectral band associated with temperature and blood pressure control mechanisms [28]. Furthermore, study conducted in 2022 on 30 healthy participants has speculated that EMF exposure may cause a shift in cardiac autonomic regulation which may lead to higher risk of cardiovascular complications as well as could be risk factor for cardiac arrhythmia and myocardial infraction; however, the changes remain insignificant [39].

2.1.1: EMF blocking devices

There are various products available to prevent or completely block the EMF exposure of human body. One of these products is HOGO system beds from Spain with an insulating system for EMFs which has been shown improvement in sleep quality and immune system in research studies [40]. Two Research studies conducted using HOGO system in 2020 and 2022 involving 25 and 18 participants respectively have shown improvement to stress response, improvement in sleep quality and reduction in biological age for the participants using real HOGO systems and no change was observed for participants using the sham HOGO system [41][42].

HOGO system beds consist of customized bed frame, mattress and blanket. The bed frame is made of laminated and vaporized beech wood. The matter is composed of natural rubbers, coconut fiber, marina wool, cashmere, bamboo, silver, graphite and organic cotton. Silver and graphite mesh is used in mattress and patented by HOGO company for removal of EMFs. Blanket is made of Merina wool claimed to improve perspiration and oxygenation. The HOGO systems connect to building grounding system for removal of EMFs [40].

Another product is EMF Bed canopy by Conscious Spaces; however, there has been no published study using this technology. This technology uses a canopy bed made from EMF blocking fabric from YShield and Swiss Shield Companies [43]. Conscious Spaces also produces EMF blocking curtains, sheets and fabrics.

This research study has investigated the efficacy of one such product called SleepGift blanket. The SleepGift blanket is manufactured by BB Holistics group based in Vancouver, Canada and the manufacturer claims on the company website that ‘SleepGift’ blanket is capable of blocking 99% EMF passing through it [44]. This blanket is 80 inch in length and 56 inch in width weighing 13.65 lbs. The SleepGift blanket is layered with EMF shielding fabric which has nano sized (averaged 0.1 microns thickness) silver participles infused in cotton fiber, cotton layer for air circulation, layer of bio ceramic beads with FIR energy [45]. Figure 2 shows the layers of blanket used in this research study.

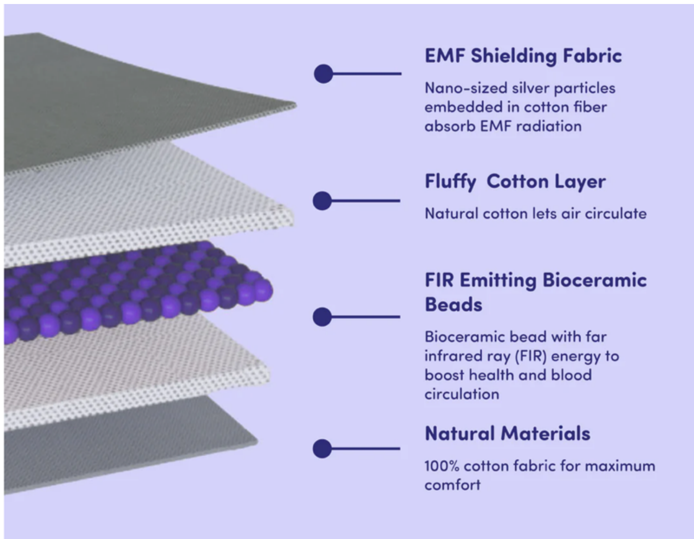

Figure 2: Layers of SleepGift blanket used in study [45]

2.2: Sleep Architecture and Sleep Quality

The term electroencephalogram (EEG) was introduced in 1924 by a German psychiatrist named Hans Berger denoting to recording of brain waves. Brain waves are signals produced by measuring the voltage differences across two points of the scalp [46]. Sleep quality is measured using EEG waves consisting of Beta, Alpha, Theta, Delta, and Gamma. Gamma waves cover frequency range from 30-60 Hz and occur when participant is conscious and focussing on problem solving or other mental processing task. Beta waves range from 13-15 Hz to 30 Hz with amplitude of approximately 30 mV and occur when participant is awake or alert and is actively processing information. Alpha waves range from 8 -13 Hz with an amplitude ranging within 30 to 50 mV. Alpha waves occur when participant is awake, but they have their eyes closed and are in relaxed stage. Theta waves range from 3-4 to 7-8 Hz with amplitude range from 50 to 100 mV. Theta associates with memory, emotions, and activity in limbic system. Delta waves range from 0.5 to 3 or 4 Hz with amplitude of 100 to 200 mV. Delta waves are observed when participant is in deep sleep or in coma [47].

There are two types of sleep, NREM (non-rapid eye movement) and REM (rapid eye movement. NREM sleep is divided into four discrete stages: N1, N2, N3 and N4. N3 and N4 are combined called slow wave sleep and have been merged as N3 stage. Each sleep stage has unique characteristics including variations in brain wave patterns, eye movements and muscle tone. A sleep episode begins with a short period of NREM to stage 1 progressing through stage 2 followed by stage 3 and finally to REM [48][49]. In terms of brain activity, sleep stage N1 is consist of both alpha and theta waves, low frequency (8-15 Hz) and high amplitude patterns of electrical activity. There is an increase in theta wave activity as sleep stage progresses from N1 to N2. Body goes into a state of deep relaxation in sleep stage N2 and theta waves dominate the activity of brain with interruption due to brief bursts of activity known as sleep spindles. Sleep spindles and K-complexes are associated with sleep stage N2. Sleep stage N3 is also referred to as deep sleep or slow wave sleep or delta wave sleep because these stages are characterized by low frequency (less than 3Hz) and high amplitude delta waves. Heart rate and respiration rate slows down dramatically during sleep stage N3. Stage N3 is followed by REM sleep which is often referred to as paradoxical sleep because of high brain activity and lack of muscle tone. REM sleep has same brain waves as wakefulness, and it is differentiated from wakefulness by eye movement recorded from EOG [47] [49].

In this research study, sleep quality is measured using Odds Ratio Product (ORP) [50]. ORP is obtained from reports generated by Cerebra software from EEG recorded using Prodigy head unit. Prodigy head unit was placed on participant's forehead and used two frontal electrodes to record EEG and two electrodes for EOG with mastoid and/or chin electrodes as reference as well as a tablet unit was kept within 5 feet of participant to record snore sounds. Figure 3 shows the connections of Prodigy head unit.

Figure 3: Prodigy Head unit connected to a participant

ORP is a continuous index for evaluating sleep depth ranging from 0 (very deep sleep) to 2.5 (full wakefulness) and value of ORP decreases as sleep stage process from wakefulness to deep sleep [50]. The ORP scale accurately predicts the awake, asleep or an ambiguous state and average ORP decreases as NREM (non-rapid eye movement) sleep progresses from N1 to N3 [50].

In ORP sleep quality algorithm, the recorded EEG is divided in 3-second epochs to calculate power spectrum density with zero overlap in between the segments. Total sum of power in each frequency range of delta band (0.33-2.33 Hz), theta band (2.67-6.33 Hz), alpha-sigma (7.0-14.0Hz) and beta (14.3-35.0 Hz) at sampling rate of 120 Hz in all 3-second epochs is sorted and divided into 10 ranks for values in each frequency range. Each epoch is assigned a 4-digit bin number representing the ranks of delta, theta, alpha-sigma and beta frequency band powers. Each 3-second epoch is then assigned the sleep stage awake or asleep from manual 30 second epoch scoring. Continuous probability range for each 4 digit bin number assigned earlier is calculated from 0 (never observed in awake epochs or during arousals) to 100 (never occurs during sleep).

Continuous probability range is the probability of being awake from total number of designated awake divided by total number of epochs with same bin number multiplied by 100. A look up table was constructed listing probability of being awake for 10,000 bin numbers. Probability is divided by 40 to calculate ORP ranging from 0 to 2.5 [50]. An example of ORP-based sleep architecture is showed in Fig 4.

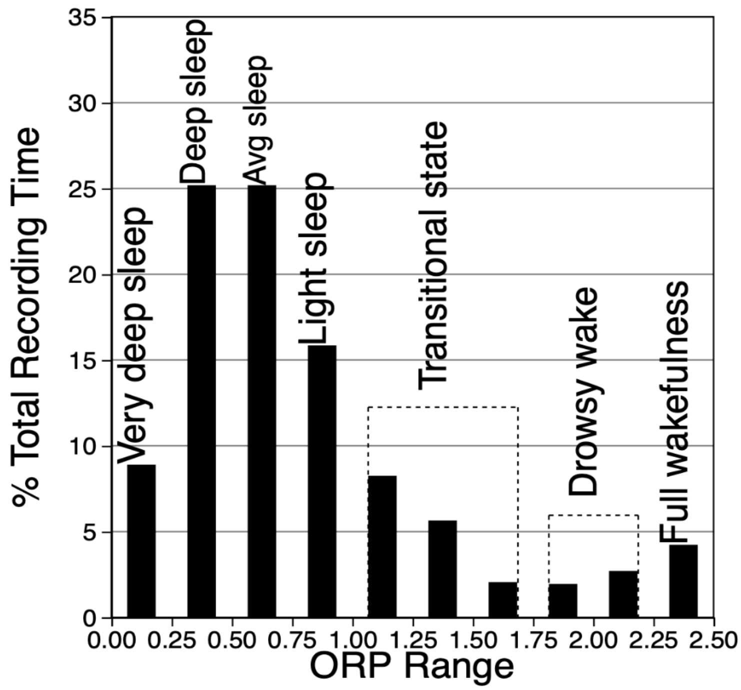

Figure 4: ORP Based Sleep Architecture – A sample from Cerebra sleep study report

Sleep architecture is further described as a percentage of recording time spent in each of the ten deciles within the total ORP range. The sum of the percentage of epochs in deciles 1 and 2 (ORP < 0.5) was used to represent the percentage of epoch spent in deep sleep. The first digit is assigned "1" if the percentage of epochs in deep sleep is in the first quartile (<10.2% of TRT), "2" if it was in the interquartile range (10.2%–28.5% of TRT), and a value of "3" if it was greater than 28.5% of TRT. The second digit was assigned a value of "1" if the percentage of epochs in decile 10 was in the first quartile of its distribution (<3.4%), "2" if in the interquartile range (3.4%–

12.5%), and "3" if greater than 12.5% TRT. Therefore, a type "1,1" indicates that both deep sleep and full wakefulness are in their respective lowest quartiles [51]. Figure 5 shows the 9 types of sleep architecture defined using the percentage range.

9 Architecture Types
1,1: Little Deep Sleep – Little Full Wakefulness
1,2: Little Deep Sleep – Average Full Wakefulness
1,3: Little Deep Sleep – Much Full Wakefulness
2,1: Average Deep Sleep – Little Full Wakefulness
2,2: Average Deep Sleep – Average Full Wakefulness
2,3: Average Deep Sleep – Much Full Wakefulness
3,1: Much Deep Sleep – Little Full Wakefulness
3,2: Much Deep Sleep – Average Full Wakefulness
3,3: Much Deep Sleep – Much Full Wakefulness

Figure 5: Sleep Architecture types [51]

2.3: HR variability

High-quality sleep is a crucial component of health; sleep health is related to cardiovascular health and other physical and psychological health facts. Heart rate variability (HRV) is commonly used in sleep and cardiovascular research. The importance of beat-to-beat variability of heart rate (HR) was reported by Hon and Lee in the 1960s [52]. Sympathetic and parasympathetic activities of the autonomic nervous system contribute to the heart rate power spectrum. Therefore, measurement of changes in HR over time (heart rate variability or HRV) provides information about autonomic functioning. HRV is derived from mathematical analysis of intervals between r-peaks of ECG in milliseconds [53]. Sleep is mentioned to be the best time for measuring PNS (parasympathetic nervous system) function due to HR being primarily controlled by PNS in supine /rest position [53][54].

Chapter 3: Methodology

This single-blind crossover study was conducted on 13 participants in the sleep lab at Riverview Health Centre, Winnipeg MB. The study was approved by the Biomedical Research Ethics Board of the University of Manitoba.

3.1: Eligibility Criteria

To participate in this study participants were determined eligible based on following criteria:

- Must be 18 to 70 years of age.
- Being generally healthy (cognitively and psychologically)
- Ability to read, speak and write English fluently

Exclusion criteria was as following:

- Being diagnosed with any neurological, intellectual disability, major depression/anxiety, bipolar disorder, schizophrenia or any other major mood disorder.
- Inability to adequately communicate in English.
- Substance abuse disorder during participation.
- Simultaneous participation in another therapeutic study
- Being on regular pain killer, sleeping or depression medication
- Diagnosed with any heart or lung disease.

Figure 6 shows the flow chart of this study. All participants signed an informed consent prior to participating in the study. All participants went through the recruitment process and filled in a screening questionnaire which determined their eligibility to participate in the study. Screening questionnaire covered questions about diagnosed sleeping disorders or any other sleeping problems, average sleep time, medical conditions related to heart or lungs, drowsiness during daytime, consumption of any regular prescribed medications and experience with using EMF blocking products. Figure 7 shows a sample of screening questionnaire.

Upon enrollment all participants were assigned an anonymized code based on the ethics standards. Consent form was the only document consisting of participants' name and assigned code together. These forms were kept in a locked cabinet. The master file including the name, code and group assignment of the participants was also saved in a separate secure server than the performance data to ensure no breach in releasing identification information of the participants or their group assignment. The demographic information (i.e., sex, age) along with eligibility assessment info was entered to the online database.

Once the participant was enrolled, they were then randomly assigned to either R1S2 or S1R2 using a randomization code based on the age (below or above 40) and gender. All participants went through four assessments, two in each cycle of real/sham for completing the participation. Participants of group R1S2 received real blanket in the first block of 10 days and sham during the second block; this was reversed for the S1R2 participants. Participants were kept uninformed about type of blanket or the group assignment. There was a washout period of 30 days between the two blocks to avoid residual effects of the previous block. Both real and sham blankets looked identical and weighed same except the color of the blanket, and same colored blanket cover was used to avoid that distinction.

The first primary outcome measure was ORP calculated by Cerebra software, and we investigated any significant changes caused in ORP after using the blanket. The secondary outcome of this study was heart rate variability calculated from ECG recorded overnight using CleveMed PSG device. We planned to enroll 30 participants by the end of the study.

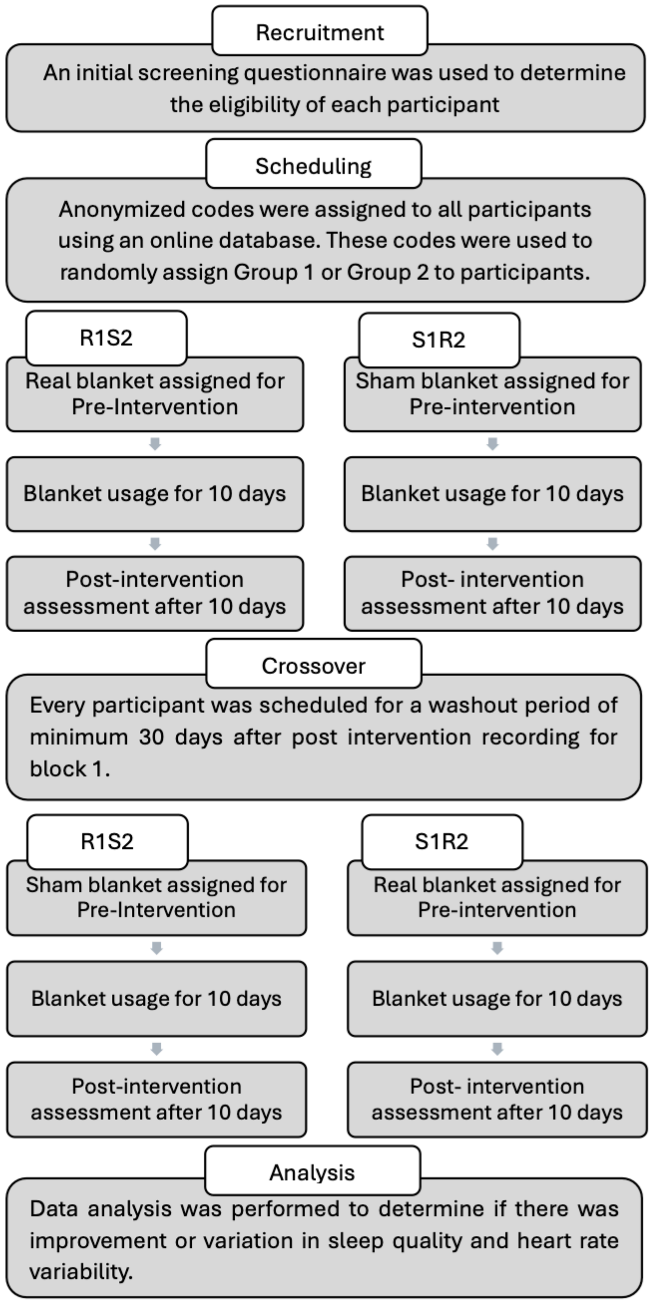

Figure 6: Design of the Study

Screening Questionnaire – EMF study

Participant Name: ___________________________
Code: _______________________ **Date: _________________________**

Do you have any sleep problem? Yes_____ NO If yes, please indication the type of sleep issue and its duration in next columns Sleep apnea ____ Not being able to fall Sleep ___ Waking up frequently_____	Last 3 months	3-6 months	6-24 months	>24 months
How many hours do you sleep in an average night?	Up to 4 hours	4-7 hours	8 hours	>8 hours
How do you rate your sleep quality?	poor	moderate	good	Excellent
Do you have any medical condition related to heart or lungs? Yes ___ No ___ If yes, please mark the duration in next columns	Last 3 months	3-6 months	6-24 months	>24 months
Are you in any regular medication? Yes ____ No_____ If Yes, please write down what medication.				
Do you have any irregular pattern of sleep due to work condition? Yes___ No___				
Do you feel sleepy or drowsy during the day? Yes____ No____				
Have you used any EMF[1] blocking product at home or at work? Yes ___ No ____ If Yes, please indicate when and how often you use.				

[1] EMF emitting electronic devices: Cell phones, tablets, computers, TVs with remote controls, routers, wireless cameras, speakers, Bluetooth, smart watches, smart meters, monitors, microwaves, etc.

Figure 7: Screening Questionnaire filled by each participant prior to starting the study

3.2: Data Collection

Sleep data is recorded using the head unit of an FDA approved Prodigy device provided by Cerebra health. Head unit records EEG, EOG and snoring sounds. CleveMed PSG device was used to record ECG and breathing signals using thoracic belt, abdominal belt, Nasal thermal canula, and blood oxygen saturation. The real SleepGift blanket and sham blanket used in the study were provided by BB holistics and the real blanket is manufactured by BB Holistics as well. Real and sham blankets both weighed about 14 lbs., while the real blanket is made with silver-infused fabric, which blocks EMF in the surroundings. We recruited 27 participants; However, due to long commitment of the research study as well as due to weight of blanket only 13 participants completed the participation.

These participants have four assessments, two in each block of real/sham. Each block of the study had pre-intervention and post-intervention assessments where the participants slept in the sleep lab at Riverview Health Centre and their sleep data and ECG signals were recorded overnight.

The participants were committed to using the blanket for 10 nights at their home after pre-intervention and then post-intervention was recorded using the same blanket on the 11th night in the sleep lab. The washout period of at least 30 days was scheduled after the post-intervention recording of block 1. Block 2 was then recorded in the exact same pattern as block 1 but using the opposite blanket. Participants were advised to follow a similar routine of sleeping and waking up while using the blanket and not to induce sleep by medications.

Participants whose data is used for statistical analysis completed both blocks with each sleep study recording lasting at least 5 hours. Participants were advised to go to bed and wake up around the same time while using the blanket. Table i shows demographic data of 13 participants who finished the two blocks of the study.

Sleep data recorded was used to extract these parameters from the EEG and ECG signals: Sleep Quality measured by average ORP for whole night, ORP for Sleep Stage N2, ORP-9 average, Sleep Latency, WASO, Arousal Index, AHI, Sleep Efficiency, time spent in delta sleep, Spindle Duration, and HRV.

Table i: Demographic Data of participants, N=13

Variables	Group R1S2	Group S1R2	Total
Total number of participants	6	7	13
Age (mean ±SD)	46.5±19.3	42±18.9	42.7±18.1
Gender (n%)			
Male	5 (83.3%)	3 (42.8%)	8 (61.5%)
Female	1 (16.7%)	4 (57.2%)	5 (38.5%)

ORP is a continuous index for evaluating sleep depth that ranges from 0 (pattern only occurring during sleep) to 2.5 (pattern only occurring during wakefulness or in arousal) and value of ORP is indirectly proportional to quality of sleep i.e. lower value of ORP represents better quality of sleep [50]. The ORP scale accurately predicts the awake, asleep or an ambiguous state and average ORP decreases as NREM (non-rapid eye movement) sleep progresses from N1 to N3 [50].

ORP-9 assesses sleep depth after an EEG arousal and is a promising marker of central sleep drive. It provides new insights into drivers of sleep stability, quality and issues underlying a patient's insomnia. Sleep latency (SL) is lights out to the first epoch of any sleep stage. Wake After Sleep Onset (WASO) is the total time the participant was awake after sleep onset. WASO is Total Recording Time (TRT) - SL – Total Sleep Time (TST). Arousal Index is calculated as the ratio of number of arousals and the Total Sleep time. The AHI is the combined average number of apneas and hypopneas that occur per hour of sleep. It is categorized into mild (5-15 events/hour), moderate

(15-30 events/hour), and severe (> 30 events/hour) [48][55]. Sleep Efficiency is calculated as the percentage of Total Sleep Time (TST) to the Total Recording Time (TRT). Spindle duration is the time elapsed between spindle initiation to the end. Spindles are interpreted as promoting sleep stability by contrasting potential waking factors arising externally [56][57].

3.3: Data pre-processing and analysis

Figure 8 shows the features extracted from the data recorded at each stage.

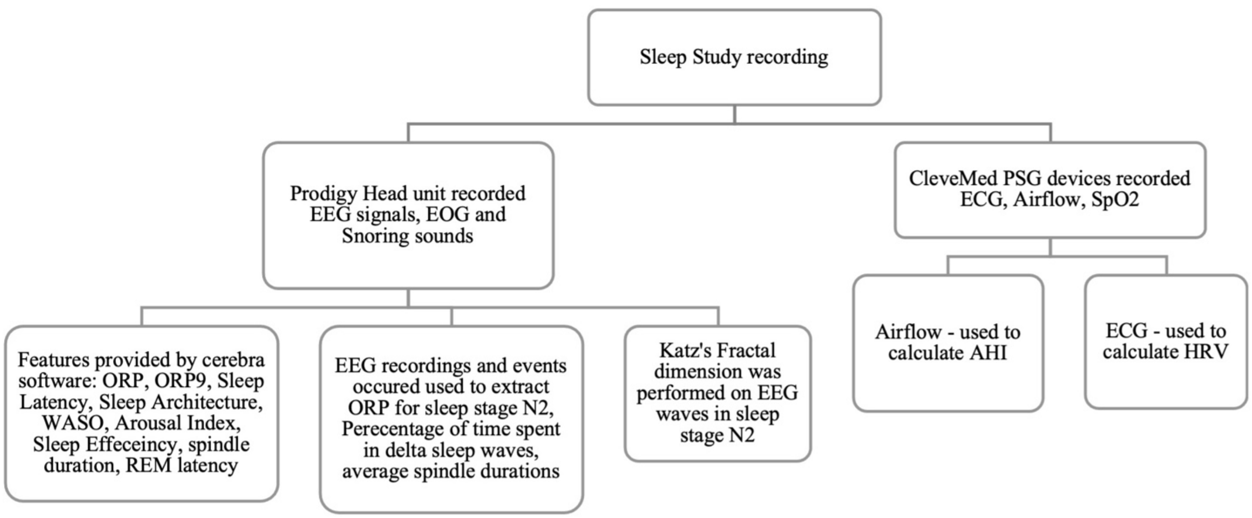

Figure 8: Features extracted from recorded data

3.3.1: Data from Prodigy Head unit and its' Analysis

Cerebra Health generated reports with extensions JSON and EDF. These reports included the events that occurred in EEG while recording. We extracted the recording times corresponding to sleep stages N1, N2, N3, REM (rapid eye movement) stage, and wake stage only and EEG data marked as bad EEG in the recording was left out from the analysis. Events were consisting of sleep stages, arousals, snoring, bad EEG, lights ON and OFF times. Figure 9 shows the sample report from cerebra software which provided the features ORP, ORP-9, sleep architecture, WASO, SL, sleep efficiency, and arousal index.

Events structure generated from prodigy device was used to extract ORP values corresponding to sleep stage N2, percentage of total sleep time spent in delta wave sleep and average duration of spindles.

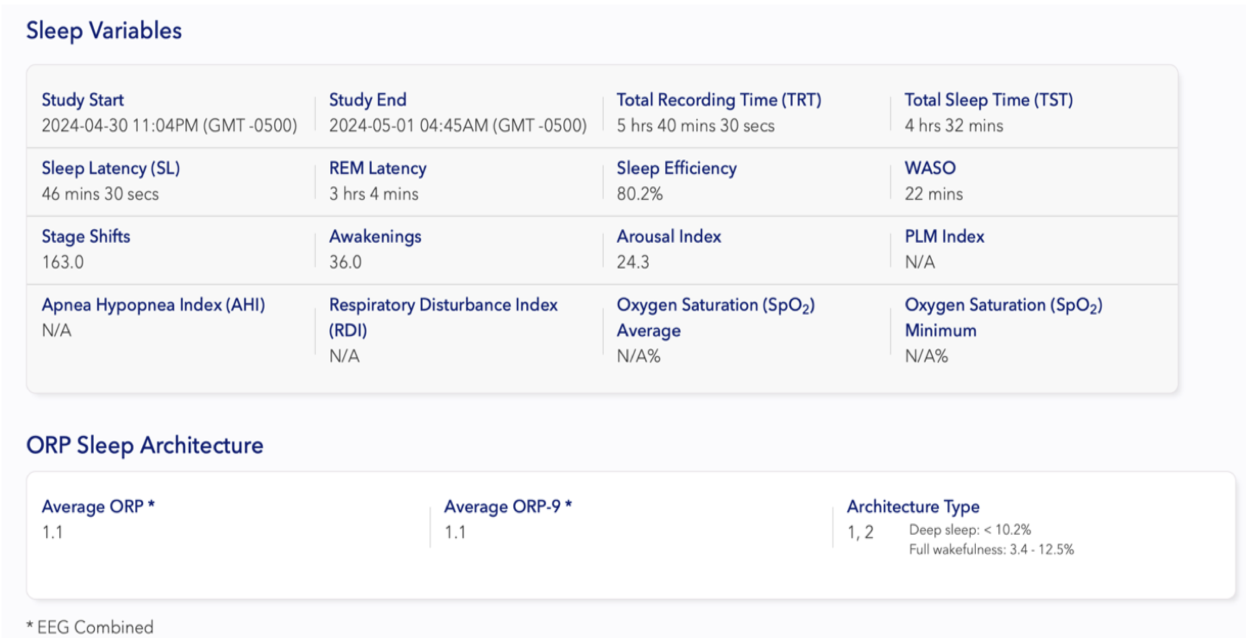

Figure 9: Sample Report from Cerebra Sleep Study

We calculated Katz fractal dimension on EEG extracted for each sleep stage N2. All the participants had spent a significant amount of time in stage N2 while we had 4 participants who did not spend any time in either stage REM or stage N3. Therefore, we considered stage N2 to include all the data in analysis. We were expecting to see lower frequency as during sleep stage N2, the transition occurs from theta and alpha waves to slow waves.

Fractal dimension (FD) is a time-domain feature which measures the complexity of the signal. The value of FD is between 1 and 2. Katz's fractal dimension is defined in Eq. 1; it is one of the most consistent methods for discriminating EEG signal due to its exponential transformation and insensitivity to noise [58].

$$D_k = \frac{\log(n)}{\log(n)+\log\left(\frac{d}{L}\right)}, \text{Eq. 1}$$

where, L is total length of the waveform, d is the planar extent of the waveform, and n=L/ā is the number of steps in waveform, where ā is average distance between successive points [58]. Figure 10 describes the process of fractal dimension analysis.

EEG signals were recorded at 120 Hz and segmented in 1 second window size with 50 percent overlap to calculate FD values. All the FD values were then averaged for all sleep stage N2 epochs for entire duration of sleep.

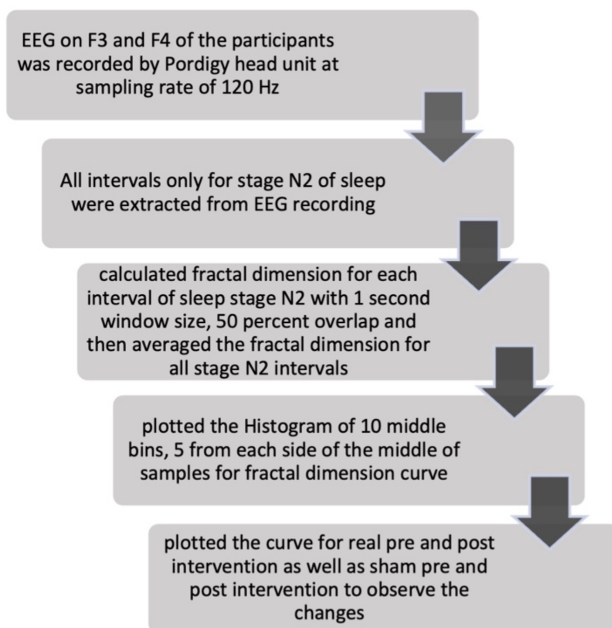

Figure 10: Flow chart showing the steps for calculating the Katz's fractal dimension curve

3.3.2: Data from CleveMed PSG Device and Analysis

Crystal PSG software was used to calculate number of apneas and hypopneas in total sleep recording time. Apneas and Hypopneas are scored by Crystal PSG software based on selected criteria such that complete cessation of breathing or more than 90% reduction in respiratory amplitude for 10 seconds or longer is scored as apnea and 30% or more reduction in respiratory amplitude for 10 seconds or longer is scored as hypopnea in association with 3 % or more decrease in blood oxygen saturation. AHI was then calculated as sum of apneas and hypopneas divided by total sleep time [55][59].

ECG signal recorded using CleveMed PSG device at sampling rate of 256 Hz and was preprocessed using bandpass filter (0.04 Hz - 40 Hz) to remove baseline wander and noise, notch filter (60 Hz) to remove power line interference (if any) and then pan-Tompkin's method was to calculate RR intervals [60].

3.3.3: Statistical Analysis

Comparing features from Group R1S2 and Group S1R2 will indicate whether the SleepGift blanket led to any significant improvement beyond placebo effect. Figure 11 shows the steps of statistical analysis performed on collected data.

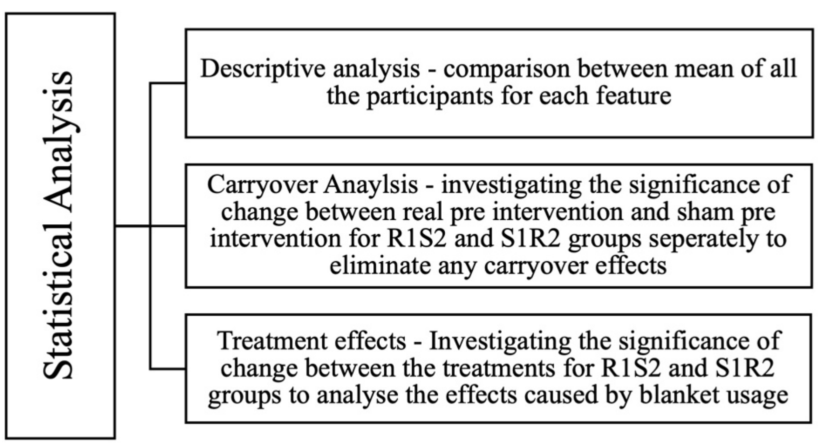

Figure 11: Flow chart of statistical analysis performed on the data. Statistical analysis is performed in three steps – Descriptive, Carryover and Treatment effects to understand the overall as well as carryover effects potentially caused by using SleepGift blanket.

Crossing over two groups provided us with a larger sample size to perform statistical analysis. The dichotomous data were presented as frequency and percentage. Data collected was tested for both normality and sphericity using Shapiro wilk test and Mauchly's test of sphericity. As most of the features resulted in violation of normality or sphericity, Wilcoxon Rank test was performed to investigate any significant change between the groups caused by treatment as well as by the time of treatment since it was a cross over study. The level of significance was 0.05. Any p-value less than or equal to 0.05 would state the variable has changed significantly.

Chapter 4: Results and Discussion

4.1: Comparison of difference in Primary outcome ORP

ORP comparison in real and sham blocks for groups R1S2 and S1R2 is shown in Fig. 12. In group R1S2, which received real blanket first and sham later, P1 and P11 experienced a decline in sleep quality for both real and sham blankets. P2 improved their sleep quality for real blanket while remaining unchanged for sham blanket. P6 remains unchanged for real and sham blanket. P9 experienced decline using real blanket and remain unchanged for sham. P12 improved sleep quality for both real and sham.

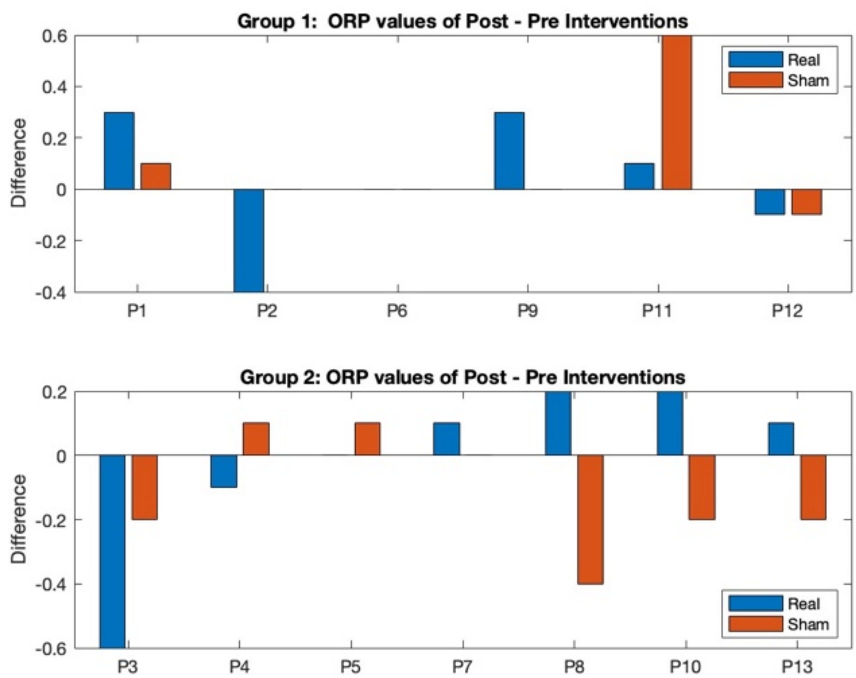

Figure 12: Plot of difference between ORP measured at Pre and Post intervention sleep recordings of Group R1S2 and Group S1R2. Positive difference in ORP indicates decline in sleep quality while negative difference in ORP indicates improvement in sleep quality.

In group S1R2, who received sham blanket first and real second, P3's sleep quality enhanced for both real and sham blanket. P4 experienced improvement in sleep quality using real blanket while experiencing decline using sham blanket. P5 shows decline for sham while remaining unchanged for real blanket and P7 shows decline while using real blanket and remains unchanged for sham blanket. P8, P10 and P13 showed improved sleep quality for sham while showing decline for real blanket. Based on the above small samples in each group, the results do not lead to any conclusion on the effect of real blanket on sleep quality in either group.

4.2: Katz's Fractal dimension for EEG waves of Sleep Stage N2

Figure 13 shows right side EEG and Fig. 14 shows left side EEG, the histogram bar plot for Katz fractal dimension for sleep stage N2 of real and sham block of all the participants. Most of the frequencies for all the four interventions remained in bin 2; therefore, no significant change has been observed.

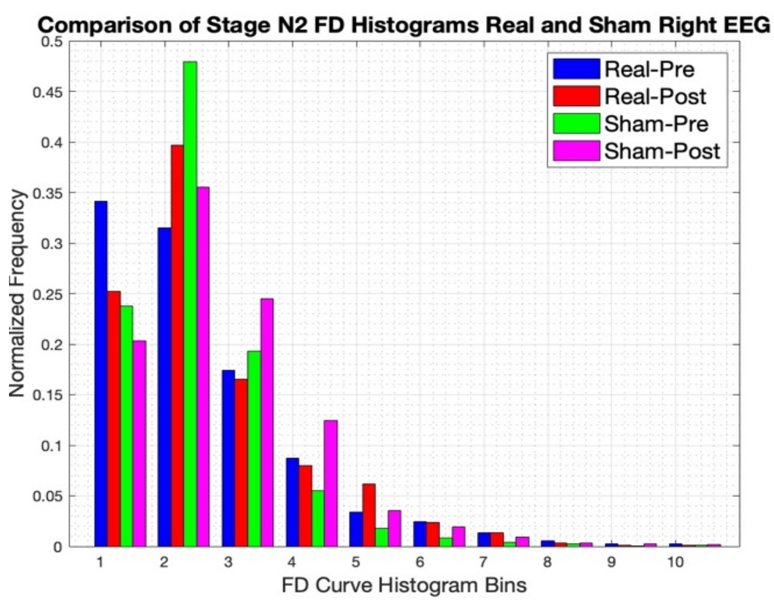

Figure 13: Katz's Fractal dimension of right-side EEG

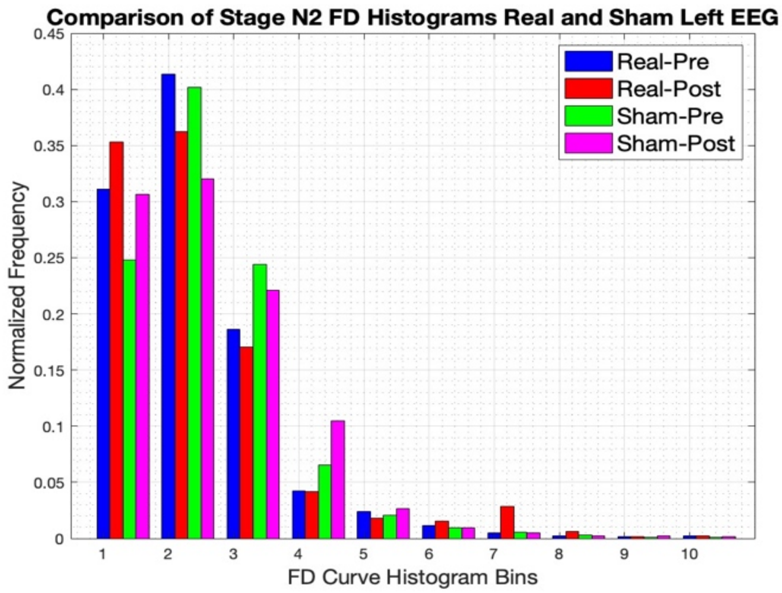

Figure 14: Katz's Fractal dimension of left-side EEG

4.3: Statistical Analysis

Descriptive analysis results are shown in plots below for calculated features (average ORP, average ORP for sleep stage N2, average ORP-9, sleep architecture, sleep latency, WASO, arousal index, percentage of time spent in delta wave sleep, AHI, sleep efficiency, RR-intervals and spindle duration) of all 13 participants. Observing the mean values of the features, no values change significantly for any of the calculated features of real intervention or sham intervention. Each plot shows the mean value of the corresponding feature for all 13 participants as well as standard error calculated at each intervention stage (real pre-intervention, real post-intervention, sham pre-intervention and sham post-intervention).

The plot in Fig. 15 shows the average ORP calculated for whole night and little to no change was observed after real or sham interventions. Further statistical tests are performed for determining the significance in change.

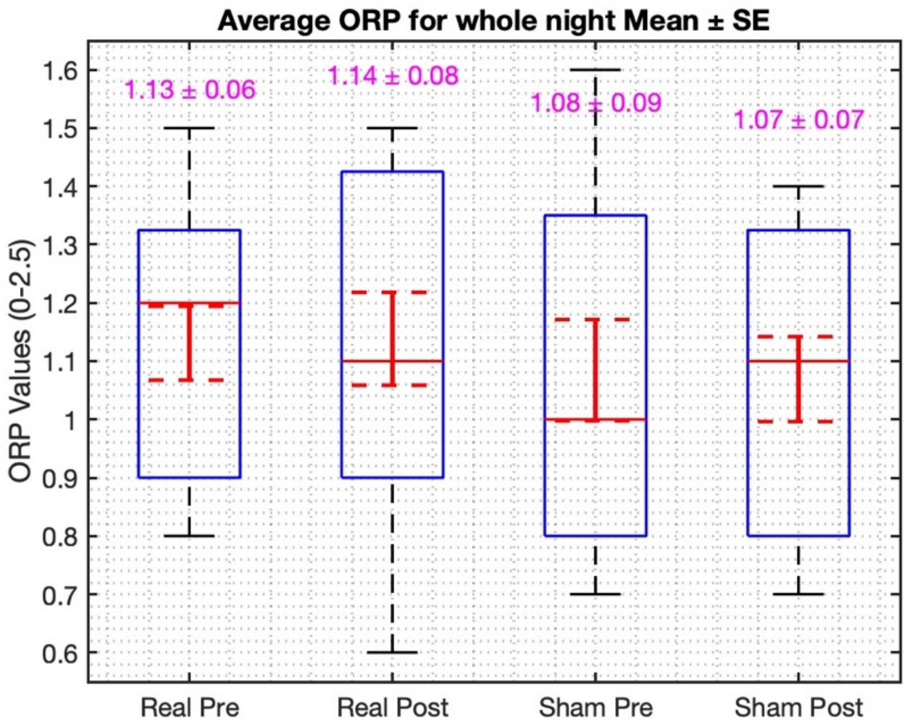

Figure 15: Average ± standard error (SE) of ORP for TRT

The plot in Fig. 16 shows average ORP values calculated in sleep stage N2 from the whole night. The mean ORP value slightly increase in both real and sham interventions. There is one participant in real block at pre-intervention stage with significantly higher value than rest of the values in group. This participant is P11 from group R1S2 who were uncomfortable about sleeping in new place. The high ORP value could be due to discomfort of sleeping in a new bed. This participants' overall ORP did not improve significantly while using the real blanket (real pre – 1.4 and real post -1.5); However, their sleep quality declined while using the sham blanket (sham pre – 0.8 and sham post – 1.4). Further, statistical analysis tests are performed to determine the overall significance of change.

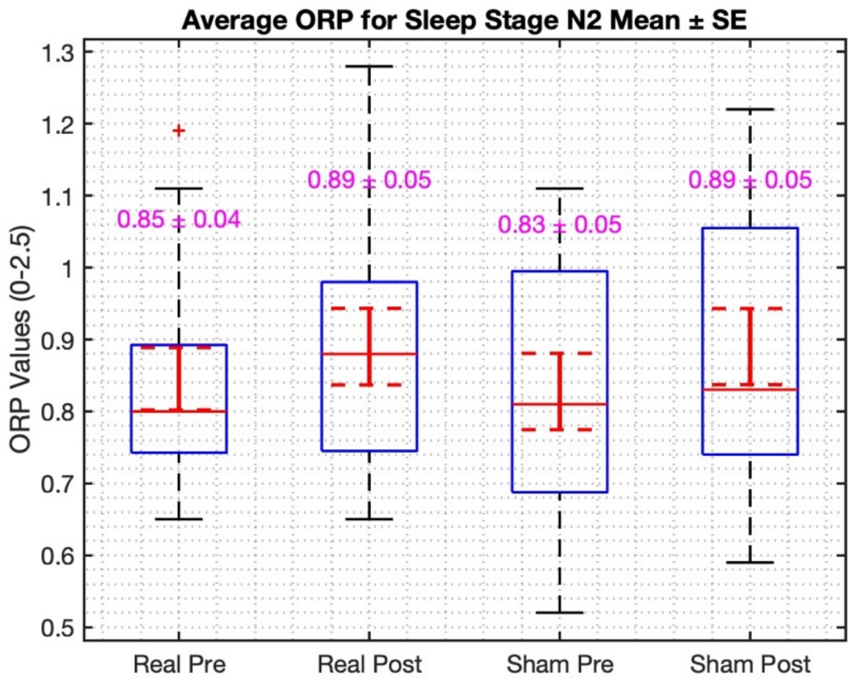

Figure 16: Average ORP for Sleep Stage N2 for TRT

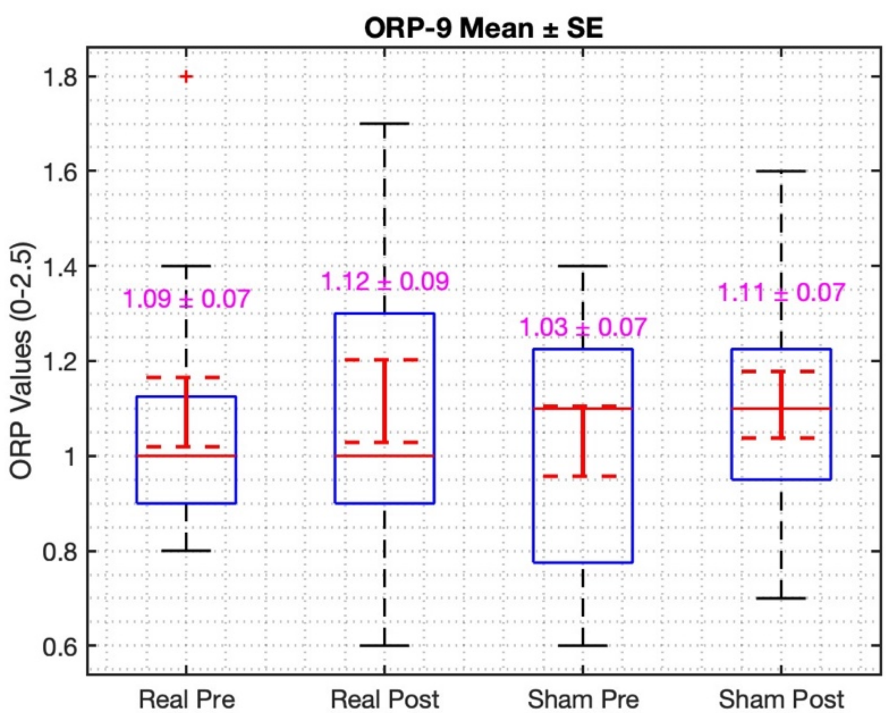

Figure 17: Average ORP-9 for TRT

The plot in Fig. 17 shows the average ORP-9. The mean value slightly increases from 1.09 to 1.12 during real intervention of the study as well as 1.03 to 1.11 during sham intervention. SE ranges from 0.07 to 0.09 showing small variability around mean value. The plot shows no significant alteration in ORP-9 values; Hence, further statistical analysis is performed.

Plot of sleep architecture stages in Fig. 18 remains relatively consistent across both real and sham blocks with minor variation in values of mean and variability.

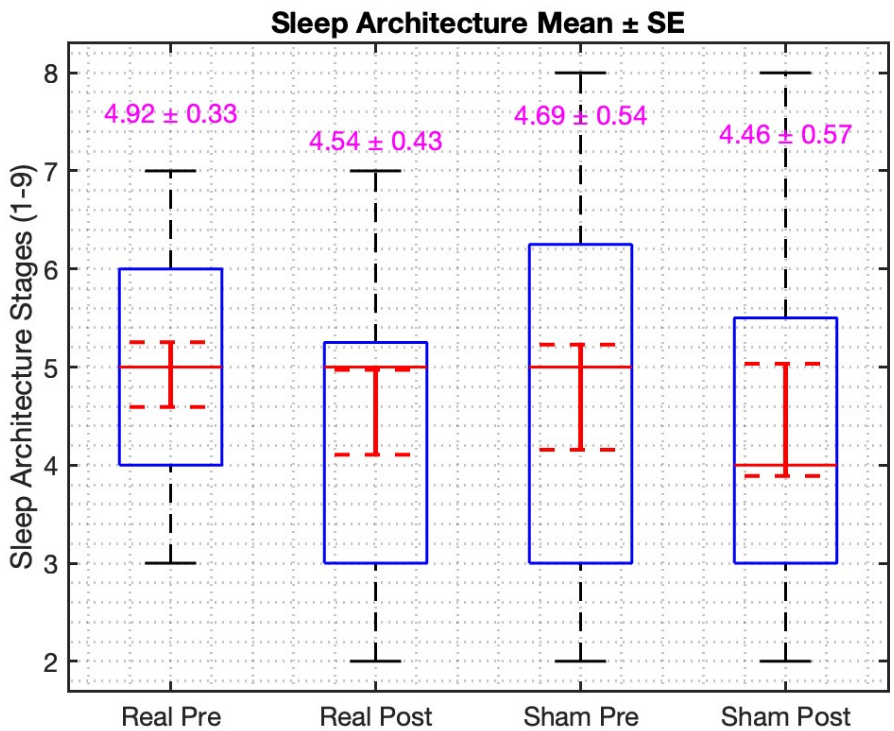

Figure 18: Sleep Architecture Stages based on 9-stages defined in methodology

The plot of sleep latency in Fig. 19 shows more variability as post-intervention for both real and sham block show higher mean and increased variability as compared to their pre-intervention counterparts. Further statistical analysis is performed to determine the overall significance of change. There are two participants (P7 and P13) in sham block pre-intervention stage with significantly higher values in sleep latency, these two participants are from group S1R2.

The first sleep study recorded for these participants at sleep lab was using sham blanket (sleep latency during sham pre for P7 is 47 minutes and P13 is 54 minutes); Therefore, sleeping in a new environment with electrodes attached to them could have been the reason for high sleep latency. In addition, the sleep latency of participant P7 decreased from 47 minutes to 25 minutes while using sham blanket and from 13 minutes to 7 minutes while using real blanket. Also, the sleep latency for participant P13 decreased from 54.5 minutes to 6 minutes while using the sham blanket as well as decreased from 10 minutes to 9.5 minutes during real branch of the study. P7 and P13 fell asleep faster while using sham blanket as compared to the real blanket.

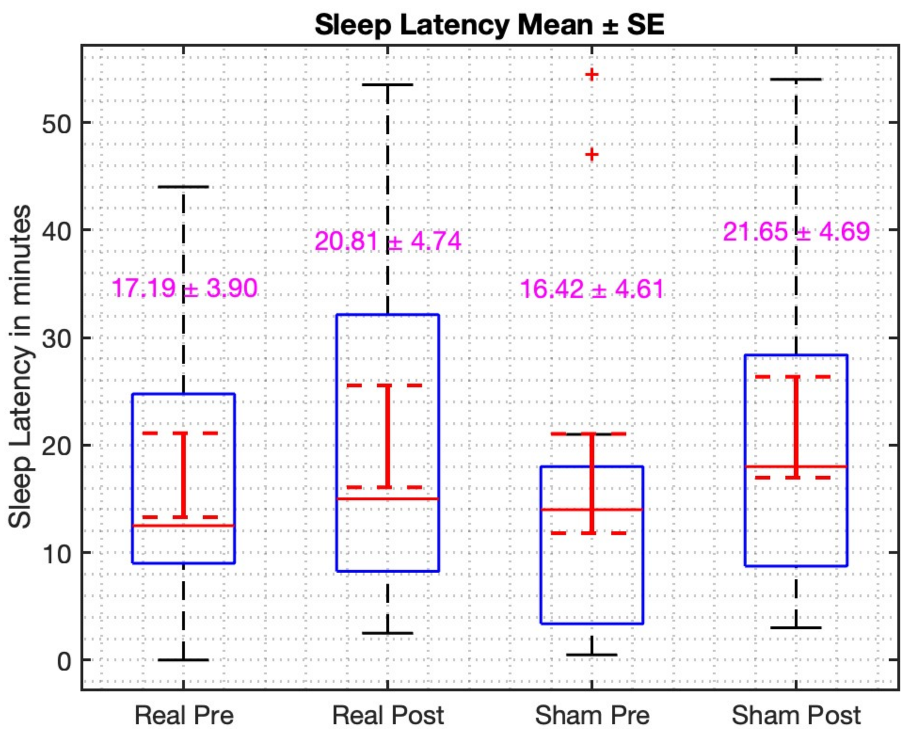

Figure 19: Sleep Latency in minutes

The plot for WASO in Fig. 20 shows that WASO remained relatively stable across the real block as the mean value is (79.4) approximately same; However, a noticeable decrease is observed from mean values of sham intervention. Participant P10 from group S1R2 who received sham blanket first has significantly higher value then rest of the participants; however, their WASO remain unchanged after real stage of study. Further statistical analysis is performed to determine the significance of change.

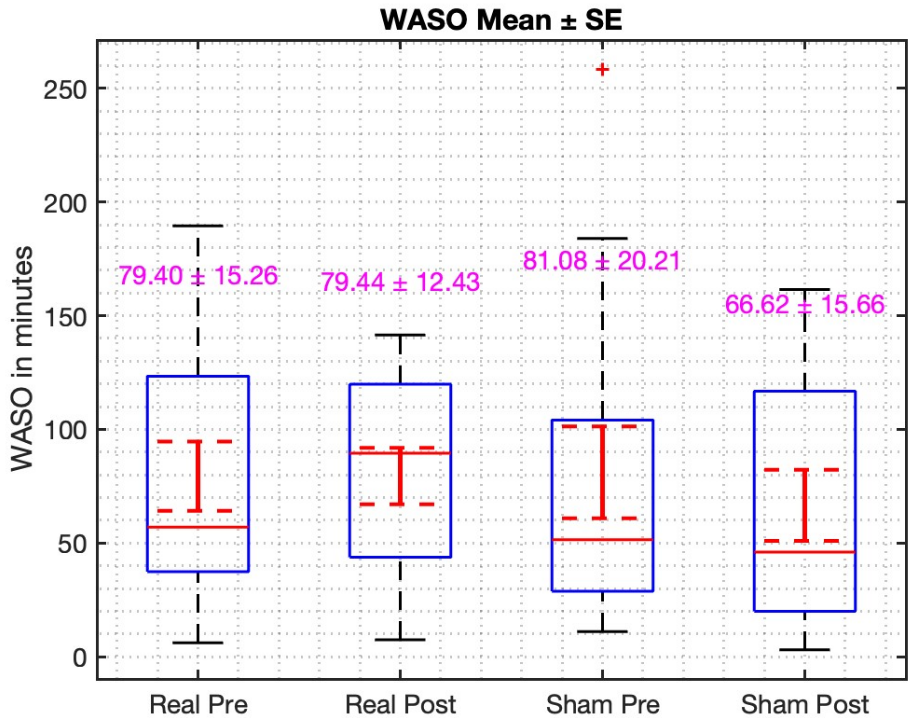

Figure 20: Wake after sleep onset

Figure 21 shows the arousal index trends across real and sham intervention for all participants. Real intervention shows a slight increase in arousal index; however, the sham intervention exhibits a slight reduction in both mean and variability. This may suggest the sham intervention might be effective in reducing sleep arousals, thereby potentially improving the sleep quality. Further statistical analysis is performed to confirm the significance of these observations.

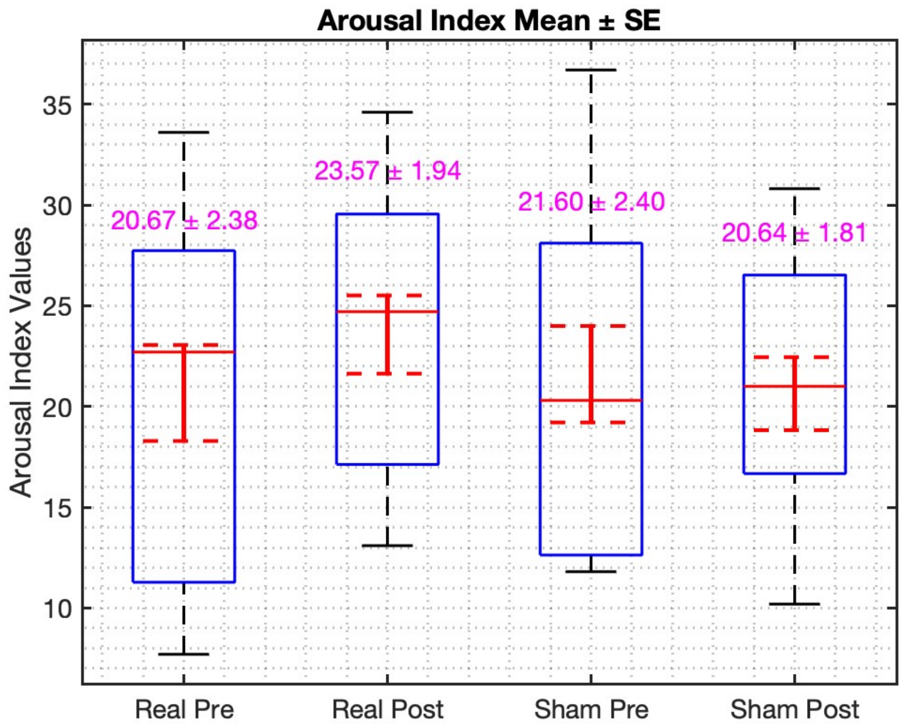

Figure 21: Arousal index

Plot in Fig. 22 shows the percentage of time spent in delta wave sleep out of total sleep time. Both real and sham interventions exhibit a slight decrease in delta wave sleep leading to speculation that amount of time spent in delta wave sleep might have decreased. Further statistical analysis is performed to determine the change and its significance.

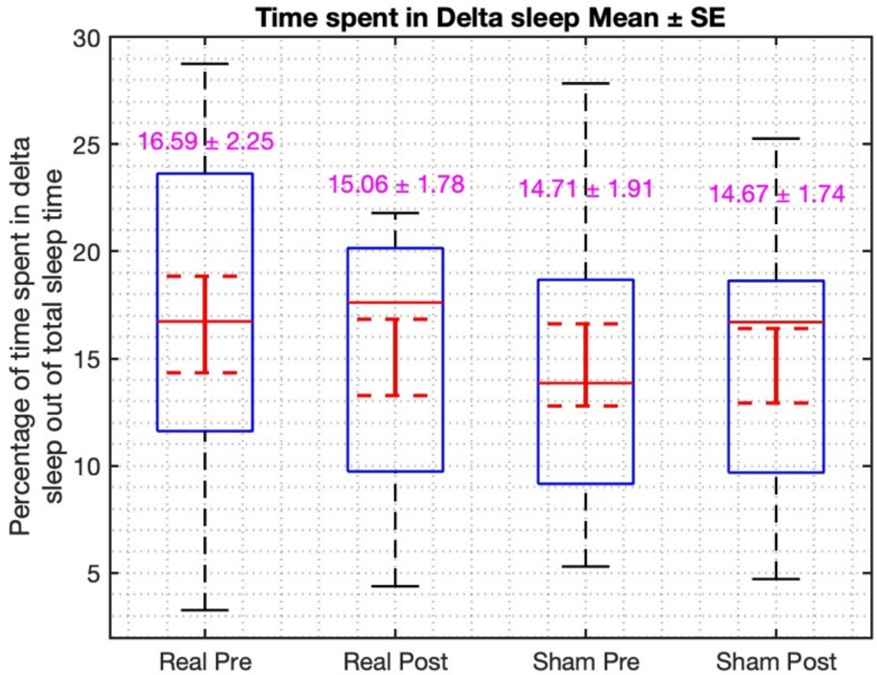

Figure 22: Percentage of time spent in delta wave sleep out of total sleep time

Real block and sham block for AHI shown in Fig. 23. Participant P13 experienced decrease in AHI from 14.54 to 7.7 while using sham blanket and increase in AHI after crossover (30 days washout period) to 22.12; however, the AHI decreased to 13.89 from 22.12 while using the real blanket. Since, the AHI decreased in both real and sham blocks of the study the reason for decline in AHI remains inconclusive. Further analysis is recommended to truly learn the impact of using SleepGift blanket.

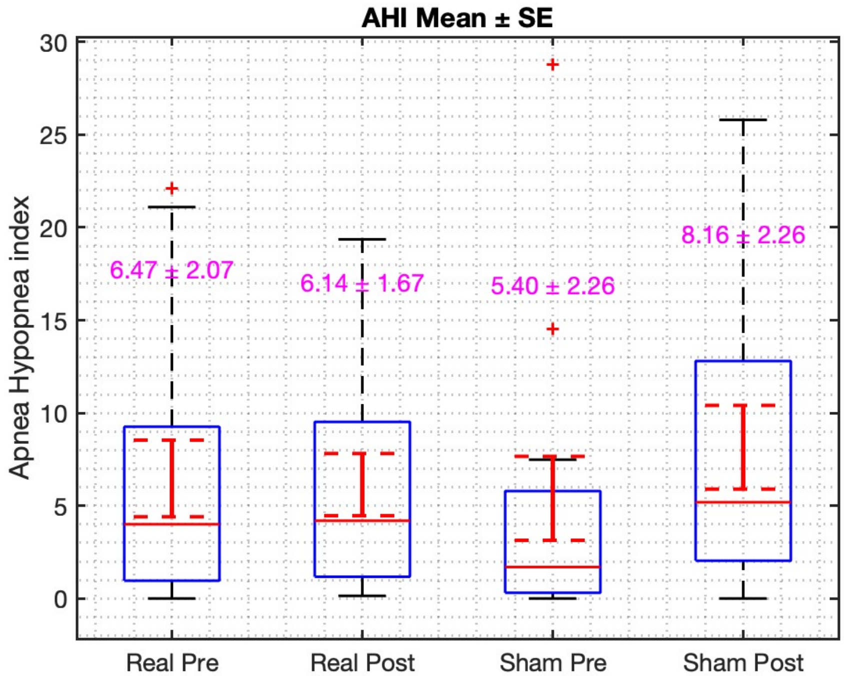

Figure 23: Apnea-Hypopnea Index of participants

Figure 24 shows the plot of sleep efficiency calculated overnight. The sleep efficiency value remains relatively stable across real intervention of the study; however, there is a slight increase in mean (from 77.12% to 79.05%) and reduction in variability during sham intervention. Participant P3 has significantly lower sleep efficiency of 43% during real pre-intervention stage which increased to 80% during the real leg of study. On the contrary, this participant is from group S1R2; hence they received sham blanket first and their sleep efficiency increased from 75% to 90% while using the sham blanket as well. Even though the difference in increase is 37% while using the real blanket and 15% while using the sham blanket, other parameters such as ORP remain unchanged for this participant. Therefore, the reason of variation remains inconclusive. Further statistical analysis is conducted to determine the significance of change.

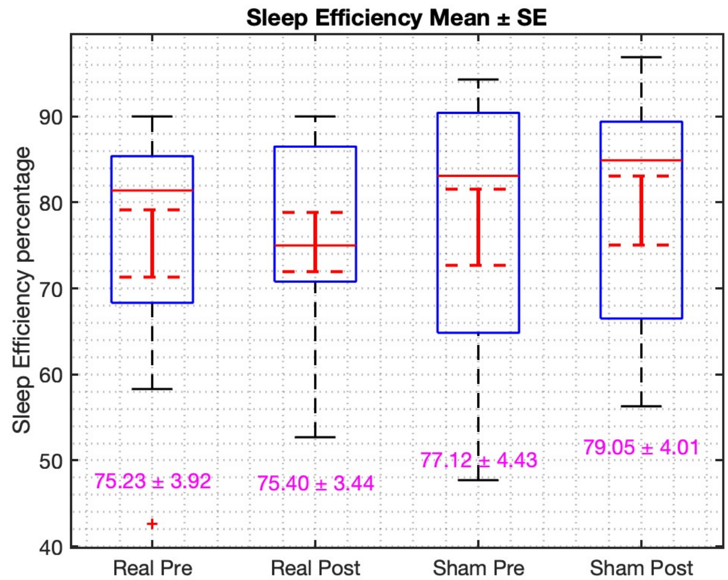

Figure 24: Sleep efficiency of participants for each night of the sleep recording

Figure 25 shows that RR intervals remain relatively stable across pre and post intervention of both real and sham blocks. Further statistical analysis is conducted to determine the significance of variation in values.

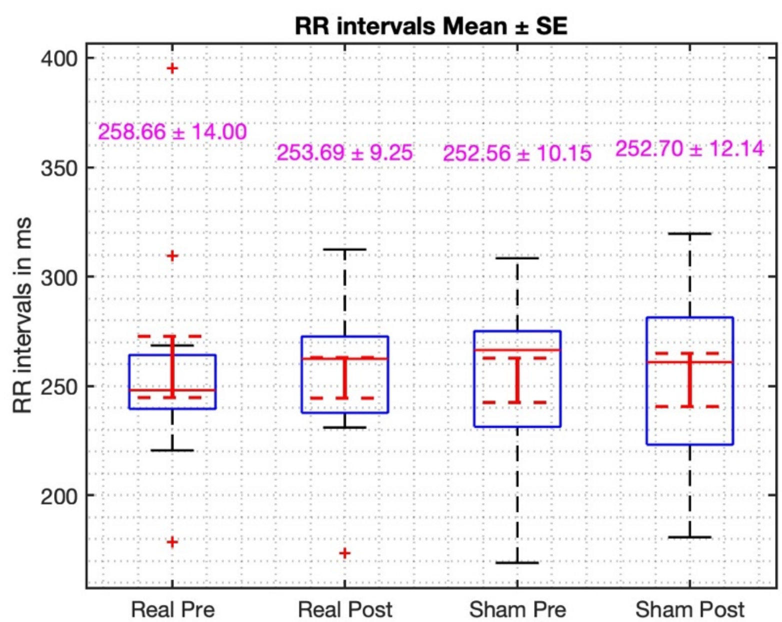

Figure 25: HR variability / RR intervals in milliseconds for sleep stage N2

Figure 26 shows that both real intervention and sham intervention exhibit stable spindle duration throughout the study. The spindle duration has similar variability as well as almost negligible variation in mean value. Further statistical analysis is conducted to determine the significance in change.

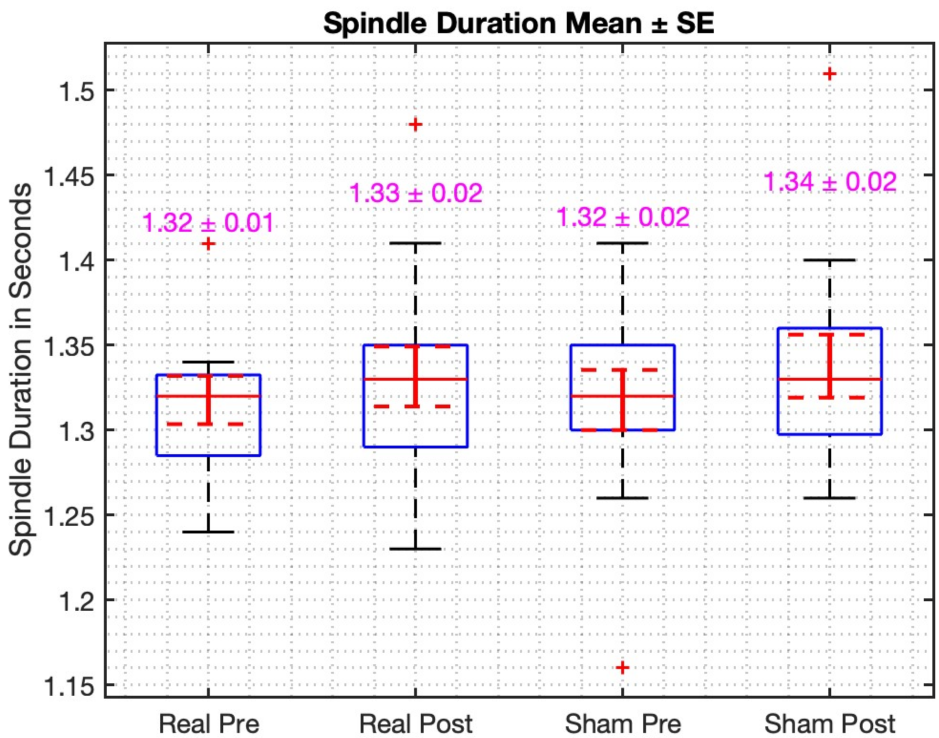

Figure 26: Average spindle duration

Result of carryover analysis is shown in table ii. Wilcoxon rank test was performed between real pre-intervention and sham pre-intervention stages of group R1S2 and group S1R2 separately to analyze carryover effects that could have been caused due to sequence of sham or real blanket assignment. P-values of WASO and sleep efficiency show that real pre-intervention and sham pre-intervention were significantly different for participants of group R1S2 as well as percentage of time spent in delta wave sleep was close to being significant. However, there is no significant difference caused in group S1R2.

Table ii: P-values obtained from Wilcoxon rank test for carryover analysis

Features	Group R1S2 – Real and Sham - pre	Group S1R2 – Sham and Real - pre
Average ORP for all night	0.131	0.394
Average ORP for Sleep Stage N2	0.249	0.310
Average ORP-9	0.104	0.104
ORP Sleep Architecture	0.102	0.112
Sleep Latency	0.463	1.00
WASO	0.056**	0.735
Arousal Index	0.463	0.735
Percentage of time spent in delta sleep	0.075*	0.735
Apnea-Hypopnea Index	0.249	0.499
Sleep Efficiency	0.028**	0.499
Average Spindle duration	0.345	0.399
RR intervals for Sleep Stage N2	0.753	1.00
Significant p-values are marked with ** and close to significant p-values are marked *		

In Table iii, percentage of time spent in delta wave sleep (out of total sleep time) has close to significant change for group R1S2 before and after using the real SleepGift blanket, while no other change is observed in both groups.

Table iii: P-values obtained from Wilcoxon rank test to analyze treatment effects between real and sham blocks

Features	Group R1S2 – Real and Sham	Group S1R2 – Sham and Real	For all 13 participants
Average ORP for all night	0.465	0.497	0.858
Average ORP for Sleep Stage N2	0.173	0.398	0.727
Average ORP-9	0.140	0.461	0.471
ORP Sleep Architecture	0.414	0.461	0.928
Sleep Latency	0.599	0.866	0.916
WASO	0.753	0.499	0.382
Arousal Index	0.225	0.735	0.388
Percentage of time spent in delta sleep	0.075*	0.866	0.221
Apnea-Hypopnea Index	0.893	0.176	0.209
Sleep Efficiency	0.463	0.612	0.675
Average Spindle duration	0.786	0.344	0.421
RR intervals for Sleep Stage N2	0.345	0.866	0.650
Significant p-values are marked with ** and close to significant p-values are marked *.			

We also measured the EMF strength using our magnetometer (EFA-2 BN 2245 by Wandel & Goltermann); it was found to be 0.2791 μT under the real SleepGift blanket, 0.3121μT under the sham blanket, and 0.3125 μT in the sleep lab outside the blanket. Shielding effectiveness of SleepGift blanket was tested by Ontario tech university, Ontario Canada using a standardized test (MIL-STD-285) method to evaluate the shielding effect of materials for EMFs. 99 percent effectiveness was determined across frequency spectrum of 100 MHz to 6GHz for the SleepGift blanket [44].

We observed from the feedback questionnaire answered by participants at the end of each block that participants found the high weight of blanket to be a hinderance while they slept, and the size was declared not enough to cover them properly. As the blankets fails to cover the full body due to short length, participants were partially exposed to EMF while using the blankets. Thus, it is still possible to absorb EMF through the head that is not covered by the blanket. Three participants who were first enrolled and screened eligible withdrew from the study after first recording due to the blanket's weight.

It was also reported that participants experienced discomfort due to the weight of the head unit (ORP measurement device) attached to their forehead used for recording sleep study as well as few participants sweat made it challenging for the head unit electrodes' connections to stay attached overnight.

Therefore, the changes remain insignificant so far and further replication of the study with larger dataset as well as suggested improvement is recommended.

Chapter 5: Limitations, Conclusion and Future work

5.1: Limitations

This study encountered several limitations that may have influenced the results and should be addressed in future.

1. Sample size: This study included only 13 participants who were able to complete the study. We recruited 29 participants, out of which majority of the participants withdrew due to long commitment, weight of the blanket, discomfort experienced in foreign bed or scheduling conflicts.
2. Participant discomfort: Several participants reported discomfort experienced due to high weight of SleepGift blanket (13.65 lbs) and Prodigy head unit used for recording EEG. This may have introduced potential confounding factors by affecting the sleep quality of participants independent of EMF shielding properties of the blanket.
3. Incomplete EMF coverage: The blankets' size (80x56 inches) was insufficient to cover the entire body of participants leading to partial exposure to EMF, especially for head. This could have influenced efficacy of the blanket.
4. Recruitment challenge: Recruiting participants was challenging for this study even with honorarium. Significant number of participants denied interest due to long commitment, conflict of schedules, travelling to the lab or sleeping outside their bed. Few participants were declared ineligible as they were unable to sleep during the sleep recording.
5. Measurement Challenges: The attachment Prodigy head unit electrodes were affected by sweating, which could have potentially compromised the quality and accuracy of EEG recordings. Additionally, use of a weighted blanket might have influenced typical sleep patterns for participants.

6. Carryover effects: Although a washout period was included, the possibility of carry over effects between real and sham periods of the study cannot be entirely ruled out. This could have influenced the results.
7. Duration of study: Each intervention lasted 10 days, which may not have been sufficient to observe long-term effects of EMF exposure reduction on sleep quality and heart health.

By addressing these limitations, the effectiveness of the SleepGift blanket on sleep quality and heart health can be more accurately determined.

5.2: Conclusion

The two objectives of this study were to investigate the efficacy of SleepGift blanket on sleep quality and heart health as it claims to block the EMF effects, and one expects to have a better sleep quality and improved heart health if the EMF effects are reduced. The results to date; however, are inconclusive. It could be mainly due to very small sample size of the study. The overall analysis of the data shows no significant or consistent change in the sleep quality and heart health of participants. It should be noted that none of the participants of this study, except one, expressed any sensitivity to the EMF. The one participant who had expressed sensitivity to EMF, showed improvement in their sleep quality with the real blanket and remained unchanged with sham blanket. Perhaps to have a fair conclusion, study participants should be selected from those who claim sensitivity to EMF. However, recruitment of such participants will be extremely challenging. Nevertheless, without even a known sensitivity to EMF, a larger dataset is needed to reach a robust conclusion about the efficacy of the SleepGift blanket on sleep quality and heart health.

We would recommend a change in length of time when the blanket is used by participants at home even though it could make the recruitment more challenging it would give participants more time to become habitual. We would also recommend for the blanket to be non-weighted as well as larger in size but still have the capability to block EMF as the weighted blanket makes it more challenging to differentiate the reason (weight of the blanket or EMF blockage) of plausible change in sleep quality.

It is concluded that investigating the efficacy of SleepGift blanket requires more testing with some changes in the study design as well as materials to explore further variations.

5.3: Future Works

To further advance the understanding and potential benefits of SleepGift blanket, several technical and methodological enhancements are recommended for future research.

1. Longitudinal Multimodal monitoring: Integrating multimodal monitoring approaches such as continuous wearable devices for real-time tracking of sleep patterns, heart rate variability and EMF exposure, could offer a comprehensive assessment of long-term effects and cumulative benefits of EMF shielding.
2. Biomechanical Analysis of blanket design: Conducting a detailed biomechanical analysis to optimize the blanket's weight distribution and material properties to simulate and improve user comfort while maintaining the shielding effect.
3. High-frequency and High-resolution EMF measurement: Utilizing measurement instruments for high-frequency and high-resolution EMF to precisely quantify the ambient and personal EMF exposure for continuous assessment throughout the study duration.
4. Neuroimaging studies: Incorporate neuroimaging techniques such as function MRI and PET to examine the neurological impacts of EMF exposure and shielding. This can provide the insights into changes in brain activity and connectivity related to sleep and cognitive functions.

5. Mathematical modeling and simulation: Develop mathematical models to simulate the interaction between EMFs and biological tissues, focussing on understanding the mechanisms and underlying observer physiological changes. Advanced computational methods can help predict the effects of various EMF shielding strategies.
6. Replication and multi-centre trials: Conducting multi-centre trials to replicate findings across the different geographic locations and population to enhance the generalization and robustness of results. Collaboration with other research institutions can provide a broader perspective and validation of the study outcomes.
7. Biofeedback and personalization interventions: Explore the integration of biofeedback mechanisms that provide real-time feedback to participants on their physiological responses to EMF exposure and shieling. Personalized intervention based on individual susceptibility to EMF effects can be developed and tested.

By implementing above suggestions in combination with technical advancements, future research can provide more detailed and reliable evidence on efficacy of SleepGift blanket and similar EMF shielding technologies, leading to better understanding and mitigation of EMF-related health risks.

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