EFFECT OF AMBIENT RADIOFREQUENCY RADIATION ON SLEEP IN HEALTHY ADULTS: A DOUBLE-BLIND, RANDOMISED, CROSSOVER PILOT STUDY

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STATEMENT OF COMPLIANCE
This document is a protocol for a pragmatic, randomised, double-blind, crossover pilot study. The study will be conducted in accordance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007/2018) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

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PROJECT SUMMARY

Sleep disturbances have reached epidemic proportions affecting four out of every ten Australians (DeloitteAccessEconomics, 2017) resulting in poor mental health (Assocation, 2013), significant neurocognitive deficits (Lowe, Safati, & Hall, 2017) and are a risk factor for mortality, cardiovascular disease, diabetes and obesity (Grandner, 2017). Whilst sleep disturbances varies by age, gender, race, weight, socioeconomic status and specific disease states, societal influences such as technology are gaining attention in polysomnographic research and may explain the rise in the prevalence of sleep difficulties since 2010. General sleep disturbance is most frequently reported in young adults (Grandner, 2017) who also happen to spend the most time using digital devices and time spent surfing the internet (Adams, Appleton, Taylor, McEvoy, & Antic, 2016) and a significant body of work has attributed poor sleep quality with participant's dependency to mobile phone use (Exelmans & Van den Bulck, 2016; Ibrahim et al., 2018; Seoane et al., 2020; Tymofiyeva et al., 2020; Yang, Fu, Liao, & Li, 2020). What isn't clear is whether the impact on sleep quality is due to RF-EMF exposure or another mechanism such as suppression of melatonin from blue light exposure (Mortazavi et al., 2018), arousal from decreasing the ability to fall asleep or other factors associated with digital device use (Tettamanti et al., 2020).

This study aims to investigate the impact of a 2.45GHz radiofrequency device on subjective and objective sleep parameters in healthy adults. A 4-week randomised, double-blind, crossover, pilot study will be conducted in 20 healthy adults. Participants will be sequentially exposed to active and inactive baby monitors and clinical, subjective and objective measures of sleep quality, actigraphy and heart rate variability will be measured. It is hypothesized that poorer sleep quality will be found during RF-EMF exposure compared to placebo exposure.

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1. GENERAL INFORMATION

1.1 Student (primary) investigator

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1.3 Funding and budget

No funding will be received for this project. The student investigator is undertaking her PhD and is supported by a scholarship from the Jacka Foundation.

1.4 Research site

RMIT University, Melbourne, Australia.

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RATIONALE & BACKGROUND INFORMATION

2.1 Research question

Does exposure to a commonly available radiofrequency device affect sleep?

2.2 Rationale for current study

Sleep disturbances have reached epidemic proportions affecting four out of every ten Australians (DeloitteAccessEconomics, 2017) resulting in altered memory formation (Walker & Stickgold, 2006), mood changes (Goel, Rao, Durmer, & Dinges, 2009), poor mental health (Assocation, 2013) and significant neurocognitive deficits (Lowe et al., 2017). Poor sleep has been shown to impair learning ability and academic performance (Seoane et al., 2020) and sleep disturbances are also a risk factor for mortality, cardiovascular disease, diabetes, obesity and are highly prevalent in mental health disorders such as depression (Baglioni et al., 2016; Grandner, 2017; Itani, Jike, Watanabe, & Kaneita, 2017; Ogilvie & Patel, 2018; Strausz et al., 2018; Xie, Zhu, Tian, & Wang, 2017; Zhai, Zhang, & Zhang, 2015) resulting in considerable social, financial and health-related costs. The cost of sleep disturbances to the health system in Australia is estimated to be around $1.8 billion annually and significantly impact healthy life, resulting in almost a quarter of million DALYs due to inadequate sleep, representing $40.1 billion in lost wellbeing (Economics, 2017). The annual cost to the Australian economy in lost work productivity due to sleep disorders is estimated to be around $17.9 billion (Economics, 2017). As a result of these concerns, the Minister for Health, Aged Care and Sport, instigated a parliamentary inquiry into 'Sleep Health Awareness in Australia' to identify the causes, impacts and costs (economic and social) of inadequate sleep and sleep disorders on the community (*Inquiry into Sleep Health Awareness in Australia*, 2018).

Whilst it is acknowledged sleep disturbances varies by age, gender, race, weight, socioeconomic status and specific disease states, societal influences such as technology are gaining attention in polysomnographic research and may explain the rise in the prevalence of sleep difficulties since 2010. General sleep disturbance is most frequently reported in young adults (Grandner, 2017), who also happen to spend the most time using digital devices and time spent surfing the internet most or every night of the week (Adams et al., 2016). Problematic smartphone use impacts around 25% of young adults (Sohn, Rees, Wildridge, Kalk, & Carter, 2019) and a significant body of work has attributed poor sleep quality and sleep disruption with mobile phone use (Exelmans & Van den Bulck, 2016; Ibrahim et al., 2018; Seoane et al., 2020; Tymofiyeva et al., 2020; Yang et al., 2020). What isn't clear is whether the impact on sleep quality is due to RF-EMF exposure or another mechanism such as suppression of melatonin from blue light exposure (Mortazavi et al., 2018), arousal from decreasing the ability to fall asleep, or other factors associated with digital devices (Tettamanti et al., 2020).

Despite the fact wi-fi enabled devices are ubiquitous throughout the home, school and work environment, wi-fi exposure studies are relatively scarce (Sârbu, Miclăuş, Digulescu, & Bechet, 2020). The majority of studies that investigate pulsed radiofrequencies on sleep quality involve near-head exposure to mobile phones in a sleep laboratory or far field exposures from nearby base stations, and reveal inconsistent associations, with limited

statistical power and short if any, follow up (Danker-Hopfe et al., 2016; Fritzer et al., 2007; Loughran, McKenzie, Jackson, Howard, & Croft, 2012; Caroline Lustenberger et al., 2013; Lustenberger et al., 2015; Schmid et al., 2012; Tettamanti et al., 2020; Vecsei et al., 2018). For example, a recent large prospective cohort study (COSMOS) identified insomnia in participants with mobile phone call time >258 min/week, but statistical adjustment suggests this association is likely due to multiple factors (Tettamanti et al., 2020). Nonetheless, it is suggested that the effects of RF-EMF on sleep outcomes are more likely to be seen after longer exposure (>30 min) and with exposure occurring during the entire night (Danker-Hopfe et al., 2016). This is supported by recent laboratory studies in healthy adults that found one-night exposure to a Wi-Fi router resulted in a reduction in global EEG power in the alpha frequency band during NREM sleep (Danker-Hopfe et al., 2020), whereas no measurable effects were seen on spectral power of spontaneous awake EEG with acute Wi-Fi exposure (60 minutes) (Zentai et al., 2015).

To investigate whether short term exposure (seven consecutive nights) to a commonly used radiofrequency device emitting 2.45GHz (baby monitor) would adversely impact subjective and objective sleep outcomes in healthy adults in their home environment, we conducted a randomised, double-blind, placebo-controlled, crossover pilot study.

3. STUDY GOALS AND OBJECTIVES

3.1 Primary objective
To investigate the impact of a 2.4GHz radiofrequency exposure on subjective sleep quality in healthy subjects.

3.2 Secondary objectives
To investigate if exposure to 2.4GHz radiofrequency during sleep impacts on objective sleep measures, heart rate variability and actigraphy.

4. STUDY DESIGN & METHODOLOGY

4.1 Study design
This is a 4-week randomised, double-blind, crossover pilot study in healthy men and women. Twenty healthy adults (18 to 55 years) will be recruited to participate in the study. The four-week study will involve baseline measures (week 1), two weeks of intervention (week 2 and 4) and a washout week (week 3) as illustrated in *Figure 2*. Once accepted into the study, the participants will undergo baseline measures in the first week which will involve daily measures (sleep diary and wearing an Actiwatch). The intervention weeks will be double blinded and will occur in weeks 2 and 4 and involve placing an active or deactivated baby monitor (2.45GHz pulse-modulated radiofrequency device) within 1 metre of the participant's bed for 7 consecutive nights. On the 7th night, participants will be required to wear a Zmachine® to assess sleep efficiency, sleep latency, sleep time, sleep staging and EEG. Participants will also be required to on the 7th night to wear a heart rate monitor (Contec TLC9803) to measure heart rate variability. At the end of each week (8th day), participants will

complete a sleep quality survey (PIRS_20). Week 3 - Washout will involve exactly the same measures as Week 1 – Baseline.

4.2 Participants and recruitment

Potential participants will be identified from the healthy adult population from Melbourne and recruited via an advertisement campaign on social media. Potential participants will be interviewed over the phone to ascertain suitability based on their medical history and inclusion and exclusion criteria using the Participant Screening Questionnaire. If deemed eligible, the Participant Information Consent Form will be emailed to explain the study. This will be followed by a phone call to address any questions they may have and arrange a time to assess their home. An assessment of the home of potential participants will be conducted to explain the study and obtain written permission. In addition, the investigator will conduct environmental measurements in the participant's bedroom at baseline to control for possible confounding variables. These measures include:

- Measuring AC magnetic field with the FM10 Fauser (gauss meter)
- Measuring radiofrequency electromagnetic energy exposure with a high frequency meter: *Gigahertz HF59B HF Analyser* which measures frequencies between 27 MHz to 3.3 GHz (with UBB27 antenna) and *Gigahertz HFW59D* measures frequencies between 2.4 and 10 GHz.

4.3 Inclusion criteria

- Healthy subjects without current sleep disturbance
- Live in a detached home
- Aged between 18 and 55
- Non-smokers
- English speaking and able to give written informed consent
- Willing to avoid digital devices at least one hour before bed
- Willing to go to bed and get up at approximately the same time over the study period.
- Willing to avoid stimulants late in the day
- Willing to abstain from caffeine and alcohol in the evenings during the intervention period (two weeks)

4.4 Exclusion criteria

The exclusion criteria are designed to exclude potential confounding factors that may impact on radiofrequency exposures, and/or physiological or metabolic function. Exclusion criteria includes:

- background of AC magnetic fields exceeds 2 mG or radiofrequencies fields exceeds 10 uW/m2 in the bedroom
- have a smart meter, meter panel or inverter on any of the walls of their bedroom
- need to use a mobile phone during the night
- pacemaker
- BMI greater than 30
- diagnosed with any chronic medical condition that affects sleep (i.e. current or previous sleep disorder, history of renal, cardiac, gastrointestinal, liver, skin, psychiatric disorders or respiratory -other than asthma not requiring continuous medication) or any other condition for which the subject is currently taking medications or in the opinion of the investigators would impede competence, compliance, or participation in the study.

- recent hospitalisation, surgery or antibiotic therapy
- taking any medications or supplements that may interfere with sleep
- pregnant or expect/attempting to become pregnant or impregnate
- peri-menopausal women with menopausal symptoms and irregular menstrual periods
- unable to give informed consent
- travelled across time zones two weeks before or during the study period
- night shift worker or history of night shift work for more than 2 years

4.5 Informed consent process
Prior to entering the participants into the trial, written consent will be obtained from each subject. Information will be given in both oral and written form and participants will be given the opportunity to inquire about the details of the study. The participant will be given a copy of the signed consent form and the original will be maintained with the records of the participant. The consent form will be approved by HREC which is established pursuant to the bylaws of the Royal Melbourne Institute Technology (RMIT) University as a sub-committee of the Research Advisory Council ("RAC") and consistent with the *National Statement on Ethical Conduct in Human Research 2007 (the National Statement)* and the *Australian Code for the Responsible Conduct of Research 2007 (the Code)*.

4.6 Enrolment
The participant will be enrolled in this study after the informed consent document has been signed. The participant will receive a study enrolment number on the first day of study and this will be recorded on all study documents.

4.7 Study intervention
Participants who are accepted into the study will receive each intervention on separate occasions in a randomised crossover sequence (that is computer generated). Interventions will involve a Uniden wireless baby monitor (BW3000 model) with a frequency range of 2.4 to 2.4835GHz and a transmitting power of 15dB that is either active or inactive placed within one metre from their head whilst they sleep. Each intervention will take place over 7-days preceded by a one-week baseline period and separated by a 7-day washout. Participants will be asked to avoid using digital devices, or screens without a blue light filter at least one hour before bed and to complete a sleep diary. The procedure will involve eight visits to the participant's home and participants will be regularly contacted across the study period to ensure compliance and to confirm they understand how to fit and use the devices. An easy-to-follow instruction booklet and instructional video will be created to enable participants to watch anytime during the study period.

4.8 Double blinding and randomisation
The participants and researchers will be blinded to the intervention allocation and the researchers analysing the data will be blinded to the intervention sequence until after the statistical analysis is complete. An independent consultant will activate or deactivate the monitors so that they look equivalent so the researchers and participants don't know the device status. A random code will be assigned to each monitor, and monitors will be provided sequentially (computer generated) to participants with the codes being changed in the second week to an active and deactivated (sham) monitor to ensure the opposite condition will be met.

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4.9 Participant reimbursement

No financial reimbursement will be involved.

Figure 1. Flow chart of the Study

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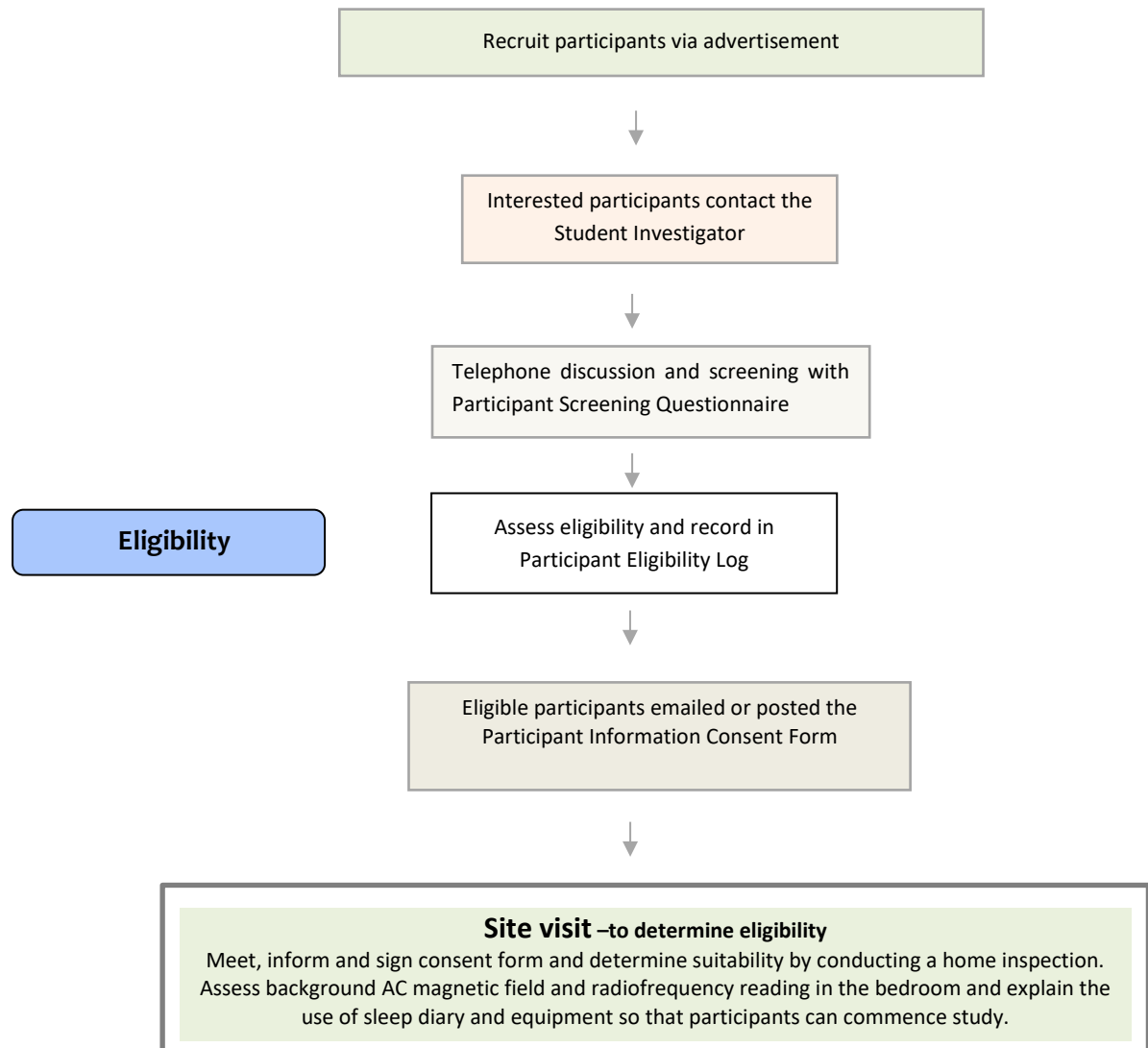
Figure 2: Week by week analysis

Week 1 - **Baseline**

INTERVENTION: None

Baseline assessment:
Daily measures
- Sleep diary
- Actigraphy

Weekly measures
- Subjective sleep quality using the Pittsburgh Insomnia Rating Scale 20 on day 8
- Objective sleep quality (sleep efficiency, sleep latency, sleep time, sleep staging and EEG) on the 7th night using Zmachine
- Heart rate variability on the 7th night using 3 lead Contec TLC9803

Week 2 – **First Intervention (end of first week)**

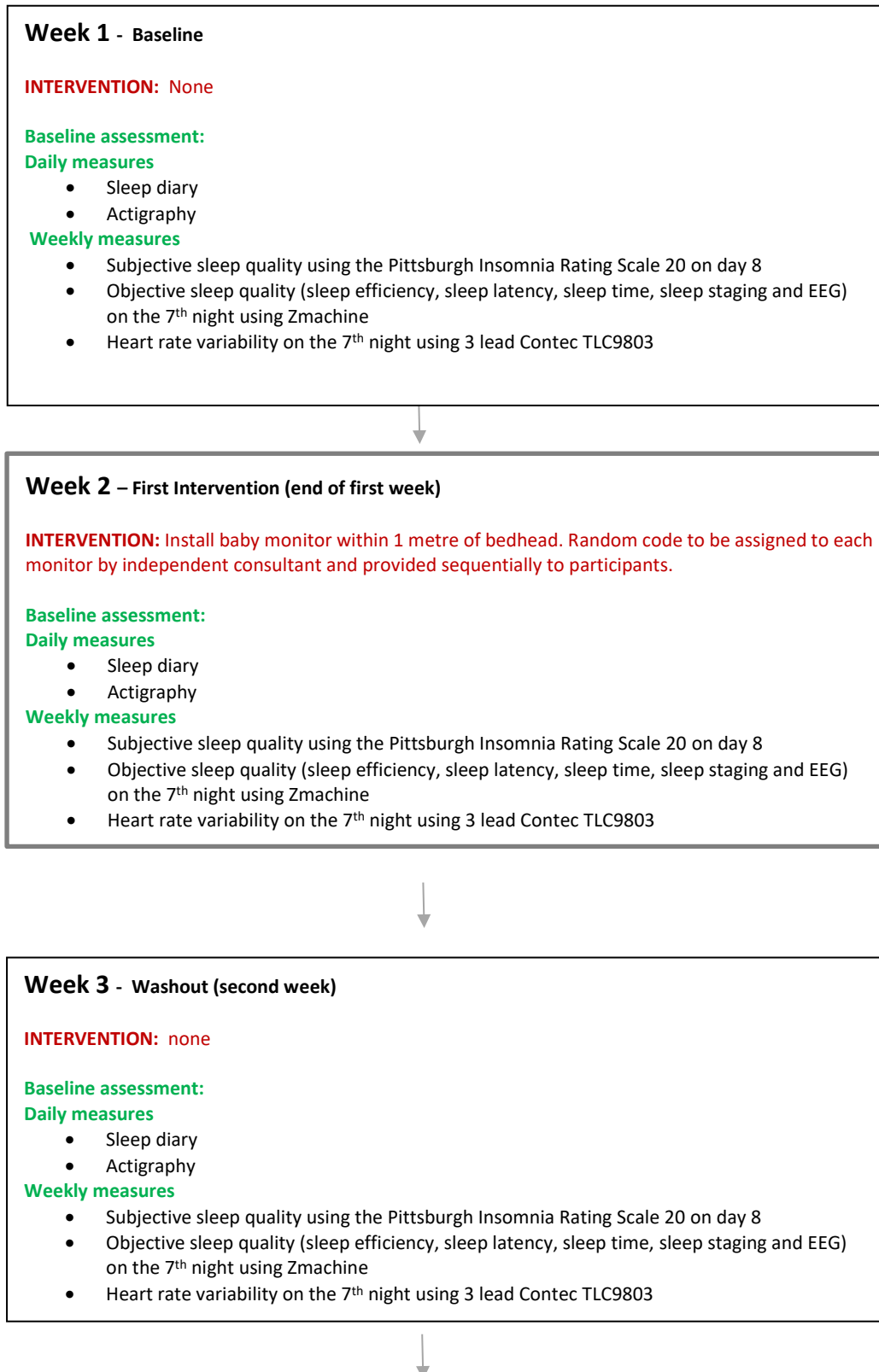**INTERVENTION:** Install baby monitor within 1 metre of bedhead. Random code to be assigned to each monitor by independent consultant and provided sequentially to participants.

Baseline assessment:
Daily measures
- Sleep diary
- Actigraphy

Weekly measures
- Subjective sleep quality using the Pittsburgh Insomnia Rating Scale 20 on day 8
- Objective sleep quality (sleep efficiency, sleep latency, sleep time, sleep staging and EEG) on the 7th night using Zmachine
- Heart rate variability on the 7th night using 3 lead Contec TLC9803

Week 3 - **Washout (second week)**

INTERVENTION: none

Baseline assessment:
Daily measures
- Sleep diary
- Actigraphy

Weekly measures
- Subjective sleep quality using the Pittsburgh Insomnia Rating Scale 20 on day 8
- Objective sleep quality (sleep efficiency, sleep latency, sleep time, sleep staging and EEG) on the 7th night using Zmachine
- Heart rate variability on the 7th night using 3 lead Contec TLC9803

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> **Week 4** - **Second Intervention**
>
> **INTERVENTION:** Install baby monitor within 1 metre of bedhead. Monitor codes changed in second intervention week to ensure the opposite condition is met.
>
> **Baseline assessment:**
> **Daily measures**
> - Sleep diary
> - Actigraphy
>
> **Weekly measures**
> - Subjective sleep quality using the Pittsburgh Insomnia Rating Scale 20 on day 8
> - Objective sleep quality (sleep efficiency, sleep latency, sleep time, sleep staging and EEG) on the 7th night using Zmachine
> - Heart rate variability on the 7th night using 3 lead Contec TLC9803

> **END OF DATA COLLECTION**
> **Data analysis**

4.10 Participant withdrawal

All participants are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice. Where possible, reasonable attempts will be made by the investigator to provide a reason for participant withdrawals. The reason for the participant's withdrawal from the study will be recorded in the participant's source documents.

4.11. Effect size estimate and power calculation

Effect size estimates were based on the findings of Lustenberger et al. (2013) who found a significant decrease in sleep time following Radiofrequency Electromagnetic Field (RF-EMF) Pulses (Mean decrease 9.23 minutes, SD 13.6) (C. Lustenberger et al., 2013). A power calculation based on these results suggested a minimum sample of 20 participants with α = .05 and power of 80%(G*Power 3.1.9.2) (Faul, Erdfelder, Lang, & Buchner, 2007).

4.12. Outcome measures

The following outcome measures will be assessed:
1. Subjective sleep quality using the Pittsburgh Insomnia Rating Scale (PIRS_20) will be completed on the 8th day of each week.
2. Objective sleep quality will be measured on the 7th night of each week using the ZMachine® (Model: DT-200) to determine sleep efficiency, sleep latency, sleep time, sleep staging and EEG power spectrum.
3. Actigraphy data will be measured throughout the study period using a daily sleep diary and the Actiwatch (Actigraph wGT3XZ-BT).
4. Heart rate variability will be measured on the 7th night of each week using the battery operated Contec TLC9803 ECG heart rate monitor with chest straps (no Bluetooth or Wi-Fi capability).

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Table 1: Timing of outcome assessments at each study visit

Parameters	Week 1 (baseline)	Week 2 (intervention)	Week 3 (washout)	Week 4 (intervention)
Height & weight (to calculate BMI at start of study)	✔			
EMF assessment (house)	✔			
Heart rate variability	✔	✔	✔	✔
PIRS20	✔	✔	✔	✔
Actigraphy data (sleep diary and actiwatch)	✔	✔	✔	✔
EEG measures	✔	✔	✔	✔

5. DATA MANAGEMENT & STATISTICAL ANALYSIS

5.1 Data collection
All physiological data will be entered and stored on a password protected computer.

5.2 Data analysis
All data will be analysed by the investigators with assistance from RMIT statistical consulting services when appropriate. Microsoft Excel and the Statistical Package for the Social Sciences software (SPSS Inc., Armonk, New York, USA) will be used for data analysis. Baseline demographic characteristics on categorical and continuous variables such as gender, BMI and age will be summarised. Exploratory analyses of the distributional characteristics of each of the outcome measures (eg.PIRS_20, actigraphy data, EEG measures) will be completed to evaluate the distributions for normality, skewness and outliers. At the baseline assessment, all data across each outcome will be correlated to evaluate the magnitude of association between the measures. Repeated measures ANOVA will be used to evaluate differences across the intervention phases of the study, with $p<0.05$ being considered statistically significant.

5.3 Data storage
During the study, data and project documentation will be stored on password-protected computers and servers. After study completion, all digital data will be stored at RMIT on password protected computers securely for the duration of minimum 15 years.

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5.4 Data confidentiality

All information will remain confidential at all times and be directly entered as electronic data and password protected with access only to researchers involved in the study. No identifiable information/data will be published. Only de-identified individual and group results will be reported and at no time will any identifiable individual results be published.

5.5 Study record retention

Post-completion of study or post-last publication of study results, records will be retained for a minimum of 15 years.

6. ADMINISTRATIVE & ETHICAL CONSIDERATIONS

6.1 Quality assurance

Before the commencement of the trial, the researchers will be trained on the use and management of recording equipment and procedural videos will be created for standardised participant instruction on the use of equipment. One researcher will collect data of each participant. Data will be transferred by this researcher into a database where it will be kept during and after the study. These data will be kept on RMIT University secure password-protected server for 15 years. Only members of research team will have access to the data. Any clinical trial conducted at RMIT University will be supervised and monitored by the University Human Ethics Committee. The RMIT HEC is equivalent to the trial monitoring committee and will provide overall supervision of the trial and ensure that it is being conducted in accordance with Good Clinical Practice (GCP) principles. Data analysis will be performed by a separate member of the research team with coded/blinded intervention conditions.

6.2 Expected outcomes of the study

This will be the first double-blind, randomised, placebo-controlled trial of exposure to 2.45 GHz radiation from a commonly available RF device specifically designed to be located in the bedroom of healthy adults. We anticipate poorer subjective and objective sleep outcomes following short term RF-EMF exposure. In light of the impact of insomnia on human health, these results may have implications for clinical practice and the use of Wi-Fi enabled devices that use 2.45GHz frequency from routers, extenders/boosters, laptops, tablets, printers, and some wireless alarm systems to fitbits and baby monitors, especially whilst sleeping.

6.3 Dissemination of results and publication policy

The collected data and information gained from participants will be analysed and reported as part of a PhD thesis and published in peer-reviewed journals and/or at scientific conferences. All these publications will be made available through the RMIT Repository in the reports as an Appropriate Durable Record (ADR) which is a publicly accessible online library of research papers.

6.4. Duration of the project

Participant recruitment will be undertaken between August and November 2019 and it is anticipated that data collection will be undertaken from October 2019 to February 2020.

6.5. Problems anticipated

Difficulties may arise with participants having issues with the monitoring equipment. To minimise attrition and ensure compliance, there will be eight visits to the participant's home and participants will be regularly contacted across the study period to confirm they understand and are confident to fit and use the devices. An easy-to-follow instruction booklet and instructional video will be created to enable participants to watch anytime during the study period.

6.6. Project management

- Nicole Bijlsma is undertaking her PhD and is the primary investigator. Her role is to formulate the research question along with her supervisor (Prof Marc Cohen), establish study design, recruit and interview participants, assess the home for eligibility and demonstrate use and location of equipment, conduct home visits, and write the paper.
- Dr Russell Conduit, is the primary supervisor who will provide advice on polysomnographic testing, analyse statistical results, and contribute to paper submission.
- Professor Marc Cohen will be involved in establishing the research question and identifying the most appropriate study design and provide advice on paper submission.
- Professor Gerard Kennedy will provide advice on statistical analysis and writing the submission.

6.7 Ethical considerations

Approval No.21794 was obtained from the RMIT Human Research Ethics Committee (HREC). Participation in the study will be purely voluntary and participants will be given a Participant Information and Consent Form to read and sign before participating which will be explained by the investigator.

6.8 Amendments to the protocol

Amendments will be submitted to the RMIT HREC for review prior to implementation as per HREC guidelines.

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