PILOT STUDY

A Pilot Study Evaluating the Feasibility and Efficacy of an In-Home Resonance-Based Electromagnetic Field Protection Device on Improving Markers of Health and Cognitive Function Among a Sample of Healthy Adults

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Abstract

Background: The dramatic increase in exposure to non-native sources of electromagnetic fields (EMF) in recent years has given rise to numerous human health concerns. The near pervasive exposure to radiofrequency (RF) emanating from wireless technologies inside the home (e.g., cell phones, wireless routers, "Smart" devices) and outside of the home (e.g., cell towers, automobiles, computers at work, tablets at school) is particularly troubling. While epidemiological studies are somewhat conflicting to date, RF exposure is currently classified by the World Health Organization as a Class 2B carcinogen. Mechanisms of activity of the deleterious effects of RF exposure on human health include the generation of excessive oxidative stress, chronic inflammation, and disruption of the production of melatonin and other hormones, all of which are believed to be due largely to the activation of voltage-gated calcium channels (VGCC). Mitigation strategies are currently generally limited to wireless device hygiene (e.g., hard-wired ethernet, turning off wireless routers at night, keeping cellphones away from the body) and metal-based shielding in the home, which can be expensive and not feasible for many. The goal of this pilot and feasibility trial was to evaluate the feasibility and preliminary signs of efficacy of an in-home resonance-based electromagnetic field protection device (BluShield) on various physiological and patient-reported outcomes commonly affected by excessive RF exposure.

Methods: A sample of relatively healthy adults was enrolled in a single arm, 12-week pilot and feasibility study. The intervention consisted of plugging in the BluShield device at home or at the participant's residence when traveling. Outcomes included laboratory panels assessing overall physiological health (CBC & CMP), blood markers related to inflammation, oxidative stress, DNA damage, and cellular senescence (Jinfiniti), a high-resolution genome-wide assessment of DNA methylation (TruDiagnostic), a validated questionnaire to assess cognitive function (CNS - Vital Signs), a wearable device to assess sleep and other physiological parameters (Oura ring), and a single-item assessment of overall health. Outcomes were compared before and after the intervention with paired *t* tests or Wilcoxon signed rank tests, depending upon the distribution of data.

Results: 25 participants enrolled in the study. All participants reported compliance with the EMF mitigation device throughout the course of the study, and no adverse events were reported. There were limited changes in conventional labs (decrease in glucose, increase in monocytes; $P < .04$]), but modest improvement in self-reported health ($P = .02$), improvements on numerous domains of the CNS – Vital Signs questionnaire (Composite Memory, Cognitive Flexibility, Executive Function, and Processing Speed; $P < .02$), wearable device parameters (deep sleep, heart rate variability, resting heart rate, and body temperature; $P < .04$), and perhaps most interestingly, hypermethylation of genes involved in RF exposure (including a key VGCC gene [*CACNA1G*]; $P = .000045$).

Discussion: The use of the BluShield is feasible and revealed improvements in some markers of sleep, cognitive function, and overall health. These improvements may be due in part to suppression of VGCC activity, which previous literature has demonstrated is activated by RF exposure and can generate oxidative stress and inflammation. An RF mitigation strategy should focus primarily on limiting modifiable exposures within the home, and the device appears to be a promising component of a comprehensive approach.. Controlled studies are needed to mitigate potential sources of confounding in this single-arm pilot study. A specific focus among populations with excessive RF exposures that are not modifiable within the home, such as those living in high-density urban settings, in close proximity to cell towers, or certain occupational hazards, also appears warranted.

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BACKGROUND

Exposure to radiofrequency (RF) electromagnetic fields has increased dramatically in recent decades. While human beings have always been exposed to low levels of RF emanating from the sun, ionosphere, and other sources native to Earth, far greater exposure to RF began occurring in the latter half of the 20th century with telecommunications, microwave ovens, radar, cordless phones, and other non-native sources. The more recent advent of cellular communication, WiFi, and Bluetooth beginning in the early 2000's, and "Smart" devices throughout the home and workplace in the last decade, has resulted in near-pervasive exposure to RF across the lifespan at levels never witnessed before in human history. While the majority of these exposures occur at frequencies considered non-

ionizing, as they do not generate heat, a large and rapidly growing body of research suggests that high levels of exposure to non-ionizing RF are detrimental to health in a variety of ways.[1]

While these potential harms are often subclinical, some people experience electrohypersensitivity (EHS) with acute exposure to RF. EHS was first proposed in the early 1990s and is marked by symptoms including headache, fatigue, irritability, cognitive dysfunction, and insomnia with acute exposure to cell phones, wireless routers, Bluetooth, Smart devices, and others sources of RF. As evidence of these symptoms continued to mount, the World Health Organization convened an international scientific meeting in 2004 in which they recognized EHS (also called idiopathic environmental intolerance attributed to EMF ["IEI-EMF"]) as "a phenomenon where individuals experience adverse health effects while using or being in the vicinity of devices emanating electric, magnetic, or electromagnetic fields".[2] Perhaps even more concerning from a public health perspective are the risks that have been identified with chronic exposure to RF among the vast majority of those who do not experience acute EHS. Decreases in sperm count, viability, and motility,[3,4] sleep disruption,[5,6] cognitive dysfunction, and increased risk of cancers[8,9] have all been noted with RF exposure. The evidence has warranted non-native RF exposure to be deemed a Class IIb – "possible carcinogen" by the World Health Organization in 2011.[10] Other well-known Class IIb carcinogens include dichlorodiphenyltrichloroethane (DDT), aspartame, lead, and many human papillomavirus (HPV) strains.

There remains some controversy regarding whether there are deleterious human health implications of the non-thermal effects of RF. However, a number of mechanisms underlying the non-thermal harms of RF have been identified, including excessive oxidative stress, DNA damage, endocrine disruption (including melatonin production), and nervous system disruption, one of the most concerning and furthest upstream mechanisms appears to be the activation of voltage-gated calcium channels (VGCC).[1] Persistent activation of VGCC increases intracellular calcium ions, which may give rise to the downstream oxidative stress and disruption of numerous physiological systems.

In light of the ubiquitous exposure in modern life, it is concerning that there are limited options to mitigate the harms of chronic RF exposure. At present, reduction of modifiable exposures (e.g., hard-wired ethernet connection at home, airplane mode when the cellphone is in pocket), in-home shielding with silver and other metal-based materials, and in extreme cases, calcium channel blocker medication usage remain the most common RF mitigation strategies among the electrosensitive and others concerned by chronic exposure. However, these strategies are limited by cost and increasing barriers to feasibility.

Thus, this study aimed to evaluate the feasibility and efficacy of an in-home resonance-based electromagnetic field protection device (Blushield) on various physiological and patient-reported outcomes affected by excessive RF exposure. The Blushield device creates scalar frequencies that are purported to compete with and minimize the harmful effects of non-native EMFs. The research team hypothesized that utilization of the device would be feasible and that there would be signals for efficacy in some of the outcomes under study.

Methods

A single-arm, 12-week pilot and feasibility study evaluating the in-home use of the resonance-based electromagnetic field protection device on health and cognitive function markers was conducted among relatively healthy adults. As an uncontrolled pilot study, blinding to the intervention was not possible. This uncontrolled design was appropriate to evaluate the feasibility of using the device, to reveal any preliminary effects on self-reported measures of health, and to explore a number of potential physiological mechanisms that may be underlying any health effects noted. Ethics approval was obtained by the Institute of Regenerative and Cellular Medicine IRB (protocol 2021-301). There were no incentives provided to participants for completing the study, other than the option to purchase the study device at a reduced cost after completing the study. The trial was registered at ClinicalTrials.gov (NCT05001646).

Study Sample

A convenience sample of 25 relatively healthy adult participants was enrolled in the study. The research team deemed this to be a sufficient sample to evaluate the feasibility of in-home use of the EMF device and offer preliminary signs of efficacy for further evaluation in larger, controlled studies. Informed consent was obtained from all study participants. The specific study inclusion and exclusion criteria are as follows:

Inclusion Criteria. (1) Any sex, gender orientation, and ethnicity; (2) Between ages 30 and 70; (3) Willing and able to participate in venipuncture, health history, clinical assessments, passive monitoring with a wearable device (Oura ring), and continuous in-home Blushield device usage.

Exclusion Criteria. (1) Change in diagnosis and/or treatment of major illness or injury within 2 years prior to screening, e.g., diabetes, cancer, cardiovascular disease, psychiatric condition; (2) Any ongoing immune system concerns or immunodeficiency disease; (3) Body-mass index (BMI) > 35 kg/m^2; (4) Any other illness, disorder, alcohol, or chemical dependence that, in the opinion of investigators, would render study participation unsuitable; (5) Unable or unwilling to provide the required biological sample; (6) Unable or unwilling to avoid pregnancy during the study period.

Intervention

The BluShield intervention under study is an in-home, plug-in device that emits omnidirectional scalar

Figure 1. Clinical trial design. A sample of 25 healthy individuals used the BluShield device for 12 weeks. Multiple outcomes were measured at baseline and after the intervention.

longitudinal waves of multiple coherent frequencies within the human responsive range that are hypothesized to compete with non-native ambient EMFs, thereby presumably mitigating some of the harms incurred by excessive VGCC activation. This is an alternative intervention to the direct blockage of EMFs using silver thread and other metal-based shielding devices. Preliminary data from unpublished in vitro and agricultural animal studies suggest changes in health biomarkers and functional status may be detectable after continuous BluShield device usage.

Each participant used the BluShield device at home for approximately 12 weeks [Figure 1]. Participants who worked outside the home were provided with another plug-in unit, and those who traveled during the course of the study were provided with a smaller, portable device to use while traveling.

Outcomes

The feasibility of the intervention was assessed by the percentage of participants who reported using the device for the full 12 weeks of the study. Any adverse events that led to discontinuation of usage of the device were recorded.

Several markers of health were assessed before and after the 12-week intervention. These include the following blood-based assessments: Comprehensive Metabolic Panel-14 (LabCorp); Complete Blood Count (LabCorp); a multi-protein plus small molecule panel of blood markers related to inflammation, oxidative stress, DNA damage, and cellular senescence (Jinfiniti Precision Medicine); and a high-resolution genome-wide assessment of DNA methylation in whole blood using the Infinium HumanMethylationEPIC BeadChip, in order to estimate biological age as well as perform an epigenome-wide association study (EWAS) to identify probes differentially methylated between the first and the second sample. A validated questionnaire to assess cognitive function (CNS – Vital Signs CORE Clinical Battery) and a self-reported single-item assessment of overall health were also administered before and after the intervention.

In addition to the outcomes assessed at baseline and after the 12-week period, a wearable device was worn for one week prior to the intervention and then continuously throughout the course of the intervention to assess sleep, heart rate variability (HRV), heart rate, respiratory rate, and body and physical activity (Oura Ring). No specific instructions on timing of the wearing of the Oura Ring were provided other than it was to be worn continuously.

Statistical Analysis

Descriptive statistics were computed to characterize the study population. The normality of study outcomes was assessed via Kolmogorov-Smirnov tests. All outcomes were relatively normally distributed and no transformations or non-parametric statistical tests were required. Paired *t* tests were thus utilized to compare study outcomes before and after the intervention. Epigenome-Wide Association Studies (EWAS), which identify genome-wide epigenetic variants (e.g., DNA methylation) associated with specific conditions, was also performed. The EWAS was performed using the *limma* Bioconductor package.[11] We performed a differential mean analysis comparing the samples before and after the intervention to see whether it was associated with changes at specific loci. Based on the available covariates, we adjusted all the regression models by sex, age, and the first three principal components. Statistical significance was defined as $P < .05$ for the paired *t* tests and $P < .0001$ for the EWAS to correct for multiple comparisons following the threshold used in the EWAS catalog.[12] All data were stored in a password-protected database (Microsoft Excel, Redmond, WA). Statistical analyses were conducted in SAS Version 9.4.1 (Cary, NC) and R version 4.3.0.

Results

25 participants were enrolled in the study. The characteristics of the study sample were as follows: the mean [standard deviation] age was 49.1 [9.5] years, 52% were male sex, 100% were Caucasian, 100% had at least a bachelor's degree, and there was a mix of urban (32%), suburban (48%), and rural (20%) place of residence.

The feasibility of the intervention was demonstrated by the fact that all 25 participants (100%) reported using the home and/or travel device during the full 12-week intervention period. 19 of 25 participants (76%) provided complete pre-/post-intervention outcomes data. No adverse events were reported that were related to the intervention device.

Monocytes increased (pre=7.65, post=8.47, $P = .03$), and glucose decreased (pre=89.0, post=82.34, $P = .04$) during the course of the intervention. There were no other significant changes in the Complete Blood Chemistry panel, the Comprehensive Metabolic Panel, or the Jinfiniti Precision Medicine panel ($P > .05$).

There were numerous improvements in the CNS–Vital Signs questionnaire before and after the intervention. The Composite Memory (pre=97.5, post=100.5, $P = .02$), Cognitive Flexibility (pre=41.1, post=49.6, $P = .0007$),

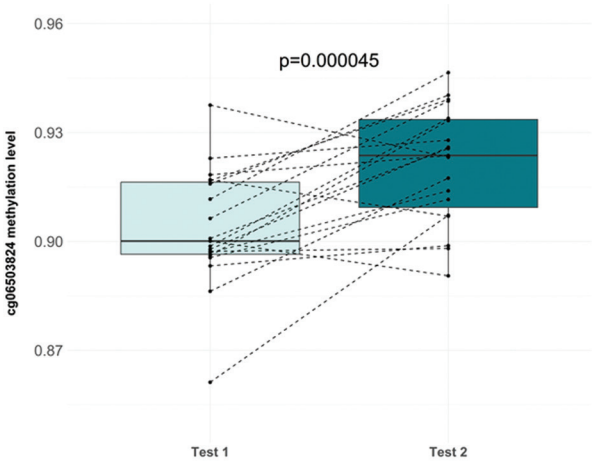
Executive Function (pre=42.0, post=50.7, P = .0004), and Processing Speed (pre=56.6, post=60.8, P = .02) domains all improved during the intervention. There were no changes in the Visual Memory, Reaction Time, Motor Speed, Complex Attention, or Simple Attention domains (P > .05).

There were also a variety of changes in physiological measures during the intervention as revealed by the Oura ring. There were meaningful improvements in five measures and a decline in one measure. Improvement in time in deep sleep (pre=90.8 minutes, post=99.1 minutes, P = .006), average resting heart rate (pre=65.0 bpm, post=63.2 bpm, P = .01), lowest resting heart rate (pre=57.3 bpm, post=56.0 bpm, P = .01), HRV (pre=29.2 ms, post=32.0 ms, P = .006), and daily trend in body temperature (pre=+0.018 C, post=-0.032 C, P = .0006) were noted after utilizing the device. During the intervention, there was an increase in awake time (pre=56.2 minutes, post=61.3 minutes, P = .04).

Study participants also reported improvement in the single-item self-reported health assessment (pre=7.66, post=8.45, P = .02).

The biological age measured in blood using multiple first- and second-generation clocks did not change significantly before or after the intervention. However, we estimated the proportion of 12 immune cell types using a deconvolution method. In brief, DNA methylation is highly cell-type specific and can be measured with high accuracy. As a result, specific patterns can be analyzed to predict individual cell type representation from bulk tissue DNA methylation analysis. This process is called DNA methylation cell deconvolution. Using this method, natural killer cells were significantly reduced in the second time point (P = .032). Finally, the EWAS identified 204 CpG sites that were differentially methylated between the first and second tests with a P < .0001. Remarkably, 94.1% of these probes were hypermethylated after the intervention, indicating a likely under-expression of the affected genes. Moreover, we used the GREAT software to perform enrichment analysis of the hypermethylated CpG sites, and we identified the ATP-sensitive potassium channel complex cellular component as significantly enriched (P = .0007). Among them, cg06503824 was mapped to the *CACNA1G* gene (P = .000045), which is one of the 18 VGCC genes [Figure 2] . Four other VGCC genes had CpG sites whose P value was close to the threshold but did not raise significance. They were *CACNA1A* (cg18292244, P = .00015), *CACNA1H* (cg03574765, P = .00043), *CACNA2D1* (cg00712593, p=0.00056; cg06398855, P = .00075), and *CACNA1B* (cg14040034, P = .00087). In all cases, the CpG sites were hypermethylated after the 12-week period.

Figure 2. Boxplot showing the differences in cg06503824 (CACNA1G) methylation levels between the first and the second test. The first test is before the intervention and the second one is after the intervention. Each dashed line represents the evolution of the CpG methylation in each participant. The P value is calculated using limma by fitting a linear model adjusting by age, sex, and technical batches.



Discussion

This pilot clinical trial found that using a resonance-based electromagnetic field protection device at home was feasible. It improved several markers of cognitive function, sleep, and self-reported overall health among a sample of healthy adults. Some of these findings (e.g. CNS Vital Signs questionnaires, improvements in deep sleep, and glucose decrease) are likely more clinically meaningful than others (e.g. slight improvement in self-reported health). Interestingly, the sleep and readiness metrics measured on the Oura Ring appear to align with the improvements noted in cognition, dovetailing on a robust literature linking sleep and cognition.[13] Two potential mechanisms underlying these findings were also identified in this study, including a potential reduction in inflammation (natural killer cells) and hypermethylation of a key VGCC gene (cg06503824 mapped to *CACNA1G*) that has previously been shown to be activated with EMF exposure.[14] Methylation of this VGCC gene, as well as some of the other VGCC genes, may be reducing the excessive intracellular calcium ions, and the downstream oxidative stress and multisystem dysfunction, generated by expression of these genes. No adverse events were reported in the study. Collectively, this study's results suggest that this device may be a safe adjuvant for use alongside other EMF mitigation strategies. This is the first study of an EMF mitigation device of this nature and future studies will be required to enable comparison of feasibility, health effects, and underlying mechanisms of activity.

With the exponential increase and pervasive use of wireless technologies in modern society, the potential health impacts of radiofrequency (RF) exposure are a growing concern. Adverse outcomes have been observed in experimental studies on a wide variety of cellular effects, including genotoxicity, proliferation and signaling, gene expression, and membrane function, among others. RF remains classified by the International Agency for Research on Cancer (IARC) of the WHO as "possibly

carcinogenic to humans" based on an increased risk for glioma associated with wireless phone use.

There has also been an increase in reports of subjective symptoms of acute electromagnetic hypersensitivity in recent years. Symptoms attributed to RF are typically nonspecific and constitutional, e.g., headache, dizziness, cognition or sleep impairment, fatigue, while others may be associated with specific sources based on presentation, e.g., vision or eye irritations related to screen use and hearing problems with cell phone use. No distinct diagnostic criteria have yet been identified, nor has EHS yet been demonstrated to constitute a discrete medical problem with related biological marker(s) or diagnostic tests. However, the design and execution of studies that could properly account for the numerous confounding factors inherent in isolating adverse effects of RF exposure are challenging to conduct due to the near omnipresence of these exposures and may explain a significant portion of these discrepancies to date.

Several mechanisms, including excessive inflammation, oxidative stress, DNA damage, neuroimmune modulation, and disruption of the production of melatonin and other hormones, have all been suggested as potentially contributory to increased risk of chronic disease and symptomatology of RF exposure among many people. Most of these deleterious mechanisms of RF exposure are believed to be due to the activation of VGCC genes that flood cells with excessive amounts of calcium. Interestingly, the hypermethylation of a key VGCC gene (*CACNA1G*) noted with the BluShield device might contribute to the improvements in sleep, cognitive function, and overall health noted in this study. The authors suspect that the positive outcomes may be due to decreased VGCC activity with the device's usage, which could have led to increased melatonin production and reduction of some markers of inflammation, although further studies are needed to confirm the hypothesis.

Strengths of the study include excellent compliance with the EMF device under study, a diverse set of outcomes that offer insights into both clinical effects and potential underlying mechanisms, and a healthy study population with limited exclusion criteria that offers considerable external validity to the findings. However, several limitations of this study are worthy of mention. First, the lack of a control group introduces many sources of confounding to the study. It is possible that some of the positive outcomes in this study plausibly attributed to the device were confounded to some extent by other variables, including changes in other health-promoting modifiable lifestyle factors (e.g. diet, physical activity). Indeed, while not an a priori outcome of the study, it was noted that physical activity was higher during the intervention than before the intervention (an increase of 1633 steps, $P < .0001$). It is unclear whether the improved sleep and physiological measures in the study contributed to that increase in physical activity or vice versa. Thus, a stronger causal inference could be obtained with controlled studies of the device to help reduce such sources of potential confounding. Another limitation is that while the study sample was drawn from a wide range of areas of residence across urban, suburban, and rural areas (thereby providing a sample with a broad range of environmental RF exposure), it was relatively homogenous in other ways. For instance, the sample consisted exclusively of Caucasian participants with at least a college degree. Future studies with a more diverse study sample will help reduce bias and further expand the inference of the findings, with respect to feasibility, health effects, and underlying mechanisms. Finally, while the sample of relatively healthy adults offers broader generalizability than a sample limited to a specific chronic disease, the research team suspects that the healthy sample resulted in some ceiling effects on study outcomes. For instance, there was limited room for improvement in most analytes on the CBC, CMP, and the multi-protein small molecule panel. Even among the outcomes for which improvements were noted in this study (e.g., sleep, cognitive function, overall health), most participants had relatively limited room for improvement. Future controlled studies among participants reporting poor overall health, sleep disturbances, or cognitive dysfunction might identify a greater effect size due to a greater potential delta from baseline.

In summary, the BluShield device appears to be feasible, safe, and associated with promising improvements in sleep, cognitive function, and overall self-reported health among relatively healthy adults. At this juncture, the BluShield device appears to be a reasonable component of a more comprehensive EMF mitigation strategy to minimize RF exposure (e.g., hard-wired ethernet at home or turning off the WiFi router at night, usage of the speaker and other methods to avoid placing a cellphone to the head, minimizing the use of unnecessary "Smart" devices at home). Future controlled studies in more diverse populations and in samples with more extreme non-modifiable RF exposures (e.g. high-density urban settings) or specific chronic conditions associated with EMF exposure (e.g. anxiety, insomnia, headache) will be helpful in reducing confounding, establishing causal relationships, enhancing generalizability, and further elucidating mechanisms of activity.

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