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IEI-EMF provocation case studies: A novel approach to testing sensitive individuals

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Abstract

The etiology of Idiopathic Environmental Intolerance attributed to Electromagnetic Fields (IEI-EMF) is controversial. While the majority of studies have indicated that there is no relationship between EMF exposure and the symptoms reported by IEI-EMF sufferers, concerns about methodological issues have been raised. Addressing these concerns, the present experiment was designed as a series of individual case studies to determine whether there is a relationship between RF-EMF exposure and an IEI-EMF individual's self-reported symptoms. Three participants aged 44-64 were tested during a series of sham and active exposure trials (2 open-label trials; 12 randomized, double-blind, counterbalanced trials), where symptom severity and exposure detection were scored using 100mm visual analogue scales. The RF-EMF exposure was a 902-928 MHz spread spectrum digitally modulated signal with an average radiated power output of 1 W (incident power density at the participant 0.3 W/m^2). In the double-blind trials, no significant difference in symptom severity or exposure detection was found for any of the participants between the two conditions. Belief of exposure strongly predicted symptom severity score for all participants. Despite accounting for several possible limitations, the present experiment failed to show a relationship between RF-EMF exposure and an IEI-EMF individual's symptoms.

Keywords: idiopathic environmental intolerance; electromagnetic hypersensitivity; radiofrequency; electromagnetic fields

Introduction

A small proportion of the population report experiencing a wide range of non-specific symptoms which they attribute to the electromagnetic fields (EMF) emitted by various electronic and wireless technologies. Commonly referred to as Electromagnetic Hypersensitivity (EHS), the condition is characterized by a variety of dermatological, neurasthenic and/or vegetative symptoms, with headaches, nausea, skin irritations, fatigue and concentration difficulties amongst the most commonly reported symptoms [Hagström et al., 2013; Hillert et al., 2002; Kato and Johansson, 2012; Rösli et al., 2004]. Generally, the reported symptoms are claimed to be triggered by technologies which emit EMF in the radiofrequency (RF-EMF) and extremely low frequency (ELF-EMF) domains of the non-ionizing radiation spectrum, at levels well below the thresholds known to cause adverse health effects in humans [ICNIRP, 1998; ICNIRP, 2010]. These devices include mobile phones and their base-stations, Wi-Fi, electricity transmission and distribution systems, and ‘smart’ meters. The condition can have major implications for an individual’s quality of life and is often associated with decrements in general health status, increased levels of distress, increased levels of health service use and serious impairments in occupational and social functioning [Johansson et al., 2010].

Yet, despite the considerable prevalence of the condition globally (estimated to be between 1.5 – 13.5%) [Baliatsas et al., 2015; Blettner et al., 2009; Eltiti et al., 2007b; Hillert et al., 2002; Levallois et al., 2002; Schreier et al., 2006; Schröttner and Leitgeb, 2008; Tseng et al., 2011], recent reviews of the scientific literature have concluded that there is no relationship between exposure to EMF and the non-specific symptoms reported by EHS individuals [Health Canada, 2015; Health Council of the Netherlands, 2009; Rösli et al., 2010; Rubin et al., 2005; Rubin et al., 2010; SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), 2015]. This discrepancy between the scientific consensus and the

subjective reports of sensitivity to EMF not only limits the treatment options and support for those who experience EHS, but also leaves some members of the public feeling uncertain and anxious about potential adverse health effects of EMF exposure. Due to the lack of evidence for an association between exposure to EMF and EHS, the World Health Organization recommended that the term Idiopathic Environmental Intolerance attributed to Electromagnetic Fields (IEI-EMF) be used in place of EHS to avoid implying a causal role of EMF in producing the reported symptoms [World Health Organisation, 2004].

Experimental provocation studies have been predominately used as a means of investigating IEI-EMF. In these studies, a participant is exposed to both active and sham EMF under controlled, preferably double-blinded protocols, while their symptomatic response to each condition is monitored. Over the past decade, a number of provocation studies using a range of EMF and varying methodologies have failed to provide sufficient evidence to support the view that IEI-EMF is directly associated with exposure to EMF [Rubin et al., 2010; SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), 2015; World Health Organisation, 2014]. Indeed, sham exposures alone have been found to be sufficient to trigger symptoms in IEI-EMF participants [Nam et al., 2009; Oftedal et al., 2007; Wilén et al., 2006]. Two studies have also reported an increase in symptoms in an initial non-blinded active exposure condition, compared to sham, but have then found no significant differences between active and sham conditions in subsequent double-blind trials [Eltiti et al., 2007a; Wallace et al., 2012]. Similarly, a recent study reported that IEI-EMF participants were unable to correctly identify when they were being exposed under double-blind conditions, despite an initial verification that they could detect active from sham conditions in an open-label trial [van Moorselaar et al., 2017]. These findings have led many to suggest that IEI-EMF may be the result of a nocebo response, where conscious or subconscious symptom *expectation* following a *perceived* exposure to EMF leads to the

formation or detection of symptoms [Hillert et al., 2008; Landgrebe et al., 2008b; Oftedal et al., 2007; Rubin et al., 2010]. Recent findings from a qualitative study, however, suggest that instead of the condition originating from a nocebo response, IEI-EMF individuals may be using the notion of sensitivity to EMF to provide a narrative to explain their medically unexplained symptoms (MUS) in an effort to make their condition more practically and emotionally manageable [Dieudonné, 2016].

Although the reviews cited above have failed to support the view that EMF exposure was related to symptoms in self-diagnosed IEI-EMF participants, it is important to note that there are a number of studies that have claimed to identify such relations, and which are often used in support of the claim that there is a causal relation. However, such studies do not provide the claimed support, but are more easily explicable in terms of methodological considerations. For example, McCarty et al. [2011] claimed an effect of on-off electric field transitions, but as the study was later criticized for lacking clear methodology, and given that it has not been replicated, this cannot be taken as evidence for a relation [Rubin et al., 2011; Rubin et al., 2012]. Similarly, Kwon et al.[2008] reported that two healthy participants were able to detect EMF at greater than chance levels, but they could not replicate their results in the same individuals a month later, which suggests that whatever caused the initial significant results, it is unlikely that it was due to a bioelectromagnetic phenomenon.

In line with the focus on methodology, both advocacy groups and some researchers have argued that the null results are due to methodological limitations, such as a failure to account for the heterogeneous nature of the condition and the way in which participants have been selected and tested. For example, it is possible that the samples tested have included a combination of both individuals who are sensitive to EMF and others who may suffer from unrelated conditions [Rubin et al., 2010]. This is problematic, as the majority of studies have

taken a nomothetic approach to testing IEI-EMF, and have therefore relied on group means which may have had potentially reduced statistical power due to the noise added to the analysis from non-responders. In addition, few studies have tested whether the exposure signal used was relevant in eliciting symptoms for each individual in the sample, which again may have potentially made the RF-EMF exposure irrelevant for many of the participants. Furthermore, while the experience of IEI-EMF is known to vary considerably between individuals in terms of the type and severity of symptoms experienced and the amount of time required for symptoms to develop and subside following exposure [Hocking, 1998; Rösli et al., 2004], the majority of provocation studies have not taken this heterogeneity into account. Instead, studies have generally used relatively standard exposure and wash-out periods across all participants, which, without verification of an open-label effect using the particular study protocol, may again make the protocol irrelevant to the reported EMF-symptom relation and make interpretation problematic.

Concerns have also been raised about whether the testing environments of provocation studies adequately reflect the conditions in which IEI-EMF individuals report symptoms. It is possible, for instance, that the laboratory setting has caused some participants to experience anxiety, which may have then affected their symptom response. It is also possible, on the assumption that there is a relation between EMF and symptoms, that participants have encountered other EMF exposures on the way to an experimental session which have then inadvertently triggered symptoms [Rubin et al., 2010]. If symptoms had been triggered by external factors prior to the experimental manipulation, this would also increase the error variance and potentially mask any real effects. However, although it is logically possible that these limitations have masked real effects of EMF on symptoms, it is important to point out that there is no substantiated evidence that this is the case; such issues need to be determined empirically.

In light of this, the present experiment was designed as a series of individual case studies to determine whether there is a relationship between RF-EMF and an IEI-EMF individual's self-reported symptoms, employing several important methodological improvements in order to overcome potential limitations of previous studies. First, the study utilized a portable exposure device which enabled double-blind testing to take place in environments where participants generally felt safe and asymptomatic, such as in their own home. This was implemented in order to reduce the stress and anxiety which may be experienced by a participant in a laboratory setting, while also reducing potential confounding effects associated with inadvertent exposures to environmental EMF emissions on the way to an institutional testing location. Second, the methodology incorporated a consideration of each participant's IEI-EMF symptom history. This included using a similar RF-EMF exposure to the one which the participant claimed triggers symptoms, and both the exposure source and reported symptoms were individually verified in an initial open-label, non-blinded trial. This limits potential 'non-responder' data from statistically confounding 'responder' data. Further to this, the study included a consideration of the reported symptom onset and recovery periods, such that the testing regime, if necessary, could be modified to incorporate these. A sufficient number of sham and exposure conditions were also used to determine statistically, within the individual, whether any symptom/exposure relation was significant. Finally, the design incorporated a fully counter-balanced protocol in order to reduce time of day and time on task effects. The aim of the study was first to test whether exposure to RF-EMF from the portable exposure device resulted in an increase in an IEI-EMF participant's nominated symptom compared to sham, and second, to determine whether IEI-EMF participants could detect the active RF-EMF signal at greater than chance levels, under double-blind conditions.

Materials and Methods

Participants

In total, twenty-five potential participants contacted the research center during the recruitment period. Of these, three participants aged 44-64 (two male) completed the study. Six participants were excluded from the study in an initial phone screen due to not meeting the eligibility criteria. The remaining sixteen participants either expressed that they did not want to continue participation in the study (after receiving a participant information sheet and speaking with the researchers via telephone) or could not be re-contacted by the researchers.

Participants were recruited through advertisements on the research center website and via a press release in the local newspaper and television network. All participants were first screened via a telephone interview to confirm eligibility for the study. To be included in the study, participants must have reported one or more *acute* symptoms which they attributed to the use of or to their personal proximity to mobile phone or Wi-Fi devices. Acute symptoms were defined as any symptom with an onset time of less than 30 min and which took less than 2 h to subside following exposure, and that could be self-managed without the need of a health professional. Participants must have also self-diagnosed or labelled themselves as having EHS or IEL-EMF for greater than 1 year. Participants were excluded from the study if they reported any serious medical or psychological illnesses, or indicated that they used recreational illicit drugs.

A mutually convenient testing time was arranged with suitable participants. The study was approved by the Human Research Ethics Committee (University of Wollongong: HE15/160), and informed written consent was obtained from all participants.

Radiofrequency Exposure

RF exposure was generated using a portable, self-contained, battery-operated device (Two Fields Consulting, St Kilda, Australia). The RF device was placed 30 cm from the participant (either on the side or to the front depending on what was comfortable for the participant) on a hard surface. The main exposure from the device was a spread spectrum RF signal in the 902-928 MHz ISM band which was digitally modulated in a similar manner to signals from Wi-Fi and 3G and 4G mobile phones. The RF signal was generated by a commercial RF modem which emitted a frequency hopping spread spectrum signal with an average radiated power output of 1 W for 30 min, or was completely EMF silent (RF OFF, sham trials). The incident RF exposure level from the side of the device facing the participant was measured using a calibrated broadband instrument with an uncertainty of ± 2.4 dB for a two-sided coverage interval and a coverage factor of 2 (Narda EMR 300 meter and Type 9 E-field probe, Narda Safety Test Solutions, Hauppauge, NY), and was found to be 0.3 W/m^2 . This RF exposure level is below the power density reference level limit of 4.6 W/m^2 specified for the Australian general public (ARPANSA RPS3) and by the ICNIRP (1998). It is important to note that the maximum localized specific absorption rate (SAR) from the exposure device used in the present study is less than that which typically results from personal mobile phone use (held against the ear in the active talking mode) due to the greater separation distance. Conversely, the whole body averaged SAR and localized SAR of the device used in the present study is greater than that which normally results from Wi-Fi and mobile phone base station signals. The device was fully enclosed in a thermally insulated case and coded inputs were used to maintain double-blinding. The device contained an independent RF monitor to check the status of the RF transmitter and each use of the device was logged using internal memory. The fields emanating during the RF ON exposure and sham conditions were demonstrated to each participant in the open-label trial using a Nardalert S3 broadband

monitor (Narda Safety Test Solutions, Hauppauge, NY). This monitor was then removed for the subsequent double-blind testing.

Questionnaires

Demographic and health questionnaire

Demographic and health screening questionnaires were used to capture data on the age, handedness, education level, gender, general medical condition, and caffeine, tobacco, alcohol, illicit and medically prescribed substance use of each participant.

Symptom history questionnaire

Two open ended questions were used to assess each participant's symptom history. These were "What are the two most immediate EMF symptoms you experience?" and "Do you suffer from any debilitating EMF symptoms?" Participants were asked to include information on the source perceived to be responsible for triggering the symptoms, the symptom severity, the time of onset and the time needed for the symptom to subside, the first time the symptom was experienced and any treatment methods used to relieve the symptom. Participants were also asked to indicate any other EMF symptoms which they regularly experienced on a checkbox list of 11 common IEI-EMF symptoms [Rubin et al., 2006].

WHOQOL-BREF

The WHOQOL-BREF [World Health Organisation, 1998] assesses how disease impairs the subjective well-being of a person across a range of domains. The questionnaire comprises 26 items, which measure quality of life in the following broad domains: physical health, psychological health, social relationships, and environment.

Symptom and Exposure Status Scale (SESS)

During the provocation trials, participants were asked to indicate symptom severity and exposure status via pen and paper 100mm visual analogue scales. Participants were asked

“how sure are you of the current exposure status *right now?*” anchored with the terms ‘Definitely OFF’ and ‘Definitely ON’, and “how strong/unpleasant is your nominated symptom *right now?*” anchored with the terms ‘Barely Detectable’ and ‘Maximum Severity’. While a full symptom history was obtained from each participant prior to testing, the symptom tested in the double-blind trials was defined as the most immediate symptom triggered during the initial open-label RF ON trial.

Design

Each participant’s symptom severity and exposure detection ability was tested under a series of 14 sham and active provocation trials. On the first day of testing, two open-label trials (1 RF OFF, 1 RF ON) were conducted, where both the participant and the researcher were aware of the exposure status. This was used to determine whether the exposure device could trigger individually-relevant symptoms in each participant. If a participant did not report symptoms or was unable to detect the exposure in the RF ON condition in this initial test, their participation in the experiment ceased at this point. The initial open-label trials were followed by a series of 12 double-blind, randomized, counterbalanced trials, consisting of 6 sham and 6 RF ON exposure conditions. This was achieved using the Excel randomization command, such that a sham and RF ON condition were treated as a pair; the conditions of each pair were randomly allocated before assigning the next pair; where more than two sequential pairs had the same order the third pair was replaced with the alternate pair order; and no more than three of the same pair-order were permitted. In total, each trial ran for 105 min (except for the RF OFF open-label trial, where there was no post-trial assessment or rest interval as there had been no exposure). For each participant, the 14 trials took 24 h to complete, spread over a period of 3 consecutive days (the number of RF ON and sham trials were matched within each day).

Testing Location

Testing was conducted in a safe, asymptomatic environment (determined by the participant) in order to reduce stress and to reduce any confounding effects due to environmental RF emissions. In all three cases, participants chose (and were tested in) their own home.

Procedure

Upon arrival at the participant's home, the researchers set up the exposure device in a comfortable area and ensured that all known electronic and RF emitting devices were switched off. All participants were then given a verbal description of the ensuing session before completing demographic and health screening questionnaires. To begin the provocation trials, participants were asked to sit comfortably in a chair with the exposure device placed approximately 30 cm from them (either to the side or in front of them, depending on what was comfortable for the participant). The progression of each provocation trial is shown in Figure 1. The first day of testing began with two open-label trials. The first open-label trial was an RF OFF (sham) trial, which began with a 15 min baseline interval (no exposure; status known to participant and researcher) to assess the participant's symptom severity pre-trial. The SESS was completed at the 1- and 14-min mark (B1 and B2) of the trial. This was followed by a 30 min exposure interval, where the exposure device was switched to an RF OFF (sham) setting (exposure status known to the participant and researcher) and the SESS was again completed at the 16-, 30- and 44-min mark of the trial (E1, E2 and E3). The RF OFF open-label trial was immediately followed by the RF ON (active) open-label trial. Again, a 15 min baseline interval (no exposure; status known to participant and researcher) was used to assess the participant's symptom severity pre-trial. The SESS was completed at the 1- and 14-min mark (B1 and B2) of the trial. This was followed by a 30 min exposure interval where the exposure device was switched to an RF ON setting (exposure status known to the participant and researcher) and the SESS was

completed at 16-, 30- and 44-min mark (E1, E2 and E3) of the trial. The exposure interval was then followed by a 30-min post-exposure assessment (no exposure; status known to the participant and researcher), where the SESS were again completed at the 46-, 60- and 74-min mark (PE1, PE2 and PE3) of the trial. The post-exposure interval was followed by a 30 min rest interval, where the participant was free to move around, rest and consume food and water before the onset of the next trial. The subsequent 12 double-blind trials followed the same progression as the open-label RF ON trial, except that during the exposure interval, the exposure device was set to either sham or RF ON (status unknown to the participant and researcher) depending on randomization and counterbalancing.

Statistical Analysis

Statistical analyses were performed with SPSS statistical package 21.0. For each individual, a Mann-Whitney U test was used to assess the difference in symptom severity and exposure detection ability, comparing the 6 sham to the 6 RF ON double-blind exposure conditions (which are treated as independent). This provides power (0.80) to detect effect sizes of > 1.6 with an $\alpha = 0.05$, which is consistent with the (anecdotal) reports of effect sizes from IEI-EMF sufferers (who claim to be able to reliably detect and/or suffer symptoms from EMF). It is important to note that there are currently no effect sizes related to actual effects of exposure, which is why one based on anecdotal reports of IEI-EMF has been used. The primary dependent variable was the difference between the baseline score at 14 min of the trial (B2) and the exposure score at 44 min of the trial (E3), for both symptom severity and exposure detection. A difference score was used to minimize the influence of baseline variability and potential carry-over effects. In order to determine the magnitude of the effect induced by the open-label exposure for each participant, an effect size was calculated, based on the difference in symptom severity for the RF ON and RF OFF condition. However, because there is no measure of variability in the open-label trial, the experimental double-

blind data was used to calculate a standard deviation. To achieve this, the effect of belief of exposure first needed to be removed. To do this, a simple linear regression was conducted to predict symptom score based on how confident each participant was that the exposure was on or off in the double-blind trials (belief of exposure), and unstandardized residuals were calculated. The unstandardized residuals were then used to calculate the standard deviation, which could then be used in the effect size calculation of the open-label trials. These linear regressions also provided important information regarding the potential relation between belief and symptom severity for each participant via the resultant r-squared values.

Results

General health status

The participants did not report any severe medical or psychological conditions. One participant reported suffering from tinnitus and one participant was on thyroid hormone replacement therapy but was clinically euthyroid at the time of the tests.

Effect size in the open-label trials

Confirming that the open-label manipulation had worked in each case, all of the calculated effect sizes in the open-label trials were extremely large (P01 = 5.97, P02 = 3.66, P03 = 6.98), and much larger than the traditionally used nomenclature of Cohen [1988], which treats the largest category of effect size as $>.5$.

Participant 1 (P01):

Symptom history

The two most common immediate symptoms the participant reported experiencing in response to EMF were headache (severity 8/10) and dizziness (severity 8/10), with an onset time of 10 min and taking up to 2 h to subside. The two most common debilitating symptoms

reported by the participant were Vertigo (with an onset time of 12 to 24 h following exposure and taking up to 2 days to subside), and confusing thoughts (onset time and time needed to subside not known). The participant also reported experiencing nausea, fatigue, eye pain, skin itching, sensation of burning on the skin, memory loss, insomnia and immune system deficiency. These symptoms were attributed to mobile phone base stations, Wi-Fi, mobile phones and wireless phones. The symptoms developed 5 years prior to testing. Although the participant reported a number of symptoms, headache was reported as the immediate symptom in the RF ON open-label trial and used as the symptom assessed in the double-blind trials.

Exposure Detection and Symptom Provocation

Open-label trial: The results of the open-label trial are shown in Figure 2a. In the RF ON condition, the participant was confident that the exposure device was emitting RF, and experienced an increase in symptom severity from baseline throughout the trial. As shown in Figure 2a, the severity of these symptoms gradually decreased during the post-exposure interval. These results indicate that the participant developed symptoms and reported detecting the active RF signal. A gradual decrease in symptom severity post-exposure was also observed. The participant did not detect the presence of RF or exhibit an increase in symptom severity in the RF OFF condition.

Double-blind trials: The results of the double-blind trials are shown in Figure 2b. Symptom severity (*Median* = 14.00 versus 34.00, $U = 15.00$, $z = -.481$, $p = .699$, $r = .139$) and detection ability (*Median* = 54.50 versus 86.50, $U = 17.50$, $z = -.087$, $p = .930$, $r = .025$) did not differ significantly between the RF ON and sham trials respectively. The regression analysis showed that 'belief of exposure' significantly predicts symptom severity ($F(1, 10) = 48.799$, $p < .001$; $R^2 = .830$).

WHOQOL-BREF

As shown in Table 1, the participant's overall quality of life, physical health, psychological health and overall health scores are below the mean population norm (but within one standard deviation). The social relationships and environment scores are above the population norms.

Participant 2 (P02):

Symptom history

The two most common immediate symptoms the participant reported experiencing in response to EMF were feelings of 'induced hangover' with an onset time of 30 seconds to 5 min (severity 5/10) and a burning sensation in the throat (severity 5/10) with an onset time of 4 to 5 min. The participant reported that the time symptoms take to subside can vary substantially depending on the exposure, but estimated a range of between 30 min to 4 h. No debilitating symptoms were reported by the participant. The participant also reported experiencing eye pain and spots on the face. The reported symptoms were attributed to mobile phones and developed 16 years prior to testing. Although the participant reported a number of symptoms, a burning sensation in the throat was reported as the immediate symptom in the RF ON open-label trial and was therefore used as the symptom assessed in the double-blind trials.

Exposure Detection and Symptom Provocation

Open-label trial: The results of the open-label trial are shown in Figure 2c. In the RF ON condition, the participant was confident that the exposure device was emitting RF, and experienced an increase in symptom severity from baseline throughout the trial. The severity of this symptom fluctuated during the post-exposure interval. These results indicate that the participant developed an individually relevant symptom and reported the presence of the

active RF exposure. In the RF OFF trial, the participant did not report the presence of RF but a slight increase in symptom severity was also observed.

Double-blind trials: The results of the double-blind trials are shown in Figure 2d. Symptom severity (*Median* = 6.50 versus 2.50, $U = 14.00$, $z = -.656$, $p = .512$, $r = .189$) and detection ability (*Median* = 49.00 versus 15.50, $U = 8.00$, $z = -1.601$, $p = .109$, $r = .462$) did not differ significantly between the RF ON and sham trials respectively. The regression analysis showed that ‘belief of exposure’ significantly predicts symptom severity ($F(1, 10) = 79.290$, $p < .001$; $R^2 = .888$).

WHOQOL-BREF

As shown in Table 1, the participant’s overall quality of life score is below the population norm, overall health score above the population norm, and the remaining domains are within the population norms.

Participant 3 (P03):

Symptom history

The two most common immediate symptoms the participant reported experiencing in response to EMF were feelings of pain and strain in the head and ears with an onset time of 1 to 5 min (severity 5/10), which they attributed to Wi-Fi. The participant reported that these symptoms subside within 5 to 15 min. The participant also indicated that they experience headache, mild dizziness, fatigue, tinnitus, and “sensations which self-highlight in the knees, elbows, tendons and lower arms” which they attributed to EMF exposure. The participant also reported experiencing a heavy head and eyelids, memory loss, pain and strain, and a tingling sensation attributed to EMF from television, however, the symptomatic response to EMF from television was unable to be tested in the current protocol. The reported symptoms developed at least 12 years prior to testing. Although the participant reported a number of symptoms, a feeling of pain and strain in the head and ears was reported as the immediate

symptom in the RF ON open-label trial and was therefore used as the symptom assessed in the double-blind trials.

Exposure Detection and Symptom Provocation

Open-label trial: The results of the open-label trial are shown in Figure 2e. In the RF ON trial, the participant was confident that the exposure device was emitting RF and they experienced an increase in symptom severity during the trial. The severity of this symptom decreased during the post-exposure interval. In the RF OFF trial, the participant did not report the presence of RF but there was a decrease in symptom severity from baseline. These results indicate that the participant developed symptoms and reported detecting the presence of RF during the RF ON exposure trial.

Double-blind trials: The results of the double-blind trials are shown in Figure 2f. Symptom severity (*Median* = 0.50 versus 1, $U = 17.50$, $z = -.082$, $p = .935$, $r = .024$) and detection ability (*Median* = 50.50 versus 47.00, $U = 12.00$, $z = -.966$, $p = .334$, $r = .288$) did not differ significantly between the RF ON and sham conditions respectively. The regression analysis showed that ‘belief of exposure’ significantly predicts symptom severity ($F(1, 10) = 34.093$, $p < .001$; $R^2 = .773$).

WHOQOL-BREF

As shown in Table 1, the participant’s overall quality of life is below the population norm, their psychological health, social relationships, physical health and environment scores are well below the population norms, and their overall health score is below the population norm (but within 1 SD).

Discussion and Conclusions

A number of methodological issues have been raised by both IEI-EMF advocacy groups and researchers as possible explanations for why provocation studies have generally failed to provide evidence of a relationship between EMF exposure and IEI-EMF symptoms. The present study was designed as a series of individual case studies which incorporated several methodological improvements to overcome limitations of previous studies. In order to determine whether these methodological improvements were adequate in providing the necessary conditions to test IEI-EMF participants, an initial open-label trial was conducted in each case.

Crucially, the results of these open-label trials show that the limitations of previous studies were sufficiently dealt with. Specifically, the testing environment and the type of exposure used were shown to be sufficient to produce the individually relevant symptoms which each participant self-nominated as being due to exposure to EMF and for each participant to report that RF exposure was indeed active in the RF ON trial. This is important, as it confirms that the environment, RF-EMF exposure device and emitting EMF strength used in the study was relevant for eliciting symptoms for these particular IEI-EMF individuals. In addition, the observed increase in symptoms over the 30 min open-label active exposure interval (on average) shows that the exposure interval was sufficient to evoke relevant symptoms in each participant, while the reduction in symptoms in the post-exposure interval demonstrates that the time course of each trial was sufficient to allow symptoms to subside prior to the next trial. The effect sizes observed in the open-label trials in each case were also extremely large (greater than 3.6), and much larger than the traditionally used nomenclature of Cohen [1988], which treats the largest category of effect size as greater than .5. These factors verify that the protocol used in the present study was appropriate for testing the sample of IEI-EMF individuals.

While all three participants displayed an increased symptom severity and were confident that they could detect the presence of RF-EMF in the RF ON exposure condition compared to RF OFF in the initial open-label trial, no significant differences in symptom severity or exposure detection between the RF ON and sham conditions were found in the double-blind trials.

These findings correspond to those reported by Eltiti et al. [2007a] and Wallace et al. [2012], who found that IEI-EMF participants had a greater symptomatic response in an initial open-label active trial compared to sham, but no difference in subsequent double-blind trials.

Likewise, in a study similar to the present investigation, van Moorselaar et al. [2017] reported that IEI-EMF participants were unable to correctly identify when they were being exposed during double-blind testing, despite participants reacting to the exposure in an initial unblinded test. Generally, the results of the present experiment agree with the majority of previous studies, which have not found any relationship between IEI-EMF symptoms and EMF exposure in double-blind provocation paradigms [Rubin et al., 2005; Rubin et al., 2010].

Interestingly, belief of exposure was found to significantly predict symptom severity, with belief accounting for 83, 89 and 77 percent of the variance for Participants 1, 2 and 3 respectively. This may explain why a sham exposure is sufficient to trigger symptoms, as has been reported previously [Nam et al., 2009; Oftedal et al., 2007; Wilén et al., 2006]. The strength of belief was particularly noteworthy in Participant 3, who reported that the experiment was designed with a deception element. As a result the participant reported detecting RF exposure in the post-exposure interval of the double-blind trials, despite specific instruction from both the participant information sheet and the researchers throughout the trial that the RF exposure was switched off during the post-exposure interval.

Although varied, each participant also scored lower than the general population in terms of overall quality of life and other measures of health on the WHO-QOL BREF questionnaire. This is consistent with the conclusions of many cross-sectional survey studies [Hagström et al., 2013; Johansson et al., 2010; Kato and Johansson, 2012], and highlights that, in addition to physical impairment, IEI-EMF can significantly impact daily functioning and quality of life. This emphasizes the importance of developing appropriate treatments and support for these individuals, but given the strong belief within the IEI-EMF community that EMF is a cause of their symptoms, this will remain challenging.

The results of the present study are limited by a number of factors. First, the results of the study cannot be generalized across the entire IEI-EMF population due to the relatively small sample size. Despite intending to recruit a larger sample, it seems that skepticism of the scientific process and of the results of previous studies, as well as warnings about the present study from IEI-EMF advocacy groups [Stop Smart Meters Australia, 2015], may have led to many IEI-EMF sufferers being persuaded not to participate. Nevertheless, the idiographic nature of the study protocol and the 6 RF ON and 6 RF OFF comparisons were designed to enable the detection of partial IEI-EMF responses within each individual case separately. Second, the exposure device used a simulated RF signal in the 902-928 MHz ISM band which, although digitally modulated like Wi-Fi and 3G and 4G signals, would not be typically reported as being the associated trigger of symptoms by individuals who experience IEI-EMF as it is a signal band reserved for industrial, scientific and medical use. The use of simulated signals in provocation studies has been criticized [Panagopoulos et al., 2015], however, as all 3 participants responded to the active signal in the initial non-blind trial, this does not seem to be an issue. Finally, the present study is unable to comment on individuals who report more chronic forms of IEI-EMF, as it was unable to assess individuals who report

more-prolonged symptoms that some IEI-EMF individuals report to result from the build-up of exposure from a variety of EMF sources over time [Hocking, 1998; Rösli et al., 2004].

Despite accounting for a number of possible limitations of IEI-EMF provocation studies to date, the results of the case studies presented here fail to demonstrate that the symptomatic response of self-reported IEI-EMF participants is affected by EMF exposure, nor that they can detect the presence of RF-EMF emissions at greater than chance levels. As in other studies, our results also support an alternative hypothesis for the etiology of IEI-EMF; that the symptoms experienced are the result of a placebo response. Indeed the size of resultant r -squared values shows that symptoms are more closely related to belief than EMF itself.

Given the increasing prevalence of distressing and debilitating IEI-EMF symptoms in the general public, there is a great need to better understand the triggers for eliciting a harmful EMF placebo response. Public messaging on the EMF topic by scientists and health administrators are no doubt significant influences [Wiedemann et al., 2014; Wiedemann et al., 2013]. A placebo etiology hypothesis also provides useful direction in developing effective treatments for people who experience IEI-EMF, whose only current solutions for minimizing symptoms involve exposure reduction strategies or the complete avoidance of all perceived exposures of EMF. Often these remedies not only involve considerable financial cost, but they can also have major implications for social and occupational functioning. Unfortunately, the ongoing debate over the etiology of IEI-EMF continues to limit the development of appropriate treatments and support of people who experience IEI-EMF.

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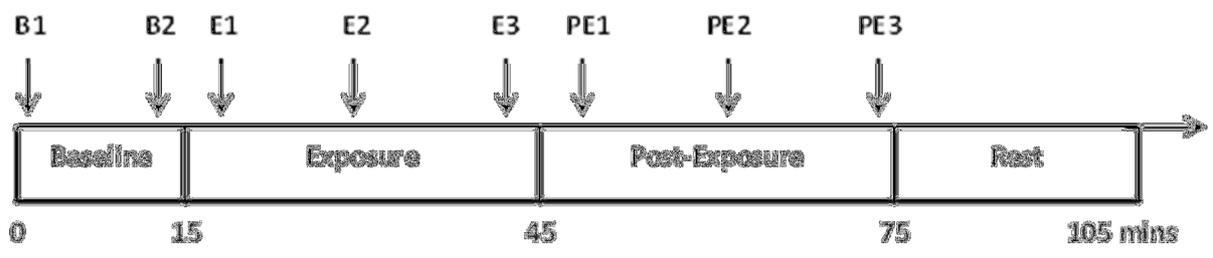
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Table and Figure Captions

Table 1: WHOQOL-BREF participant domain scores and mean population norms. Mean population scores were derived from [World Health Organisation, 1998].

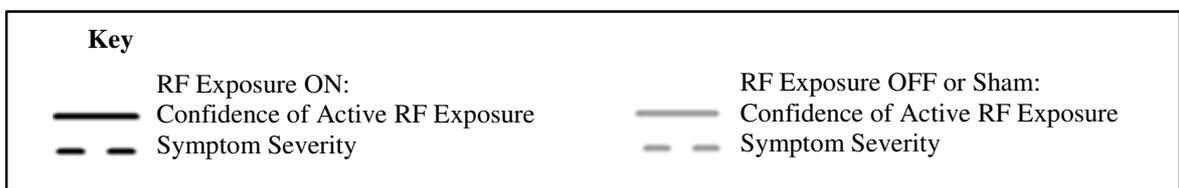
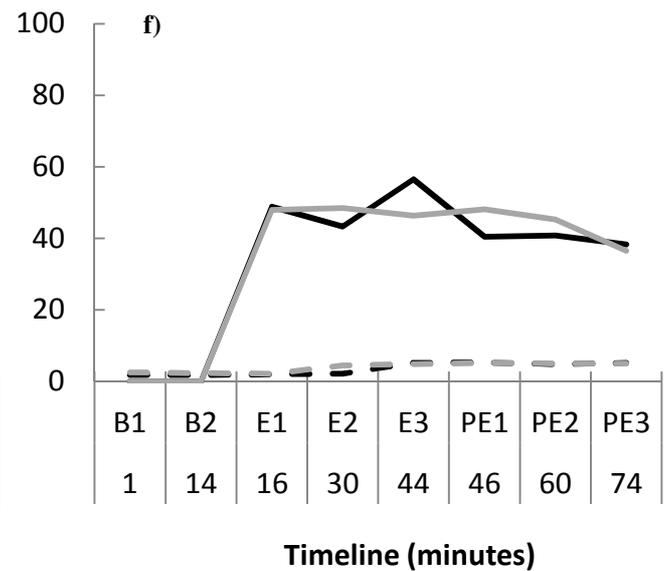
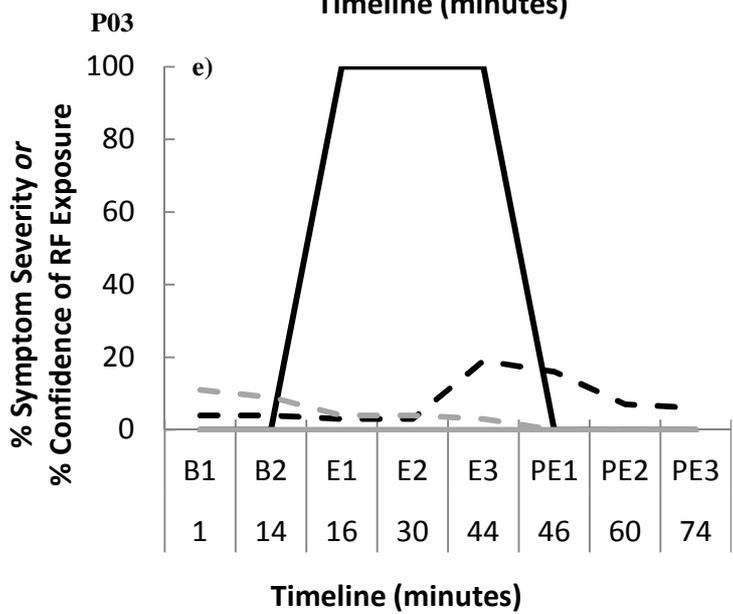
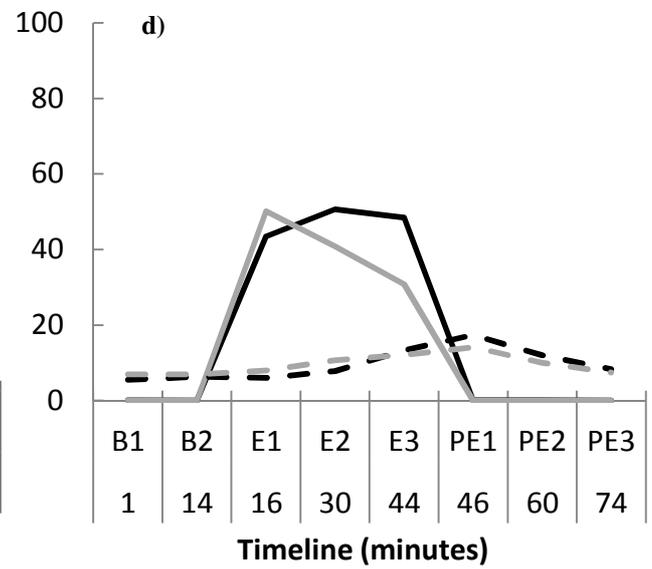
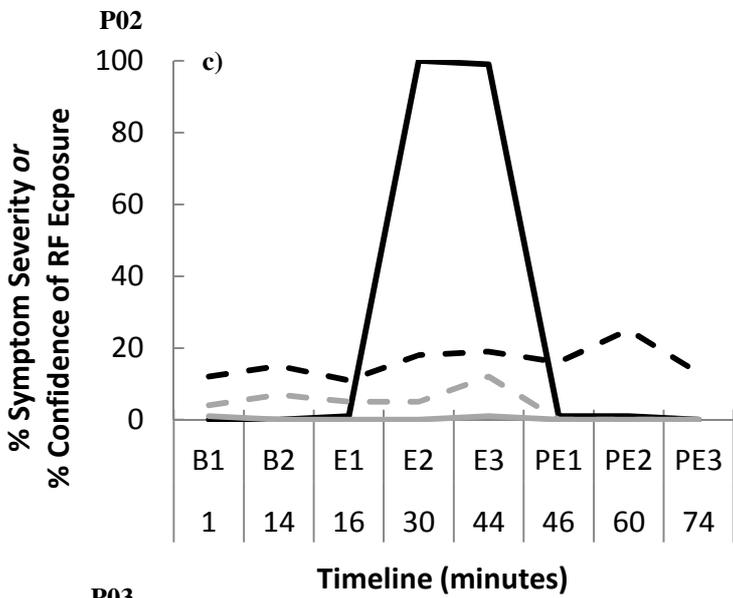
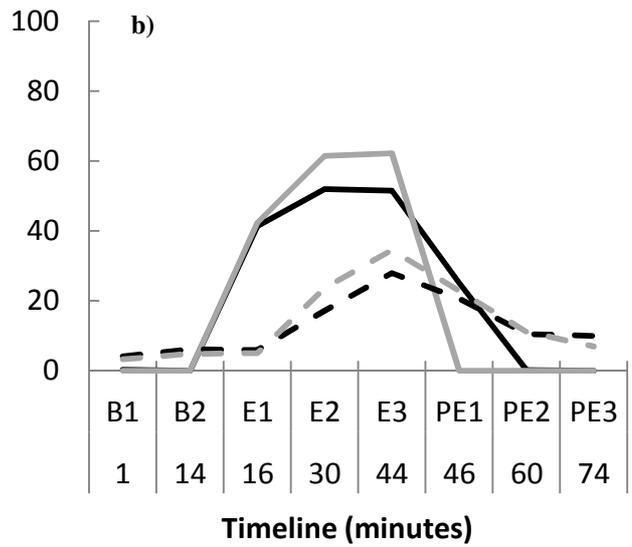
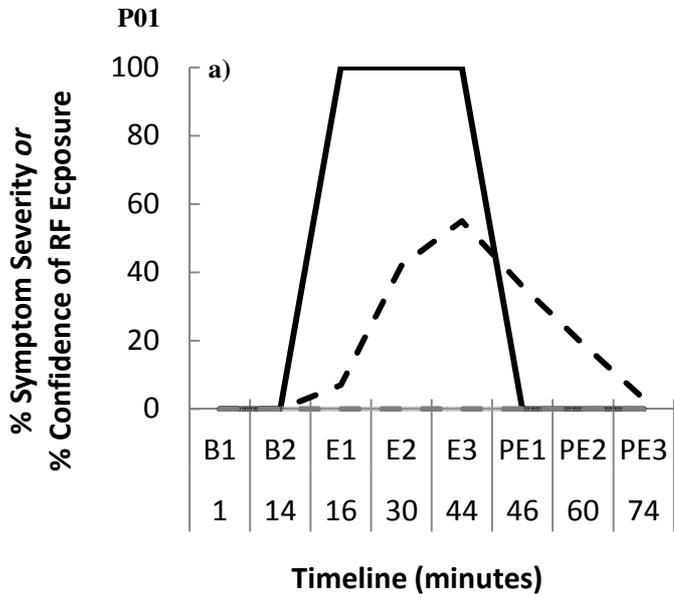
Figure 1: Provocation trial design. Each trial begins with a 15 min Baseline (B) interval, followed by a 30 min Exposure (E) interval, a 30 min Post-Exposure (PE) interval and a 30 min Rest interval, with a total trial time of 105 mins. Arrows represent the time points where the SESS was administered.

Figure 2: Mean exposure detection and symptom severity scores across the Baseline (B1 – B2), Exposure (E1 – E3) and Post Exposure (PE1 – PE3) intervals for P01, P02 and P03 are shown, for the open-label (RF ON and OFF) [left column; a, c, e] and double-blind provocation trials (RF ON and sham) [right column;b, d, f] separately.



Open-label trials

Double-blind trials



Domain	P01 Domain Score	P02 Domain Score	P03 Domain Score	Population Norms (SD)
Overall Quality of Life	4	3	3	4.3 (0.8)
Overall Health	2	5	3	3.6 (0.9)
Physical Health	63	81	88	80.0 (17.1)
Psychological Health	69	63	38	72.6 (14.2)
Social Relationships	81	56	0	72.2 (18.5)
Environment	75	69	94	74.8 (13.7)