PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Design of an ecological momentary assessment study of exposure to radiofrequency electromagnetic fields and non-specific physical symptoms
AUTHORS	Bogers, Rik; Bolte, John; Houtveen, Jan; Lebret, Erik; van Strien, Rob; Schipper, C.; Alkadhimi, Mehdi; Baliatsas, Christos; van Kamp, Irene

VERSION 1 - REVIEW

REVIEWER	Stacy Eltiti Ph.D. Assistant Professor Biola University United States I have no competing interests to declare.
REVIEW RETURNED	06-Apr-2013

GENERAL COMMENTS	I commend Bogers and colleagues in their development of a well-designed study that will ecologically examine whether there is a relationship between exposure to RF EMFs and symptoms in IEI-EMF individuals. The use of personal exposimeters will provide real time information regarding level of exposure these individuals experience in their everyday lives and the use of digital diaries will aid in the recording of those symptoms while they are actually happening. Below are some minor revisions, suggestions, and questions for further clarification that I feel should be addressed before the manuscript is ready for publication. Page 3 line 13 and 17: Throughout abstract and paper the term “electro hypersensitivity” should be replaced with “IEI-EMF.” Page 5 line 17 -22: Also need to include that because there is no scientific evidence that symptoms are caused by exposure to RF EMF the WHO coined the term IEI-EMF Page 8 lines 49 - 54 says, “main questions of the present study include: what are the processes (antecedents, correlates) that cause within-person variability in daily experiences, and how do people differ in these processes.[17].” As the study design is correlational in nature you need to remove any causal language in the paper. Instead this sentence should read, “main questions of the present study include: what are the processes (antecedents, correlates) that are related to within-person variability in daily experiences, and how do people differ in these processes.[17]. Page 11 line 24 references the EMPASIS study. Need to provide a citation for this study. At several other points in the paper citations are also missing (e.g., p. 14 line 46). Be sure to go through and double check that all citations have been included. Page 13 line 52 and Figure 1– Are the regression coefficients shown

	standardized regression coefficients? Page 15 line 23 – 25 says, “Exposure from mobile phone use by the participants themselves will not be measured properly by the exposimeter …” Can the authors expand on what exactly they mean by this. Is it simply not measured at all? Is it measured inaccurately and if so does it over or under calculate level of exposure? Will participants be aware that the exposimenter will not measure personal mobile phone use? Page 16 line 13 - may want to include question regarding EMF avoidance or use of EMF shielding material to reduce EMF exposure after onset of symptoms. Page 16 line 40 – 46 it says, “It can in principle not be excluded that the data are manipulated by placing the meters next to a (assumed) source of EMF before an alarm cue is expected. To minimize the chance of such anticipation effects, the alarms are programmed at random intervals.” This is probably the biggest concern with this design. Given that it is not double blind this leaves open the possibility of participants manipulating level of exposure or reporting false information in response to demand characteristics. Other than the alarms to try and control for this happening, are there other ways for the researchers to determine if participants are purposefully manipulating EMF exposure? Page 16 line 50 says, “In the statistical analysis, false-positive associations due to multiple testing may arise.” The authors rightly point out that with so many tests being conducted this will increase the likelihood of obtaining significance and the importance of replication if significance is found this study. However, the authors also need to discussion and recommend what statistical measures will be used to reduce experimentwise alpha error. I also highly recommend that the authors read the article referenced below by Simmmons, Nelson, and Simonsohn (2011), which demonstrates that the false-positive rate is likely to be much greater than .05 due to what they call “researcher’s degrees of freedom” in statistical choices. They also provide recommendations on ways to improve statistical reporting. Simmons, J.P., Nelson, L.D., & Simonsohn, U. (2011). False-positive psychology: Undisclosed flexibility in data collection and analysis allows presenting anything as significant. Psychological Science, 22(11), 1359-1366. doi: 10.1177/0956797611417632 Another limitation of the design that should be addressed in the discussion section is the issue of correlation vs. causation. The authors need to recognize from the outset that if significant relationships are found between exposure to RF EMF and symptoms that their conclusions need to be stated in terms of how these two factors are related rather than making conclusive statements regarding the causality of symptoms due to RF EMF exposure. It is important for the authors to note that while the external (ecological) validity of the findings increase with this design, compared to randomized double blind control trials, the internal validity is rather weak.

REVIEWER	Michael Witthöft Postdoctoral Researcher Department of Clinical Psychology and Psychotherapy

	Johannes Guteberg-University of Mainz Germany I have no competing interests.
REVIEW RETURNED	12-Apr-2013

GENERAL COMMENTS	The proposed study protocol contains the description of an ecological momentary assessment study that aims at testing a possible association between every day exposure to radiofrequency electromagnetic fields and the experience of physical symptoms in persons with self-reported electromagnetic hypersensitivity. Participants will be recruited from a large epidemiological study on electromagnetic hypersensitivity. Based on power analysis, the planned sample consists of 60 participants with high self-reported electromagnetic hypersensitivity. Personal exposure to RF EMF will be objectively assessed using exposimeters. Symptoms and psychological factors will be assessed by electronic diaries. The study type is explained as an epidemiological panel study. Data analysis is based on multilevel regression analysis. Study limitations mainly comprise the comparatively high costs and the lack of a healthy control group, but the limitations are adequately discussed and rather negligible given the lack of comparable research in this area. The study rational design, and methods are scientifically justified and methodologically sound. This is an excellent study protocol. The methods are selected carefully and described in appropriate detail. I also welcome the authors' decision to not exclude participants with other psychopathologies. Minor point: Abstract: -Second line method and analysis: The acronym RF EMF should be explained at first usage.

VERSION 1 – AUTHOR RESPONSE

Reviewer: Stacy Eltiti Ph.D.
Assistant Professor
Biola University
United States

I have no competing interests to declare.

I commend Bogers and colleagues in their development of a well-designed study that will ecologically examine whether there is a relationship between exposure to RF EMFs and symptoms in IEI-EMF individuals. The use of personal exposimeters will provide real time information regarding level of exposure these individuals experience in their everyday lives and the use of digital diaries will aid in the recording of those symptoms while they are actually happening. Below are some minor revisions, suggestions, and questions for further clarification that I feel should be addressed before the manuscript is ready for publication.

Page 3 line 13 and 17: Throughout abstract and paper the term "electro hypersensitivity" should be replaced with "IEI-EMF."

In the revised version of the manuscript, "IEI-EMF" is consistently used.

Page 5 line 17 -22: Also need to include that because there is no scientific evidence that symptoms are caused by exposure to RF EMF the WHO coined the term IEI-EMF

We have added “because scientific evidence of a causal relationship between EMF exposure and symptoms is lacking” to the sentence.

Page 8 lines 49 - 54 says, “main questions of the present study include: what are the processes (antecedents, correlates) that cause within-person variability in daily experiences, and how do people differ in these processes.[17].” As the study design is correlational in nature you need to remove any causal language in the paper. Instead this sentence should read, “main questions of the present study include: what are the processes (antecedents, correlates) that are related to within-person variability in daily experiences, and how do people differ in these processes.[17].

We agree with Prof. Eltiti that causal language should be avoided. We changed the sentence to “Diary methods can properly address the question what the correlates and antecedents are of within-person variability in daily experiences”.

Page 11 line 24 references the EMPASIS study. Need to provide a citation for this study. At several other points in the paper citations are also missing (e.g., p. 14 line 46). Be sure to go through and double check that all citations have been included.

The EMPHASIS study was cited earlier in the article but a citation is added at the indicated place. Also at p.14 line 46 (of the original manuscript) a citation is added. We checked the other citations for correctness.

Page 13 line 52 and Figure 1– Are the regression coefficients shown standardized regression coefficients?

No. We have extended the following sentence to clarify the meaning of the regression coefficient: “It can be seen that at a power of 80%, the detectable regression coefficient is slightly over 1.5, which corresponds to an increase of 1.5 on the sum of 10 symptoms (range 0-40) at an increase of 1 in perceived exposure (range 0-4)”.

Page 15 line 23 – 25 says, “Exposure from mobile phone use by the participants themselves will not be measured properly by the exposimeter …” Can the authors expand on what exactly they mean by this. Is it simply not measured at all? Is it measured inaccurately and if so does it over or under calculate level of exposure? Will participants be aware that the exposimenter will not measure personal mobile phone use?

In the near field, the exposimeters are unable to correctly measure the exposure, resulting in overestimations or ‘clipping’ in which the maximum measurement value of 10 V/m is registered. We have added this sentence to the text. We will not explicitly mention this to the participants, except if they ask for a reason why we request them to register their personal mobile phone use.

Page 16 line 13 - may want to include question regarding EMF avoidance or use of EMF shielding material to reduce EMF exposure after onset of symptoms.

Avoidance of EMF is actually asked for in the diary. On p.12 line 3 and p.16 line 3 we added this information.
After the measurement period, the participants are requested to complete a short questionnaire containing background questions on their sensitivity to EMF. One open-ended question asks what

measures the participants usually take to reduce their symptoms. Participants can report EMF avoidance or shielding there.

Page 16 line 40 – 46 it says, “It can in principle not be excluded that the data are manipulated by placing the meters next to a (assumed) source of EMF before an alarm cue is expected. To minimize the chance of such anticipation effects, the alarms are programmed at random intervals.” This is probably the biggest concern with this design. Given that it is not double blind this leaves open the possibility of participants manipulating level of exposure or reporting false information in response to demand characteristics. Other than the alarms to try and control for this happening, are there other ways for the researchers to determine if participants are purposefully manipulating EMF exposure?

We agree with Prof. Eltiti that a risk of manipulation cannot be excluded. We can check for unusual exposure patterns, although high and prolonged exposure peaks are not necessarily a result of manipulation. As in most observational studies that use questionnaires to collect data, we have to rely on truthful and correct reporting by the participants. Only if a large part of the participants manipulate EMF exposure will the results be biased, whereas an occasional case of manipulation is likely to be averaged out in the results for the group as a whole.

Page 16 line 50 says, “In the statistical analysis, false-positive associations due to multiple testing may arise.” The authors rightly point out that with so many tests being conducted this will increase the likelihood of obtaining significance and the importance of replication if significance is found this study. However, the authors also need to discussion and recommend what statistical measures will be used to reduce experimentwise alpha error. I also highly recommend that the authors read the article referenced below by Simmmons, Nelson, and Simonsohn (2011), which demonstrates that the false-positive rate is likely to be much greater than .05 due to what they call “researcher’s degrees of freedom” in statistical choices. They also provide recommendations on ways to improve statistical reporting.
Simmons, J.P., Nelson, L.D., & Simonsohn, U. (2011). False-positive psychology: Undisclosed flexibility in data collection and analysis allows presenting anything as significant. Psychological Science, 22(11), 1359-1366. doi: 10.1177/0956797611417632

In the revised manuscript we mention the procedure that we intend to address the issue of false-positive associations: “To take into account the possibility of false-positive associations, the expected proportion of falsely rejected hypotheses will be controlled using a sequential Bonferroni-type procedure described by Benjamini and Hochberg.” This method takes into account the number of erroneous rejections and not only the question whether any error was made, and has a gain in power compared to methods that control for the familywise error rate.
We thank the reviewer for the reference by Simmons et al. We think the recommendations they give for reporting are useful, and if applicable, we will follow these guidelines. Some of the guidelines have already been implemented, e.g. by presenting a power analysis and publishing details on the study protocol before the study is carried out.

Another limitation of the design that should be addressed in the discussion section is the issue of correlation vs. causation. The authors need to recognize from the outset that if significant relationships are found between exposure to RF EMF and symptoms that their conclusions need to be stated in terms of how these two factors are related rather than making conclusive statements regarding the causality of symptoms due to RF EMF exposure. It is important for the authors to note that while the external (ecological) validity of the findings increase with this design, compared to randomized double blind control trials, the internal validity is rather weak.

We fully agree that causation cannot be proven with this design. In the discussion we added the sentence “Also, it should be noticed that significant relationships between RF-EMF exposure and

symptoms not necessarily have to be causal relationships."
With respect to the internal validity, we included the sentence "Although the external (ecological) validity of the design is high, compared to double-blind trials such as provocation studies in the laboratory, the internal validity is lower".

Reviewer: Michael Witthöft
Postdoctoral Researcher
Department of Clinical Psychology and Psychotherapy
Johannes Guteberg-University of Mainz
Germany

I have no competing interests.

The proposed study protocol contains the description of an ecological momentary assessment study that aims at testing a possible association between every day exposure to radiofrequency electromagnetic fields and the experience of physical symptoms in persons with self-reported electromagnetic hypersensitivity. Participants will be recruited from a large epidemiological study on electromagnetic hypersensitivity. Based on power analysis, the planned sample consists of 60 participants with high self-reported electromagnetic hypersensitivity. Personal exposure to RF EMF will be objectively assessed using exposimeters. Symptoms and psychological factors will be assessed by electronic diaries. The study type is explained as an epidemiological panel study. Data analysis is based on multilevel regression analysis. Study limitations mainly comprise the comparatively high costs and the lack of a healthy control group, but the limitations are adequately discussed and rather negligible given the lack of comparable research in this area. The study rational design, and methods are scientifically justified and methodologically sound. This is an excellent study protocol. The methods are selected carefully and described in appropriate detail. I also welcome the authors' decision to not exclude participants with other psychopathologies.

Minor point:

Abstract:
-Second line method and analysis: The acronym RF EMF should be explained at first usage.

We thank Dr. Witthöft for his positive comments. In the main text of the article, the first usage of RF EMF is in the first sentence of the introduction and explained at that point.