Perception of electromagnetic fields (EMF) - pre-test of an exposure set-up

Published: 13-12-2013
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The aim is to assess if people can perceive if the exposure-unit is on or off.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38671

Source
ToetsingOnline

Brief title
Perception of electromagnetic fields

Condition

- Other condition

Synonym
healthy volunteers

Health condition

gezonde vrijwilligers

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: - EMF (electromagnetic fields), - exposure, - provocation

Outcome measures

Primary outcome

The primary outcome will be the percentage of correct guesses of the exposure conditions. If overall the percentage of correct guesses exceeds 54% then the exposure set-up needs to get adjusted to get rid of unwanted clues.

Secondary outcome

Clues as to whether the applied exposure conditions are true or sham conditions reported by study participants (such as clicks, light)

Study description

Background summary

Individuals who attribute their health complaints to electromagnetic fields (EMF) are frequently referred to as *electromagnetic hypersensitive* (EHS). The ability to sense exposure to EMF, or *electromagnetic sensibility*, has been described as a likely prerequisite for EHS.
Electromagnetic sensibility may be reported via acute, transient symptoms, or by just sensing the fields. No scientific evidence corroborates that electromagnetic sensibility exists, or that short-term exposures to non-ionizing electromagnetic fields causes any health effects. However, in severe cases, subjects who suffer from EHS may be severely limited in their daily activities and wellbeing. Strategies on how EHS affected persons can be helped are urgently needed. In the near future, we plan to perform an experimental study where we offer individuals reporting they can sense electromagnetic fields the possibility to verify this hypothesis with a personalized testing procedure. Since it is paramount for such a study that exposure testing can be performed under perfectly double blind conditions, without any clues as to whether the applied exposure conditions are true or sham conditions, we plan to first perform a test to check our exposure unit with a group of at least 20 healthy volunteers for each one of two exposure units. In the current scientific literature there is no indication that healthy

volunteers are able to feel electromagnetic fields as will be applied here.

Study objective

The aim is to assess if people can perceive if the exposure-unit is on or off.

Study design

We will perform an experimental pre-test in a group of at least 20 healthy volunteers each to test our two exposure units. Volunteers will be exposed to five different frequency bands: Three different mobile phone base station frequencies: GSM900, GSM1800 and UMTS; cordless phone frequency (DECT) and wireless internet connection frequency (WiFi); as well asa second unit with extremely-low-frequency magnetic fields (ELF-MF: 50Hz sinus field plus four different levels of other frequency components) will be applied (10 x 5 = 50 exposure conditions in total).
Per volunteer, the testing procedure of our exposure unit will be performed during a one-time visit of the study centre at the Institute for Risk Assessment Sciences, Utrecht University, encompassing: (a) explaining the experiment (signing informed consent), (b) filling in a short questionnaire indicating self-rated electromagnetic sensibility and regarding EHS (c) performing a series of 5 x 10 randomized exposure sessions (35min) and indicating exposure conditions (on/off) per exposure session (d) filling in a short questionnaire regarding any clues as to exposure condition and EHS and indicating self-rated electromagnetic sensibility. Finally, if desired by the respective volunteer, the percentage of correct guesses of the exposure conditions will be communicated. Total time needed per volunteer is estimated to not exceed one hour.
In order to also assess experimenter-blinding (i.e. to achieve double-blinding), the project assistant performing the experiment will also be asked to report whether he or she thought the exposure was on or off for at least 1 of the testing procedures.

Intervention

For each one of the five different exposure types, volunteers will undergo a series of 10 randomized exposure conditions with 5 times sham and 5 times true exposure. Exposure duration will be 30 seconds, with a break of 5 seconds between exposure sessions. Volunteers will be asked to indicate whether they thought the exposure was on or off.

Study burden and risks

Participants will have to visit the University Utrecht only once, for a maximum of one hour. Volunteers will be exposed to very short duration exposures, at levels as they can be regularly encountered in the everyday environment (in

type and strength) , at levels far below legal threshold levels and where no evidence exists of adverse effects on health or on well-being. Scientific literature does not indicate that tehere are any health risks.
An incentive of ¤10,- (gift voucher) for the completed visit and an allowance for travelling costs will be given to the volunteer.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- healthy adults
- men and women
- between 18 and 65 years

Exclusion criteria

- adults with hearing aids
- adults being deaf or being blind

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	13-12-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22402
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL45809.041.13
OMON	NL-OMON22402