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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22402

Source
Nationaal Trial Register

Health condition

Healthy volunteers.

Sponsors and support

Primary sponsor: IRAS
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

The primary outcome will be the percentage of correct guesses of the exposure conditions per
exposure unit.

Secondary outcome

We will inquire information about unwanted clues as to exposure conditions (e.g. clicking sounds by

the antenna or amplifier, etc.).

Study description

Background summary

For usage in provocation experiments, two custom-made mobile exposure units were developed, which can generate extremely-low frequency magnetic fields and radio-frequency electromagnetic fields. Field types and strengths are as encountered in everyday life (e.g. from a WiFi). The units can produce repeated sham/true exposure conditions in random order selected by a computerized randomization scheme in order to achieve double blinding.

In this trial we test whether the units can indeed achieve double-blinded exposure conditions, meaning that there are no unwanted clues from which a person can tell when exposure is on, such as sounds or vibrations. 25 healthy volunteers per unit are exposed to short repeated sham and true exposures and are asked when they thought exposure was on and why they thought so. The primary outcome is the percentage of correct answers.

Study objective

The exposure set-up is able to achieve truly double-blind exposure conditions.
The objective is to assess if people can tell if the exposure unit is on or off. The testing of our exposure unit aims at identifying and eliminating any potential unwanted clues as to the exposure conditions.

Study design

Directly before and after testing.

Intervention

For each one of five different exposure types (electromagnetic field signals), 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 very short break between exposure sessions. Volunteers will be asked to indicate whether they thought the exposure was on or off.

Contacts

Public
Universiteit Utrecht, Institute for Risk

Assessment Sciences (IRAS), Environmental
and Occupational Health

Postbus 80178
A. Huss
Utrecht 3508 TD
The Netherlands
030 – 253 84 61
Scientific
Universiteit Utrecht, Institute for Risk
Assessment Sciences (IRAS), Environmental
and Occupational Health

Postbus 80178
A. Huss
Utrecht 3508 TD
The Netherlands
030 – 253 84 61

Eligibility criteria

Inclusion criteria

Adult healthy volunteers (between 18 – 65 years old) will be included.

Exclusion criteria

For the exposure pre-testing the following exclusion criteria apply so as to ensure that they could pick
up potential clues as to the exposure conditions:
- hearing aids
- being deaf or blind or having obvious serious uncorrected hearing or vision problems.

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-01-2014
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-01-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38671
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4258
NTR-old	NTR4394
CCMO	NL45809.041.13
OMON	NL-OMON38671

Study results