GESOND' - testing for electromagnetic sensibility

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In this scientific project, persons who experience that they react within short time periods to certain electromagnetic fields are offered the opportunity to assess this in their homes: Can they indeed by repetition identify when the EMF signal is...

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

Summary

ID

NL-OMON40434

Source
ToetsingOnline

Brief title
*GESOND'

Condition

- Other condition

Synonym
electromagnetic sensibility

Health condition

electrogevoeligheid

Research involving
Human

Sponsors and support

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

Intervention

Keyword: - Electromagnetic Hypersensitivity, - EMF (electromagnetic fields), - exposure, - provocation trial

Outcome measures

Primary outcome

The primary outcome of the study will be the difference in self-rated electromagnetic sensibility as measured on a 100 mm visual analogue scale comparing the rating at 2 months after testing in the immediate testing arm with the scoring prior to testing in the delayed testing arm.

Secondary outcome

The secondary outcomes will be (a) the frequency of persons able to by repetition correctly assess whether exposure is present or absent in the double-blind testing, and (b) the longitudinal course of self-rated electromagnetic sensibility in the subsequent questionnaires (baseline, directly pre/post-testing at home visit and follow-up after home visit), as measured on a 100 mm visual analogue scale.

Study description

Background summary

Are some people sensitive to electromagnetic fields? This is the central question of the study *GESOND*, which stands for *sensibility for electromagnetic signals study*. The study is performed by the University of

Utrecht and the GGD Amsterdam.

Study objective

In this scientific project, persons who experience that they react within short time periods to certain electromagnetic fields are offered the opportunity to assess this in their homes: Can they indeed by repetition identify when the EMF signal is present and when not?

Study design

All participants will be visited at home either immediately, or delayed after a few months. During the home visit they will be asked to do a series of test rounds to assess whether an exposure is present or absent: The exposure unit that sends out the signal does so in a double blind fashion. This means that neither participants nor the study assistant know beforehand whether the signal is present or absent in any of the test rounds. All participants receive their personal results (the amount of correct answers) directly afterwards.
To assess the effect of participation on the study, participants are asked to fill in a questionnaire about their perception of electromagnetic sensibility beforehand, and 2 and 4 months later.

Intervention

Participants can choose which signal they want to get tested from an array of selectable signals, such as DECT phone, WiFi or base station signals, or extremely-low frequency fields, such as a LED lamp. These signals are alike those as encountered in real life.

Study burden and risks

Burden: the subjects have to call the centralized phone number, fill in the questionnaires, undergo the personalized testing procedure at home (a maximum of 2x4 hours). Risks: Persons who report they usually experience certain reactions or symptoms upon exposure, would be expected to experience these also upon (perceived) experimental exposure. The experimental exposure consists of signals that are regularly encountered in everyday environments, at levels very far below legal threshold levels. A multitude of studies have applied similar exposures at (partly) higher levels, and have not detected harmful effects to health or well-being. Benefit: Participants receive a home visit in which they can verify their own hypothesis of reacting within minutes to certain EMF signals.

Contacts

Public
Universiteit Utrecht

Yalelaan 2
Utrecht 3584 CM
NL
Scientific
Universiteit Utrecht

Yalelaan 2
Utrecht 3584 CM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The study population for the experiment will consist of up to 40 adult subjects reporting electromagnetic sensibility. Adult participants (older than 18 years old), with sufficient profiency in Dutch language, will be included if they report electromagnetic sensibility, i.e. the ability to sense one of the available experimental (real-life) EMF signals within minutes of being exposed, or developing acute and transient health complaints that occur and disappear within 15 minutes if exposure is short.

Exclusion criteria

Inability to complete the administered questionnaires, e.g. due to insufficient knowledge of the Dutch language or cognitive impairment. Time between start of exposure and sensing

exposure or development of symptoms plus recovery time from symptoms exceeds 15 minutes.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	23-07-2014
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

No registrations found.

In other registers

Register	ID
CCMO	NL45964.041.14