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The effect of mobile phone use on symptoms and neuroendocrine function in 'normal' and 'hypersensitive' users

Submission date	Recruitment status	[_] Prospectively registered
21/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/10/2008	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Exposure to pulsed 900 MHz Global System for Mobile Communications (GSM) radiofrequency fields will be associated with higher symptom reporting and altered neuroendocrine function in comparison to exposure to unpulsed radiofrequency fields or a 'sham' condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study has been approved by the Institute of Psychiatry/South London and Maudsley NHS Trust Ethical Committee (Research)(reference: 131/02)

Study design
Double-blind, within participants, randomised controlled trial

Primary study design
Observational

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Sensitivity to radiofrequency fields / electrosensitivity

Interventions
Each participant will be exposed to each of three conditions: pulsed 900 MHz GSM radiofrequency fields, unpulsed radiofrequency fields of the same mean power, and a sham (placebo) condition. Each of these conditions will last for 50 minutes. The order these conditions will be presented in for each participant will be determined using block randomisation.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Our primary outcome will consist of self-reported headache severity during exposure, recorded using a 0-100 mm visual analogue scale.

Secondary outcome measures
Secondary outcomes will include: self-reported severity for nausea, fatigue, dizziness, skin itching, tingling or stinging, sensations of warmth or burning on skin, and eye pain or dryness.

Neuroendocrine outcomes will include: plasma levels of cortisol, adrenocorticotropic hormone, growth hormone and prolactin.

Secondary outcomes will be recorded during each of the three experimental provocations.

Overall study start date
01/09/2003

Completion date
30/06/2005

Eligibility

Key inclusion criteria
Two samples will be tested, consisting of 'control' and 'sensitive' participants. To be eligible for the sensitive group, participants must report experiencing often headaches within 20 min of using a GSM mobile phone. Only participants who do not attribute any symptoms to mobile phone signals will be eligible for inclusion in the control group.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 participants will be recruited for each group

Key exclusion criteria
Participants will be excluded if: under 18, over 75, pregnant, suffering from a psychotic illness, currently using antidepressants, or if they report severe symptoms at baseline while in the testing room.

Date of first enrolment
01/09/2003

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Mobile Phone Research Unit
London
United Kingdom
SE5 9PJ

Sponsor information

Organisation
Mobile Telecommunications and Health Research programme (UK)

Sponsor details
MTHR, c/o HPA Centre for Radiation Protection
Chilton
Didcot
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OX11 0RQ
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Sponsor type
Other

Website
http://www.mthr.org.uk

Funder(s)

Funder type
Not defined

Funder Name
Funded by the UK Mobile Telecommunications and Health Research programme (MTHR)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	06/03/2006		Yes	No
Other publications	Within participants double blind randomised provocation study:	15/04/2006		Yes	No