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A randomised controlled trial to investigate the effectiveness of the healthy sexual functioning module and selective serotonin reuptake inhibitor medication to treat deviant sexual arousal as part of the HM prison sex offender treatment programme

Submission date
24/04/2006

Recruitment status
Stopped

Registration date
07/06/2006

Overall study status
Stopped

Last Edited
24/01/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
MRD 12/92

Study information

Scientific Title
A randomised controlled trial to investigate the effectiveness of the healthy sexual functioning module and selective serotonin reuptake inhibitor medication to treat deviant sexual arousal as part of the HM prison sex offender treatment programme

Acronym
HSF-SSRI

Study objectives
To determine whether either the healthy sexual functioning (HSF) module of the sex offenders treatment programme or selective serotonin reuptake inhibitor (SSRI) medication have a positive impact on relevant psychological mechanisms associated with sexual offending

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by South East MultiCentre Research Ethics Committee, Kent on 18/10/2005, reference number: 05/MRE01/82

Study design
HSF: Randomised, open controlled parallel study. SSRI: Randomised, double-blind, placebo-controlled parallel study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Prison/detention

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Deviant sexual arousal

Interventions
HSF evaluation: consenting eligible subjects will be randomised to either treatment with the HSF module (receiving treatment in the next available treatment slot) or a waiting list control group (receiving HSF treatment after study assessments have been completed).

SSRI evaluation: consenting eligible subjects will be randomised to either fluoxetine or placebo for a period of 20-26 weeks (the randomisation will be balanced for allocated group in the HSF evaluation, if consent is given for this evaluation also).

Added 05/02/10: trial stopped by 2007 because of recruitment problems.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Fluoxetine

Primary outcome measure
The multiphasic sex inventory - sexual obsessions sub-scale

Secondary outcome measures
HSF: penile plethysmography and impulsivity scale (sex offender treatment programme)

SSRI only:
1. Fantasy visual analogue scale
2. Sexual outlet inventory
3. Yale-brown obsessive-compulsive scale
4. Hospital anxiety and depression scale
5. Mood visual analogue scale and Udvalg for Kliniske Undersogelser (UKU) side effect rating

Overall study start date
01/09/2006

Completion date
01/09/2009

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Consent to treatment in HSF module of HM prison sex offender treatment programme with written informed consent.

In addition, for SSRI sub-study, any one of the following:
1. Sexual preoccupation (either from clinical assessment or based on the multiphasic sex

inventory [MSI] obsession scale)
2. A compulsive aspect to their offending (based on clinical judgement)
3. Mood state being an important contributor to their offending (based on clinical judgement)
4. Impulsivity (based on clinical judgement or impulsivity score)

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
240 in each evaluation (maximum 480 participants)

Key exclusion criteria
HSF evaluation: urgent treatment need as assessed by the treatment manager

SSRI sub-study only:
1. Presence of psychotic disorder or major mood disorder, epilepsy, uncontrolled seizure disorders, diabetes, major cardiac problems or severe renal failure.
2. Concomitant treatment with psychoactive medication which may interact with the effects of the SSRI e.g. neuroleptic or antidepressant medication
3. Concomitant treatment with an anti-androgen
4. Concomitant treatment with an anti-coagulant
5. Current treatment, or treatment within the last 4 weeks with SSRI
6. Previous adverse reaction to an SSRI

Date of first enrolment
01/09/2006

Date of final enrolment
01/09/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Newcastle
Newcastle-upon-Tyne
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NE3 4ES

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
c/o Ms Kay Pattison
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University of Liverpool
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Thompson-Yates Building
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Sponsor type
Government

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
National Forensic Mental Health Research and Development Programme, reference number: MRD 12/92, http://www.nfmhp.org.uk/ (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration