

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	☒ Prospectively registered
Registration date 07/06/2006	Overall study status Stopped	☐ Protocol
Last Edited 24/01/2023	Condition category Mental and Behavioural Disorders	☐ 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

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

The multiphasic sex inventory - sexual obsessions sub-scale

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

United Kingdom

England

Study participating centre

University of Newcastle

Newcastle-upon-Tyne

United Kingdom

NE3 4ES

Sponsor information

Organisation

Department of Health (UK)

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

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration