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A study to see if fluoxetine will help reduce the symptoms of problematic sexual arousal in adult men serving a prison sentence when compared with a placebo (dummy) drug

Submission date
05/02/2026

Recruitment status
Not yet recruiting

Registration date
16/06/2026

Overall study status
Ongoing

Last Edited
22/10/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Problematic sexual arousal (PSA) is characterised by persistent and intense sexual thoughts, physiological arousal, urges, and behaviours that are distressing and difficult to control. Prisons have people with symptoms of PSA being exhibited during their stay, not all of which are people with a sexual conviction.
Recent research has provided evidence for selective serotonin reuptake inhibitors (SSRIs) as an alternative treatment to testosterone-lowering medications. A number of research studies have been conducted into the use of various SSRIs (mainly sertraline and fluoxetine). These studies have reported promising results for the role of SSRIs in the treatment of PSA, including a less severe side effect profile and cost-effectiveness.
This trial aims to investigate whether fluoxetine can reduce PSA in patients who have been referred to the prison's Medication to Manage Problematic Sexual Arousal (MMPSA) service by comparing its effectiveness and cost effectiveness over a 6-month period when compared with patients taking a placebo drug.

Who can participate?
Adult (18 years or older) patients who have been referred to the prison's Medication to Manage Problematic Sexual Arousal (MMPSA) service.

What does the study involve?
We will undertake a double blind randomised controlled trial, recruiting at least 196 patients and randomising them to fluoxetine or a matching placebo in a 1:1 ratio so that there are equal numbers in each group. We will ask patients to complete questionnaires at baseline (before the blinded treatment is given), then at 3 and 6 months after the treatment has been started. Patients will complete a daily log to report any side effects, changes to other medications they are taking, and any healthcare contacts during the trial.
At the end of the 6-month trial period for each patient, the Forensic Psychiatrist will be unblinded and decide on their treatment as part of standard care.

The trial hopes to prove that fluoxetine is effective and cost effective to use in patients exhibiting PSA symptoms so that the guidelines can be amended to allow fluoxetine to be prescribed in the community.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Nottingham Trent University (UK)

When is the study starting and how long is it expected to run for?
January 2027 to January 2028

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
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Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
1007974

Sponsor's protocol code number
NTU-FASAR-SPON-001

Study information

Scientific Title
Randomised controlled trial of fluoxetine for the treatment of problematic sexual arousal in adult males serving a custodial sentence

Acronym
FASAR

Study objectives
The primary objective of this trial is to determine whether fluoxetine prescribed over 6 months is effective in reducing problematic sexual arousal in adult males referred to the Medicines to Manage Problematic Sexual Arousal service in prisons when compared with placebo according to the trial-adapted Sexual Compulsivity Scale (SCS).

Secondary objectives:
1. To determine the efficacy of fluoxetine (dose 20mg / 40mg / 60mg daily) for reducing PSA in adult males referred to the MMPSA service at 3 months compared to placebo according to the trial-adapted Sexual Compulsivity Scale (SCS).
2. To determine the efficacy of fluoxetine (dose 20mg / 40mg / 60mg daily) for improving wellbeing in adult males referred to the MMPSA service at 3 and 6 months compared to placebo according to the Warwick–Edinburgh Mental Wellbeing Scale (WEMWBS) for wellbeing.
3. To determine the efficacy of fluoxetine (dose 20mg / 40mg / 60mg daily) for improving anxiety and depression in adult males referred to the MMPSA service at 3 and 6 months compared to placebo according to the Hospital Anxiety and Depression Scale (HADS) for anxiety and depression.
4. To determine the efficacy of fluoxetine (dose 20mg / 40mg / 60mg daily) for reducing paedophilic and/or hebophilic interests in adult males referred to the MMPSA service at 3 and 6 months compared to placebo according to the Problematic Sexual Interest Questionnaire (PSIQ).
5. To assess the cost-effectiveness of fluoxetine compared to placebo using QALYs derived from the EQ5D-5L and the SCS at 3 and 6 months.
6. To understand the timing and motivations for change, prior help-seeking, and the service, treatment, and personal factors (including views on mandatory use, expectations, and expected continuation/discontinuation) that influence engagement with MMPSA collected in the Treatment Considerations questions in the PROMs booklet at baseline.
7. To understand participants' experiences, side-effects, wellbeing, and engagement over time while taking MMPSA, and how these factors influence continuation, perceptions of helpfulness, and evolving views on voluntary versus mandatory use collected in the Experience and Impact section of the PROMs booklet at 3 months and 6 months. To understand the triggers for and/or barriers to referring someone for medication and understand any systemic or individual barriers to people continuing with a referral.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 20/04/2026, Wales Research Ethics Committee 3 (Health and Care Research Wales, Floor 4, Crown Building, Cathays Park, Cardiff, CF10 3NQ, United Kingdom; -; Wales.REC3@wales.nhs.uk), ref: 26/WA/0041

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment, Efficacy

Study type(s)
Efficacy, Treatment

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

Interventions
The main study is designed as a double-blind randomised controlled superiority trial with two arms. Eligible consenting patients will be randomised to receive either fluoxetine (20mg capsule) or placebo (Microcrystalline cellulose). All patients will be reviewed at approximately 4 weeks, with the dose increased to 40mg if no or partial clinical response, and then to 60mg after a further approximately 4 weeks if needed. Maximum dose will be 60mg/day.
Patients will be randomised on a 1:1 basis, stratified by site. The randomisation service will be provided by Sealed Envelope Ltd. (https://www.sealedenvelope.com) in consultation with the statistician based at STU.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Fluoxetine [N-methyl-3-phenyl-3-[4-(trifluoromethyl)phenoxy]propan-1-amine]

Primary outcome(s)
The efficacy of fluoxetine in reducing problematic sexual arousal in adult males referred to the Medication to Manage Problematic Sexual Arousal service compared to placebo as measured by the trial-adapted Sexual Compulsivity Scale at baseline and 6 months later.

Key secondary outcome(s)
1. To determine the efficacy of fluoxetine for improving wellbeing in adult males referred to the MMPSA service compared to placebo using the Warwick–Edinburgh Mental Wellbeing Scale (WEMWBS) at 3 and 6 months. The WEMWBS consists of 14 positively phrased Likert items. The scoring range for each item is from 1–5 and the total score is from 14–70, with higher scores indicating greater wellbeing.
2. To determine the efficacy of fluoxetine for improving anxiety and depression in adult males referred to the MMPSA service compared to placebo using the Hospital Anxiety and Depression Scale (HADS) at 3 and 6 months. This scale provides separate scores for anxiety and depression, with the minimum possible score for each sub-scale being 0, and the maximum being 21. Scores between 0–7 are interpreted as normal, 8–10 as mild, 11–15 as moderate, and 16 or over as severe.
3. To determine the efficacy of fluoxetine for reducing paedophilic and/or hebophilic interests in adult males referred to the MMPSA service compared to placebo using the Problematic Sexual Interest Questionnaire (PSIQ) at 3 and 6 months.
4. The Treatment Considerations and the Experience and Impact sections of the PROMs booklet will be used to understand referral behaviours by patients and their experiences of the MMPSA pathway at 3 and 6 months. Further validation and concurrent validation of the PSIQ will be undertaken during the trial.
5. To assess the cost-effectiveness of fluoxetine compared to placebo using QALYs derived from the EQ5D-5L and the trial-adapted Sexual Compulsivity Scale at 3 and 6 months. QALYs will be calculated using utility data collected from the EQ5D-5L, which is a preference-based measure consisting of five questions with five levels of response; these are converted into utility-index scores ranging from 0 to 1, where a higher score indicates a better quality of life.

Completion date
31/01/2028

Eligibility

Key inclusion criteria
1. Male.
2. Aged 18+ years.
3. Currently detained at one of the prison sites running the trial and referred to the MMPSA service
4. Total Sexual Compulsivity Scale score (used in standard care) of 15+ or a score of 3 or 4 on any one item.
5. Diagnosis of problematic sexual arousal made by a Forensic Psychiatrist or other relevant specialist.
6. Clinician determination that it is appropriate to prescribe fluoxetine.
7. Understands written and verbal English sufficiently to have the trial explained to them.
8. Has the capacity to give informed consent.
9. Agrees to use appropriate contraceptive methods during the trial and for 6 months after.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Male

Total final enrolment
0

Key exclusion criteria
1. Current pharmacological treatment with an SSRI/anti-androgen/Gonadotropin-releasing hormone agonist.
2. Contraindication to Selective serotonin reuptake inhibitors.
3. Major mental illness (e.g. schizophrenia or other psychotic disorders) if acutely unwell and therefore unable to give informed consent.
4. Patients with epilepsy.
5. Currently prescribed medication that interacts with the 5-HT system, meaning it has serotonin effects.
6. Currently on prophylactic medication that has an impact on sexual arousal.
7. Currently prescribed testosterone/oestrogen supplement therapy.
8. Risk of harm to self/others is deemed too high to be randomised to placebo.
9. Planned release date is within 9 months (including shortened sentences).
10. Prison transfer to a prison where Medication to Manage Problematic Sexual Arousal service is not available within the next 9 months is highly likely or actually planned.

Date of first enrolment
11/01/2027

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre

The trial will take place in several prisons in England and Wales.
-
-
England
-

Sponsor information

Organisation
Nottingham Trent University

ROR
https://ror.org/04xyxjd90

Funder(s)

Funder type

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. The CI and trial statistician will have access to the final dataset. Should PIs or others require access to the final dataset, this will require approval by the TMG, TSC and Sponsor and will only be made available following trial completion and publication. A data sharing agreement may be required.

IPD sharing plan summary

Available on request