ISRCTN97554826 https://doi.org/10.1186/ISRCTN97554826

A study exploring a women-only, trauma - informed residential rehabilitation pathway for drug dependent women leaving prison

Submission date
15/12/2025

Recruitment status
Not yet recruiting

Registration date
07/01/2026

Overall study status
Ongoing

Last Edited
16/02/2026

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
Female prisoners are more likely than male prisoners to use Class A drugs. They often commit crimes to support their drug use and, when they are sent to prison, they frequently ask for help with that drug use. Many women leave prison without a support plan to stay off drugs and most do not even have a safe place to live. Women can find drug treatment services that accept both men and women difficult because of their experiences of trauma and violence. So it is possible that women-only residential rehabilitation (WORR) might work better in supporting their recovery. WORR services can provide specialist women-centred support, safe accommodation, and help with other issues such as trauma, mental health and finding a job
We will examine whether moving women directly from prison to WORR services can support their long-term recovery from drug use, helping both them and their children live better lives. As well as long term recovery from drug dependency, we will explore all the other ways in which the women's lives might have improved, such as employment, housing, relationships with children and better mental and physical health. However, there is currently limited evidence on whether RR is more effective than community treatment in supporting long-term recovery, improving health, and breaking cycles of trauma and drug use that can affect future generations. This research is needed to understand whether residential rehabilitation offers unique benefits for women leaving prison and how it might reduce re-offending and improve outcomes for them and their children.
This study is part of six work packages and will test whether the best way to evaluate this rehabilitative pathway from prison to WORR is through conducting a randomised controlled trial (RCT). However, because we know that RCTs in criminal justice settings are challenging to get right, we are conducting a feasibility study. This will help us work out whether an RCT is the best way to test whether going from prison to WORR is the most effective way to support women leaving prison and trying to recover from drug dependency or whether other methods are effective. We will also conduct a health economic analysis to explore the scope of costs, benefits and value for money of WORR.
The feasibility study aims to assess the feasibility of evaluating a resettlement pathway for drug

dependent criminalised women (DDCW) leaving prison, comprising of immediate transfer to a women-only, gender-and trauma- informed residential rehabilitation facility, in achieving long term recovery from dependent drug use compared to treatment as usual.

Who can participate?
Women who are using or have used services for support with drug dependency and are due for release from prison. These women will be given a brief information sheet containing information on the study by one of the two routes:
1.A member of the research team when they visit the prison to carry out interviews/focus groups as part of work package 4 will introduce the study and provide a copy of the summary information sheet to women identified by the
offender manager or SPOC (Specific Point of Contact) as due for release and as potentially suitable for the study based on the criteria.
2. A copy of the summary information sheet given to potentially suitable women by the prison's drug liaison officers.

What does the study involve?
In the study, eligible and consenting participants will be randomly allocated to be transferred to a women-only, gender and trauma-informed residential rehabilitation service upon release for up to 12 weeks or usual care.
Usual care is likely to vary depending on the area to which a woman moves to on release and is likely to consist of but is not limited to, community drug services, supported housing, counselling, location to recovery approved premises and in some cases women will not engage with drug services after release.
Outcome measures will be collected at baseline, 3 months and 6 months and qualitative interviews will be conducted with consenting participants at 3 and 6 months.
Following consent, the baseline appointment will be led by a trained researcher. Participants will complete a set of validated questionnaires to assess their well-being and recovery status. All participants will be asked to complete a 3-month and 6-months post-treatment follow up. These participants will be contacted via their preferred method of contact by a researcher and arrange to complete the outcome measures again. Participants can choose to meet in their home or a safe location to complete their follow up appointment.
The participant will be asked to complete the same questionnaires as the baseline as well as the following additional measures:
1. Collection of a urine sample (optional)
2. Record of self-reported drug use
To maintain engagement, the researcher will check in with participants every 4 weeks by phone or text to update contact details and offer any signposting support.

What are the possible benefits and risks of participating?
Participants in the intervention arm may benefit from specialised programmes to aid in their recovery. This may involve support addressing substance use in the context of broader mental, physical, and emotional well-being. Specialist provision is available for women with histories of domestic violence, sex work, and parenting responsibilities.
Completing the questionnaires and engaging with the researcher may provide participants with an opportunity to reflect on and discuss their experiences of prison in a supportive setting. Additionally, by contributing to this feasibility study and sharing their views and opinions, participants may help to shape future research. Their input could play an important role in informing the design and development of a full trial,should the study progress.
The main burden of taking part in this research is the time taken to complete the questionnaires at each time point (baseline, 3 and 6 post randomisation). Care has been taken to reduce the burden on participants where possible and only collect data that is directly related to the study

objectives.
There is the potential for participants to become distressed as some of the questions will ask about their mental and physical health, experiences of being in prison and their children. If a participant becomes distressed or upset during the follow up appointment or interview aspect of the appointment, they will be given the opportunity to pause the interviews, move on from that topic or end the interview/questionnaire.
The participant will be informed they can withdraw from any aspect at any point in the study.
The researcher collecting the information is experienced in working with women in prisons and will be trained to approach and discuss potentially upsetting topics sensitively and to provide signposting if appropriate.
Participants assigned to residential rehabilitation may experience some upset if transferred to residential rehabilitation that is far from their home address or family/children.

Where is the study run from?
University of York (UK)

When is the study starting and how long is it expected to run for?
Recruitment begins in March 2026 for 4 months until July 2026. The study ends May 2027.

Who is funding the study?
National Institute for Health Research (NIHR) Public Health Research Programme: NIHR166825 (UK)

Who is the main contact?
Rachel Ellison, rachel.ellison@york.ac.uk or arrow-study@york.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Central Portfolio Management System (CPMS)
71471

National Institute for Health and Care Research (NIHR)
166825

Integrated Research Application System (IRAS)
360681

Study information

Scientific Title
Assessing Residential Rehabilitation for Women (ARROW): assessing the potential of a women only, gender- and trauma-informed residential rehabilitation pathway for drug dependent women leaving prison: a feasibility study

Acronym
ARROW

Study objectives
This study aims to assess the feasibility of evaluating a resettlement pathway for drug dependent criminalised women leaving prison, comprising of immediate transfer to a women-only, gender and trauma-informed residential rehabilitation facility, in achieving long term recovery from dependent drug use compared to treatment as usual. To achieve this, the study will evaluate:
Objective 1: the feasibility of recruiting women to the intervention

Objective 2: the acceptability of the intervention to participants
Objective 3: elements of the study procedures for testing in a future study

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/12/2025, North East - York Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8079; york.rec@hra.nhs.uk), ref: 25/NE/0210

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Drug-dependent women leaving prison

Interventions
In the trial, participants will be randomly allocated to be transferred to a women-only, gender and trauma-informed residential rehabilitation service or usual care. Usual care is likely to vary depending on the area to which a woman moves to on release and is likely to consist of but is not limited to, community drug services, supported housing, counselling, location to recovery approved premises and in some cases women will not engage with drug services after release.

Outcome measures will be collected at baseline, 3 months and 6 months and qualitative interviews will be conducted with consenting participants at 3 and 6 months.

Identification and Recruitment:
Prison-based drug treatment staff will identify women that are or have used their services for support with drug dependency and are due for release from prison.

These women will be given a brief information sheet containing information on the study by one of the two routes:
1. A member of the research team when they visit the prison to carry out interviews/focus groups as part of work package 4 will introduce the study and provide a copy of the summary information sheet to women identified by the offender manager or SPOC (Specific Point of Contact) as due for release and as potentially suitable for the study based on the criteria.
2. A copy of the summary information sheet given to potentially suitable women by the prison's drug liaison officers.

Those women provided with a summary information sheet and interested in taking part can approach the in-prison specific point of contact (SPOC) or be approached by the researcher/RDN researcher to confirm eligibility for the study as per the inclusion and exclusion criteria. Women eligible for the study will be given the full PIS and a chance to discuss the study and any questions and informed they will need to be assessed for rehab suitability. They will then be assessed for suitability for residential rehabilitation (RR) by a member of the rehabilitation team.

Those women who are suitable for RR and eligible as per the study inclusion criteria will be given a minimum of 2 days to consider if they would like to take part in the study. If they agree, another visit will be scheduled where women will have informed consent taken and baseline data collected by the researcher/RDN.

Those who do not meet the criteria will not be recruited on to the study and will continue to receive usual care upon release out of prison (this will be explained to the participant prior to giving consent).

Consent:
Women who meet the criteria and wish to take part will be asked to provide written informed consent. Participation in the study will be entirely voluntary and informed consent will be obtained via paper consent form. Participants will have time to ask any questions about the study and request more time to think about their participation. The researcher will determine the participant's capacity to provide informed consent including that the participant can can understand the information given to them about the study, retain the information, be able to relay the information back and can make a decision about participation.
Participants will consent to being part of the feasibility study as well as being invited to take part in qualitative interviews (explained below).
They will also be asked to share contact details for themselves and 2 trusted recovery supports (e.g. a family member or friend) to help maintain contact after release.

Baseline Assessment:
Following consent, the baseline appointment will be led by the trained researcher. Participants will complete a set of validated questionnaires to assess their well-being and recovery status. This discussion may be upsetting to the participant and so the researcher has been trained to handle these questions sensitively. The questionnaires will be collected in person and on paper in the first instance, then uploaded on to redcap at the university of York by the researcher (or a member of the York trials unit). The standardised measures are:
1. Substance Use Recovery Evaluator (SURE)
2. Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)
3. Patient Health Questionnaire-9 (PHQ-9) PHQ-9 (depression)
4. General Anxiety Disorder-7 (GAD-7) (anxiety)
5. EQ-5D-5L (quality of life)
We expect this to take around 45-60 minutes.

Randomisation and Intervention:
Participants will then be randomly assigned (1:1) to one of two groups using a secure online system:
1. Residential Rehabilitation (RR): Participants will be transferred to a women-only, gender- and trauma-informed residential rehab service upon release for up to 12 weeks
2. Treatment as Usual (TAU): Participants will receive the standard community-based support available in their area. The researcher will not be blind to the allocation.

Follow-Up and Interviews:
All participants will be asked to complete a 3-month and 6-months post-treatment follow up. These participants will be contacted via their preferred method of contact by a researcher and arrange to complete the outcome measures again. Participants can choose to meet in their home or a safe location to complete their follow up appointment.The participant will be asked to complete the same questionnaires as the baseline as well as the following additional measures:

1. Collection of a urine sample (optional)
2. Record of self-reported drug use

Participants will also be invited to take part in a qualitative interview during these follow-ups. These interviews will explore their experiences of support and recovery, guided by a topic guide. The discussion will cover areas such as their physical and mental health, relationships and social support, access to housing, education, and treatment services, and their personal values and beliefs. The conversation will be guided by what each participant feels is most relevant and comfortable to share. These interviews will be recorded for transcribing and coding purposes.

To maintain engagement, the researcher will check in with participants every 4 weeks by phone or text to update contact details and offer any signposting support.

We expect the follow up visits to take around 30-60 minutes for the questionnaires to be completed and an additional 30-60 minutes if they decide to take part in the optional interview.

Health Economics (Work Package 6):
To understand the broader costs and benefits of the RR pathway, a health economics analysis will be conducted. This will assess the feasibility of collecting economic data and explore the value for money of RR compared to usual care.

Data will be collected on:
1. Costs of delivering RR (e.g. staffing, facilities, medical care)
2. Use of services such as healthcare, housing, social care, and criminal justice
3. Wider impacts, including employment status and whether participants' children are in state care
Participants will self-report service use through tailored questionnaires, with space to include services not listed.
Quality of life will be measured using the EQ-5D-5L at baseline, 3, and 6 months. The completeness and clarity of this data will be reviewed to inform the design of a future full-scale trial.

Intervention Type
Behavioural

Primary outcome(s)
Abstinence assessed via urine test at 3 and 6 months post randomisation

Key secondary outcome(s))
Patient-Reported Outcome Measures (PROMs) using validated questionnaires, including:
1. The Substance Use Recovery Evaluator (SURE), a patient-reported outcome measure of recovery from alcohol and other drugs.
2. Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS), a 7-item questionnaire developed to enable the monitoring of mental wellbeing in the general population and evaluate projects which aim to improve mental wellbeing.
3. PHQ-9, a 9-item, self-completed questionnaire for screening, diagnosing, monitoring and measuring the severity of depression.
4. GAD-7, a 7-item, self-completed questionnaire used as a screening tool and severity measure for generalised anxiety disorder.
5. Modified EQ-5D-5L, an instrument for use as a measure of health outcome that is applicable to a wide range of health conditions and treatments. The descriptive system has five health

domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) with five response options for each domain (no problems, slight problems, moderate problems, severe problems, and extreme problems).
All PROMs collected at baseline, 3 and 6 months post randomisation.

6. Adverse events recorded using a bespoke form designed to record any untoward events during a participant's time in the trial. These can be reported at any time through a woman's time on the study but will be specifically asked about 3 and 6 months post randomisation
7. Participant resource use data collected at baseline, 3 and 6 months post randomisation
8. Residential rehabilitation service resource use collected post-intervention
9. Release planning form collected at baseline
10. Treatment as Usual Form collected at 3 and 6 months post randomisation
11. Screening, consent, recruitment and withdrawal data collected throughout the duration of the trial

Completion date
01/12/2026

Eligibility

Key inclusion criteria
1. Women who are 18 years old and over
2. Require support with substance use and associated needs
3. Are willing to receive support or engage in treatment
4. Have capacity under the Mental Health Act
5. Can speak English to a sufficient level to understand the intervention and research materials
6. Are due for release before the end of the recruitment period but with a minimum of 6 weeks left prior to release

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. On remand
2. Pregnant
3. Has complex unmanaged mental health needs, is not engaging with mental health support or is presenting in crisis
4. Requires personal/nursing care
5. Has a significant cognitive impairment or severe learning difficulties that affect functioning and may require support that cannot be provided onsite

Date of first enrolment
02/03/2026

Date of final enrolment
01/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hmp/ Yoi Eastwood Park
Falfield
Wotton-under-edge
England
GL12 8DB

Study participating centre
Hmp Foston Hall
Foston
Derby
England
DE65 5DN

Study participating centre
Hmp Downview
Sutton Lane
Sutton
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SM2 5PD

Study participating centre
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Styal Road
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SK9 4HR

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

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 from the Chief Investigator, Professor Sharon Grace (sharon.grace@york.ac.uk) and /or the Trial Manager (arrow-study@york.ac.uk).

IPD sharing plan summary

Available on request