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# Pre-birth assessments for women who use substances in pregnancy

**Submission date**
23/07/2025

**Recruitment status**
No longer recruiting

**Registration date**
23/07/2025

**Overall study status**
Ongoing

**Last Edited**
23/07/2025

**Condition category**
Pregnancy and Childbirth

[ ] 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

This study looks at how pregnant women who use alcohol or drugs are assessed before their baby is born (this is called a pre-birth assessment) and how social workers and the women themselves experience this process. The number of newborn babies being taken into care has risen in recent years. Many of these cases involve parents with drug or alcohol problems. However, we don't know much about how women feel about these assessments, or how social workers are trained to carry them out. The Willow Study aims to find out how women experience pre-birth assessments, what support they get and how they feel about it. It plans to understand the views and experiences of social workers who carry out these assessments and how social workers and women communicate. The study will also learn about the support available before, during, and after legal proceedings (like court hearings), collect numbers on how often pre-birth assessments happen in three local areas, and work with parents and social workers to come up with suggestions on how to improve the process. The goal is to make sure pregnant women who use substances are better supported, and that social workers have the right tools and training to carry out assessments fairly and compassionately.

Who can take part?

Women aged 18 or over who recently (in the past 12 months) had or are currently going through a pre-birth assessment and who have used alcohol or drugs or were in treatment for drugs or alcohol during pregnancy. Women will be invited through services they already use, like local social work teams. The study also includes social workers and other professionals who are involved in these assessments.

What does the study involve?

The research will take place in three areas: two in England and one in Wales. It will include:
1. Interviews with women about their experiences during and after the pre-birth assessment. These interviews can be in person, on the phone, or online. Participants can choose what they are comfortable with, and they can stop at any time.
2. Interviews and focus groups with social workers and managers. These will explore their views, challenges, and training around working with pregnant women who use substances.

3 Analysis of anonymised data (without names) from the local councils. This will include details like how many pre-birth assessments were done, when they happened, and what the outcomes were.

The study also involves a Parent Advisory Group, made up of parents with experience of the system, who have helped shape the questions and materials to ensure they are respectful and appropriate. The findings will be used to create best practice recommendations for social workers, so that future pre-birth assessments can be done in a more supportive and effective way. This research has been carefully planned with people who have lived experience of pre-birth assessments and child protection services. The team is committed to ensuring the study is ethical, respectful, and useful.

What are the possible benefits and risks of participating?
It is hoped that taking part will help women in the future by improving the way that social workers assess women who use or are in treatment for drug or alcohol use.

For women, there is a risk that talking about their experiences may be upsetting.

Where is the study run from?
The Willow Study is a collaboration between:
1. University of Sheffield, UK
2. Cardiff University, UK
3. King's College London, UK
4. Liverpool John Moores University, UK

When is the study starting and how long is it expected to run for?
January 2025 to December 2026

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

Who is the main contact?
Dr Shirley Lewis, s.j.lewis@sheffield.ac.uk

# Contact information

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Public, Scientific, Principal investigator


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## Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Protocol serial number
NIHR206557

## Study information

### Scientific Title
The Willow Study: pre-birth assessments for women who use substances in pregnancy: women and social work views and experiences

### Acronym
The Willow Study

### Study objectives
Research aim:
To explore how pre-birth assessments for women who use substances in England and Wales are experienced by women and social workers, and to develop practice recommendations in consultation with experts by experience based on those findings.
Research objectives:
To explore the views and experiences of social workers in undertaking pre-birth assessments for

pregnant women who use substances.
2. To understand women's experiences of pre-birth assessments, including timings of assessments, pregnancy, birth and postnatal experiences.
3. To gain insights into communication and interactions between social workers and women.
4. To understand what support was needed and provided for women before, during and after court proceedings.
5. To understand the prevalence of women who use substances in pregnancy who undergo pre-birth assessments.
6. To use learning from this study to co-produce (with women and other stakeholders) best practice recommendations on undertaking pre-birth assessments with women who use substances.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
1. approved 14/04/2025, School of Allied Health Professions, Nursing and Midwifery Ethics Committee (The University of Sheffield, Western Bank, Sheffield, S10 2TN, United Kingdom; +44 (0)114 222 2000; l.v.unwin@sheffield.ac.uk), ref: 066269

2. approved 30/04/2025, Barnardo's Research Ethics Committee (Tanners Lane, Barkingside, IG6 1QG, United Kingdom; -; brec@barnardos.org.uk), ref: 26

## Study design
Mixed-method study design

## Primary study design
Observational

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Substance use/treatment for substance use in pregnancy in women who undergo pre-birth assessments with Children's Services

## Interventions
This is a mixed-method study design involving qualitative interviews and focus groups with women and practitioners and quantitative data analysis over 3 sites (2 in England and 1 in Wales). The mixed-method study uses a critical realist approach. Interviews and focus groups will be undertaken with 45 professionals and 25 women in three local authorities in England and Wales. The study will collect data from each local authority about the number of pre-birth assessments and how many include substance use to help us understand the prevalence of substance use in pre-birth assessments.
Throughout the study, the research team will adhere to the principles of co-production through working with a parental advocacy group and establishing a steering group of experts. This will ensure that the study remains relevant and is disseminated appropriately.

Qualitative data will be analysed through reflexive thematic analysis. Thematic analysis is a reflexive approach to data analysis that allows for the application of a range of theoretical perspectives and is used to identify themes and meanings from the data. Further sense-making

and analysis will be conducted in stakeholder workshops with mothers and practitioners before co-developing recommendations.

Quantitative Analysis: We will conduct secondary analysis of social care records. Local authority data officers will extract routinely collected data from their records. These anonymous data will be imported into R. Given the under-researched population, initial work will be descriptive to create a profile of the population of interest compared to the general population. Discussions with local authorities indicate that over 5 years, there will be 3000 women who have pre-birth assessments and have a substance use condition. We expect some coding discrepancies between sites and will build a codebook which will be cross-referenced with sites to ensure consistency in responding and meaning of responses across sites, allowing for comparison. If possible, inferential statistics will be run to determine predictors of pre-birth assessments for women who use substances compared to those who do not. These will primarily be conducted with logistics regressions. Where possible for child outcomes (e.g. care status of baby), logistic regressions will be used, accounting for the nested nature of the data using random intercepts. To adjust for potential confounds between those who do and don't use substances during pregnancy (e.g. age, ethnicity), propensity score matching will be conducted before inferential statistics at a ratio of 1:1 using nearest match methods and also 1:4 as part of sensitivity analysis. Nearest match methods and 1:4 ratio of matching will be used to preserve and boost the power in the sample. Imputation will be conducted for missing data, along with complete case analysis to assess the impact of missing data on findings.

### Intervention Type
Other

### Primary outcome(s)
The primary outcome measures are assessed through the secondary analysis of social care records. Local authority data officers will extract routinely collected data from their records.

Quantitative outcomes
1. Pre-birth assessments measured using logistic regression to identify predictors
2. Care status of baby measured using logistic regression with random intercepts to account for nested data
3. Population profile characteristics (e.g. age, ethnicity) measured using descriptive statistics
4. Predictors of pre-birth assessments measured using logistic regression after propensity score matching (1:1 and 1:4 ratios)
5. Impact of missing data assessed using imputation and complete case analysis

Qualitative Outcomes
1. Themes and meanings from qualitative data identified using reflexive thematic analysis
2. Insights from stakeholder perspectives (mothers and practitioners) explored through stakeholder workshops and used to co-develop recommendations

### Key secondary outcome(s))
There are no secondary outcome measures

### Completion date
31/12/2026

## Eligibility

### Key inclusion criteria
Inclusion criteria for women:
1. Age 18 or over
2. Able to give informed consent
3. Experience of a pre-birth assessment in the last 12 months or currently undergoing assessment.

Inclusion criteria for professionals:
Any professional involved in undertaking pre-birth assessments for women within the three local authorities

### Participant type(s)
Service user, Other

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
Unable to give informed consent
1. Not had a pre-birth assessment within 12 months
2. Not used / in treatment for substance use

For professionals:
Not involved in pre-birth assessments

### Date of first enrolment
01/06/2025

### Date of final enrolment
31/03/2026

## Locations

### Countries of recruitment
United Kingdom

England

Wales

**Study participating centre**
**Northumberland County Council**
County Hall
Morpeth
United Kingdom
NE61 2EF

**Study participating centre**
**Leeds City Council Child Services**
6th Floor East, Merrion House
110 Merrion Way
Children's Services
Leeds
United Kingdom
LS2 8BB

**Study participating centre**
**Newport Barnardo's Partnership - Integrated Family Support Service**
Newport City Council Civic Centre
Godfrey Road
Newport
United Kingdom
NP20 4UR

# Sponsor information

**Organisation**
University of Sheffield

**ROR**
https://ror.org/05krs5044

# 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 the current study are not expected to be made available due to the sensitivity of the research.

### IPD sharing plan summary
Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |