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Pre-birth assessments for women who use substances in pregnancy

Submission date
23/07/2025

Recruitment status
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

Study website
https://sheffield.ac.uk/ahpnm/research/children-and-young-people/willow-study

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Mixed methods using qualitative interviews and focus groups and a critical realist approach

Study setting(s)
Built environment/local authority, Charity/Voluntary sector, Community, Home

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 measure

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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/01/2025

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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
England

United Kingdom

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

Sponsor details
Firth Court
Western Bank
Sheffield
England
United Kingdom
S10 2TN

Sponsor type
University/education

Website
https://sheffield.ac.uk/

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

Publication and dissemination plan

The results will be shared through:
Reports and summaries for professionals.
Leaflets and updates for parents.
Webinars and practice briefings.
Academic publications.
A summary for participants who want to receive the findings.

An impact plan will be developed so that the findings are disseminated to the participating local authorities and wider practitioners and policymakers. This will include, for example, practice webinars and articles for Community Care (an online social work resource) about the findings. Findings will be disseminated in Wales through an Exchange Wales webinar and a dedicated resource page.

Outputs:
A minimum of two academic journal articles in social work journals, e.g. British Journal of Social Work, Child and Family Social Work
Report and Brief Summary – for social workers
Practice Recommendations – summary of created practice recommendations for social workers, local authorities and policy-makers
Report for parents – summary of report and practice recommendations for parents
Conference presentation – presentation of findings at a social work conference (e.g. EuSARF)
Practice briefings/webinars – webinars to share findings with practitioners and academics

Engaging key stakeholders:
Key organisations that need to be informed about the work include children's social care and drug treatment services. We will inform those organisations through publication of the outputs above. We will also update key organisations throughout the research process through the study critical reference group. In addition, we will contact groups such as the Association of Directors of Children's Services and Research in Practice to invite members to practice briefings and disseminate information. We will work with the participating local authorities to discuss the best way to disseminate the findings within those authorities.

Intention to publish date

31/12/2027

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