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BREATHE: A Realist Evaluation study to understand smoking tobacco cessation and how to support pregnant women with this

Submission date
16/01/2026

Recruitment status
Recruiting

Registration date
23/03/2026

Overall study status
Ongoing

Last Edited
23/03/2026

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
The BREATHE Study is looking at how best to support pregnant women to stop smoking, especially women living in areas of social deprivation.
Smoking during pregnancy increases the risk of premature birth (baby born before 37 weeks), babies being smaller than expected for their stage of pregnancy, stillbirth,and health problems for both mother and baby
Although all pregnant women are entitled to free stop-smoking support, the type and level of support varies across England. This study aims to understand:
• What works to help pregnant women stop smoking
• Who it works best for
• In what circumstances it works
• Why it works
The study will also look at whether stop-smoking services are linked to lower rates of premature birth, small babies, and stillbirth.
The goal is to develop recommendations to improve stop-smoking support for pregnant women, particularly those living in deprived areas.

Who can participate?
1. Pregnant women:
• Aged 18 or over
• English speaking
• Receiving antenatal care
• Involved in, or eligible for, stop-smoking services
2. Staff:
• Aged 18 or over
• English speaking
• Involved in providing stop-smoking support (clinical or non-clinical roles)
In addition, the study will use anonymous routine hospital data from all women who received maternity care at the participating hospitals over a one-year period.

What does the study involve?
1. Interviews:
• Around 5–10 women and 5–10 staff members at each hospital will be interviewed.
• Interviews will take place by phone or video call.
• Women may be interviewed up to three times during pregnancy.
• Interviews will focus on experiences of stop-smoking support and what helped or did not help.
2. Routine hospital data:
• Anonymous, non-identifiable hospital data will be collected for one year.
• This will include information such as smoking status at booking, referrals to stop-smoking services, and birth outcomes.
• No personal identifying information will leave the hospital sites.
All interview recordings will be transcribed and anonymised. Participants will not be named in any reports.

What are the possible benefits and risks of participating?
Possible benefits:
• Helping improve stop-smoking services for pregnant women.
• Contributing to knowledge that may reduce premature birth and stillbirth.
• Giving women and staff the opportunity to share their experiences.
There is no direct medical benefit to participants.

Possible risks:
• Some women may feel mild emotional discomfort when discussing smoking or pregnancy experiences.
• Participants can skip any question or withdraw at any time without giving a reason.
• Confidentiality may only be broken if there is a serious concern about someone's safety.
No significant risks are expected.

Where is the study run from?
The study is sponsored by King's College London.
It is being carried out at three NHS hospital trusts in West Yorkshire:
• Leeds Teaching Hospitals NHS Trust
• Calderdale and Huddersfield NHS Foundation Trust
• Mid Yorkshire Teaching NHS Trust
These hospitals are part of the West Yorkshire and Harrogate Local Maternity and Neonatal System.

When is the study starting and how long is it expected to run for?
The study started in September 2025. It will run for 22 months, finishing in July 2027.

Who is funding the study?
The study is funded by Tommy's, a UK charity that funds research to prevent pregnancy complications and baby loss. The funder has not influenced the design of the study.

Who is the main contact?
Chief Investigator:
Dr Tomasina Stacey
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Additional identifiers

Integrated Research Application System (IRAS)
364173

Central Portfolio Management System (CPMS)
72284

Study information

Scientific Title
Realist EvAluation to understand smoking Tobacco cessation and How to support pregnant womEn

Acronym
BREATHE Version 1

Study objectives
1. To identify contexts and mechanisms leading to both positive and negative outcomes of smoking cessation in areas of social deprivation.
2. To understand the relationship between the contexts, mechanisms and outcomes of smoking cessation in areas of social deprivation.
3. To identify and assess a range of outcomes in smoking cessation in areas of social deprivation, and any unintended consequences.
4.To determine optimal theories and produce a set of recommendations to successfully support women to stop smoking in pregnancy who live in deprived areas.

Secondary Clinical objective:
To determine whether smoking cessation services reduce the incidence of women with a singleton pregnancy giving birth to a baby who is:
a. born preterm (before 37 weeks' gestation)
b. small for gestational age
c. stillborn

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 14/01/2026, South Central - Hampshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; hampshireb.rec@hra.nhs.uk), ref: 26/SC/0020

Primary study design
Observational

Secondary study design
Qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Smoking tobacco cessation in pregnant women

Interventions
The study will run for 22 months across three NHS Trusts in West Yorkshire. It involves two main components:
Interviews with pregnant women who smoke or have recently quit, and with staff who deliver smoking cessation support.
Analysis of routinely collected maternity and neonatal data from the participating Trusts (e.g. gestation at booking, smoking status, referral to services, birth outcomes).

Participants and data collection:
Pregnant women: Women aged 18 or over, receiving antenatal care, identified by their clinical team as smokers or recent quitters. Around 5-10 women from each site will be interviewed.
Staff: Midwives, stop smoking advisors and other maternity staff involved in smoking cessation care. Around 5-10 staff from each site will be interviewed.
Each participant will be invited to take part in one interview only. Interviews will be conducted remotely (telephone or video call), at a time convenient to the participant. Interviews will last approximately 45–60 minutes. Women and staff will be asked about their experiences of smoking cessation care, what worked well or less well, and in what situations. The researcher may share some ideas (“programme theories”) and ask for feedback. Interviews will be audio-recorded (with consent), transcribed, and anonymised. Participants can skip questions or stop at any time.

Data analysis:
Qualitative data will be analysed using a realist logic.
Quantitative data will be analysed with descriptive statistics to answer the secondary clinical outcome
Routinely collected maternity and neonatal data will be aonymised before transfer to the research team, and analysed to confirm, falsify, or refine elements of the programme theorie

Intervention Type
Behavioural

Primary outcome(s)
1. Contexts and mechanisms leading to both positive and negative outcomes of smoking cessation in areas of social deprivation measured using realist CMO configurations from interviews with staff and women at months 5 -18

2. The relationship between the contexts, mechanisms and outcomes of smoking cessation in areas of social deprivation measured using realist CMO configurations from interviews with staff and women at months 5 -18

3. Outcomes in smoking cessation in areas of social deprivation, and any unintended consequences measured using realist CMO configurations from interviews with staff and women at months 5 -18

Key secondary outcome(s)
1. Pregnancy and neonatal outcomes measured using quantitative routinely collected clinical data at months 5 -18

Completion date
30/07/2027

Eligibility

Key inclusion criteria
1. Staff interviews: involved in the smoking tobacco cessation pathway as staff (as clinicians and /or non-clinicians), are 18 years or older, and English speaking.
2. Pregnant women interviews: are involved or eligible to be involved in the smoking tobacco cessation pathway as service users, are 18 years or older, and English speaking.
3. Routine electronic hospital data: maternity and neonatal service users, collected over a continuous 12-month period at each site (January 2025 to December 2025).

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Not English speaking
2. Aged under 18 years
3. Not willing to participate in the research

Date of first enrolment
01/03/2026

Date of final enrolment
01/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
England
LS9 7TF

Sponsor information

Organisation
King's College London

Funder(s)

Funder type
Charity

Funder Name
TOMMY'S

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available