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Developing an intervention to help pregnant women decide whether to vaccinate or not

Submission date
12/02/2025

Recruitment status
Recruiting

Registration date
28/02/2025

Overall study status
Ongoing

Last Edited
08/10/2025

Condition category
Other

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

Plain English summary of protocol
Background and study aims
Pregnant women are at increased risk of being serious ill from illnesses such as flu and covid-19, and their babies are at risk of serious complication from these and whooping cough. Despite this, many pregnant women choose not to have vaccinations whilst they are pregnant.
This study aims to find out from pregnant women, how they want information about vaccination to be available to them, and what it should look like. During this study we will work on making an informational resource that is suitable for pregnant women, and we will get feedback on early stages of the design.

Who can participate?
Anyone who is over the age of 18 and either pregnant, or a healthcare professional working with pregnant women (for example GPs, nurses, midwives). We will make sure people who want to take part are able to understand what they need to do.

What does the study involve?
Participants will be asked to talk to a researcher (they can be part of a small group instead of one-to-one if they prefer) over the phone or video call online. We will talk to them about how they would like to receive information about vaccinations to help us develop our new information.
We will give participants the chance to talk to us again once we have made some initial designs of the information, and we will include feedback as we make it.

What are the possible benefits and risks of participating?
The benefits of taking part in this study is that it will help us to understand what pregnant women want and need from information designed to inform about vaccinations during pregnancy. This will help us to tailor the information in an intervention to help pregnant women make an informed decision about whether to have a vaccination or not.
There are no known disadvantages or risks associated with participating, other than the time it takes to take part. As the questions are related to the vaccinations during pregnancy there is the possibility that discussions may discuss sensitive topics. Whilst we do not think this is likely, if

this does happen, we will offer to pause or end the interview so as not to cause any upset. We expect that the interviews will take between 45-60 minutes depending on how much participants want to say.

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

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

Who is funding the study?
The study is funded by the National Institute for Health and Care Research (NIHR) and is funded by the 'Research for Patient Benefit' scheme (UK)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
335374

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 59050, NIHR206660

Study information

Scientific Title
Developing an intervention to increase vaccination uptake amongst pregnant women using a person based approach

Study objectives
Aims:
To develop an intervention informed by theory and evidence to increase vaccination (Covid-19, flu and whooping cough) amongst pregnant women.

Objectives:
1. Undertake qualitative interviews to explore vaccine information needs and preferences of pregnant women (particularly less-visible groups). To explore clinicians' views of their role in providing this information to pregnant women.
2. To define key features and guiding principles for an intervention to increase uptake of vaccination amongst pregnant women, based on Person-Based Approach to intervention development.
3. Undertake qualitative interviews to receive user feedback on the intervention, using 'Think Aloud' methodology. To modify intervention content based on feedback and receive feedback on revised versions.
4. To have a full intervention ready at the end of the study for testing in future research

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/02/2025, London - Camberwell St Giles Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8256; camberwellstgiles.rec@hra.nhs.uk), ref: 25/PR/0117

Study design
Qualitative

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vaccine in pregnancy

Interventions
This is a qualitative study involving semi-structured interviews with pregnant women (focus groups will also be offered to pregnant women if they prefer) and clinicians involved in the care of pregnant women (GPs, midwives, nurses, and pharmacists), to determine how to design a new intervention for pregnant women, to provide information to help with vaccination decisions.

It will involve a two-phased intervention development design, based on the Person-Based Approach (PBA). PBA focuses on user involvement and uses qualitative research to understand how users will engage with interventions. It allows for users to influence changes to the intervention and to make sure they are effective before implementation. Traditionally, the PBA involves three phases: Intervention Planning, Intervention Optimisation, and Intervention Implementation and Mixed Methods Process evaluation. This study will include Phases 1 and 2, with Phase 3 conducted in a later, separate study.

Qualitative interview schedules, analysis of qualitative data, and development of the intervention will use the Illness Risk Representation (IRR) Framework to understand and address pregnant women's vaccination beliefs and behavior. The IRR Framework is based on Health Psychology theory and suggests that individuals' risk and efficacy appraisals impact behavior. The IRR Framework explains beliefs underlying risk appraisals and identifies areas to change behavior. The intervention will use the IRR Framework to target an increase in vaccination.

Phase 1: Intervention Planning
1.1 Existing qualitative research: Phase 1 is informed by previous qualitative research conducted by the research team on views and beliefs of flu vaccination in pregnancy, and qualitative research on views of vaccinations following the Covid-19 pandemic (RfPB: NIHR203598).

1.2 New qualitative research: New research within this study will explore what pregnant women want from an intervention. This will consist of interviews (or focus groups if preferred) with pregnant women to explore what information pregnant women want, how they want messages to convey information, and where and when they think pregnant women should be made aware of the intervention. This will inform guiding principles (what the intervention needs to do to address needs of target users and increase engagement with the intervention).

Qualitative interviews (1.2)
Sampling and recruitment: Semi-structured interviews or focus groups (depending on the preference of participants) will be conducted with up to 40 pregnant women and 20 clinicians. Maximum variability sampling will be employed to recruit women (age, ethnicity (including non-English speaking women), vaccination history during pregnancy, deprivation, stage of pregnancy) and clinicians (profession, age, years since qualification) from a range of demographics. High-risk populations such as black women will be over-recruited to capture views and needs of this group. High-risk populations such as women from black ethnicities will be recruited via a community group (MAMTA) that provide support and health education to improve child and maternal health amongst Black and Minority Ethnic women in Coventry. Recruiting via community groups, and community leaders has been successful in previous research, in building trust and confidence for this population in taking part in research. We will aim to recruit participants who both have had and have not had vaccinations, in order that wide views are captured.

Pregnant women will be recruited from antenatal and community clinics at participating hospitals and community groups (including MAMTA). Study information will be given to participants by midwives/community leaders and asked to contact researchers if happy to participate. Interviews will be conducted remotely (telephone or video-call) and will take 45-60 minutes (participants will be offered the choice of a shopping voucher, or a one-off thank-you payment via BACS).

Clinicians (health professionals that are involved in pregnant women's care, including midwives, GPs, nurses, and community pharmacists) will be recruited via hospitals, professional networks, and social media. Interviews will be conducted remotely and will take 30-45 minutes.

Participants will receive written participant materials and will provide verbal or written consent prior to participation. All participants will be reimbursed for their time (participants will be offered the choice of a shopping voucher, or a one-off thank-you payment via BACS).

Data collection: Topic guides for interviews (or focus groups depending on individual participant choice) will explore what information pregnant women want and need to make vaccination decisions, where and how they want this information, and what a suitable intervention looks like. Interview schedules and analysis of interviews will be informed by the Illness Risk Representation (IRR) Framework, as a theoretical framework to understand vaccination beliefs and behavior of pregnant women. The IRR Framework provides an understanding of beliefs influencing risk appraisals and how to change them to change behavior. Topic guides for interviews with clinicians will explore their view of their role in information provision to pregnant women and what they feel women are responsive to in terms of vaccination information. All interviews will be audio recorded and transcribed by a University-approved transcription service.

Data analysis: Interviews and focus groups will be analysed using a Codebook approach to Thematic Analysis, which provides a flexible approach to qualitative analysis using a structured codebook, whilst recognising the interpretative nature of data coding. The six phases of Thematic Analysis will be applied to the data: 1. Familiarisation with the data; 2. Generating initial codes; 3. Generating themes; 4. Reviewing potential themes; 5. Defining and naming themes; 6. Producing the report. Interviews will be conducted and analysed using the IRR Framework, as a method of understanding vaccination decision-making and to identify needs from an intervention. A coding frame will be developed with the data and will be revised iteratively. Both inductive and deductive approaches to thematic analysis will be employed, whereby themes will be developed from the data, and by domains of the IRR Framework. PPI contributors will be involved in analysis. Anonymised coding reports and thematic summaries will be shared and will receive PPI feedback. This will inform communication with the design company to shape the intervention.

The Proposed Intervention
Mode and content of the intervention will be determined during the study and informed by existing and new evidence (Phase 1). The intervention will target informational needs identified by pregnant women and clinicians, and will be informed by behaviour change theory; based on the IRR Framework to understand beliefs underlying pregnant women's risk appraisals (perceptions of risk to becoming ill) and targeting these through the intervention.

The intervention will draw on the evidence base and on clinical expertise to ensure accurate information and appropriate approaches to presenting it are taken. It is likely to include strategies to correct misconceptions and myths about vaccinations, provide clear messages around guidance and recommendations, signposting to trusted organisations, clear information about where, when and how vaccinations are available (to overcome practical barriers), information on safety and effectiveness of each vaccination, stage of pregnancy or time of year vaccinations are offered, and sources of information for more information or support.

It is anticipated there will be sections for flu, whooping cough, and COVID-19 vaccinations, although exact content, mode, and style will be informed by qualitative work (Phase 1). Sections will include different approaches to make it engaging (e.g., text, audio). Whilst acknowledging that the pregnant population in the UK is very diverse, the intervention developed will take a universal approach, but will be intended for all audiences, and easily translated into other languages.

The intervention will be in a format that can be easily shared with any pregnant woman requiring more information on vaccinations. It will be aimed at all pregnant women to provide information to support their vaccination decisions. A secondary aim will be providing partners and families of pregnant women with information to support vaccination decisions. Intervention development will involve the engagement of a specialist design company (experienced in developing health-related interventions) to develop intervention materials.

Phase 2: Intervention Optimisation

This phase involves inductive qualitative work using Think Aloud Methods, to elicit user feedback on early versions of the intervention (a prototype of the intervention) (e.g., content, language, colours, messages) using mock-ups of the intervention (depending on mode decided by Phase 1, this will be written material, screenshots of webpages or similar) with the focus on content and usability of materials. It aims to understand target user views of using the proposed intervention materials. Materials will then be modified based on user feedback, with further qualitative work ensuring modifications have addressed the feedback and have improved the intervention.

Sampling and recruitment

Recruitment of pregnant women for Phase 2 will include giving participants from Phase 1 the opportunity to be involved in Phase 2. Additional pregnant women will also be recruited from the same sources as in Phase 1. Approximately 20 pregnant women will be interviewed in this phase, aiming to recruit a varied sample demographically (age, ethnicity, deprivation area, stage of pregnancy), and women who are both in favour of vaccinations and vaccine hesitant to explore a range of views.

Data collection

Semi-structured interviews or focus groups (depending on the preference of participants) will be conducted with pregnant women in Phase 2, to explore their views of the prototype intervention. This phase will explore views on messages, content, design, and appropriateness. Think Aloud methods will involve participants verbalising feelings about the materials as they work through them. They will not have seen the materials before, so this will capture their initial reactions.

In addition to immediate and verbal responses elicited from the Think Aloud methodology (based on PPI feedback), participants will be offered the opportunity to provide feedback on materials in other formats if preferred (e.g., video-call chat functions, commenting on word or paper documents, or by emailing researchers reflections after the session). Interpretation of written materials will be made available for non-English speaking participants.

Data analysis

Interviews will be conducted and analysed using the IRR Framework, as a method of understanding vaccination decision-making and to identify needs from an intervention. A coding frame will be developed with the data and will be revised iteratively. Both inductive and deductive approaches to thematic analysis will be employed, whereby themes will be developed from the data, and by domains of the IRR Framework. PPI contributors will be involved in analysis. Anonymised coding reports and thematic summaries will be shared and will receive PPI feedback. This will inform communication with the design company to shape the intervention.

Analysis of the qualitative data collected in Phase 2 will follow similar patterns as in Phase 1, whereby thematic analysis will be conducted on all interviews and focus groups, with this phase of analysis involving the creation of a table of changes to intervention materials that are identified as being needed during this process (in line with the PBA approach). Findings from this

phase will inform refinements to the intervention materials. Cycles of review and refinement will continue until the user feedback confirms the intervention materials are appropriate and suitable to be used by pregnant women. It is anticipated that there will be two rounds of feedback.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Measured by interviews at approximately 6, 9 and 12 months:
1. Pregnant women's information preferences and needs about vaccination using qualitative interviews
2. Clinicians' views on pregnant women's information needs using qualitative interviews
3. Key features and guiding principles for an intervention to increase uptake of vaccination amongst pregnant women
4. User feedback on the intervention at various stages of development using qualitative interviews
Thematic analysis will be used for analysis.

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

Completion date
31/03/2026

Eligibility

Key inclusion criteria
Pregnant women:
Pregnant women at any stage of pregnancy, with any vaccination history. Pregnant women will be over the age of 18 years, with the capacity to consent. Translation services will be used for interviews where English is not the first language, but participants are required to be able to read the participant information sheet in English.

Clinicians:
Clinicians working with or providing care to pregnant women, including (but not limited to) GPs, midwives, nurses and community pharmacists. Clinicians will be over the age of 18 years.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
Any participant who does not have the capacity to consent, or is unable to read the study information in English will be excluded.

Date of first enrolment
10/04/2025

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

As this is a qualitative study, we do not have ethical approval to make whole transcripts available, and this is not included in our consent process.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	for Clincians version 1.1	07/02/2025	28/02/2025	No	Yes
Participant information sheet	for pregnant women from community groups version 1.1	07/02/2025	28/02/2025	No	Yes
Participant information sheet	pregnant women from hospitals version 1.1	07/02/2025	28/02/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.0	23/01/2025	28/02/2025	No	No