Full/long title of the study

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

Short study title/acronym

Intervention to increase vaccination in pregnancy

Protocol version number and date

Version 1.0, 11th Jan 2025

Research reference numbers

IRAS Number	335374
Sponsor reference number	RG_24-114
ISRCTN number	Tbc
REC reference number	tbc

This protocol has regard for the HRA guidance

Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to adhere to the signed University of Birmingham's Sponsorship CI declaration.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature: Date: 11/11/2024

Name: (please print): Jo Parsons

Sponsor statement:

Where the University of Birmingham takes on the sponsor role for protocol development oversight, the signing of the IRAS form by the sponsor will serve as confirmation of approval of this protocol.

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Key study contacts

Chief Investigator: Dr Jo Parsons, [updated.e.parsons@bham.ac.uk]

Sponsor: University of Birmingham

Funder: NIHR Research for Patient Benefit

Key Protocol Contributors: Protocol was developed by the Chief Investigator

Study summary

Study Title:

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

Internal ref. no. (or short title):

Intervention to increase vaccination in pregnancy

Study Design:

Qualitative study, with intervention development

Study Participants:

Pregnant women and clinicians (including midwives, GPs, Nurses and community pharmacists)

Planned Size of recruitment target (if applicable):

Phase 1; 40 pregnant women, 20 clinicians

Phase 2; 20 pregnant women

Follow up duration (if applicable):

No follow-up, but participants in phase 1 will be invited to two interviews in phase 2.

Planned Study Period:

January 2025- March 2026

Committees:

This study will have a study management group, Advisory group and PPIE group

Aim:

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

Funding and support in kind

FUNDER(S)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
NIHR Research for Patient Benefit, Grange House, 15 Church Street, Twickenham, TW1 3NL. 020 8843 8000.	Funding received for the study totalling £170,661.00

Role of study sponsor and funder

The study has been funded by NIHR RfPB, and will be sponsored by the University of Birmingham.

The sponsor and funder will have no involvement in final decision or conduct of study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

Roles and responsibilities of study management committees/groups and individuals

This study will have a study management group consisting of co-applicants on the study providing expertise and guidance on recruitment, data collection, data analysis and dissemination.

There is an independent Advisory group consisting of expert and lay members to provide independent guidance to the research team, including on any challenges encountered.

There is a PPIE group consisting of four PPIE members who will provide advice and support to the research team throughout the study, and ensure the research considers pregnant women's views and experiences throughout.

Protocol contributors

This protocol has been developed by the Chief Investigator and the research team.

The sponsor or the funder will have no involvement in final decision or conduct of study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

Members of the public have been consulted on the proposed design of the study, as detailed in the protocol.

KEY WORDS:

Pregnancy, intervention development, vaccination, qualitative research

Study flow chart

A flow diagram showing an overview of the study can be found in Appendix 1.

A Gantt chart can be found in Appendix 2.

Study protocol

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

1. Background

Pregnant women and their unborn babies are at increased risk of serious illness from diseases including Influenza (flu), Pertussis (whooping cough) and Covid-19. Pregnant women are four times more likely to be hospitalised with flu, and mortality rates are significantly higher amongst pregnant women than non-pregnant women [1,2]. Pregnant women who contract Covid-19 are at increased risk of admission to intensive care, and increased risk of death, for both pregnant women and their babies, compared to pregnant women without a Covid-19 diagnosis [3,4,5]. Flu, whooping cough and Covid-19 vaccination safety, effectiveness and protection from serious complications, hospitalisation, and death are evidenced [6,7,8,5]. This is a significant, yet

preventable healthcare problem. Flu and Whooping cough vaccinations, and more recently Covid-19 Vaccinations/ boosters are routinely offered to pregnant women.

Despite availability of free vaccinations during pregnancy in the UK less than 20% of all pregnant women received Covid-19 vaccinations during 2021 [9], compared to 79% of the general population. Uptake of flu vaccination amongst pregnant women only reached 37.9% during the 2021/22 flu season [10].

Historically there have been mixed messages surrounding safety of vaccinations in pregnancy [11], particularly for Covid-19, from media and even healthcare professionals [12]. There is a need to understand beliefs and perceptions of pregnant women and those who may influence decisions. An intervention that also increases friends and families' knowledge of the importance of vaccination, will further help pregnant women's decisions.

2. Rationale

Previous work by the lead applicant has explored factors affecting pregnant women's vaccination decisions. Pregnant women often hold misconceptions about flu vaccination [13], and underestimate their illness susceptibility and severity [13], impacting on their vaccination decisions. Recent systematic reviews have shown barriers to Covid19, flu and whooping cough vaccination amongst pregnant women include concerns around safety (particularly for babies), concerns about efficacy of vaccinations and sociodemographic factors (such as ethnicity, employment) [14].

Black or Black British ethnicity and higher deprivation have been linked to lower flu vaccination uptake [15]. Vaccine hesitancy during the Covid-19 pandemic is associated with younger age and BME ethnicity [16]. Work conducted by the lead applicant led to development of an animation to target flu vaccination amongst pregnant women, but further interventions are needed in a world where we live with Covid-19. Covid-19 is likely to influence pregnant women's vaccination perceptions and beliefs about their vulnerability to infection. It is likely different views and decision-making processes are in place for different vaccinations, especially as Covid-19 is a recent (and fairly rapid) vaccination programme.

This new intervention will primarily target Covid-19 vaccination, but will be designed as a single source of information for all vaccinations offered during pregnancy. The research team led by JP have recently completed qualitative research (RfPB: NIHR203598) examining how pregnant women feel about vaccinations during pregnancy (flu, whooping cough and Covid-19), and whether perceptions have changed since Covid-19. It examines whether Covid-19 has influenced pregnant women's perceptions of vulnerability to health and illness. This research shows that pregnant women underestimate risks of Covid-19, and have misconceptions and mistrust around the Covid-19 vaccination and messages[17]. This new research will help bring together what we know about vaccination decisions during pregnancy, and examine how information should be provided in an intervention.

This research will reduce risk of infection, complications and mortality during pregnancy by developing an intervention to help pregnant women make informed decisions about whether to accept vaccinations, aiming to increase vaccinations amongst this population. This research is important to tackle complications and mortality in pregnancy from diseases that are largely preventable by vaccination. Increasing the suboptimal rates of vaccination amongst pregnant women has potential to reduce serious negative consequences and improve health of pregnant women and their unborn babies, as well as reducing the burden and costs to the NHS caring for these women and infants.

This research is important to determine what pregnant women, and clinicians involved in their care, feel is needed from an intervention. For an intervention to be effective and appropriate, it needs input from the population it is targeted at. The Person-Based Approach (PBA) to intervention design ensures user feedback is incorporated throughout design and development [18].

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

3. Theoretical framework

This study uses qualitative methods. It will involve a two-phased intervention development design, based on the Person-Based Approach (PBA) [18]. PBA focuses on user involvement and uses qualitative research to understand behavioural aspects of user engagement with interventions. It allows for iterative user involvement to adapt interventions and resolve issues to ensure they are effective before implementation [18].

The PBA uses a three-phase approach to intervention development; Intervention Planning, Intervention Optimisation and Intervention Implementation and Mixed Methods Process evaluation [18]. This study will include Phases 1 and 2, with phase 3 (involving examining the feasibility of implementation of the intervention) conducted in a future stage of research. Previous health interventions using the PBA include self-management of hypertension [19,20], and for cancer survivors [21]. Qualitative interview schedules, analysis of qualitative data and development of intervention will use the Illness Risk Representation (IRR) Framework [22,23] to understand and address pregnant women's vaccination beliefs and behaviour. The IRR Framework is based on Health Psychology theory [24,25] proposing that individuals' risk and efficacy appraisals impact behaviour. The IRR Framework explains beliefs underlying risk appraisals and identifies areas to change behaviour (such as accepting vaccination).

4. Research question/aims

Aims

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

4.1. Objectives

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

4.2. Outcome

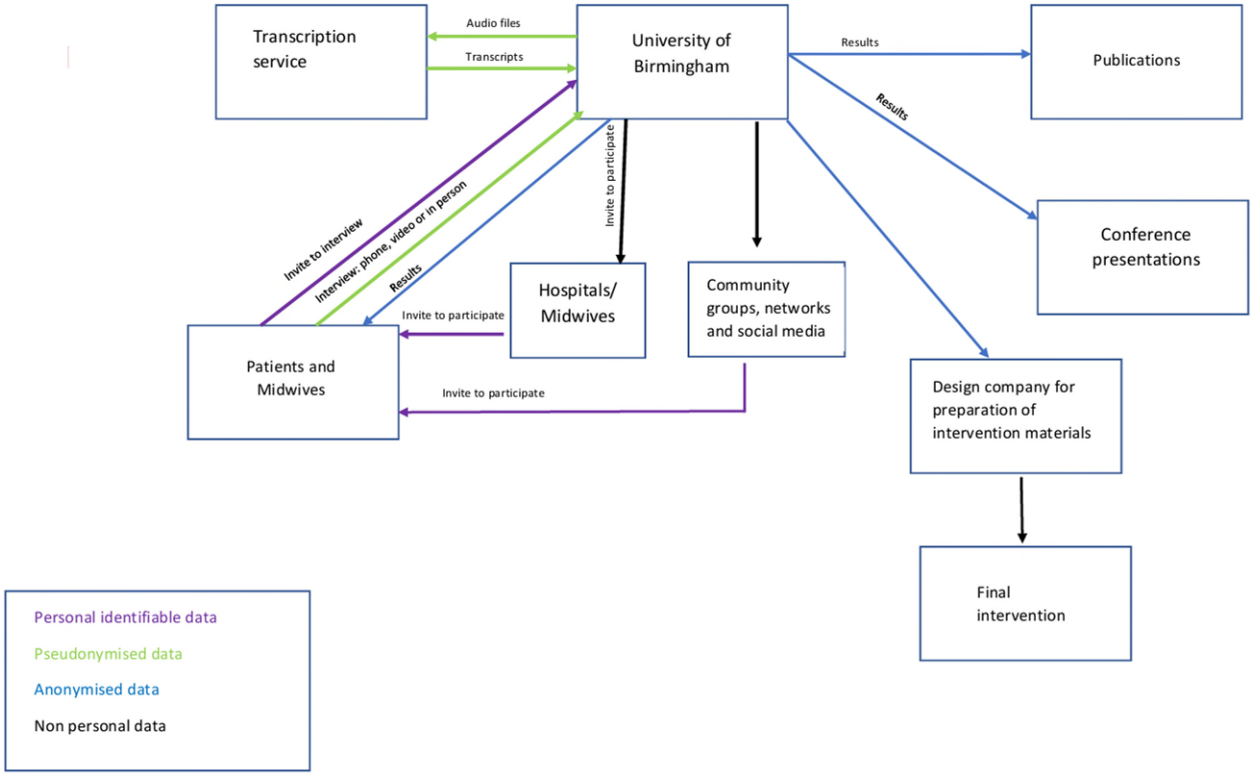
Preferences and needs of pregnant women from intervention

Early intervention materials

Final intervention

5. Study design and methods of data collection and data analysis

Data Map



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 [13], and qualitative research on views of Covid-19 vaccination and impact of pandemic on wider vaccination beliefs (RfPB: NIHR203598).

1.2 New qualitative research: Previous and ongoing research has examined how pregnant women engage with or feel about vaccination, but further research will explore what pregnant women want from an intervention. This includes interviews with pregnant women to explore what information pregnant women want, message framing preferences to convey right information in a trustworthy and acceptable way, and where and when intervention should come from. This will inform guiding principles (what the intervention needs to do to address needs of target users and increase engagement with the intervention) [18].

Qualitative interviews (1.2)

Sampling and recruitment

Semi-structured interviews or focus groups (depending on the preference of participants) 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 for whom an interpreter will be provided), 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 vaccinations, and decline vaccinations in order that wide views are captured.

Participants 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 (or the healthcare professional that gave them the information who will pass on verbally to the research team) if happy to participate. Interviews will be conducted remotely (telephone or video-call) and will take 45-60 minutes.

If participants prefer to take part in a focus group, these will be held remotely via Microsoft Teams, and will be arranged once 4-6 participants are available, at a time convenient for all (participants will be contacted by telephone or email to arrange the focus group, using the contact details provided to the research team). All questions and procedures will be the same for focus groups, as interviews (including consent which will obtained verbally at the start of the focus group).

Clinicians (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 [22,23], as a theoretical framework to understand vaccination beliefs and behaviour of pregnant women. The IRR Framework provides an understanding of beliefs influencing risk appraisals and how to change them to change behaviour. Semi-structured interviews with clinicians will explore 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 be audio recorded, listened to and transcribed either by the investigator or by a professional transcription service working for the University of Birmingham.

Data analysis

Interviews and focus groups will be analysed using a Codebook approach to Thematic Analysis [26], which provides a flexible approach to qualitative analysis using a structured codebook, whilst recognising the interpretative nature of data coding [26]. 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 [26], whereby themes will be developed from the data, and by domains of the IRR Framework [22, 23]. 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. NVivo will be used to aid data organisation and analysis.

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 vaccinations, 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 to 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 [27], 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 (if recruitment results in more women who are in favour or not in favour of vaccinations, techniques to balance the two groups will be made, such as more purposive sampling of one group). Consent will be taken from each participant at the start of each interview they agree to take part in.

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 [27] 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 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

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) [28] 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.

Phase 3 Intervention implementation and process evaluation (including feasibility testing of implementation of the intervention) is outside the scope of this study, but funding will be sought to continue this work, and to complete phase 3 of the PBA to explore how pregnant women would feel being invited to participate in a future randomised controlled trial testing intervention effectiveness.

6. Study setting

Participants will be recruited from two participating hospitals (PIC sites) and community groups (including MAMTA). Study information will be given to participants by midwives/ community leaders and asked to contact researchers (or the healthcare professional that gave them the information who will pass on verbally to the research team).

Clinicians will be recruited from the two participating hospitals, professional networks and relevant social media groups. Interested clinicians will be asked to contact the research team directly.

7. Participant recruitment

7.1. Eligibility Criteria

Pregnant women and clinicians (including midwives, GPs, Nurses and community pharmacists) will be recruited to the study.

7.1.1. Inclusion criteria

Pregnant women:

- Currently pregnant
- 18 years of age or over
- Capacity to consent
- Any vaccination status (had or not had vaccinations during current pregnancy)

Clinicians:

- Currently having contact with pregnant women, including some involvement with vaccination decisions, recommendations or conversations
- 18 years of age or over
- Capacity to consent
- Any period of time since qualification

7.1.2. Exclusion criteria

Pregnant women:

- Outside of stated age range.
- Not currently pregnant.
- Unable to consent to participating

Clinicians:

- Outside of stated age range
- No contact with pregnant women regarding vaccinations
- Unable to consent to participating

7.2. Recruitment target

This study aims to recruit:

20 clinicians

40 pregnant women in phase 1, and 20 pregnant women in phase 2 (participants in phase 2 will be invited to two interviews).

7.2.1. Size of recruitment target

The size of recruitment target has been derived based on previous qualitative research on a related topic, with similar aims and a similar timeline.

This recruitment target aims to achieve saturation of data, but no formal sample size calculations are applicable for qualitative research.

7.2.2. Recruitment technique

Pregnant women:

Purposive and convenience sampling will be employed. Clinicians and community leaders will approach pregnant women in their care/ at their groups and explain the study. Interested participants can contact the research team directly, or details can be passed on to the research team by the midwives or community group leaders.

Clinicians:

Purposive sampling will be employed. Invitations to participate will be sent to clinicians at participating hospitals for display in communal areas and distribution via email, and via professional networks and social media groups.

This recruitment technique has been successfully used by the research team in previous, related studies about vaccination with pregnant women and midwives. This approach is appropriate given the qualitative nature of the study.

7.3. Recruitment

7.3.1. Participant identification

Participants will be recruited from two participating hospitals acting as Patient Identification Centres (PICs), and community groups offering support for pregnant women (such as MAMTA). The study will be added to the CRN portfolio

Study information will be given to participants by midwives/ community leaders and asked to contact researchers (or the healthcare professional that gave them the information who will pass on verbally to the research team) if happy to participate.

Clinicians (midwives, GPs, Nurses and community pharmacists) will be recruited via hospitals, professional networks and social media. Posters and adverts will be used to inform potential participants about the study.

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).

The research team will screen patients for eligibility in the study once they have expressed an interest, and will send participants study information. The research team will then arrange a suitable interview date and time with participants.

7.3.2. Consent

Before committing to participate in the study, interested participants will be sent study materials to review. Participant information sheets will inform participants of the purpose of the research, how their data will be processed, used and stored, potential risks and benefits of taking part in the research and how to withdraw from the study if they choose to. They will also be sent a consent form to read.

Written consent will be obtained by all participants in advance of the interview or focus group, using econsent via electronic consent form, or remotely immediately before-hand, followed up by return of signed consent

form in a stamped addressed envelope. Only participants that have the capacity to consent will be eligible to participate.

Participants will be given the opportunity to ask any questions on receipt of the study materials, and again at the start of the interview/ focus group, to make sure they are happy with everything and have no questions or concerns.

8. Safety reporting

There are no anticipated Adverse Events, Adverse Reactions and Serious Adverse Events resulting from this study due to it being non-interventional. In the unlikely scenario that an event occurs that is assessed by the CI as being serious, unexpected and possibly related to the study, these events will be reported in accordance with the sponsor's safety reporting procedures to the REC and Sponsor.

9. Ethical and regulatory considerations

Participants will be informed of potential risks and benefits associated with taking part in the study, detailed in the participant information sheet.

Participants will be informed that:

- Taking part in this study will help us to understand what pregnant women want and need from an intervention designed to inform about vaccinations during pregnancy. This will help us to tailor the information in an intervention to help them 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 development of an intervention about vaccinations during pregnancy there is the possibility that discussions may discuss sensitive topics. Should this occur, the researcher 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 you have to say.

Whilst it is not anticipated that the interviews/ focus groups will cause participants any distress, researchers will be aware of any needs of the participants, and will offer to pause the interview/ focus group if they do become distressed. Support will be offered to participants if necessary in the form of relevant organisations, and signposting them to contact their GP.

Appropriate ethical approval will be sought on the methods and protocol prior to study commencement.

9.1. Assessment and management of risk

Whilst we anticipate no risks we consider the following:-

1. Confidentiality and data protection risks for participants, to mitigate this study ID codes will be assigned to participant data with only authorised members of the study team having access to identifying links.
2. Potential risk of participants becoming upset during interviews, if this happens and the participant needs to take a break the interview will be paused and resumed if they are happy to continue or rescheduled.
3. Any potential risks identifying participants being at risk of harm to themselves or others during the study, if this happens local safeguarding procedures will be followed and participants will be advised to contact their healthcare professional. This may involve notifying participant's healthcare team, confidentiality will be breached in order to do so.
4.
5. IData integrity risks will be managed in line with the Data Management Plan (DMP) associated with the study.
6. If pregnant participants feel faint during an interview, the interview will be stopped, participants will be encouraged to contact their healthcare team and given the option to continue or reschedule when they feel well enough to proceed. If a participant becomes unresponsive medical attention will be sought (e.g. by dialling 999) and the interview will be stopped.

7. If a participant suffers a pregnancy loss following consent but prior to interview, it will be suggested to participants that the interviews/ participation is ceased so as not to incur upset to the participant.

9.2. Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from a REC for the study protocol, informed consent forms and other relevant documents e.g. advertisements. The research team will follow the following principles:

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- An annual progress update will be submitted to the sponsor within 30 days of the anniversary date of the approval of the study and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

The following regulatory review and compliance issues have been considered:

- Before any site can enrol patients into the study, the Chief Investigator or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.
- For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

Any amendments to the study will involve amendments to the protocol, which will be logged with a new version number and date. A log of amendments will be maintained with version number, date and reason for change.

The research team will seek advice from sponsorship and/or REC regarding whether an amendment is substantial or non-substantial.

All changes will be communicated to relevant stakeholders by email, detailing the changes made, reasons for changes, and accompanied by an updated protocol.

9.3. Peer review

The study has been peer reviewed by the funder (NIHR RfPB) during the two stage funding application process.

9.4 Patient & Public Involvement

This study have received Patient & Public Involvement (PPI) input throughout the design and development phases of the study, including prior to the grant application being submitted.

The study will have a PPI group consisting of four members of the public, a lay member of the advisory group, and a PPI co-applicant who will attend research group meetings. PPI involvement will be fundamental to all stages of the process.

9.4. Protocol compliance

Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach. While it is not anticipated that serious breaches are applicable in this study, any incidents identified that are likely to affect to a significant degree the safety or mental integrity of the participants or scientific value of the study will be reported as serious breaches to the REC and study Sponsor in accordance with the Sponsor's serious breaches reporting procedures.

The study quality will be assured by frequent study management meetings, advisory meetings and PPIE meetings. Updates on progress and any challenges will be discussed at these meetings. Additionally, required reports will be submitted to the funder where appropriate.

9.5. Data protection and patient confidentiality

All investigators and study site staff must comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

Any hard copies of documents (personal data from pregnant women or midwives expressing an interest in participation) will be destroyed after data is entered digitally. Until the information is entered digitally it will be stored in a locked cabinet at University of Birmingham, in a locked office, completely separate to the research data. Only named study researchers will have access to the key for the cabinet.

Any hard copy consent forms will be scanned and stored in a password protected file on an encrypted university network drive at University of Birmingham. Once scanned and stored hard copies of consent forms will be destroyed in confidential waste. Electronic consent forms will be held completely separately from the research data. Only named study researchers will have access to the password protected files. They will be retained for 10 years and then destroyed, in line with University policy. Audio files of the verbal consent will be stored on a University of Birmingham server in a separate location to the interview transcript data, accessible only to the researchers and password protected, saved on encrypted University network drives. At the end of the study the files will be archived according to University archiving policy and deleted after 10 years.

Interview transcripts will be pseudonymised or allocated a unique ID and stored digitally. All study data will be stored only on University servers, where access to this data is restricted to only the study researchers. Key to pseudonyms or IDs will be saved in a password protected document, separate from interview files.

When publishing the study, we will provide contextual information about the participating pregnant women and clinicians, but this will be presented in aggregate and will not allow individuals to be identified. In publishing the interview study we will use quotes from the interviews. We will ensure that these are fully pseudonymised and any contextual information provided will not identify the patient.

The University of Birmingham research team will have access to the study data. All team members will adhere to the collaboration agreement between University Hospitals Coventry and Warwickshire and the University of Birmingham within which sits the data sharing agreement.

9.6. Indemnity

This study will be covered by indemnity insurance of the sponsor; the University of Birmingham.

The University of Birmingham has in place Clinical Trials indemnity coverage for this trial which provides cover to the University for harm which comes about through the University's, or its staff's, negligence in relation to the design or management of the trial and may alternatively, and at the University's discretion provide cover for non-negligent harm to participants.

With respect to the conduct of the trial at Site and other clinical care of the patient, responsibility remains with the NHS organisation responsible for the clinical site and is therefore indemnified through NHS Resolution. The NHS have a duty of care to participants whether or not the participant is taking part in a clinical trial and the normal NHS complaints mechanisms will apply.

9.7. End of study and archiving

This is a 15 month study, which will be considered complete once data collection, data analysis and dissemination has been finished.

At the end of the study the files will be archived according to University archiving policy and deleted after 10 years.

9.8. Access to the final study dataset

The research team will have access to the final dataset. The data analysis will be conducted by the Chief Investigator and the Research Fellow (RF), but additional members of the research team may be asked to contribute to analysis, and would therefore have access to anonymised transcripts. Only the Chief Investigator and RF will have access to the audio files.

Consent forms reflect possible use of data for secondary analysis.

10. Dissemination policy

10.1. Dissemination policy

The main output from this study is the production of a complete intervention, that aims to inform pregnant women and their families about vaccinations. Following analysis, a final report will be prepared. This report will be submitted to the funder, and publication of results will be developed by the research team.

Dissemination of findings to the public:

Summaries of the findings from the qualitative research (what pregnant women and clinicians told us they want from an intervention), and on the development process of the intervention will be shared with members of the public and stakeholders via women's organisations and social media groups. Participants will also be given the opportunity during the consent process to indicate they would like to receive a summary of the findings.

A summary of findings, infographics and blogs will also be shared on a dedicated study webpage hosted by the University of Birmingham.

Dissemination to healthcare professionals:

Summaries of findings, infographics and blogs will be shared with clinicians. This will include presentations to clinician team meetings (such as midwife team meetings).

Findings will contribute to e-learning modules (for organisations such as Royal College of General Practitioners and Royal College of Midwives), designed to provide education of strategies to employ to encourage vaccination uptake amongst pregnant women.

Dissemination to wider academic audience:

We will publicise findings at local and national conferences (such as the annual MBBRACE conferences or Royal College of Midwives annual conference), in open-access journals, on relevant social media (such as via MAMTA's social media pages), University of Birmingham webpages and press releases.

Dissemination to policymakers and professional bodies:

Summary of findings sheets for vaccination and maternal health policymakers and professional bodies (including NHS England, MBRRACE and JCVI) will be available to download via dedicated study webpages on University of Birmingham website, and will be shared to professional bodies using established contacts within the research team.

Representatives from policy and professional organisations will be invited to attend a dissemination event to discuss the findings and future recommendations at the end of the study.

Any IP arising from the study will be owned by the University of Birmingham. The funders will be acknowledged in all reporting of the results (publications, conference presentations etc).

10.2. Authorship eligibility guidelines and any intended use of professional writers

The research team will be named authors on the final study report, and will be given the opportunity to be authors on any published manuscripts.

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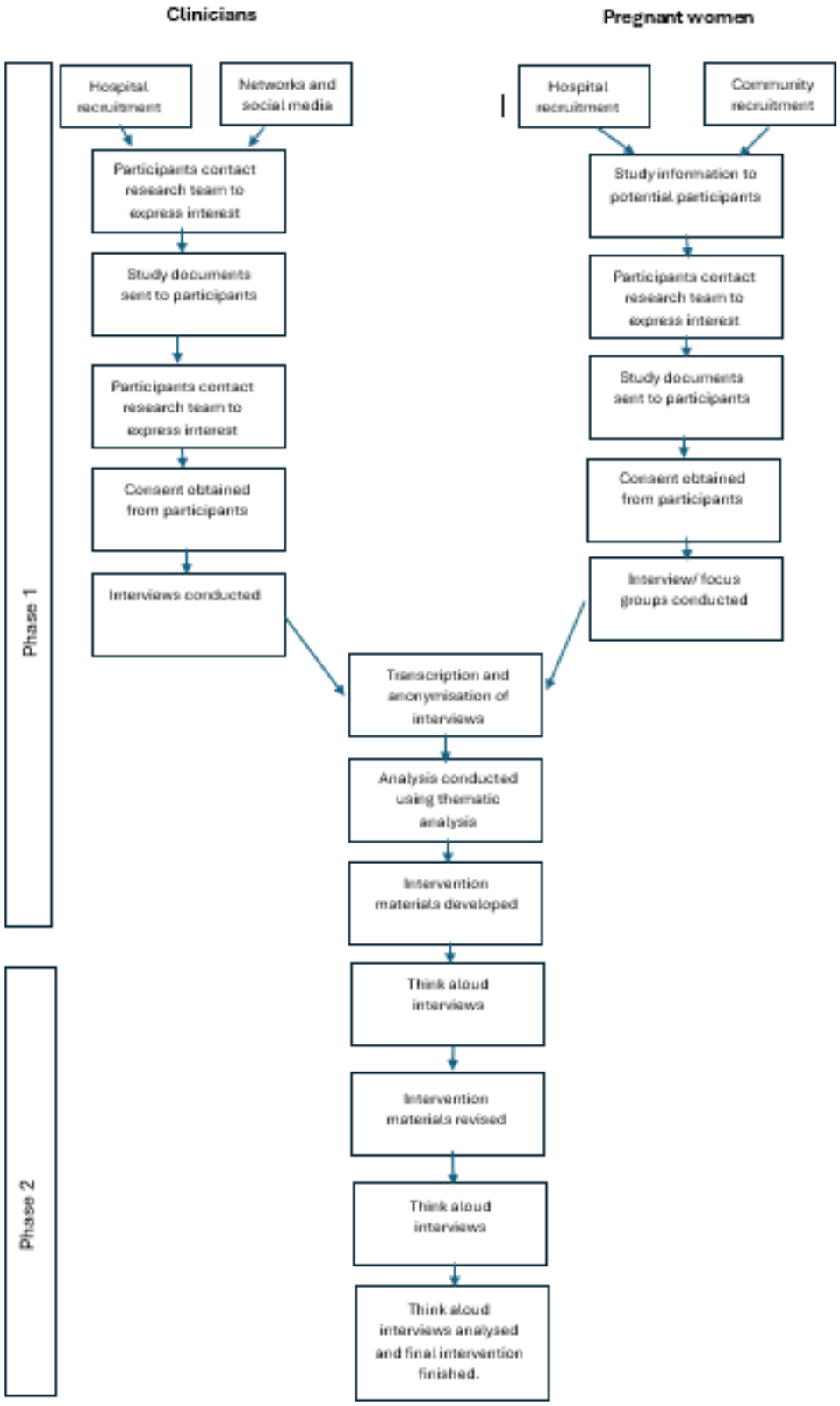
12. Appendices

12.1. Appendix 1- Flow diagram



12.2. Appendix 2- Gantt chart

RfPB	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Jan-25	Feb-25	Mar-25	Apr-25	May-25	Jun-25	Jul-25	Aug-25	Sep-25	Oct-25	Nov-25	Dec-25	Jan-26	Feb-26	Mar-26
Study start															
Sponsorship and ethical approval															
Phase 1:															
Recruitment for Phase 1															
Data collection for Phase 1															
Transcription and analysis															
Intervention development and refinement															
Phase 2:															
Recruitment for Phase 2 (if needed)															
Think aloud round 1															
Refinement															
Think aloud round 2															
Transcription and analysis															
Refinement and final intervention															
Dissemination:															
Summary sheets															
e-learning modules															
Stakeholder workshop															
Preparation of publications and conference															
Study management															
Advisory meetings															
PPI meetings															
Research team meetings															

12.3. Appendix 3- Required documentation

Consent form for clinicians v1.0

Consent form for pregnant women v1.0

Content for clinician poster/ advert v1.0

Demographic collection form for clinicians v1.0

Demographic collection form for pregnant women v1.0

Data flow map v1.0

Division of Sponsor responsible form v1.0

GCP refresher certificate

PIS clinicians v1.0

PIS pregnant women for community recruitment v1.0

PIS pregnant women for hospital recruitment v1.0

PIC agreement (blank)

Reply slip v1.0

Research integrity training certificate

Short CV CI v1.0

Topic guide clinicians v1.0

Topic guide pregnant women v1.0

12.4. Appendix 4 – Amendment History

Amendment No.	Protocol version No.	Date issued	Author(s) of changes	Details of changes made