Participant Information Sheet- pregnant women from community groups

Study title: – Developing an intervention to increase vaccination uptake amongst pregnant women using a person based approach

Chief Investigator: Dr Jo Parsons

Researcher: Dr Jo Parsons (University of Birmingham) and Dr Cath Grimley (University of Warwick)

Introduction

We would like to invite you to take part in the above titled research study. Before you decide whether you would like to take part it is important for you to understand why the research is being carried out and what it would involve for you. Please take time to read the information carefully and ask the study team if you would like any further information or if anything is not clear. Please keep this copy of the Participant Information Sheet for your own reference.

Part one

What does this study involve?

This study is looking at what pregnant women want from an intervention (a set of information) that is designed to inform about vaccinations (for flu, whooping cough and Covid-19), and help women make the decision about whether to accept vaccinations or not. We are planning on talking to pregnant women, and clinicians (midwives, GPs, Nurses and community pharmacists) to find out some of the main things that an intervention should include, and how and where it should be available to pregnant women. This will help us to design an intervention that will work well.

FUNDED BY
NIHR | National Institute for Health and Care Research
This study is funded by the National Institute for Health Research (NIHR) [Research for Patient Benefit (NIHR203598)]. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Taking part in this study will involve participating in up to three interviews. Interviews would be done either over the telephone or via video call (depending on personal preference at the time of the interview). A researcher will arrange with you (by telephone or email), a convenient time to conduct the interview. Interviews will take approximately 45-60 minutes and will be audio recorded. If you prefer, you may be able to talk to us as part of a small group (a focus group) rather than one-to-one. Please let us know if you would prefer this.

You will be invited to take part in the first interview which will discuss what you would want to see from an intervention, and then you would be given the opportunity to take part in one or two additional interviews, where you will be shown some early examples of the intervention and you will be asked to give us your views on these. At the start of the interview, we will ask you a few background questions (such as age, gender, geographical area and any health-conditions that may influence vulnerability to illness) so that we can give some context to who we speak to. You do not have to answer these questions if you do not wish to. We will also ask you to confirm verbally that you are happy to take part in the interview. Participating in the first interview does not mean you have to take part in the subsequent two interviews. You will be given the option each time to agree or refuse to take part in the additional interviews.

Why have I been chosen?

You have been selected because you have been identified by a leader at a community group, or you have seen this study advertised (for example on social media), and you are pregnant.

What will happen if you agree to take part?

If you would like to take part in this study, please complete the accompanying reply slip to let the research team you are interested by posting it in the pre-paid envelope that has been given to you within this pack, or return it to the group leader that gave it to you. Alternatively, you can contact the Chief Investigator; Dr Jo Parsons (contact details are at the end of this document) for further information stating how you have heard about this study.

One of the researchers (Dr Jo Parsons or Dr Cath Grimley) will then contact you using the details you have provided. They will discuss the study with you and organise an interview at a time that is convenient for you either by telephone or by remote video (i.e. using a computer package such as Microsoft Teams). Before the interview commences, consent will be taken either in writing by emailing or posting the consent form to

you, using an electronic consent form or verbally at the start of the interview followed up by a form in the post. We will take your consent by asking you to identify yourself and then replying to the consent questions. If you answer yes to all of the consent questions and are happy to proceed with the interview, we will begin by asking you to answer a short set of additional questions that will include your age, gender, ethnicity, relevant health conditions and to confirm that you are pregnant. Both the consent and short set of additional questions will be audio recorded. Audio transcriptions will be transcribed either by the investigator or by a professional transcription service working for the University of Birmingham. If you do not have access to a telephone or video call equipment (like a smart phone, tablet or laptop) you may ask a family member to help you with this.

What does the study involve?

We understand that talking about vaccinations in pregnancy might be upsetting to some people (although we will not be asking you directly about your experiences or views of vaccinations), so please be assured that you will be able to stop or pause the interview at any time should you need to. Advice on how to get further support or information about vaccinations during pregnancy can also be given if you would like it. In the interview, we will ask you about some of the main things that an intervention should include, and how and where it should be available to pregnant women We will also send all participants a summary report from the study after it is completed for your own interest.

Do I have to take part?

No. Participation in this study is completely voluntary and choosing not to take part will not affect you or any medical or pregnancy related healthcare in any way. You can also choose to withdraw your participation at any time, within two weeks of the interview, without giving a reason by contacting one of the research team. Further details about withdrawing from the study are provided later on in this document.

What are the possible benefits?

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 to help them make an informed decision about whether to have a vaccination or not.

What are the possible disadvantages?

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 we anticipate no risks we consider the following:-

1. There is a potential risk you may become upset during interviews, if this happens and you need to take a break the interview will be paused and resumed if you are happy to continue or rescheduled.
2. If it is identified during your participation in the study that you may be at risk of harm to yourself or others, local safeguarding procedures will be followed. This may involve notifying your healthcare team, confidentiality will be breached in order to do so.
3. If you feel faint during an interview, the interview will be stopped, you will be encouraged to contact your healthcare team and given the option to continue or reschedule when you feel well enough to proceed.
4. If you suffer a pregnancy loss following consent but prior to interview, the interviews/ your participation in this study will be stopped. We will also advise you to contact your healthcare team for support. You would be welcome to come back to us to take part in the interview should you wish to.

Expenses and payments

If you choose to complete the interview you will receive a £10 gift voucher as a thank you for taking part.

Will my taking part be kept confidential?

Yes. With your permission the interview will be recorded which will be listened to and transcribed either by the investigator or by a professional transcription service working for the University of Birmingham. Once transcribed the recording will be destroyed. Any real names and the name of the general practice you attend (if mentioned) will be removed from transcriptions. However, although there is an expectation of confidentiality in the focus groups, it cannot be guaranteed due to the nature of group discussions.

Part Two

Who is sponsoring, insuring, funding and reviewing the study?

The study is led and sponsored by the University of Birmingham and has been funded by the National Institute for Health Research (NIHR) [Research for Patient Benefit (NIHR206660)]. In addition, the study has been reviewed by Camberwell St Giles Research Ethics Committee (IRAS ID:335374).

The University of Birmingham has in place Clinical Trials indemnity coverage for this study 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 study at Site and other clinical care of the patient, responsibility remains with the organisation responsible for the site.

What if there is a problem?

If you have any concerns about the study you can speak to a member of the research team in the first instance, contact details are available towards the end of this information sheet.

If you remain unhappy with their response and wish to make a complaint you can contact the University of Birmingham's Research Ethics Governance and Integrity team via researchgovernance@contacts.bham.ac.uk

If you have any concerns or wish to make a complaint about how your information has been handled you can contact the University of Birmingham's Data Protection Officer on dataprotection@contacts.bham.ac.uk

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

What will happen to the data collected about me?

The University of Birmingham is a publicly funded organisation, therefore it has to ensure that it is in the interest of the public to use personally identifiable information from people who have agreed to participate in research. This means that when you agree to take part in a research study we will use your data in the ways needed to conduct the research study.

The information we receive from you will be used to undertake this study and we will act as the data controller for this study. We are committed to protecting the rights of individuals in line with data protection legislation. The University of Birmingham will keep interview data and identifiable information about you for 10 years from the date of any publication which is based upon it, in accordance with the University's Records Retention Schedule.

To safeguard your rights, we will use the minimum personally identifiable information possible. Data taken from interviews will be pseudonymised straight after data collection. This means that all direct and indirect identifiers will be removed from the interview data and will be replaced with a unique participant number. The key to identification will be stored separately in a secure location to the research data to safeguard your identity. The only people in the University of Birmingham or the University of Warwick who will have

access to information that identifies you will be the researchers conducting the research study and anyone who needs to audit the data collection process, should that be required.

We might use the data collected during this research in future research, but this would always only be with anonymised data. You would not be able to be identified in any future research either. Additionally, data from this research might be used to inform future research to inform AI technology or similar. Again, any data used from this study in this way would be anonymised.

Your details will only be used to contact you about the study where needed, and to make sure that relevant information about the study is recorded and to oversee the quality of the study. If you would like to find out more about how we use your information please contact Dr Jo Parsons, Chief Investigator.

Data Sharing

Whilst taking part in this study your rights to access, amend or move your information are limited as we need to manage your information in a specific way to ensure the research to be reliable and accurate. The University of Birmingham has in place policies and procedures to keep your data safe.

In addition, the data may be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research study.

For further information please contact the Information and Data Compliance Team at [dataprotection@contacts.bham.ac.uk] or refer to the University of Birmingham Research Privacy Notice which is available here:

[insert link]

What will happen if I do not want to carry on being part of the study?

Taking part in this study is entirely voluntary, if you decide to withdraw this will not affect you in any way. This includes if you have already agreed to take part and given consent. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You can withdraw from the study at any point up to two weeks after the interview has taken place, any personal information will be removed, and you will not be contacted by the research team again.

If you wish to withdraw from the study, please contact Jo Parsons by email at the contact details at the end of this document.. A confirmation email or letter will be sent to confirm that your data has been removed and your data will be securely deleted with no further contact.

What will happen to the results of the study?

Data collected from the interviews and other components of the study will be analysed and findings will be published in academic papers and conference presentations. Findings will directly inform the development of a new intervention to provide information about vaccinations to pregnant women.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name, contact details, age group, ethnicity, postcode (this will just be used to calculate deprivation information and will then be deleted). People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of Birmingham is the sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Storing all information on University secure computers and systems
- Using password protected documents that only the research team have access to
- Replace all participant names with anonymous ID numbers

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information by;

- asking one of the research team

- reading the information available at **www.hra.nhs.uk/patientdataandresearch**
- contacting the University of Birmingham's Data Protection officer by emailing dataprotection@contacts.bham.ac.uk

Further Information:

For further information about this study or if you have any questions about any aspect of the study or your participation, please contact the Chief Investigator:

Dr Jo Parsons

University of Birmingham

Email: j.e.parsons@bham.ac.uk

You can also contact the Patient Advice and Liaison Service (PALS) at <*Insert local PALS contact details – delete this text on completion*> for confidential advice and support.

This study is covered by the University of Birmingham's insurance and indemnity cover. If you wish to contact the sponsor's representative you can do so be emailing the University of Birmingham's Research Ethics Governance and Integrity team via:Researchgovernance@contacts.bham.ac.uk

Who should I contact if I have concerns or need support relating to Covid-19?

If you have any specific concerns or need any support in relation to Covid-19, information and sources of support can be found at the following websites:

https://www.nhs.uk/conditions/coronavirus-covid-19/

https://www.gov.uk/coronavirus

Thank you for taking the time to read this Participant Information Sheet.