SNAP2 Trial

PARTICIPANT INTERVIEWS

INFORMATION SHEET

- We'd like to hear about your experiences of blood pressure monitoring at home following a hypertensive pregnancy.
- This leaflet explains what is involved if you decide to take part in the interviews.
- Please take time to read the leaflet carefully and discuss with friends and family if you wish.
- If you would like further information, please contact us on snap2@phc.ox.ac.uk.

- We want to interview women who have taken part in the SNAP2 trial following their pregnancy.
- We would also like to interview women who have decided not to take part in the trial.
- We want to ask you about your experiences of postnatal care and how remote monitoring has worked (if applicable).
- There are no extra hospital visits required for the interview.
- We will interview you at a time and place that suits you- by telephone, online or face to face.
- We'd like to talk to you up to 3 times, but one interview will be fine.
- You can decide to stop taking part at any time.

Important things you need to know:

What is the purpose of this study?

The purpose of this study is to understand how self-management of blood pressure after pregnancy has worked in practice.

We want to hear from women who have used the SNAP-2 self-management app, those who have received usual care and those who have declined to take part in the SNAP2 Study.

We want to understand how people feel about monitoring their blood pressure themselves at home after leaving the hospital. We will also talk to a group of people who are not doing this self-management to see how their experiences compare.

Even if someone doesn't want to be part of the main study or drops out later, we'll still invite them to an interview to learn more about why they declined and what they think about this self-management approach.

Why have I been invited?

We would like to interview women who have been invited to take part in the SNAP2 study.

Do I have to take part?

No, it is entirely your decision as to whether to take part or not. If you decide not to take part, or if you agree but later change your mind, this will not affect your care in any way.

You are free to withdraw at any time without giving a reason.

What will happen if I take part in the interview?

You may have as much time as you wish to consider your participation and have the opportunity to ask questions. If you agree to take part, you will be asked to sign a consent form. You will receive a copy of the signed consent form. If you are completing the interview remotely, the consent form will be read out loud and we will ask you to confirm that you agree with each statement. A copy of the consent form will be posted or emailed to you.

You do not have to come for any extra hospital visits. The interview can take place remotely, at a time that suits you.

A member of the research team will interview you, and the interview will be recorded. We expect the interview to take between 30-60 minutes. A partner or companion is welcome to sit in on the interview with you. If you are interested in talking to us more than once, we can arrange a follow up interview. You will be given a £20 voucher for your participation in each interview you give, (up to three).

What are the possible benefits and disadvantages of taking part in the study?

We don't expect any direct benefit for women taking part in an interview, although people sometimes find it helpful to talk about their story and experiences. The study is not the same as counselling. However, we can provide a list of useful contacts about where to get more help, if you want. We do not anticipate any disadvantages from taking part in the interview, apart from the time taken to complete the interview.

Will my taking part be kept confidential?

Yes, all information that is collected during the interview will be kept strictly confidential. You will be given a study number (like a code) so that you cannot be directly linked to any information you provide to us. Any directly identifiable information that you provide in the interviews will be removed when the interview is transcribed. We will only use names and contact details to arrange the interview, these will be held securely by the study team and will be stored until the interviews are completed.

Responsible members of the University of Oxford and the relevant NHS trusts may be given access to the study data for monitoring and/or audit of the study, to ensure that the research is complying with applicable regulations.

The interview will be audio-recorded so that it can be written up later. The recordings will be deleted after the analyses have finished. The person who does the typing (transcription) will be approved by the University of Oxford, who have confidentiality and data protection contracts, and third-party security assessment, in place. They will delete their copy of the recording and transcript once it has been sent to the researchers.
We may use some direct quotations in publications arising from the research study, but no individuals will be identifiable from these quotations.

For further details regarding what will happen to the data we collect, please see "What will happen to my data?"

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you in order to undertake this study and we will use the minimum personally-identifiable information possible.

We will store the de-identified research data and any research documents with personal information, such as consent forms, securely at the University of Oxford for 20 years after the end of the study.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting the qualitative researcher (details at the end of this document).

What will happen if I don't want to carry on with the study?

You can withdraw from the interview study at any time without giving a reason.

You will be free to stop a scheduled interview or the interview itself at any point. Once the interview has taken place, you have two weeks to withdraw from the study should you wish to. In this case your data can be securely destroyed if you wish. After two weeks, data will be included in results, but you will not be identifiable and no quotes from the interviews will be used in any outputs.

What if there are any problems?

If you wish to complain about any aspect of the way in which you have be approached or treated during the course of this study, you should contact the SNAP2 Trial Manager, or email snap2@phc.ox.ac.uk or you may contact the University of Oxford Research Governance, Ethics and Assurance Team (RGEA) office on RGEA.complaints@admin.ox.ac.uk.

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in the study.

What will happen to the results of the study?

When we have completed all the interviews, our findings from them will be summarised with the use of some anonymous direct quotations. These anonymised results will be presented at conferences and published in scientific journals. You and/or your baby will not be identified in any report or publication from this study.

Participation in future research?

If you agree to be contacted for future research, your name and contact details (phone number/email address/postal address as guided by your preference) will be held in a secure database in the Department of Primary Care Health Sciences for 10 years, along with a copy of your consent form. Agreeing to be contacted about future research does not oblige you to take part in it, and you can request that your name and details are removed from this register at any time.

Who is organising and funding the research?

The research is being financed by the National Institute for Health Research. The sponsor is the University of Oxford, and the research is being managed by the Primary Care Clinical Trials Unit, at the University of Oxford's Department of Primary Care Health Sciences. Your doctor will not be paid for including you in this sub-study.

The Chief Investigator for this study is Professor Richard McManus.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by South Central Oxford B Research Ethics Committee (Reference Number: 24/SC/0071)

How have patients and the public been involved in this study?

Service users who have experienced high blood pressure during pregnancy have helped develop what research questions should be asked and the design of the patient-facing documents. They are involved in the trial management group and will continue to be involved in the study.

What happens now?

If you are interested in taking part in the interview study, or would like more information, please speak to the qualitative researcher who will arrange a convenient time to meet you and explain more about the process, the contact details are listed below.

Contact for further information and to take part.

If you would like to take part or have any questions, please contact the sub-study researcher: XXXX
Department of Primary Health Care, University of Oxford, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG.
Email: snap2@phc.ox.ac.uk
Tel: XXXX

The study welcomes and values participation from all ethnic/racial groups.

Thank you for considering taking part in this sub-study.