More information (continued)

During the study a note will be placed in your antenatal folder. This will let other healthcare professionals know you are taking part in the study. Responsible members of the University of Oxford and the relevant NHS trusts may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/

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

Has anyone reviewed the study?

The study has been approved by Cambridge South Research Ethics Committee (reference number: 24/EE/0045).

What will happen to the results of the study?

You can read the results on our website at http://www.primarycare.ox.ac.uk—you can also access the scientific journal articles about the study here.

7 Who is paying for and running the study?

The research is being financed by the National Institute for Health Research Applied Research Collaboration.

Funds have been allocated to the University of Oxford's Department of Primary Care Health Sciences.

The sponsor of the study is the University of Oxford. The Chief Investigator for the study is Dr Katherine Tucker.

8 What if there are any problems?

If there is a problem or you have any concerns, you can contact the study co-ordinator (details below).

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 this study. NHS indemnity operates in respect of the clinical treatment with which you are provided.

9 If you want to make a complaint

If you wish to complain about any aspect of the way in which you have been approached or treated in this study, you should contact the study team (mypregnancycare@phc.ox.ac.uk) or you may contact the University of Oxford Research Governance, Ethics & Assurance Team, email: rgea.complaints@admin.ox.ac.uk

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact 01865 221473 or email PALS@ouh.nhs.uk.

10 Study Co-Ordinator

For more information about the study please contact the trial manager, Dr Katherine Tucker on mypregnancycare@phc.ox.ac.uk

You do not have to decide now, take time to think about it. Participants are eligible to begin participating in this study from around the 17th week of pregnancy.

This study is funded by the NIHR

The My Pregnancy Care study

Blood pressure and urine protein monitoring in pregnancy

A summary of the study

- This study is testing a new mobile phone app. This app supports additional blood pressure monitoring and self-testing of urine for protein during pregnancy. This could help earlier detection of rising blood pressure and pre-eclampsia
- About two thirds of the people taking part will use the app and self-monitor their blood pressure and urine, and the other third will not. **All women will continue to receive routine NHS care during their pregnancy.** The group you are in will be decided by chance.

If you take part in this study:

We will explain the study and ask for your consent. We will let you know if you're in the self-monitoring group or will continue to receive usual care

We will call you at around 30 weeks (if applicable) to check everything is ok and complete some questionnaires

After birth we will complete questionnaires and collect your BP monitor if you have one

Self-monitoring group

- You will be asked to measure your **blood pressure daily** from the start of the study, and submit the readings via the app. This will mean taking **2 readings, 1 minute apart** (5 minutes total) every day until delivery. If these are raised you may be asked for more readings.
- You will be asked to **dip your urine for protein weekly**, and send the readings via the app.

FUNDED BY NIHR | National Institute for Health and Care Research
UNIVERSITY OF OXFORD
NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

1 Why are we doing this study?

Around one in ten pregnant women will have high blood pressure, often requiring medication. Rising blood pressure can be a sign of pre-eclampsia, which is usually detected at routine appointments.

We would like to find out if using an app to support home blood pressure monitoring and urine testing can improve the identification of pre-eclampsia and blood pressure control.

2 Why am I being asked to take part?

You are invited to take part in the study as you have high blood pressure and are pregnant.

3 What should I do if I want to take part?

The first step is to **contact the research team** who will arrange your first appointment.
Contact: Dr Katherine Tucker
Email: mypregnancycare@phc.ox.ac.uk

4 What will happen if I take part?

You will be asked to sign a consent form to say you agree to take part in the study.

Following one of your antenatal appointments, we will ask you some brief questions about your medical history, your pregnancy and day-to-day life. We will check your height, blood pressure and urine results. This will take around 20 minutes.

About two thirds of the people in the study will be randomly selected to be in the self-monitoring group. The other third will be in a usual care group. **All women will continue to receive routine NHS care**. The next sections explain what will happen for women in each group:

Usual care group

You will carry on receiving your usual care, the same as you did before the study. **We will not provide you with the app, a BP monitor or urine tests if you are in this group.**

The usual care group are very important to the research. We will follow you up throughout the study in the same way as the people who are in the self-monitoring group.

Self-monitoring group

If you are in the self-monitoring group we will give you a blood pressure monitor and urine testing kits, and show you how to use them. We will tell you how you can access the My Pregnancy Care app and website.

You will be asked to take your own blood pressure readings **everyday for the rest of your pregnancy, ideally in the morning. We suggest taking 2 readings, 1 minute apart. You will need to submit your second blood pressure reading daily using the app.**

You will also be asked to dip your urine to check for protein once a week (you may be asked to do it more frequently if your blood pressure is high), and submit this using the app.

What will happen if I have high or low BP readings?

If you are in the self-monitoring group and your blood pressure is high or low, the app will send you clear instructions about what to do next.

Your readings will be reviewed by a healthcare professional, and if needed you **may be asked to increase, or decrease the dose of your blood pressure medication**. If this is the case, you will get a notification explaining the medication change through the app. You will also be given a booklet which will help you to understand what your blood pressure readings mean.

This study is funded by the NIHR

After delivery (both groups)

The study will finish around 2 months after your pregnancy has ended. At the end of the study we will ask you to answer some more questions, no matter which group you were in. If you are in the self-monitoring group we will ask you to return your monitor. A researcher will also access your medical notes after your pregnancy has ended to look at your health during the pregnancy.

5 Possible advantages and disadvantages of taking part

Taking part in the study may give you better understanding about your blood pressure.

We think there is very little risk of harm in taking part. All women will still receive their usual pregnancy care while in this study. The only disadvantage is the extra time taken to measure blood pressure and urine protein for women chosen for the self-monitoring group and the additional time spent with the study team.

We hope that in the longer term, the study results will improve the management of high blood pressure in pregnancy and help with earlier diagnosis of pre-eclampsia.

6 More information about taking part

Do I have to take part?

No, taking part is entirely voluntary and will not affect your current or future NHS treatment. You can talk to your GP or midwife for independent advice about taking part.

What happens if I change my mind?

If you do decide to take part but change your mind later, you are free to withdraw at any time.

To do this, you can e-mail the study co-ordinater on mypregnancycare@phc.ox.ac.uk

You do not need to give us a reason. This will not have any effect on your current or future NHS treatment. Any information you have given up to that point would still be used in the study results. You will need to return the blood pressure monitor to your maternity hospital or the research team.

Will my expenses be paid?

Your study appointments will be planned at the same time as your usual appointments. If this is not possible, we can carry out these over the phone or pay back any additional travel expenses.

Will my taking part in this study be kept confidential?

We will send a letter to your GP to inform them that you are enrolled in the study.

We will be using information from you and your medical records in this study. Research is a task that we perform in the public interest. The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible.

We will keep identifiable information for 5 years after the study has finished. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely at the University of Oxford for 5 years after the end of the study. You will be given a study number so that any information that you provide to us will be made anonymous. Data regarding medical history, blood pressure and NHS resource use will be collected for study outcomes from the clinical record. All study data will be owned by the University of Oxford, kept in locked cupboards/secure servers in locked rooms with restricted access. Anonymised data may be shared with other researchers for research purposes. Data from the app/text is stored securely on University servers behind NHS firewalls and owned by the University of Oxford.

Your contact details will be stored in order to invite you to follow-up visits and will be retained for a maximum of 12 months following the study in case we need to check any details with you. Those consenting to contact for future studies will have their details kept for up to 5 years.