More information (continued)

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.

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.

Has anyone reviewed the study?

The study has been approved by an NHS Research Ethics Committee (reference number: 17/WM/0241).

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

The research is being financed by the National Institute for Health Research. 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 this study is Professor Richard McManus.

8 What if there are any problems?

If there is a problem or you have any concerns, you can contact the study coordinator (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 Dr Katherine Tucker, on bump@phc.ox.ac.uk or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) email: ctrg@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.

10 Study co-ordinator contact details

For more information about the study please contact the trial manager, Dr Marloes Franssen on **bump@phc.ox.ac.uk or 0800 9150045**

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 up to the 23th week of pregnancy.

The BUMP study

Blood pressure monitoring in pregnancy:

Can you help?

A summary of the study

- This study is testing whether additionally monitoring blood pressure at home during pregnancy can help the early detection of hypertension and pre-eclampsia.
- Half the people taking part in the study will be asked to monitor their blood pressure (self-monitoring group), the other half will not self monitor. **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 the BUMP study

The flowchart below shows you the study appointments that will happen for people in the BuMP study. Your usual appointments will also take place.

20 weeks → **30 weeks** → **After birth**

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 to check everything is ok.

After birth we will complete questionnaires and collect your BP monitor if you have been monitoring.

Self-monitoring group: taking your blood pressure

- You will be asked to measure your blood pressure from 20 weeks. This will mean taking **2 readings** (5 minutes total) on at least three days each week. • This will happen until **delivery or until your BP is raised**—if your blood pressure is raised you will be asked to take readings **everyday.**

Funded by NIHR

UNIVERSITY OF OXFORD

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

1 Why are we doing this study?

Around one in ten women will have high blood pressure in pregnancy. For some women this may be a sign of pre-eclampsia, which is usually detected in routine appointments through blood pressure and urine checks. We would like to find out if home blood pressure monitoring might help early identification of hypertension (high blood pressure) and pre-eclampsia.

2 Why am I being asked to take part?

You are invited to take part as you have a higher risk of pre-eclampsia. Risk factors can be first pregnancy, age or weight, or a history of pre-eclampsia. You may have other risk factors.

3 What will I need to do if I want to take part?

The first step is to contact the research team who will arrange your first appointment.
Contact: study team
Tel: 0800 9150045
Email: bump@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. Additionally, you may be invited to part in interviews and/or observations for which there is a separate information sheet.
You may be part of a pilot study in which we aim to recruit up to 50 women at one hospital to test the study procedures. This will involve the same procedures as described in this information sheet.

At your appointment at 20 weeks, we will ask you some brief questions about your medical history, your pregnancy and day-to-day life. This will take around 20 minutes.

Half the people in the study will be randomly selected to be in the self-monitoring group and the other half will be randomly selected to be in a usual care group.

The next sections explain what will happen for women in each group:

Usual care group

This means that you will carry on receiving your usual care as you did before the study.

We will not be providing you with a blood pressure monitor if you are in this group.

The usual care group are very important to the research. We will follow you up at the end of 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 show you how to use it. We will tell you how you can access the BuMP app and website.

You will be asked to take your own blood pressure readings **three times a week** for the rest of your pregnancy or until you develop high blood pressure. You can take your readings flexibly to suit you—but it can be helpful to take them at the same time to help you remember.

You will need to send your second reading each time you measure your blood pressure —through the app or a free text message.

This study is funded by the NIHR

What will happen if I have high or low blood pressure readings?

If you are in the self-monitoring group and your blood pressure is high or low, the system will send you clear instructions about what to do next. You will also be given a booklet which will help you to understand what your blood pressure readings mean.

If your blood pressure becomes raised during the study you will be asked to take and send in your **blood pressure readings every day.**

After pregnancy (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 research member 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 information and understanding about your blood pressure.

We think there is very little risk of harm in taking part. All women will still receive their usual care while in this study. The only disadvantage is the extra time taken to measure blood pressure 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 information from this study will improve the diagnosis of high blood pressure and pre-eclampsia during pregnancy.

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 to get 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 phone, write to or e-mail the study co-ordinator on 0800 9150045 or bump@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 if you have one.

Will my expenses be paid?

Your BUMP 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?

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.