Participant information sheet

Telemonitoring and/or Self-monitoring of blood pressure in Hypertension: A randomised controlled trial (TASMINH4)

We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it would involve for you. Please read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The research will compare different ways of providing care for people who may benefit from having their blood pressure lowered. Raised blood pressure is common and although it causes very few symptoms, treating blood pressure can reduce the chance of stroke or heart disease occurring in the future. At present, decisions about how much blood pressure medication to take and when to change it are usually made by general practitioners (GPs) and nurses taking blood pressure in the surgery.

Patients taking part in the study will be randomised to one of three groups: a) a group of people receiving normal care from their GP, b) a group who self-monitor their blood pressure or c) a group who self-monitor their blood pressure and send the results to their doctor via free text. The self-monitoring groups will measure their own blood pressure at home using an electronic blood pressure monitor but one group will record their readings manually and send their readings in to their GP practice whilst the other will transmit their readings electronically to their GP using a free text service via mobile phone. Depending on the average blood pressure reading that patients get at home the GP may adjust their medication to aim for a target blood pressure which gives the best health outcome according to current research.

The aim of the research is to find out if this new way of providing care is better than the way care is currently provided by your GP. We aim to find out whether high blood pressure is better, or as well controlled, if it is adjusted according to home readings rather than clinic readings, and whether telemonitoring results in better control than self-monitoring alone.

Why have I been invited?
You have been invited to take part in this study because you have a diagnosis of raised blood pressure (hypertension) and a recent blood pressure recorded at your practice was higher than recommended. Your name has been identified by health professionals at your surgery by searching their computer records. We aim to recruit about 1100 people to the study. However, should you already be taking part in a blood pressure study please let us know as it is unlikely you will be able to take part in this trial.

Do I have to take part?
It is up to you to decide to join the study. If you do agree to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the care you receive.

What will happen to me if I take part?
You are being invited to attend a clinic run at your GP surgery for further discussion of the research. A researcher will explain the study to you and answer any questions you may have. If you decide to take part you will be asked to sign a consent form. The researcher will measure your blood pressure and ask you some questions about your general health and what tablets you are taking.

A computer will decide at random (i.e you will have an equal chance of being placed in one of the three groups) which type of blood pressure management you will have. One third of the people taking part will continue with their usual care, one third will self-monitor only and one third will self-monitor and use a free text service to submit their readings. We do not know which the best group is for patients to be in but each group will receive care that is at least as good as your usual care.

a) <u>Usual care group</u>

You will continue to see your GP and/or practice nurse in the same way you currently do for periodic blood pressure checks and adjustment of your medication as required. If you are in this group, the way you receive care for your high blood pressure will not change.

b) <u>Self monitoring group</u>

If you are chosen to be in the self-monitoring group, you will be trained to use an electronic blood pressure monitor by the research team, so that you feel competent in what you are being asked to do. You will be lent an electronic blood pressure machine and given simple advice on how often to measure your blood pressure and what the blood pressure readings mean.

c) Telemonitoring group

If you are chosen to self-monitor and telemonitor you will be trained to use an electronic blood pressure monitor and how to submit the resulting blood pressure readings to your GP by free text. You will be given as much time as you need to feel comfortable with the process.

All patients in all groups will be asked to see their GP for a review of the medication they take for their blood pressure following the first clinic. All patients will be asked to attend two further clinics, one after six months and one after a year. Study clinics will take place at your GP surgery and each visit will last about one hour. Your medical records will be reviewed as part of the research. The study will last 12 months.

What will I have to do?

At each study clinic, your blood pressure will be taken by a member of the research team and you will be asked to fill in a questionnaire about your health. Your height and weight will be measured at the first clinic and weight measured at subsequent clinics. If you are in the self-monitoring or the telemonitoring group you will be asked to monitor your own blood pressure at home twice a day for one week per month for a year using an electronic blood pressure machine provided by the research team. The self-monitoring group will be asked to record all their readings on the forms provided and the telemonitoring group will be shown how to submit their results electronically. Depending on the blood pressure readings, in both the self-monitoring and telemonitoring group, your GP may decide to adjust your medication. They will notify you if this is the case.

You will also be asked by the research nurse if you would be willing to take part in an interview to talk about your views and experiences of self-monitoring. Each interview would last between ¾ hr to 1¼ hrs and would be audiorecorded. We are hoping to interview approximately 30 patients.

What are the possible risks and benefits of taking part?

Your GP will continue to decide which medication is best for you whichever group you are in. It is possible that people in the self-monitoring and telemonitoring groups may be more anxious than those receiving normal care, although we found this was not the case in previous studies including self-monitoring that we have carried out. People in the self-monitoring and telemonitoring groups may feel they benefit from understanding more about their blood pressure and having it more closely monitored.

Involvement of your General Practitioner (GP)
Your GP is collaborating in the study. Any blood pressure readings that the research team take will be shared with your GP, as will the home blood pressure readings taken by those allocated to the self-monitoring and the telemonitoring group. Any decisions involving medication changes or adjustments will only be made with the consent of the GP.

Will my taking part in the study be kept confidential?
All information provided and obtained will be treated with the strictest confidentiality. Your medical records will be reviewed as part of the research. The only people with direct access to study information will be the research teams from Primary Care Clinical Sciences at the University of Birmingham and the Nuffield Department of Primary Care Health Sciences at the University of Oxford. The study data will be stored in accordance with the Data Protection Act at the University of Oxford. The study data may be looked at by responsible individuals from the University of Oxford, the University of Birmingham, regulatory authorities or from the NHS Trust to check that the study is being carried out correctly.

We will share identifiable data (for instance name, date of birth, NHS number) in a secure manner (including encryption during data transfer) with the NHS Health and Social Care Information Centre which may be used to help contact you (for instance if you move away) and to provide information about your health status. We will use similar data to provide information about your health status from your practice.

What will happen if I don't want to carry on with the study?
Your participation is voluntary and you are free to leave the study whenever you wish without giving a reason. You will then receive your usual care for your blood pressure from your GP or nurse as you did before the study. If you are in the self-monitoring or the telemonitoring group, you may choose not to continue self-monitoring or to stop telemonitoring but still attend the follow-up clinics after 6 and 12 months. We may still need to use the data already collected but would not collect any further information if you did not want us to. Although you do not have to give a reason for leaving the study, we may ask if you are willing to discuss your reasons for deciding not to continue as it may be important to other people taking part the study.

What if there is a problem?
If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions on <<insert relevant phone number>>. Any complaint about the way you have been dealt with during the study will be addressed. If you remain unhappy and wish to

complain formally to someone independent of the research team, you can do this by contacting Ms Heather House, Head of CTRG Team, University of Oxford, 01865 572224.

What happens when the research study stops?
You will go back to having your blood pressure looked after by your GP. If you wish to be more involved in your blood pressure care, for example by measuring your blood pressure at home, you will need to discuss this with your GP. People in the self-monitoring and the telemonitoring groups will need to return the equipment they have on loan from the study.

What will happen to the results of the research study?
The research will be published in medical journals. A summary of the findings of the study will be made available to everyone who has taken part.
It will not be possible for you to be identified in any report or publication.

Who is organising and funding the research?
The study is organised by a team of researchers led by Professor Richard McManus from the Nuffield Department of Primary Care Health Sciences at the University of Oxford and Primary Care Clinical Sciences at the University of Birmingham. It is funded by the NHS via an NIHR programme grant awarded to Prof 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. This study has been reviewed and been given a favourable opinion by Oxford B Research Ethics Committee.

Further information and contact details
The research team are available on the following numbers if you have any questions.

Research Helpline	**0800 915 8543**
Prof Richard McManus, (GP and study lead)	**01865 617 852**