Participant Information Sheet

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SMaRT BP CKD Self Monitoring and Realisation of Target Blood Pressure in CKD Semi Structured Interview

Name of Researchers: Professor M Taal, Professor N Selby, Dr Heather Buchanan, Dr Bethany Lucas

IRAS Number: 321439

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve. Please take time to read the following information carefully. One of our team members will go through the information sheet with you and answer any questions you have. Feel free to ask for more information or to clarify parts of the study that you do not understand. If you wish you can talk to other doctors, nurses, friends and family about the study.

What is the purpose of the study?

The aim of the research study is to see if an approach to lowering blood pressure that has been researched previously is appropriate and achievable in people with chronic kidney disease (CKD) looked after in hospital renal clinics. We would like to know if a self-monitoring approach used in primary care where patients monitor their own blood pressure and then increase or change their own medications following a pre-agreed plan is acceptable to patients. We will ask for feedback through an interview format to gain insight into the intervention and to learn from patients what helped adopt the home blood pressure monitoring and explore any potential challenges they face.

We believe that this will help to guide blood pressure treatment in patients with kidney disease, but we need to perform research studies to prove the benefits.

Why have I been invited?

You are being invited to take part because you have consented to SMaRT BP CKD study and were randomised to the home blood pressure monitoring group.

Do I have to take part?

No. It is completely up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights. If you withdraw or decide not to take part, it will not affect the standard of care you receive in any way. If you decide not to take part in the interview aspect of the study you can continue in the study as before.

What will happen to me if I take part?

If you are given information about the study and are considering taking part, one member of our research team will contact you and arrange to meet you to discuss the study. They will take the time to ensure that any questions or concerns that you may have are answered to your satisfaction. We will also check with you at this point that it is possible and safe for you to take part. After this, you will be asked to sign a form to say you consent to be part of the study. Once you have agreed to take part in the study, we will make arrangements for you to start the study.

The study involves:

- Taking part in this study requires you to undertake an interview either via video call, telephone call or face-to-face

The interview

Once you have agreed to take part in the study, the interviewer will contact you to make arrangements for the interview. All interviews will be recorded for the analysis.

On the consent form, you can choose how you would like the interview to happen. This can happen in one of 3 ways:

1) Video call – Video calls will happen via MS teams. We will not be able to use other platforms. MS teams is the only platform considered secure enough to perform the interview. If you choose this option, you will need to download the app to a smart phone or computer. We can help you with this. The interviewer will then email you a diary invite with a link that you click on to enter the interview. The interview will contain a 'live' video of the interviewer so you can see their face. You can either have your own video on or off. If your

video is on, the interviewer will see your face. Only the audio from video calls will be recorded using a digital recording device, the video will not be recorded. The interviewer will be in a private room, so no-one else can overhear the conversation.

2) Telephone call – The interviewer will call you on a telephone number of your choice at the assigned time. Telephone calls will be performed with the interviewer on speaker phone, so this can be recorded using a digital recording device. The interviewer will be in a private room, so no-one else can overhear the conversation.

3) Face-to-face. Face-to-face interviews will be recorded using a digital recording device. This interview can happen at a location of your choice. However, this needs to be done somewhere it is easy to talk and not too noisy.

The interview will take approximately 60 minutes. However, the interview can stop at anytime if you are not happy to continue or feel tired or unwell. If you need to stop the interview, we can arrange to finish at another time if you would like to do so. The information discussed in the interview will remain confidential and the transcript will be anonymised. An external company approved by University Hospitals of Derby and Burton will transcribe the interview.

1-4 weeks after the interview, at a time convenient to you, the interviewer will ask you to review a summary of the interview to check this is accurate. Once the interview has been reviewed and agreed with you We may still use this information if you choose to withdraw from the study after the interview has finished.

Clinical care

Your kidney team and GP /family doctor will be made aware of both your involvement in the study. The study will not affect any treatment that you may be receiving for other conditions.

Expenses and payments

Unfortunately, no payment can be offered to you for your participation in this study. Transport, child care and parking costs will be reimbursed and if desired transport via a taxi can be arranged and paid for by the research team. We will endeavour to arrange your study visits at a similar time to your renal clinic visits if possible to minimise trips to the hospital.

What are the possible disadvantages and risks of taking part?

The main disadvantage of taking part in the study is the time taken for the interview, this is expected to be about 60 minutes. Reviewing the interview is expected to take around 20 minutes.

What are the possible benefits of taking part?

The information we get from this study may not help you directly. In the future, we hope that it will allow us to better understand how to help people manage their blood pressure in chronic kidney disease and find a patient-centred way of doing this. The interviews will help us to identify ways we may be able to improve this.

What happens when the research study stops?

Your treatment for your medical conditions will continue as normal. When the research study is completed, we will analyse the data. The results will be published and may lead to further research studies or a change in the way we treat and measure blood pressure in patients with kidney disease. We can send you an information sheet letting you know the results and what they mean.

What if there is a problem?

We do not expect anything to go wrong. If you have any concerns or queries about any aspect of this study, you should ask to speak to one of the research team who will be happy to meet you (contact number 01332 340131 ext. 88262). Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital PALS department (Office: 01332785156, Text: 07799337500 Email: uhdb.contactpalsderby@nhs.net).

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your legal costs. NHS indemnity will apply to activities which take place within the NHS.

How will we use information about you?

We will need to use information from you and your medical records for this research project.
This information will include your:

- NHS number
- Initials
- Contact details such as address

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. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. Personal data and research data will be kept securely for 5 years. We will write our reports in a way that no-one can work out that you took part in the study. The data from the study will also be reported in Dr Bethany Lucas' PhD thesis in a way where you will be not be able to be identified.

In accordance with the University of Nottingham (where Dr Bethany Lucas' is registered for a PhD) the Government and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

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.
We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our website https://www.uhdb.nhs.uk/research-how-we-use-your-information

- by asking one of the research team
- by sending an email to uhdb.dataprotectionofficer@nhs.net, or by ringing us 01332 788 645

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

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far will still be used in the project analysis unless you specifically wish that it is not.

Involvement of the General Practitioner/Family doctor (GP)

If you agree to take part, we will write to your doctor to inform them of your involvement.

What will happen to the results of the research study?

The results of the study will be submitted to journals for publication and to scientific meetings for presentation. A report of the results will also be published. You will not be identified in any report/publication unless you have given permission for this. Copies of these will be available on request where possible.

Our results are published in a regular patient information leaflet produced by the renal department at Royal Derby Hospital, you can also ask about the results of the study at your routine outpatient follow up appointment.

Who is organising and funding the research?

This research is being organised by Professor Taal, Professor Selby and Dr Heather Buchanan at the University of Nottingham and Department of Renal Medicine, Royal Derby Hospital. The research is being funded by a doctoral research NIHR grant awarded to Dr Bethany Lucas as part of her PhD. University of Derby and Burton NHS Foundation Trust is sponsoring the research.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Proportionate Review Research Ethics Committee.

Further information and contact details

For further information or to discuss this research study please contact any of the following:

Professor Maarten Taal

Professor of Medicine

(Chief Investigator)

Professor Nick Selby

Professor of Medicine

Contact:

Department of Renal Medicine

Royal Derby Hospital

Tel: 01332 789344 (direct line)

To find out more about the regulation of Research within the NHS visit: www.hra.nhs.uk