**Participant Information Sheet**

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# **SMaRT BP CKD S**elf Monitoring **a**nd **R**ealisation of **T**arget **B**lood **P**ressure in **CKD**

**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 achievable in people with chronic kidney disease (CKD) looked after in hospital renal clinics. One of the best treatments to reduce heart attacks and strokes for people with CKD as well as preserving kidney function is to treat high blood pressure. Guidelines now suggest that the “top” number of a blood pressure reading (the systolic) should be less than 120mmHg for most people with CKD. We believe that by monitoring blood pressure at home using a provided blood pressure monitor and allowing people to increase or change their own blood pressure tablets (using a pre-agreed plan of how and when) we can help people achieve lower blood pressure.

We will randomly assign 50 people in the study to carry out the home monitoring on top of their usual clinic care and 50 people will receive usual clinic care without extra monitoring so we can compare the two groups.

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 chronic kidney disease and your average clinic blood pressure readings have been over the new recommended target blood pressure in the last 6 months. We are inviting 100 patients to take part.

**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.

**What will happen to me if I take part?**

If you are given information about the study and are considering taking part, a 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. To determine if you are eligible for the study we will need to check your blood pressure again using an automated blood pressure machine that takes an average of 3 readings taken a minute apart. After this if your blood pressure is ok to continue in the study and you want to take part, 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:

- Randomisation- you will be randomly assigned to either normal renal clinic care or home blood pressure monitoring and increasing or changing your blood pressure tablets alongside your normal renal clinics. 50 people will be in each group.
- Study visits at the beginning of the study, 6 months in and 12 months for participants in both groups:

  - Measurements including blood pressure, height and weight
  - Blood and urine tests (see below)
  - Questionnaire
- If you are assigned to the home blood pressure monitoring group you will be given a blood pressure monitor to keep and a member of the research team will show you how to use it and explain how and when to measure and record your blood pressure readings.
- If you are in the home blood pressure group a member of the research team will review your medications with you and will agree a written plan with you of how your blood pressure medications would be increased or changed if your blood pressure at home remains over target.
- You will be asked to measure your blood pressure for twice a day for a week of every month and will be provided with a colour coded sheet to record your blood pressure.
- Using your personalised plan if your blood pressures at home are over target you will increase or change your medications every 2 months.
- A member of the research team will contact you when you are due to review your medications to go through any questions you may have
- Any prescriptions you require for blood pressure medications during the study will be done by the research team, who will also keep your GP up to date.

At the 6 month visit if you have been in the home blood pressure group you will be asked if you would like to take part in a single up to 60 minute interview with the research team to give feedback on your experience in the study (a separate information leaflet and consent form will be provided). The study will run for 12 months.

All study visits will take place in the Royal Derby Hospital where you usually attend for your renal clinic appointments. The questionnaires can be done remotely and posted out to you with a pre-paid return envelope or done during study visits. You will be given dedicated contact details for the study team to contact with any questions you may have throughout the study

*Randomisation*

In order to compare the intervention to normal blood pressure management in renal clinics we will be randomly allocate you to either the “standard care” or “intervention” group. The research team,

your doctor or you cannot choose which group you will be in. The randomisation is done by a web-based system and will allocate people randomly into each group (like drawing lots or rolling a die) but will make sure that the groups are matched in terms of participant ages, sex and stage of CKD. After this has been done you will be informed which group you are in.

*Study visits*

Study visits will be conducted after consent (baseline), at 6 months and 12 months for both groups in the study. Details about your medical history, medications and some measurements will be taken.

*Measurements*

We will take some other measurements at each study visit. These will give us information about your blood pressure and kidney function.

1. We will ask you to sit and have your blood pressure measured by an automatic machine that takes the average of a few blood pressure readings.
2. We will also do your blood pressure sitting and standing to look for a drop when you stand up
3. Your height and weight will be measured.
4. We will take some blood and urine samples from you these are part of your routine care and will be the same as your pre-clinic blood tests. These will be accessed by the research team. We will not store any samples taken.

*Home blood pressure monitoring*

After randomisation if you are randomised into the home blood pressure monitoring group a member of the study team will give you a blood pressure monitor for you to use at home. We will explain how and when to use the machine and provide you with a blood pressure diary. We will also discuss with you what target systolic blood pressure to aim for. Blood pressure readings can either be recorded manually in the diary by writing them down and you can use the software provided with the monitor to download the readings onto a computer as well if you would like.

You will be asked to measure your blood pressure twice every morning for a week every month. The first reading will be discarded as this is often falsely high. You will compare the second reading you take against a colour coded chart to see if this blood pressure is above or below target. Because your blood pressure is different with every heart beat we will look at the trend of blood pressure readings before changing your medication. At study visits we will devise a

personalised medication plan for you, and discuss your blood pressure target. This will be similar to how we normally increase or change your blood pressure tablets in renal clinic but you will make these changes yourself based on home blood pressure readings. Any prescriptions or blood tests that you need after making these changes will be done by the study team and you will have a secure email address and phone number for the study team.

*Questionnaire*

At the initial visit, 6 month visit and 12 month visit we will also ask you to complete a questionnaire that has been used previously in research to try and understand how people view their kidney disease. We want to know if this questionnaire is easy to use and understand and in the future as it might affect how people feel about their blood pressure and treatments.

*Clinical care*

Your kidney team and GP /family doctor will be made aware of both your involvement in the study and the proposed blood pressure medication plan if you are in the group doing the home monitoring. All prescriptions for your medications if you are in the home monitoring group will be done by a clinical member of the research team and they will also inform your GP of the changes in writing and update the renal clinic software so your renal doctors are also aware. 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 risks from taking part in the study are mainly related to symptoms from your blood pressure going becoming too low. Low blood pressure can make people feel dizzy, and in serious cases this may make people fall.

Some medications that we use for blood pressure can affect the salts (electrolytes) in your blood and we would routinely recheck blood tests after increasing some medications. In your plan we will

arrange blood tests if these are required. The main risk is an increased in a salt called potassium, if this is high you may need to attend hospital for a repeat blood test or even admission.

During the study we will ask you to report any potential side effects and will record these. If you are admitted to hospital this will be recorded and reported.

While participating in the study the treatment of your disease will continue as normal, if you are monitoring your blood pressure and changing your medications yourself with support from the research team both the renal doctors and your GP will be made aware of your involvement in the study and the medications you are taking. There will be no delay to your routine NHS care if you participate in the study.

**What are the possible benefits of taking part?**

This study aims to find a sustainable way to reduce blood pressure for patients with chronic kidney disease. We know from previously published research that lower blood pressure has benefits for heart disease, strokes and reducing the risk of kidney function getting worse. The data we obtain from the study may help us gain a greater understanding how home blood pressure monitoring can be used for patients with kidney disease, and could potentially help us monitor patients better or improve treatments for other patients in the future.

**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. If you are in the home monitoring group we will also provide them a copy of your medication plan.

**Will any genetic tests be done?**

No genetic tests will be performed as part of this study.

**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 and will form part of Dr Bethany Lucas' PhD thesis. 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

**Schedule of Events for SMaRT BP CKD X=all participants (X)= those in the blood pressure measuring group only**

| | Screening | Initial visit | Month 1-2 | Month 2 | Month 2-6 | 6 months | Month 6-12 | 12 months |
|---|---|---|---|---|---|---|---|---|
| Blood pressure measurement (3 readings taken by an automatic machine) | X | X | | | | X | | X |
| Written consent | | X | | | | X | | |
| Lying and standing blood pressure | | | | | | X | | X |
| Blood tests (usual clinic blood tests, results recorded for research) | | X | | | | X | | X |
| Urine test (usual clinic urine test, results recorded for research) | | X | | | | X | | X |
| Medication review | | X | | | | X | | X |
| Illness Perceptions Questionnaire (IPQ-R) | | X | | | | X | | X |
| Agree blood pressure target | | X | | | | | | |
| Blood pressure medication plan | | (X) | | | | (X) | | (X) |
| Record home blood pressure readings (one week a month, 2 readings a day) | | | (X) | | (X) | | (X) | |
| Change medications based on blood pressures recorded as per pre-agreed plan | | | (X) | | (X) | | (X) | |
| Phone call from research team | | | | (X) | | | | |
| Invitation to semi-structured interview | | | | | | (X) | | |
| Semi-structured interview (if consented) | | | | | | | (X) | |