UNIVERSITY OF BIRMINGHAM

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Participant Information Sheet

The RePROM Pilot Trial

Full study title: ***The use of an electronic Patient-Reported Outcome Measure in the Management of Patients with Advanced Chronic Kidney Disease – The RePROM Pilot Trial***

Version 1.1 – 07/02/2018

UNIVERSITY OF BIRMINGHAM | CPROR
CENTRE FOR PATIENT REPORTED OUTCOMES RESEARCH

Overview of the study

We would like to invite you to take part in the research being conducted by the University of Birmingham and the Chronic Kidney Disease (CKD) team at the Queen Elizabeth Hospital, Birmingham. In the study we would ask you:

1) To agree to being closely monitored by the kidney team for 12 months. As part of this process you would need to fill out a short paper questionnaire approximately every 3 months. At the same time, the research team would need access to your hospital medical notes to help the monitoring process.

2) You may also be asked to complete short electronic questionnaires about your health using a smartphone or computer.

3) Finally, we will also ask you to consider taking part in a short interview at the end of the study to tell us about your experience.

Please note: To take part in the study, you must be signed up to the myHealth patient portal system at Queen Elizabeth Hospital. If you are not already a user of myHealth, the nurse at QE will arrange this for you.

1. Invitation and brief summary

We would like to invite you to take part in our research study. This is voluntary. It is your choice whether or not to take part. If you decide not to take part, no-one will think badly of you, and it will not affect the way you are treated by the hospital nor alter your treatment/standard clinical care.

If you do take part, you can still withdraw at any time, without having to give a reason. We will check at each three-month standard care clinic visit that you are still happy to continue your participation.

Before you decide we would like you to understand why the research is being done. This leaflet tells you the purpose of the study, and explains what will happen if you decide to take part. A nurse from our research team will also talk to you about the study in clinic, to help you to decide whether or not to take part. Please ask any questions. You can also talk to others about the study if you wish, such as your GP or family.

2. Purpose and background to the research

Chronic Kidney Disease (CKD) affects around 1 in 7 people in the UK. Some people with advanced CKD may go on to need demanding treatments, such as dialysis which can affect their quality of life.

Some researchers and doctors believe it would be helpful for patients to provide reports about their symptoms and quality of life in between their regular hospital appointments by completing a questionnaire on their computer or smartphone. We call these questionnaires ‘electronic Patient-Reported Outcome Measures’ or ePROMs.

If the ePROM report shows that a patient needs urgent care, we think this will help a doctor take action straight away, rather than waiting until the next clinic appointment. We believe this could help to manage a patient's CKD and symptoms better.

No-one has tried using ePROM reporting for people with CKD, so we need to find out if it will work. In this study, we will test an ePROM system in a small group of patients with CKD, who are being treated at the Queen Elizabeth Hospital in Birmingham.

This is a pilot study. We will use the results to plan a much larger clinical trial, which will help show if ePROM reporting in the NHS is actually better for patients.

3. Why have I been invited?

The kidney team at the Queen Elizabeth Hospital are sending this invitation to all people who are recorded on their computer system as having advanced CKD, and who might be eligible for this study.

4. What would taking part involve?

If you agree to take part, you will be randomly assigned to one of 2 groups:

- **ePROM reporting group** – in addition to your normal healthcare appointments, we will ask you to provide monthly ePROM reports about your health using a smartphone or computer in-between your regular clinic appointments. The reports would also be added to your electronic hospital record, but would only be available to view by you, your hospital care team and the research team.
- **Control (no reporting) group** – you would continue with your regular healthcare without sending ePROM reports. This is so we can compare the ePROM system with usual hospital care to see which is better.

Whichever group you are assigned to, you will be closely monitored for the study by the kidney research team at the Queen Elizabeth Hospital every 3 months for 1 year. We would try to do this while you are already in clinic for your routine CKD appointment. Every 3 months we will:

- Ask you questions about your health.
- Ask you to complete a short paper questionnaire.
- Review your medical notes.

We think this will take around 30-45 minutes on your first visit and 20 minutes for the other visits.

We will post the paper questionnaire out to you about 1 week before your appointment so you can complete it at home and bring it with you to clinic. Occasionally, we may contact you over the phone.

At the end of the study we will ask you to fill in a short questionnaire (10-15 minutes) telling us about your experience.

Finally, we may also ask if you are willing to be interviewed about your experiences at the end of the study. This is optional. The interview would last approximately 30-45 minutes. We can do this during a clinic visit, over the phone, or at a time and place of your choosing.

5. ePROM Reporting System

If you are assigned to the ePROM reporting group, we will teach you how to use the system during your first visit – this will take approximately 10 minutes. You will also be given an information leaflet on the system to take away with you. You will also have access to a training video, which you can view on your computer, tablet or smartphone.

You will receive reminders when your ePROM report is due. The reminders will be sent by text or email, depending on your preference.

When you submit your ePROM report, the system will automatically give you advice on how to manage your symptoms based on your answers. A kidney nurse may call you if the ePROM flags any issues that need to be addressed. The reports would also be added to your electronic hospital record, but would only be available to view by you, your hospital care team and the research team.

If your ePROM report shows that you need to be seen urgently, the system will send an alert to you and to the renal team at the Queen Elizabeth Hospital. If this happens, during office hours - Monday to Friday, between 09.00 and 17.00 - a renal nurse may contact you using your preferred method (e.g. landline, mobile) to discuss your ePROM report.

The doctors at the Queen Elizabeth Hospital will be able to see your all your ePROM reports in your medical notes, and they might talk to you about them during your routine appointments.

We will give you a help-line number to contact with the CKD team during office hours if you have any concerns. Outside of office hours you should contact your GP surgery or out of hours GP if you have any concerns about your health or care after completing the questionnaire.

6. What are the possible benefits of taking part?

We do not know if using the ePROM system will have any benefits. If you are assigned to the ePROM reporting group, we think you might benefit from being more closely monitored by the CKD team, but we need to do this study to help find out.

If the ePROM reporting system is shown to be helpful in a large clinical trial, future patients with advanced CKD may benefit from its use across the NHS.

7. What are the possible disadvantages and risks of taking part?

There are no risks to taking part in the study, only the use of your time. For participants in both groups, the extra information we collect for the study will make your appointments a little longer.

If you are assigned to the ePROM reporting group, it will take time to complete each report – about 10-15 minutes. The ePROM questionnaire will ask you about your quality of life and symptoms. Sometimes patients can become upset when answering these types of questions. We will give you a help-line number you can call during office hours if you wish to speak to someone in the CKD team to discuss your concerns. Outside of office hours we would ask you to contact your GP if you have any concerns about your health or care after completing the questionnaire.

8. Who is organising and funding the research?

This study is being sponsored by the University of Birmingham (Study number: RG_16-141). It is funded by the UK National Institute for Health Research, which is part of the Department of Health (funder's reference: PDF-2016-09-009).

9. How have patients and the public been involved in this study?

A group of patients and members of the public helped to develop this research topic and the research questions that should be asked. The group helped to design the study and develop this leaflet. They will continue to be involved throughout the study.

10. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been

reviewed as part of the larger RePROM project, and given favourable opinion by <insert REC details> Research Ethics Committee. The REC reference number is <insert ref>.

11. Will my taking part in this study be kept confidential?

All information about you will be handled in confidence. All information provided throughout this research is protected under the *UK Data Protection Act (1998)* and will only be used by those on the research team at the University of Birmingham and at the Queen Elizabeth Hospital, Birmingham.

Information sent from the Queen Elizabeth Hospital to the University of Birmingham will be securely stored and only used for this research project. The study will do its utmost to keep your information confidential, therefore your name will not be mentioned in any report of this research.

As part of the study, staff at the Queen Elizabeth hospital will need to review your medical history by accessing your electronic healthcare record. They will also make a note of your blood test results at each clinic visit, and look to see if you have had any other hospital appointments, or if you have been admitted as an inpatient.

If you are part of the ePROM reporting group, staff will review your reports when necessary and may use the information you provide to help plan your care.

If you decide to take part in the interview at the end of the study, we will ask your permission to record it using a secure digital recorder. We will then ask a reputable company to produce a written version of the recording called a transcript. The company will need to sign a confidentiality agreement before they do so. We will then remove all identifying information from the transcript. After this, we will delete the original recording. We will only use anonymised quotes from the transcript in any publication or report.

If the study research nurse becomes concerned for your wellbeing during a study review, they will discuss their concerns with you, to determine the best course of

action. With your permission, the research nurse may need to consult with a senior member of the study and/or your treating clinician to address these concerns. In exceptional circumstances, the research nurse may need to do this without your prior permission if they are concerned for your safety.

12. Involvement of General Practitioner / other healthcare practitioner

If you decide to take part in this study, we will contact your GP to let them know.

13. What if something goes wrong?

If you have a concern about any aspect of this study, please speak to a member of the research team who will do their best to answer your questions. You can contact the research team on <*insert site contact number*>. If you are harmed in any way, insurance is in place to deal with any negligence. If you are unhappy and wish to complain formally, you can do this by contacting the NHS Patient Advisory and Liaison Service (PALS). Their contact details are at the end of this leaflet.

14. What if I do not want to take part?

The decision to take part in this study is entirely your choice. You can change your mind at any stage. If you decide not to carry on, a member of the research team will make arrangements for your standard clinical care to continue.

If you wish to withdraw, please contact the research team on <insert site contact details>.

15. Will my travel expenses be reimbursed?

We will reimburse your travel expenses (including car parking fees) for all study clinic visits.

16. What happens if new information becomes available?

Sometimes we get new information about the topic being studied. If this happens, a member of the research team will tell you and discuss whether you should continue in the study. If your research doctor is happy for you to continue in the study, you will have the option to decide whether you wish to continue. A member of the research team may ask you to re-sign a consent form if you decide to continue.

If you decide not to carry on, a member of the research team will make arrangements for your standard clinical care to continue.

17. What happens when the research study stops?

At the end of the study the CKD team at the Queen Elizabeth hospital and your GP will continue to look after you and your treatment.

The study may be stopped early if you start dialysis, or receive a transplant, or if your kidney function (eGFR) falls to 5% or lower. In this case, again the CKD team at the Queen Elizabeth hospital and your GP will continue to look after you and your treatment.

18. What will happen to the results of the research study?

We plan to publish the results in a leading scientific journal and present at international scientific conferences. You will not be named in any published report or

presentation. You will be sent a summary of the results unless you tell us that you do not want one. The ePROM reporting system will be tested further in future research conducted by the study team.

19. Do you have any further questions?

General information about the study is available on the study website, here: www.birmingham.ac.uk/RePROM

For specific information about this research study, please use the contact details below.

Contact Information

If you would like to speak to someone about the study please contact:

< Contact Name > <Job Title>

<Telephone and/or E-mail>

Support can also be found through the NHS Patient Advisory and Liaison Service (PALS)

Tel: *<insert local PALS contact number(s)>* Email: *<insert local PALS email address>*