RePROM Renal Electronic Patient Reported Outcome Measures

UNIVERSITY OF BIRMINGHAM

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Participant Information Sheet

User Testing for the RePROM Study

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 – 07/02/18

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 renal research team at the Queen Elizabeth Hospital, Birmingham. In the study, we will ask you:

1) To test a system that allows patients with Chronic Kidney Disease (CKD) to provide reports to their hospital kidney team about their health using a computer or smartphone.

2) To take part in a short interview after you have tested the system to tell us about your experience.

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 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 need to help decide. 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 health 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 the 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. Researchers at the University of Birmingham, and doctors and nurses at Queen Elizabeth Hospital in Birmingham are setting up a study to test ePROM reporting in patients with CKD. We would like your help to test the ePROM system.

We will use your feedback to help design an ePROM system which we will then test in a larger study.

3. Why have I been invited?

The renal research 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?

You will be invited to test the ePROM system in the presence of a researcher.

The testing will take place at one of the following locations, whichever is most convenient for you:

- The Queen Elizabeth hospital main building
- Institute for Translational Medicine (Old QE hospital heritage building)
- The University of Birmingham

We will ask you to take part in a short interview afterwards to tell us what you thought of the ePROM system and how you feel it could be improved. This interview will be audio recorded. We expect the whole session to last up to an hour.

We may invite you for a follow-up testing session to evaluate any changes we have to make to the system based on your, and other patient's, feedback.

5. What are the possible benefits of taking part?

We do not think you will have any direct benefit from taking part in the study. If you take part, it will help us to build a system that works for patients with CKD. If the ePROM reporting system is shown to be helpful in a large clinical trial, future patients with CKD may benefit from its use across the NHS.

6. 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. The user testing session will take around 1 hour. The ePROM questionnaire will ask you about your quality of life and symptoms. Occasionally, some patients can become upset when answering these questions. You can pause or stop the testing session if you wish. We can also put you in contact with a member of the Queen Elizabeth Hospital kidney team to discuss your concerns if you would like.

7. 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).

8. 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.

9. 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>.

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

All information about you will be handled in confidence. All information you provide 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.

We will ask your permission to record the study interview 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.

11. Involvement of General Practitioner / other healthcare practitioner

We will not notify your GP if you decide to take part in this user testing, but you should feel free to discuss this with them if you would like.

12. 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.

13. 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 <insert site contact> using the details at the end of this leaflet. We will include your data in the study analysis 5 working days after the testing session and interview. It will not be possible to remove your data after this point as it will be combined with other participant's data in an anonymised dataset.

14. Will my travel expenses be reimbursed?

We will reimburse any travel expenses (including car parking fees) incurred when attending the testing session(s).

15. 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.

16. What happens when the research study stops?

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

17. 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 identifiable 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.

18. 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>*