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RePROM pilot/feasibility study in chronic kidney disease

Submission date
19/02/2018

Recruitment status
No longer recruiting

Registration date
28/02/2018

Overall study status
Completed

Last Edited
13/03/2023

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
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. These questionnaires are called 'electronic Patient-Reported Outcome Measures' or ePROMs. If the ePROM report shows that a patient needs urgent care, this will help a doctor take action straight away, rather than waiting until the next clinic appointment. This could help to manage a patient's CKD and symptoms better. No-one has tried using ePROM reporting for people with CKD, so the aim of this study is to test an ePROM system in a small group of patients with CKD who are being treated at the Queen Elizabeth Hospital in Birmingham. The results will be used to plan a much larger study to show whether ePROM reporting in the NHS is actually better for patients.

Who can participate?
Patients who are over 18 and have advanced chronic kidney disease

What does the study involve?
Participants are randomly allocated to one of two groups. One group continue to receive usual care, while the other group are asked to provide monthly reports on their health status using an online electronic Patient-Reported Outcome Measure (ePROM) system.

What are the possible benefits and risks of participating?
It is not known whether using the ePROM system will have any benefits. Participants in the ePROM group might benefit from being more closely monitored by the CKD team, but this study is needed to find this out. If the ePROM reporting system is shown to be helpful in a large study, future patients with advanced CKD may benefit from its use across the NHS. There are no risks to taking part in the study, only the use of participants' time. For participants in both groups, the extra information collected for this study will make their appointments a little longer.

Where is the study run from?
The study is being run by the University of Birmingham. Participants will be recruited at the Queen Elizabeth Hospital, Birmingham (UK)

When is the study starting and how long is it expected to run for?
January 2017 to December 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Derek Kyte
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Study website
https://www.birmingham.ac.uk/RePROM

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36497

Study information

Scientific Title
The use of an electronic Patient-Reported Outcome Measure in the management of patients with advanced chronic kidney disease – the RePROM pilot trial

Acronym
RePROM

Study objectives
To assess the feasibility of undertaking a randomised controlled trial (RCT) of the use of electronic Patient-Reported Outcomes (ePROMs) in the management of patients with advanced Chronic Kidney Disease (CKD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Edgbaston Research Ethics Committee, 26/02/2018, ref: 18/WM/0013

Study design
Randomized; Both; Design type: Treatment, Complex Intervention, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Advanced Chronic Kidney Disease

Interventions
Participants randomised to the intervention arm will commence monthly self-reporting of their health status using an online electronic Patient-Reported Outcome (ePROM system), after receiving a face-to-face training session. Reporting will continue for 12 months. Participants will receive automated reminders 24 hours prior to each scheduled self-report and 24 hours after a failure to report if necessary, these will be delivered via the secure hospital patient portal, text message, email or a landline telephone call, according to participants' preferences. Participants may also upload additional ad-hoc reports to the system as well, if they feel this is necessary (e. g.: if they wish to communicate a sudden change in symptoms). The ePROM system will provide tailored information to patients in response to each report (both scheduled and ad-hoc) and

alert the clinical team of patient deterioration according to a priori determined alert threshold criteria established in the trial intervention development study. After receiving training during the study setup period, the renal clinical team will monitor for ePROM alerts and will respond with appropriate clinical action, in line with standard clinical practice.

Participants randomised to the control group continue to receive usual care.

Intervention Type
Other

Primary outcome measure
Feasibility is measured via review of recruitment and retention rates, data collection processes, data completeness and adherence to the ePROM intervention, at the end of the trial

Secondary outcome measures
1. Health-related quality of life is measured using the validated EQ-5D-5L at baseline, 3, 6 9 and 12 months
2. Clinical condition is measured using: Serum Creatinine, Calcium, Phosphate, Bicarbonate, Albumin, eGFR, ACR, blood pressure, and for participants with diabetes: glucose and HbA1c, at baseline, 3, 6 9 and 12 months
3. Clinical event data, including: progression to end stage renal disease, contact with health care professionals in secondary care (outpatient clinics and A&E), inpatient hospitalisation and death, are measured using Clinical Report Forms at baseline, 3, 6 9 and 12 months
4. Health resource use data are measured using Clinical Report Forms at baseline, 3, 6 9 and 12 months

Overall study start date
01/01/2017

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Aged ≥18 years old
2. Ability to provide fully informed consent for participation in the study
3. Patients under the care of the renal services at Queen Elizabeth Hospital Birmingham (QEHB)
4. Patients meeting the trial definition of advanced CKD: an eGFR ≥6 and ≤15 mL/min/1.73m2 (inclusive) OR a projected risk of progression to end-stage renal failure within 2-years ≥20% using the 4-variable Tangri renal risk calculator

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 66; UK Sample Size: 66

Total final enrolment
66

Key exclusion criteria
1. Patients unwilling to use the ePROM intervention
2. Patients who, in the opinion of the consenting professional, cannot speak, read or write English sufficiently well to complete the ePROM unaided
3. An episode of acute kidney injury (defined in accordance with national guidelines) within the last 3 months
4. Patients meeting the trial definition of End Stage Renal Disease (currently receiving dialysis /scheduled to start in the next 2 weeks OR received/scheduled date to receive a kidney transplant OR eGFR < = 5ml/min/1.73m2)
5. A terminal illness that, in the opinion of the consultant consultant assessing eligibility, is likely to lead to the death of the patient within 6 months of starting participation in the study

Date of first enrolment
31/10/2018

Date of final enrolment
04/04/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital Birmingham
University Hospitals Birmingham NHS Foundation Trust
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Sponsor information

Organisation
University of Birmingham

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 11/12/2020:
Planned publication in a high-impact peer-reviewed journal. Additional trial documents will be made available on the study website at: https://www.birmingham.ac.uk/RePROM

Previous publication and dissemination plan:
Planned publication in a high-impact peer-reviewed journal. Additional trial documents will be made available on the study website at: https://www.birmingham.ac.uk/RePROM

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 11/12/2020:
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

Previous IPD sharing statement:
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/10/2018	11/12/2020	Yes	No
Results article		18/03/2022	13/03/2023	Yes	No
HRA research summary			26/07/2023	No	No