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Overcoming barriers to research in patients with kidney disease

Submission date	Recruitment status	[X] Prospectively registered
02/08/2024	Recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
22/08/2024	Ongoing	[_] Results
Last Edited	Condition category	[_] Individual participant data
09/05/2025	Urological and Genital Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Kidney disease is a common condition that affects around 1 in every 10 adults over the age of 35 years. Most patients who currently agree to take part in research are mainly white, despite people from “underserved ethnic communities” – this means people who have been denied opportunities in society, partly because of their ethnicity in this case - are more likely to be diagnosed with kidney disease. Patients have been asked for their views about taking part in kidney research and they told us about different barriers such as differences in communication needs; understanding what research is; and concerns that research would interfere with their care. Indeed, non-English speaking patients were less likely to take part in the survey. The researchers believe that if these barriers can be addressed, it will help more people living with kidney disease participate in research. The study aims to develop a toolkit so the research team can engage with more people from these communities for future research projects.

Who can participate?
Patients with kidney disease aged 18 years or over from one of the six main ethnic communities served by the NCA Kidney Centre

What does the study involve?
Patients will be invited to participate in the interviews to establish a sample representing each of our main ethnic communities, with attention to the inclusion of a wide age range, sex balance and coverage of the centres, and main kidney treatment modalities (dialysis, transplant and non-dialysis chronic kidney disease patients). Participants will be involved in a 15-minute discussion with one of the research team members to hear more about the study, and so that participants can provide consent to participate. Then an informal 60-minute interview, with a research ambassador to discuss their views. In addition, members of the renal research team and other research teams around the NCA will be interviewed to understand their thoughts about diverse and underserved communities and obstacles that they think prevent greater engagement of diverse ethnic communities to participate in research.

What are the possible benefits and risks of participating?
Insights gained are expected to help research be more inclusive, which could benefit more people living with kidney disease in the future. No risks are envisaged.

Where is the study run from?
Northern Care Alliance NHS Foundation Trust

When is the study starting and how long is it expected to run for?
May 2024 to April 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) Programme

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
341007

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 62038, IRAS 341007, NIHR205362

Study information

Scientific Title
Understanding and overcoming barriers to research involvement of patients with kidney disease from underserved communities

Study objectives
Can we understand the barriers that prevent people living with kidney disease from participating in research within our large catchment population of 1.55 million from a geographical area encompassing six ‘places’ in the integrated care system (ICS) structure

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/05/2024, South West – Cornwall and Plymouth (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8071, (0)207 104 8079, (0)207 104 8143; cornwallandplymouth.rec@hra.nhs.uk), ref: 24/SW/0050

Study design
Observational qualitative study

Primary study design
Observational

Secondary study design
Qualitative study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Kidney disease

Interventions
The research participants will be identified by the direct care team who look after them. They will represent the different ethnic communities, all age groups and modalities of kidney treatment.

The participants will be given an information sheet translated into their native language, and information about the study will be supplemented with a short video if required.

Consent will be undertaken by the research team.

The participant will then undergo a one-to-one meeting with a research ambassador in which a narrative interview will be undertaken. This will take place in the trust's premises and will be structured around a topic list. The interview will last for about 1 hour and will explore how their ethnic and cultural background influences their experience of kidney disease and engaging with clinical services and research; whether barriers to research participation exist and ways to overcome them; how they might be supported and encouraged to participate in future research. The responses to the participant will be recorded, with their permission.

This will be the only encounter that the participant has in the research study.

Interviews will be undertaken with around 10 members of the renal research team and 10 members of other research teams around the NCA to learn about their understanding of diverse and underserved communities; obstacles that they think prevent greater engagement and what would provide them with more confidence to approach patients from diverse ethnic community backgrounds to increase research engagement.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Stage 1. Research staff’s view on approaching patients from diverse backgrounds measured using a questionnaire at a single timepoint for each participant
Stage 2. A nuanced understanding of the lived experiences of people from diverse ethnic communities relating to living with kidney disease, accessing healthcare, and participating in research measured using biographical interviews at a single timepoint for each participant
Stage 3. Development of the toolkit for approach for research engagement and a targeted information campaign measured using data collected throughout the study

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/05/2024

Completion date

Eligibility

Key inclusion criteria
1. 18 years of age or more
2. Patients with kidney disease under the care of the NCA kidney centre
3. Selected from one of the six main ethnic communities served by the NCA kidney centre

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
1. <18 years of age
2. Lacking the cognitive capacity to consent to participate in the research

Date of first enrolment
31/08/2024

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salford Royal Hospital
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Sponsor information

Organisation
Northern Care Alliance NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal. Answers from the biographical interviews with patients will be used to design a toolkit for researchers to use in the future and for bespoke information campaigns directed to the communities to help patients with kidney disease take part in research.

Intention to publish date

01/04/2026

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date