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LINK-UP: novel interventions in kidney disease - user perspectives

Submission date	Recruitment status	[_] Prospectively registered
27/05/2025	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/10/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
22/10/2025	Urological and Genital Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Kidney disease affects more than 1 in 10 adults in the UK and can lead to serious health problems like kidney failure, heart disease, and fatigue. It can also make everyday life harder due to strict diets, medications, and reduced physical ability.

To help people manage their kidney health, a digital tool called "My Kidneys & Me" was created with input from patients and healthcare professionals. It gives personalised information and support to help people better understand and manage their condition. A previous study showed that this tool helped people feel more confident about managing their kidney disease.

However, it can be difficult to make tools like this part of everyday healthcare. This study aims to find out what helps or gets in the way of creating and using lifestyle and wellbeing support for people with kidney disease. Researchers will speak to patients, carers, healthcare staff, and others to learn how to make future tools more effective, inclusive, and easier to use.

Who can participate?
Adults aged 18 or over can take part if they:
- Have been diagnosed with kidney disease, or think they might have it (eligibility will be checked)
- Are a relative, friend, or carer of someone with kidney disease
- Work with kidney patients (for example, healthcare staff, charity workers, service managers)
- Have experience or knowledge of kidney disease through another role

People who are not connected to kidney disease in any way, or who cannot give informed consent, cannot take part.

What does the study involve?
If you take part, you'll be asked to share your thoughts and experiences in one of the following ways:
- A one-to-one interview
- A "think aloud" interview, where you talk through your thoughts while using or reviewing something
- A group discussion (focus group) with others

You'll also be asked to fill out a short online survey before the interview. The questions will be flexible so you can speak freely and openly.

What are the possible benefits and risks of participating?
Risks:
- The interview or group discussion will take up to 1 to 1.5 hours.
- Talking about personal experiences might be upsetting. You can pause, skip questions, or stop at any time.
- If you seem distressed, the interviewer will check in with you and may suggest speaking to your GP. If something serious comes up (like a safety concern), the research team may need to share that information, but they will try to let you know first.

Benefits:
- You'll receive a 30 pound gift voucher as a thank you.
- If you attend in person, your travel costs will be paid back.
- You'll be helping to improve support and services for people with kidney disease.

Where is the study run from?
The study is based at the University of Leicester and Leicester General Hospital. Interviews can be done in person at these locations or online via video call.

When is the study starting and how long is it expected to run for?
March 2025 to June 2029.

Who is funding the study?
Stoneygate Trust (UK)

Who is the main contact?
Gurneet Kaur Sohansoha, Clinical Trials Coordinator
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)
346105

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 64972, NIHR303940

Study information

Scientific Title
noveL InterveNtions in Kidney disease - User Perspectives

Acronym
LINK-UP

Study objectives
To understand the user perspectives and experiences, barriers and facilitators to the design, development, evaluation, and implementation of novel interventions for people with kidney disease including health, wellbeing and lifestyle interventions. Users may include but not limited to patients, carers or support, clinicians, administrative staff, any healthcare professionals and similar, commissioners, service managers, charity representatives or any other stakeholder group.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/04/2025, West Midlands - Edgbaston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048137; edgbaston.rec@hra.nhs.uk), ref: 25/WM/0060

Study design
Observational qualitative

Primary study design
Observational

Study type(s)
Treatment

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

Interventions
LINK-UP is a qualitative study. This involves speaking in depth with researchers about their experiences and opinions. This may take the form of a one-to-one interview or a focus group

with a few other participants. Discussions may be conducted via telephone, video call, or in person at an appropriate venue.

All interviews and focus groups will be led by an experienced researcher trained in qualitative research methods. Discussions will be digitally recorded, professionally transcribed verbatim (written up word-for-word), anonymised, and translated where necessary. They will be analysed using appropriate qualitative methodologies to explore different perspectives on the barriers and facilitators to the successful implementation of lifestyle interventions for patients with kidney disease (KD), and to identify processes that support successful implementation.

This study will recruit participants with KD, their significant others and non-professional carers, healthcare professionals or similar, commissioners, policy makers, charity organisations, and other stakeholders involved in the care of kidney patients, kidney service design, planning and delivery, or the wider kidney community. We plan to recruit a total of at least 50 participants.

This will be a multi-centre study, with patients recruited from both primary care (for example, first point of contact such as GPs) and secondary care (for example, those who see a specialist kidney doctor). The University Hospitals of Leicester (UHL) will be the hosting NHS site. Patients in secondary care will be recruited from KD clinics at UHL by screening clinic lists prior to approaching the patient. Patients from primary care will be recruited from primary care CKD clinics (LUCID clinics – the Leicester, Leicestershire and Rutland virtual CKD clinic, which is a UHL service supporting the management of patients with CKD in primary care with specialist secondary care consultant input).

Additionally, the study will be advertised through local, regional, and national groups and on social media so participants will be able to self-refer from outside of Leicester, Leicestershire and Rutland to take part in the study by contacting the study team directly. The study will also allow patients with a kidney condition to refer a significant other of their choice to take part in the study if they would like to.

Participants will be recruited after being sent an information sheet and completing a consent form. If they then wish to proceed, they will be informed to contact the research team directly by a method of their choosing (email, phone or face-to-face). The researcher will answer any questions and arrange a suitable date, time and venue for the interview, allowing at least 24 hours after reading the information sheet.

To gather some basic information on whom we interview, we will ask participants to complete a short survey online. This will be completed before the interview. The survey asks about age, gender, ethnicity, and the connection to a person (or persons) with a kidney condition. If participants are unable to fill this in or experience difficulty, a researcher will be able to assist them before the interview takes place.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Qualitative analysis of transcripts from conducted interviews and focus groups investigating user perspectives of novel interventions in kidney disease

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
29/06/2029

Eligibility

Key inclusion criteria
Inclusion criteria for CKD patients referred from a clinic and/or by HCP:
1.Patients with established KD according to the National Institute for Health and Care Excellence (NICE) guidelines
2.Aged 18 and above
3.Willing and able to give informed consent and comply with the study protocol

Inclusion criteria for self-referred CKD patients:
1.Patients perceived to have a kidney condition or progressive kidney disease
2.Aged 18 and above
3.Willing and able to give informed consent and comply with the study protocol

Inclusion criteria for non-CKD patients:
1.Participant does not have a kidney condition, but is affected by it as a relative, friend, or spouse of someone living with a kidney condition OR
2.Participant is involved in the care and management of people with a kidney condition OR
3.Participant has knowledge or experience of kidney disease in some other capacity (e.g., charities or other support organisations)
4.Aged 18 or above
5.Willing and able to give informed consent and comply with the study protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Exclusion criteria for CKD patients:
1. Patients without established KD according to NICE guidelines
2. Inability to give informed consent or comply with the protocol for any reason

Exclusion criteria for non-CKD patients:
1. Is not associated, has no relationship or provide care to someone with a kidney condition
2.Inability to give informed consent or comply with the protocol for any reason

Date of first enrolment
27/05/2025

Date of final enrolment
30/06/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
The Stoneygate Trust

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date