ISRCTN15795212 https://doi.org/10.1186/ISRCTN15795212

Improving access to kidney transplantation

Submission date
29/07/2025

Recruitment status
Recruiting

Registration date
06/08/2025

Overall study status
Ongoing

Last Edited
02/09/2025

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
A living-donor kidney transplant (LDKT) is one of the best treatments for kidney failure. Less than 20% of those eligible receive an LDKT each year. There is also evidence of socioeconomic and ethnic inequity. Improving equity in living-donor kidney transplantation has been highlighted as an international research priority.
The research team want to help people with kidney disease get a kidney transplant. In some countries, hospital teams try to help people to find someone who might want to give them a kidney. However, we don't know if this extra help increases someone's chance of getting a kidney transplant, or whether it doesn't. This study is designed to find out if the extra support is helpful and whether it is something the NHS should fund across the UK.
The extra support offered includes one-to-one dedicated discussions about the patient's kidney transplant options, and transplant specialists visiting them at home to speak to their family and friends about kidney problems and how they can help. Participants and their family/friends will be given leaflets and shown pictures that explain kidney transplants and kidney donation in simple language without medical jargon.

Who can participate?
Patients aged 18 years and over who are currently on the transplant waiting list or are soon to be added to the waiting list for a kidney transplant

What does the study involve?
Participants will be randomly allocated to one of two groups. Group 1 will receive usual NHS care. Group 2 will receive the following care:
1. Potential donor identification: A meeting with an LDKT nurse specialist to elicit any personal barriers to LDKT, and to discuss their network of family and friends and their possible suitability for donation.
2. NHS outreach to potential donors: A letter from a hospital doctor to their family and friends about kidney donation and how to donate.
3. Home-based family engagement and education: A LDKT nurse specialist and a kidney donor visit the participant and their family at home, to talk about kidney disease, transplantation and what it is like to donate a kidney.
At the end of the study we will see if people in Group 2 are more likely to have a LDKT than people in Group 1.
In addition, some participants will be invited to consider participating in interviews as part of the

process evaluation to understand their reasons for (non)participation, their experience of the interventions, the impact on NHS care pathways, and barriers and facilitators to implementation from patient, family/friend and a range of healthcare professional perspectives.

What are the possible benefits and risks of participating?
There are no guaranteed benefits from taking part in this study. People allocated to receive extra support may have an increased chance of receiving a kidney transplant, but we do not know at this stage whether this will be the case. However, information collected during this study may benefit people with kidney disease in the future.
There are no physical risks to taking part in this study. The study will take up some of the participants' time. Sometimes discussions with family members and friends can be difficult. Some people with kidney disease have told us that it's sometimes easier if other people have these conversations, which is why the extra support offered in this study tries to help with this.

Where is the study run from?
The study sponsor is the University of Bristol.The UK Clinical Trials Unit is NHS Blood and Transplant. The ASK trial is happening at 20 NHS hospitals across England and Wales.

When is the study starting and how long is it expected to run for?
January 2023 to October 2029

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

Who is the main contact?
Prof. Pippa Bailey, ask@nhsbt.nhs.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
337402

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 59909; Grant Code: NIHR160325

Study information

Scientific Title
The ASK Trial: a trial of a patient and family outreach service to improve AccesS to living-donor Kidney transplantation

Study objectives
To determine the effectiveness and cost-effectiveness of a multicomponent intervention to improve access to living-donor kidney transplantation. To increase the proportion of eligible kidney patients who receive a living-donor kidney transplant by supporting disadvantaged individuals to overcome barriers to accessing a living-donor kidney transplant.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/05/2025, Wales Research Ethics Committee 1 Cardiff (Health and Care Research Wales, Castlebridge 4, Cardiff, CF11 9AB, UK; +44 (0)2922 940912, +44 (0)292 2940931; Wales.REC1@wales.nhs.uk), ref: 25/WA/0132

Study design
Randomized; Both; Design type: Process of Care, Education or Self-Management, Complex Intervention, Management of Care, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Living-donor kidney transplantation

Interventions
This trial is a two-arm, parallel group, pragmatic, individually randomized, controlled, type 1 hybrid effectiveness trial of a patient and family outreach service to improve access to living-donor kidney transplantation. The service will be compared with usual care. It will take place at 20 hospitals in the UK.

Participants will be people with advanced kidney disease in need of a kidney transplant, and their family and close friends. Participants will be allocated 1:1 to either Group 1: intervention group or Group 2: usual care, stratified by site.

The intervention outreach service comprises:
1. Potential donor identification: The participant meets with a living kidney donation (LKD) specialist nurse, or other appropriately trained and delegated member of the team, to discuss their family members' awareness of their kidney disease, and potential donor candidacy.
2. NHS written outreach to potential donors: A standardized NHS letter to the participant's family and friends, accompanied by a plain language information sheet.
3. Home-based family engagement and education: An education and engagement session in the participant's home led by an LKD nurse specialist, or other appropriately trained member of the team, and a living kidney donor.

The intervention will be delivered by specialist nurses and previous living kidney donors.

As well as investigating whether the new service is effective in a real-world context, we will determine if it is cost-effective: a Markov model-based economic evaluation with a 10-year time horizon will be developed to compare trial arms.

As a type 1 hybrid effectiveness-implementation trial, a mixed-methods process evaluation will be undertaken to evaluate intervention delivery fidelity, acceptability, reach, mechanisms of action, how existing care pathways are affected, the influence of context, and barriers and facilitators to implementation.

Intervention Type

Other

Phase
Not Specified

Primary outcome(s)
Proportion of participants who receive a living-donor kidney transplant (LDKT) within 18 months of randomisation (excluding LDKTs from non-directed altruistic donors outside the sharing scheme) at 18 months

Key secondary outcome(s))
1. Time to receipt of a LDKT (excluding LDKT if from a non-directed altruistic donor outside the sharing scheme) measured at 18 months
2. Probability of receiving an LDKT as estimated by Kaplan-Meier methods at 18 months
3. Transplant candidates with at least one donor at each stage of assessment:
3.1. Initial evaluation by coordinators completed
3.2. Nephrological assessment completed
3.3. Surgical assessment completed
3.4. Registered to UK Living Donor Sharing Scheme (if applicable, and reason for entry into sharing scheme, e.g., ABO blood group incompatible [ABOi], Human Leukocyte Antigen [HLA] incompatible [HLAi], better match required)
3.5. Donated/date set for donation
4. Total number and % in each stage
Descriptive statistics for the number of donors per recipient registered to the UK Living Donor Sharing Scheme, with reasons will be presented. Patient self-reported total number of donors at any of the above stages 3.1-3.4. Measured at 18 months
5. Patient activation measured using the Patient Activation Measure-13 (PAM-13). Mean PAM score (0-100) and number and % of each PAM level (1-4) at baseline and 4 months
6. Perceived social support measured using Interpersonal Support Evaluation List-12 (ISEL-12). Mean total ISEL-12 score (/36) at baseline and 4 months
7. LDKT knowledge measured using the Rotterdam Renal Replacement Knowledge-Test (R3K-T). Mean total R3K-T score (/11) at baseline and 4 months
8. Quality of life measured using EQ-5D-5L. Mean EQ-5D-5L index value and mean EQ-VAS score (/100) at baseline and 4, 9 and 18 months
9. Adherence measured at 4 months:
Intervention group:
9.1. Participants who have first intervention meeting (number and %)
9.2. Participants who have letters sent to family/friends (and number of letters sent per participant) (number and %)
9.3. Participants receiving home visits by intervention team (and number of home visits per participant) (number and %)
9.4. Content compliance (quantitative checklist for home visit content) (number and % with each item completed)
Usual care group:
9.5. Number and % who incorrectly received at least one component of the intervention because of a research team error
10. Resource use measured using Modular Resource-Use Measure (ModRUM) at baseline and 18 months (mean or median will be presented depending on distribution)

Other outcome measures:
11. Health literacy measured using Single Item Literacy Screener (SILS-1) at 4 months
12. Transplant beliefs measured at 4 months

Completion date
31/10/2029

Eligibility

Key inclusion criteria
1. Adults (age >= 18 years)
2.1. Have been referred for/are being assessed for kidney-only transplant listing
Or
2.2. Are active on the UK kidney only transplant waiting list

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Active malignancy
2. Signs or symptoms of active cardiac disease (e.g. angina, arrhythmia, New York Heart Association functional class 3/4 heart disease, symptomatic valvular heart disease)
3. Chronic intractable systemic infection
4. Active substance addiction/misuse
5. Body mass index (BMI) >=40 kg/m2
6. A transplant MDT expectation that they are unlikely to be suitable for transplantation following pending investigations (e.g., cardiopulmonary)
7. A potential living kidney donor undergoing surgical assessment or approved for kidney donation
8. Been registered on the UK transplant wait list for multiple organ transplant, e.g. simultaneous pancreas kidney or simultaneous liver kidney transplant

Date of first enrolment
15/10/2025

Date of final enrolment
01/01/2028

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
Cardiff
United Kingdom
CF14 4HH

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
Lyndhurst Road
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United Kingdom
BN11 2DH

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Cheltenham General Hospital
Sandford Road
Cheltenham
United Kingdom
GL53 7AN

Study participating centre
Portsmouth Hospitals University NHS Trust
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Swansea Bay University Local Health Board
Tonna Hospital
Tonna Uchaf
Tonna
Neath
United Kingdom
SA11 3LX

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

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

Study participating centre
University Hospitals Plymouth NHS Trust
Derriford Hospital
Derriford Road
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Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
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EX2 5DW

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository: the University of Bristol's Research Data Repository (https://data.bris.ac.uk). The data will be available for a minimum of 10 years.

Quantitative trial data
Participants will be requested to provide consent to data sharing. Data will only be made available for sharing if explicit consent has been provided. The anonymised trial dataset will be accessible via the repository after the trial has been completed. Qualitative trial data

The anonymised qualitative data transcripts will be suitable for sharing with other researchers who may wish to undertake a thematic synthesis or analyse the interviews using a different methodology to the one proposed in this study. Consent for the sharing of the interview transcripts to other researchers will be explicitly sought from interviewees prior to the interview, and this confirmed with the interviewee following the interview. Transcripts will be anonymised with all personal identifiers and possible identifiers redacted. This includes details that may identify other people mentioned in the interview, e.g. clinicians, family members. When consent has been provided by the research participant, the anonymised transcript will be made available to other researchers. Although the qualitative transcripts will be anonymised, due to personal issues being discussed, we cannot rule out the risk of reidentification and therefore as a double safeguard, access to these transcripts will be controlled. Requests for Controlled data through the University of Bristol are referred to an appropriate Data Access Committee (DAC) for approval, before data can be shared with bona fide researchers, after their host institution has signed a Data Access Agreement. The University's DAC comprises the following: Assistant Director of Research Services (Library), Information Rights Officer (FOI, Data Protection), Head of Research Governance (ethics), Assistant Director IT Services (data security), Research Contracts (if commercially sensitive), Academics, e.g. the PI. The procedure for accessing data can be found here: https://www.bristol.ac.uk/staff/researchers/data/accessing-research-data/

If the DAC grants access to the data, a University of Bristol Data Access Agreement is drawn up and signed by the applicant, their host institution, and the University of Bristol. The University of Bristol's Research Data Service will oversee this.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes