

# Improving access to kidney transplantation

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<b>Registration date</b> 06/08/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/08/2025	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

### Contact name

Dr Catherine Bain

### Contact details

NHS Blood and Transplant Clinical Trials Unit  
Cambridge  
United Kingdom  
CB2 0PT  
+44 (0)1223 588182  
catherine.bain@nhsbt.nhs.uk

### Type(s)

Scientific

### Contact name

Prof Pippa Bailey

### Contact details

University of Bristol  
North Bristol NHS Trust  
Bristol  
United Kingdom  
BS10 5NB  
-  
pipa.bailey@bristol.ac.uk

**Type(s)**

Public

**Contact name**

Mrs Viona Rundell

**Contact details**

NHS Blood and Transplant Clinical Trials Unit  
Cambridge  
United Kingdom  
CB2 0PT  
-  
ASK@nhsbt.nhs.uk

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

337402

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**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**

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 measure**

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

## **Secondary outcome measures**

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

**Overall study start date**

01/01/2023

**Completion date**

31/10/2029

## **Eligibility**

**Key inclusion criteria**

1. Adults (age  $\geq 18$  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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 592; UK Sample Size: 592

**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)  $\geq 40$  kg/m<sup>2</sup>

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**

01/09/2025

**Date of final enrolment**

01/01/2028

## **Locations**

**Countries of recruitment**

England

United Kingdom

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

Worthing

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

United Kingdom

B15 2GW

**Study participating centre**

**University Hospitals Plymouth NHS Trust**

Derriford Hospital

Derriford Road

Derriford

Plymouth

United Kingdom

PL6 8DH

**Study participating centre**

**Royal Devon University Healthcare NHS Foundation Trust**

Royal Devon University NHS Ft

Barrack Road

Exeter

United Kingdom

EX2 5DW

## **Sponsor information**

**Organisation**

University of Bristol

**Sponsor details**

Senate House

Tyndall Avenue

Bristol

England

United Kingdom

BS8 1TH

+44 (0)1173940177

research-governance@bristol.ac.uk

**Sponsor type**

University/education

**Website**

<http://bristol.ac.uk/>

**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**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**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