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ASK: Improving access to kidney transplantation

Submission date
30/10/2020

Recruitment status
No longer recruiting

Registration date
06/11/2020

Overall study status
Completed

Last Edited
31/10/2024

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
This study follows previous research to understand barriers to people receiving a living-donor kidney transplant. This found some people with kidney disease are less confident having discussions about their treatment, and doctors can find it difficult to engage them in these discussions. As a result some people don't know that a living-donor kidney transplant is a treatment they could have. Some people with kidney disease struggle to identify possible kidney donors, and report difficulties having conversations about kidney donation with family and friends. Some people find it difficult to get the information they need from leaflets and websites.

Sometimes hospital teams help people who have kidney disease to find someone who might want to give them a kidney. However, we don't know if this extra help does increase someone's chance of getting a kidney transplant, or whether it doesn't. This study is the first step in understanding if the extra support is helpful and whether it is something the NHS should fund across the UK.

Who can participate?
Adults who are on the kidney transplant waiting list and who don't have a living kidney donor who is being assessed by a transplant surgeon for donation.

What does the study involve?
There will be two groups in this study. Group 1 will receive the usual NHS care and support. Group 2 will receive a package of extra support that might increase participants chances of getting a kidney transplant. We do not know if the extra support being offered actually helps or not, this is why we are doing this study. We also don't know what people with kidney disease and their families think about the extra support being offered and whether it is a good use of resources.

Participants will be put into one of the two groups. The research nurse will use a computer program that will randomly put participants into one of the groups. Which group participants go into is decided by a computer.

People in Group 2 will receive extra support. This includes i) hospitals providing the family and friends of people with kidney disease with simple-language information on living kidney

donation, and links to educational animations, and ii) a home visit from two transplant specialists to talk to a patient and their family and friends about living with kidney disease and treatment options. Simple-language living kidney donation information will be provided, and educational animations shown. Remote virtual 'visit'/link as optional alternative to home visit if restrictions on home visits related to Covid-19.

What are the possible benefits and risks of participating?
Possible benefits: There is no guarantee that people will benefit from taking part in this study. People allocated to receive extra support this may have an increased chance of receiving a living-donor kidney transplant, but we do not know at this stage whether this will be the case. Information collected during this study may benefit people with kidney disease in the future.
Possible risks: There are no physical risks to taking part in this study. The study will take up some of the participant's time. Sometimes discussions with family members and friends can be challenging. The transplant specialists doing the home visits will be sensitive and check with participants before the home visit what they are happy for them to discuss. The transplant specialists will continue to provide support after the home visit if this is required.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
January 2018 to December 2023

Who is funding the study?
1. Wellcome Trust (UK)
2. Kidney Care UK

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
287507

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 287507, Sponsor's number 2020-4883, WT 214554/Z/18/Z

Study information

Scientific Title
The ASK trial: a two-arm, parallel group, pragmatic individually-randomised controlled feasibility trial of a complex multicomponent intervention to improve AccesS to Kidney transplantation

Acronym
ASK

Study objectives
This study evaluates a multi-component complex intervention (comprising healthcare professionals engaging with a patient's social network, simple-language educational information and animations, home-based patient and family education and engagement) designed to improve access to and uptake of living-donor kidney transplants. The feasibility trial aims to determine whether:
- the intervention is feasible to implement in the NHS
- the intervention is acceptable to patients and their social network
- the trial methods are acceptable.

If the intervention is feasible to deliver and evaluate, a later planned effectiveness trial will evaluate if the intervention is effective at improving access to living-donor kidney transplantation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/01/2021, West Midlands - South Birmingham Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8388; southbirmingham.rec@hra.nhs.uk), ref: 21/WM/0003

Study design
Two-arm parallel-group pragmatic individually-randomized controlled feasibility trial of a complex multicomponent intervention

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Improving access to living-donor kidney transplantation for people with advanced kidney disease

Interventions
Intervention arm participants receive:
• Clinician letter to potential donors regarding transplant need and option of living kidney donation plus simple-language living kidney donation information sheet. Links to educational animations.
• Home-based patient and family education and engagement. Education on living with kidney disease and treatment options. Simple-language living kidney donation information, educational animations, and facilitated discussions regarding donation. Remote virtual 'visit'/link as optional alternative to home visit if restrictions on home visits related to Covid-19.

Control arm participants receive:
• Usual care

Total duration of follow-up for both study arms – 3 months.

Randomisation of eligible individuals with concealed allocation will be undertaken using internet-based REDCap software with the support of the Bristol Randomised Trials Collaboration (BRTC) of the Bristol Trials Centre using minimisation. Participants will be randomly allocated 1:1 to the intervention arm or to the usual care arm, stratified by site to ensure a balance in terms of local differences.

Intervention Type
Other

Primary outcome measure
1. Recruitment: % of those eligible and approached who consent to randomisation at invitation
2. Retention: % completing follow up questionnaire approximately 4 weeks after baseline visit questionnaire

Secondary outcome measures
1. Size of the eligible population – at screening
2. Adherence to intervention/trial and fidelity of delivery of the intervention - % of participants in intervention arm who receive both intervention components; number of letters sent to

potential donors per participant in intervention arm; % of participants who complete questionnaires at baseline and approximately 4 weeks after baseline; number of protocol deviations reported; observed fidelity of intervention delivery (fidelity of delivery of the first meeting part of the intervention will be assessed using implementer self-report against a structured checklist and qualitative interviews with participants and implementers. Fidelity of the home visits will be assessed through structured observations with a quantitative checklist, qualitative observation notes, and participant and implementer qualitative interviews)
3. Acceptability of intervention and trial methods assessed through qualitative interviews
4. Barriers and facilitators to intervention implementation in different settings – measured by time to green light at each site and time to recruitment of first participant, and delivery of each intervention component
5. Estimates of the effect of the intervention on possible mediators of the intervention – measured through questionnaires measuring patient activation, social support, living-donor kidney transplant knowledge and health literacy at baseline and approximately 4 weeks later
6. Assessing data quality of linkage to UKRR data regarding planned outcome for later main trial (at 3 months follow-up data on the later RCT outcome [receipt of living-donor kidney transplant] will also be extracted from UKRR data and compared with data extracted from hospital records at site)
7. Impact on existing healthcare delivery measured through qualitative interviews with healthcare professionals after 3-months of study being active at study site
8. Cost-drivers measured at feasibility trial completion (major cost-drivers will be identified from data on the intervention costs, and healthcare resource use data. Participant self-reported quality of life data will also be collected in questionnaires)

Overall study start date
01/01/2018

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. English-speaking adults (age ≥18 years)
2. Individuals active on the UK Kidney Transplant only waiting list
3. Individuals who do not have any potential living kidney donors currently undergoing surgical assessment for donation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

60

Total final enrolment
62

Key exclusion criteria
Individuals who lack the Mental Capacity (as determined by their healthcare team) to consent to participation.

Date of first enrolment
18/10/2021

Date of final enrolment
01/08/2023

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
Gloucester Royal Hospital
Gloucestershire Hospitals NHS Foundation Trust
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United Kingdom
GL1 3NN

Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Kidney Care UK

Results and Publications

Publication and dissemination plan
The results of the study will be published in peer-reviewed journals and all participants will be offered a plain English summary of the main findings of the study.

Intention to publish date
01/10/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. At recruitment participants will be asked to provide written consent for sharing of anonymised data with other researchers. Data from participants who consent to this will be made available to other researchers on request after a period of exclusive use by the researchers of five years following completion of the study. The study team will have exclusive use of the data to design and secure funding for a full-scale RCT.
Data will be uploaded to the University of Bristol's Research Data Repository: https://data.bris.ac.uk/data/
A summary of the data available will be detailed on the study website and all publications arising from the research. Potential new users can also actively search the University of Bristol's data repository.
Audio files of the recorded interviews will not be suitable for sharing as they carry a high risk of allowing the research participant to be identified, and the content of interviews will potentially be highly sensitive. Although the qualitative transcripts will be anonymised as personal issues will be discussed we cannot rule out the risk of identification. Therefore access to these transcripts will be controlled. Requests for Controlled data through UoB are referred to an appropriate Data Access Committee (DAC) for approval, before data can be shared with researchers, after their host institution has signed a Data Access Agreement. The DAC comprises: Assistant Director of Research Services, Information Rights Officer, Head of Research Governance, Assistant Director IT Services, Research Contracts, Academics - the PI. The procedure for accessing data can be found here:
https://www.bristol.ac.uk/staff/researchers/data/accessing-research-data/

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		20/01/2023	31/01/2023	Yes	No
HRA research summary			28/06/2023	No	No
Preprint results		29/10/2024	31/10/2024	No	No