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Intervention for medication management in kidney transplant recipients

Submission date
03/04/2024

Recruitment status
No longer recruiting

Registration date
13/05/2024

Overall study status
Ongoing

Last Edited
09/07/2025

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
Kidney transplantation is the best and most cost-effective treatment for end-stage kidney disease. Kidney transplant recipients are required to take lifelong immunosuppression medication (ISM) to prevent the body from rejecting the transplanted kidney. However, up to 60% of patients report not taking ISM as prescribed. It is necessary to develop evidence-based interventions to support patients with medication self-management and the challenges associated with taking ISM, to ensure successful patient and transplant outcomes.
This study aims to develop and assess the feasibility and acceptability of a self-directed psycho-educational intervention booklet to support ISM taking in kidney transplant recipients.
The study consists of two phases. Phase 1 will inform intervention development by improving our understanding of kidney patients' lived experiences of taking medication. Phase 2 aims to assess the feasibility and acceptability of the intervention from both patient and healthcare professional perspectives.

Who can participate?
Phase 1: Adults living with kidney disease. Participants must be able to speak and understand English. Participants cannot be under the care of a psychiatrist for a mental health condition.
Phase 2: Adults living with a kidney transplant, who have been prescribed immunosuppression medication and experience challenges with medication taking. Participants must be able to read and speak English. Participants cannot be under the care of a psychiatrist for a mental health condition. Healthcare professional participants will be those involved in kidney transplant recipient care, i.e. consultant nephrologists, specialist renal transplant nurses, renal pharmacists and renal psychologists.

What does the study involve?
Phase 1: Patients living with kidney disease will complete a one-to-one semi-structured interview with a member of the research team to discuss their experiences of taking medication, including any motivations or barriers surrounding medication taking.
Phase 2: Kidney transplant recipients will be sent a self-directed psycho-educational intervention booklet to work through. Before and after the intervention, participants will complete questionnaires assessing medication-taking behaviour, distress, quality of life, illness perceptions, medication beliefs and satisfaction with information about treatment. Participants

may also take part in an interview to share their experiences of the intervention. Healthcare professionals involved in kidney transplant recipient care will be given the intervention booklet to review. Following this, they will complete a survey and optional interview to explore their thoughts and opinions of the intervention.

What are the possible benefits and risks of participating?
Results of Phase 1 will improve knowledge of lived experiences of taking medication as a kidney patient and inform the tailoring of the intervention to this population. All Phase 2 participants will receive an intervention that will potentially improve medication self-management. Participation will help inform future research to support medication management in kidney transplant recipients.
Phase 1 participants may find discussing experiences of living with a kidney transplant and taking medication distressing. Phase 2 participation will require some time commitment to work through self-guided material. Although unlikely, it is possible that completing Phase 2 questionnaires may cause some distress.

Where is the study run from?
The day-to-day running and management of the project will be carried out in the academic offices of the Immunoregulation Laboratory (Guy's Hospital) and the Health Psychology Department, King's College London (Guy's Hospital). Recruitment will be conducted at Guy's Hospital Kidney Clinic.

When is the study starting and how long is it expected to run for?
June 2021 to June 2025

Who is funding the study?
Kidney Research UK (KRUK)

Who is the main contact?
1. Dr Lyndsay Hughes, lyndsay.hughes@kcl.ac.uk
2. Dr Antonia Cronin, antonia.cronin@gstt.nhs.uk

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
325672

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 61537, IRAS 325672

Study information

Scientific Title
Development and pilot feasibility testing of an intervention to support immunosuppression medication adherence in kidney transplant recipients

Study objectives
The primary aim is to assess the feasibility of a self-directed intervention to support immunosuppression medication self-management in kidney transplant recipients.

Parameters for assessing feasibility include: eligibility rates, uptake and retention rates, and acceptability from both patient and healthcare professional perspectives.

Secondary objectives include changes in self-reported adherence and targeted process variables from baseline to 6 weeks post-intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 31/07/2024, London - London Bridge Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048229; londonbridge.rec@hra.nhs.uk), ref: 24/LO/0496

Study design
Interventional non-randomized

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Kidney transplant recipients

Interventions
All participants will be allocated to the intervention arm. They will be sent the self-directed intervention booklet to work through in their own time. The psychoeducational manual aims to support kidney transplant recipients with their immunosuppression self-management through a combination of educational and psychological components. For example, how to manage side effects, forming strategies to remember to take the medication, and gaining an understanding of how it works. A follow-up questionnaire will be sent 6 weeks post-intervention to assess changes in adherence and targeted process variables.

Intervention Type
Behavioural

Primary outcome(s)

Feasibility will be assessed by collecting descriptive data on eligibility, recruitment and retention rates. The following will be determined:
1. Eligibility rate, recorded as the percentage of patients screened who meet the inclusion criteria
2. Uptake, recorded as the percentage of eligible patients agreeing to participate in the study by the end of recruitment
3. Retention, recorded as the percentage of participants who remain until the end of the study (i. e. complete the post-intervention questionnaire)

Key secondary outcome(s))
Measured at baseline and 6 weeks post-intervention:
1. Medication adherence measured using the Medication Adherence Report Scale (MARS-5): overall scores as well as intentional and unintentional non-adherence sub-scale scores
2. Transplant perceptions measured using the Brief Illness Perception Questionnaire (BIPQ)
3. Medication beliefs measured using the Beliefs about Medicines Questionnaire-Specific (BMQ-Specific): necessity and concern sub-scale scores, as well as a necessity-concerns differential.
4. Psychological distress measured using the Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS)
5. Symptom occurrence and distress measured using the Modified Transplant Symptom Occurrence and Symptom Distress Scale-59 (MTSOSD-59)
6. Self-efficacy surrounding symptom management and medication taking measured using the Theory of Planned Behaviour
7. Satisfaction with information about treatment measured using Satisfaction with Information about Medicines Scale (SIMS)
8. Quality of life measured using EQ-5D-3L

Completion date
01/02/2026

Eligibility

Key inclusion criteria
Phase 1 inclusion criteria:
1. 18 years of age or over
2. Living with kidney disease
3. Speak and understand English

Phase 2 patient participant inclusion criteria:
1. 18 years of age or over
2. Living with a kidney transplant
3. Prescribed immunosuppression medication.
4. Read and speak English
5. Evidence of sub-optimal immunosuppression medication adherence,i.e. a score of ≤23 on the Medication Adherence Rating Scale (MARS-5)

Phase 2 healthcare professional participant inclusion criteria:
1. The healthcare professional is a consultant nephrologist, specialist renal transplant nurse, renal pharmacist or renal psychologist working in Guy’s Kidney Clinic.

Participant type(s)

Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Phase 1 exclusion criteria:
1. Currently under the care of a psychiatrist for a mental health condition
2. Insufficient command of English

Phase 2 patient participant exclusion criteria:
1. Currently under the care of a psychiatrist for a mental health condition
2. Evidence of optimal immunosuppression medication adherence on the Medication Adherence Rating Scale (MARS-5), i.e. a total score of 24 or 25
3. Insufficient command of English

Date of first enrolment
01/08/2024

Date of final enrolment
01/02/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guys Hospital
Guys Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
King's College London

Organisation
Guy's and St Thomas' NHS Foundation Trust

Funder(s)

Funder type
Charity

Funder Name
Kidney Research UK (KRUK); Grant Codes: ST_002_20210728

Alternative Name(s)

Funding Body Type
Private sector organisation

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

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 available upon request from the corresponding author on reasonable request. The PI (Dr Antonia Cronin, antonia.cronin@gstt.nhs.uk) will be the contact to approve and send out copies of any data. Any data shared will be de-identified. Only data from participants who have consented to their data being shared/used in future research studies will be shared.
Both qualitative and quantitative data may be requested. Data will only be shared for the purpose of research.

IPD sharing plan summary
Available on request

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