ISRCTN17122775 https://doi.org/10.1186/ISRCTN17122775

# Participant acceptability of exercise in kidney disease

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 30/01/2017 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 30/01/2017 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 04/10/2022 | Urological and Genital Diseases | |

## Plain English summary of protocol

Background and study aims

The kidneys are responsible for filtering out the waste products and excess water in the blood, and converting them into urine. If the kidneys stop working properly, then the body is unable to get rid of the waste products building up in the blood. Eventually, the kidneys are no longer able to support the body's needs (kidney failure) and so a treatment to replace the work of the failed kidneys is needed. Having a kidney transplant can transform the life of a patient whose kidneys have failed through disease. However, a high rate of heart disease in these patients limits the survival of the kidney and the length and quality of life. There is a lack of rigorous research into the role of increased physical activity in the management of cardiovascular risk in kidney transplant patients. Regular exercise is likely to have cardiovascular benefits for renal transplant patients, yet strategies to increase physical activity are not currently part of routine care. Given their unusual, non-traditional heart risk factors and delicate immune systems, current guidelines on the best frequency, intensity, time and mode of exercise may not be appropriate for this kidney transplant recipients. Appropriate guidance is therefore vital to improve heart disease outcomes, the survival of the transplant and to help these patients better manage their risk of developing heart disease. The aim of this study is to compare three different aerobic exercise programmes in kidney transplant patients.

Who can participate?

Adults with CKD who have had a kidney transplant at least 12 weeks previously.

What does the study involve?

Participants are randomly allocated to take part in one of three different exercise programmes for eight weeks. The first programme involves 16 minute interval training, which involves short bursts of high intensity exercise at intervals of four, two and one minute, separated by two minutes of active rest (light exercise). The second programme involves four lots of four-minute high intensity training separated by three minutes of active rest. The third programme involves continuous brisk cycling on a cycling mashine for around 40 minutes at a constant speed. At the end of the study, the participation and attendance of patients is recorded in order to see which of the programmes is most feasible for them.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their physical fitness levels. There is a very small risk of accident or injury during the assessment visits and during the exercise training.

Where is the study run from?
Leicester General Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2017 to January 2022

Who is funding the study?
Heart Research UK (UK)

Who is the main contact?
Dr Alice Smith
aa50@leicester.ac.uk

# Contact information

### Type(s)
Public

### Contact name
Dr Alice Smith

### Contact details
Leicester Kidney Exercise Team
Academic Unit
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW
+44 116 258 4346
aa50@leicester.ac.uk

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
32879

# Study information

### Scientific Title
Participant Acceptability of Exercise in Kidney Disease (PACE-KD)

## Study objectives
Primary Objective:
To evaluate the feasibility (recruitment, retention and completion) of three different supervised aerobic exercise programmes in kidney transplant recipients.

Secondary Objectives:
1. To assess participant experience and acceptability
2. To assess changes in physical function, body composition, habitual physical activity and non-invasive CVD risk factors.
3. To assess relevant blood, saliva and urinary markers of metabolic health, systemic inflammatory status and immune function.
4. To assess the tolerability, practicality and patient perceived usefulness of these assessments of cardiovascular disease risk.
5. To assess patient perception of their illness and symptoms, activity levels, quality of life.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
East Midlands - Nottingham 2 Research Ethics Committee, 04/01/2017, ref: 16/EM/0482

## Study design
Randomised; Interventional; Design type: Treatment, Prevention, Physical

## 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 below to request a patient information sheet

## Health condition(s) or problem(s) studied
Renal failure

## Interventions
Participants are randomised to one of the following three 8 week interventions through random number generation:

HIIT programme A:
Each session will consist of 16-min interval training with intervals of 4, 2 and 1 min duration at 80%, progressing to 90% VO2peak over the 8 weeks, separated by a 2 min active rest (~60% VO2peak) giving a total exercise time of 30 min.

HIIT programme B:
Each supervised session will consist of 4 x 4-min of interval training at 80% VO2peak, progressing to 90% VO2peak over the 8 weeks, separated by a 3 min active rest (~60% VO2peak) and with a final 5 recovery minute stage to ensure that overall work done is matched for both exercise protocols, therefore also giving a total exercise time of 30 min.

MICT Exercise Intervention:
Each supervised session will consist of continuous brisk cycling for ~40 min with a target RPE of 12-14 (somewhat hard). This is equivalent to 50-60% VO2peak and will be matched for energy expenditure with the HIIT sessions.

In all groups, participants take part in 24 supervised training sessions over 8 weeks (approximately 3 sessions per week)

## Intervention Type
Behavioural

## Primary outcome measure
1. Recruitment rate is assessed by recording the percentage of eligible invited, percentage of invited approached and percentage of approached consented throughout the study
2. Compliance rate is assessed through recording the percentage of sessions attended by participants throughout the study
3. Retention/completion rate is assessed by recording the percentage of participants completing all elements of the study throughout the duration of the study

## Secondary outcome measures
1. Physical function is measured by the gait speed test, the sit-to-stand tests and the plantarflexion strength test at baseline, mid-intervention, immediately post-intervention and three months post-intervention
2. Heart function is measured using Non-invasive cardiac output measures (NICOM) at baseline, mid-intervention, immediately post-intervention and three months post-intervention
3. Anthropometry is measured using standard measures at baseline, mid-intervention, immediately post-intervention and three months post-intervention
4. Body composition is measured using bioelectrical impedance analysis at baseline, mid-intervention, immediately post-intervention and three months post-intervention
5. Arterial stiffness is measured using pulse wave velocity at baseline, mid-intervention, immediately post-intervention and three months post-intervention
6. Oxygen saturation is measure using a pulse oximeter at baseline, mid-intervention, immediately post-intervention and three months post-intervention
7. Habitual physical activity is measured using an accelerometer at baseline and immediately post-intervention
8. Muscle Oxygen Saturation is measured using Near-infrared spectroscopy (NIRS) between training weeks 1-2 and between training weeks 7-8
9. VO2 Peak is measured using a cardiopulmonary exercise test at baseline and immediately post-intervention
10. Urine bacterial content is analysed from a urine sample at baseline, mid-intervention and

immediate post-intervention
11. Clinical parameters (co-morbidities, medication, blood test results) will be taken from medical notes at baseline, mid-intervention, immediately post-intervention and three months post-intervention
12. Blood samples for markers of immune function and inflammation and CVD risk factors will be taken via venepuncture at baseline, mid-intervention, immediately post-intervention and three months post-intervention
13. Immune function and markers of inflammation will be assessed via saliva samples at baseline, mid-intervention, immediately post-intervention and three months post-intervention
14. Patient satisfaction will be measured by a Patient Satisfaction Questionnaire at the end of study involvement
15. Acceptability and satisfaction will be assessed via interviews and focus groups at the end of study involvement
16. Illness symptoms will be assessed via an Illness-Symptom Questionnaire at each exercise training session
17. Disease related symptoms will be measured via the Renal Patient Outcome Scale (POS-S Tx) at baseline, mid-intervention, immediately post-intervention and three months post-intervention
18. Fatigue will be measured via the Fatigue Scale at baseline, mid-intervention, immediately post-intervention and three months post-intervention
19. Quality of life will be measured via the EuroQual (EQ5D) at baseline, mid-intervention, immediately post-intervention and three months post-intervention
20. Illness perception will be measured via the Illness Perception Questionnaire (IPQ-R) at baseline, mid-intervention, immediately post-intervention and three months post-intervention
21. Functional capacity will be measured via the Duke Activity Status Index (DASI) at baseline, mid-intervention, immediately post-intervention and three months post-intervention
22. Pain will be measured via the Brief Pain Inventory (BPI) at baseline, mid-intervention, immediately post-intervention and three months post-intervention
23. Sleep quality will be measured via the Pittsburgh Sleep Quality Index (PSQI) at baseline, mid-intervention, immediately post-intervention and three months post-intervention
24. Sleepiness will be measured via the Epworth Sleepiness Scale (ESS) at baseline, mid-intervention, immediately post-intervention and three months post-intervention

### Overall study start date
01/01/2017

### Completion date
31/01/2022

## Eligibility

### Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 18 years or above
3. Diagnosed with CKD and are a kidney transplant recipient
4. Received kidney transplant > 12 weeks prior to entering the study

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 24; UK Sample Size: 24

### Total final enrolment
20

### Key exclusion criteria
1. Female participants who are pregnant, lactating, or planning pregnancy during the course of the study
2. Scheduled elective surgery or other procedures requiring general anaesthesia during the study
3. Any other significant disease or disorder (i.e. significant co-morbidity including unstable hypertension, potentially lethal arrhythmia, myocardial infarction within 6 months, unstable angina, active liver disease, uncontrolled diabetes mellitus (HbA1c > = 9%), advanced cerebral or peripheral vascular disease) which, in the opinion of the patients own clinician, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study
4. Inability to give informed consent or comply with testing and training protocol for any reason

### Date of first enrolment
01/02/2017

### Date of final enrolment
31/01/2021

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Leicester General Hospital**
University Hospitals of Leicester NHS Trust
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

## Sponsor information

### Organisation
University Hospitals of Leicester NHS Trust

### Sponsor details
Leicester General Hospital
Gwendolen Road
Leicester
England
United Kingdom
LE5 4QF
+44 1162 584109
uhlsponsor@uhl-tr.nhs.uk

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/02fha3693

## Funder(s)

### Funder type
Charity

### Funder Name
Heart Research UK

### Alternative Name(s)

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Other non-profit organizations

### Location
United Kingdom

## Results and Publications

### Publication and dissemination plan
The results of this study will be presented in abstract form at relevant scientific and medical conferences, and will be published in appropriate peer-reviewed journals.

## Intention to publish date
31/12/2022

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

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

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 21/05/2022 | 23/05/2022 | Yes | No |
| Protocol article | | 24/09/2017 | 04/10/2022 | Yes | No |
| Results article | Qualitative study | 01/04/2022 | 04/10/2022 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |