# PROTOCOL

**FULL TITLE:** A study to assess the acceptability of an online weight prevention programme for new kidney transplant recipients - The wEight in Renal Transplant Online Study (ExeRTiOn).

**Short Title:** The wEight management in Renal Transplant Online Study- ExeRTiOn


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This trial will be conducted in compliance with the protocol, GCP and the applicable regulatory requirements.

**Sponsor Representative:** Liba Stones, R&D Manager, King's College Hospital

**Funder:** King's College Hospital

**Study Site:** King's College Hospital, London, SE5 9RS

## Table of Contents

# 1 INTRODUCTION

The primary aim of this project is to create an online weight management tool (Physical activity, weight management and cognitive behavioural therapy) to prevent significant weight gain following kidney transplantation. Designing the online interactive weight management resource for kidney transplant patients will involve patient and health care professional input through Qualitative methodology such as 'Think-Aloud' interviews and one-to-one semi-structured interviews. This online resource will be called "exertion" and will be created by the research team, with technical support from the SPIKA Software Company.

Results from this study will refine the resource, and lead to a study application for a randomised controlled feasibility trial where we plan to test the "exertion" online application. Therefore this project has potential to influence clinical practice for kidney transplant recipients. It will allow patients, who may not have routine access to physio or dietetic input to address weight gain with support. A study flow chart summarising the project can be found below.

## 1.1 STUDY FLOW DIAGRAM ExeRTiOn

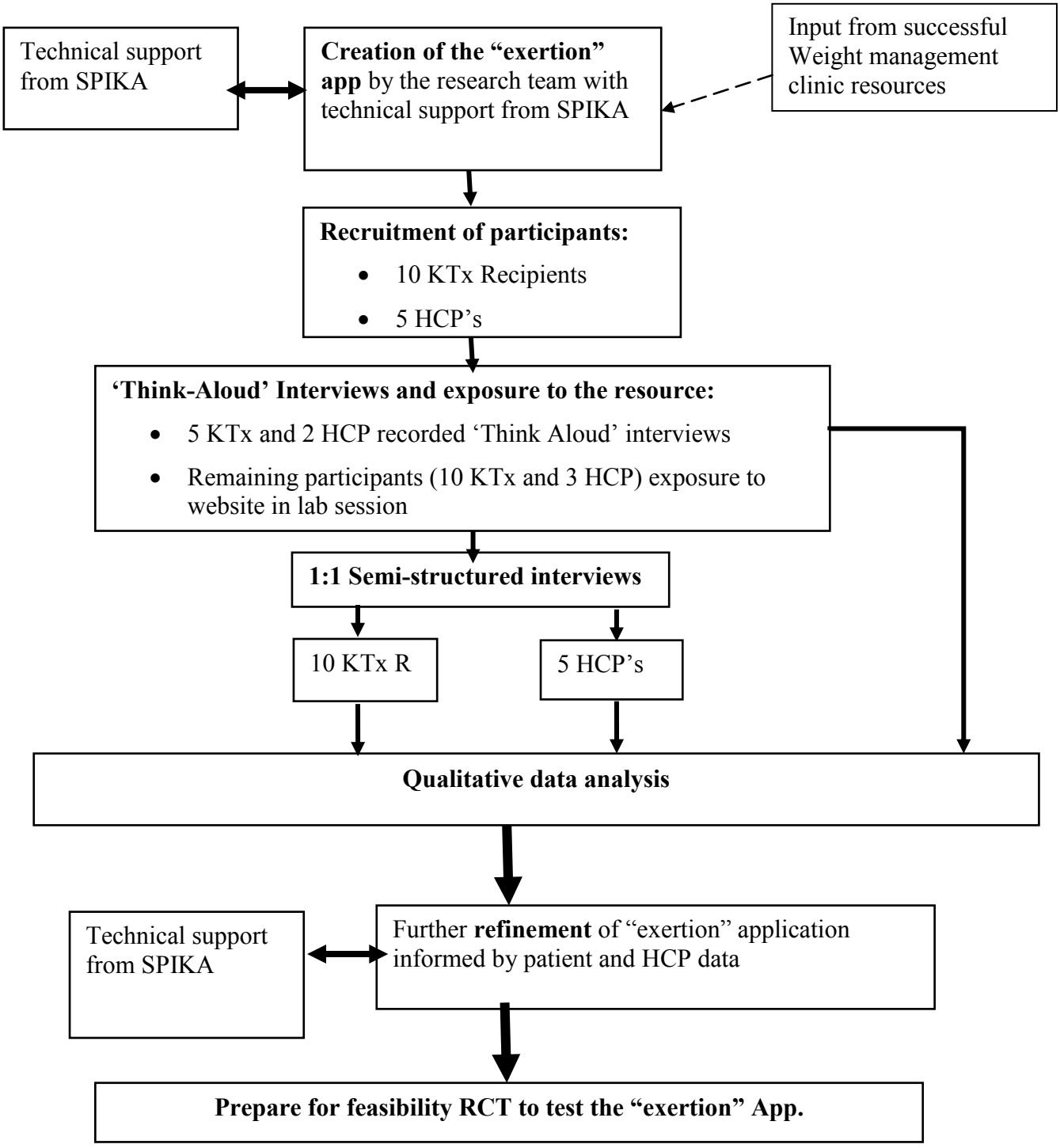


**Figure 1. Study flow diagram.**

## 2 BACKGROUND AND RATIONALE

Physical activity and exercise play a beneficial role in maintaining the health of those with chronic illnesses however poor physical functioning among patients with chronic kidney disease (CKD) is well recognised (1, 2). Kidney Transplantation (KTx) is an effective treatment option for life threatening end-stage kidney disease and becomes cost-effective over the average lifespan of the transplant, although it is not without associated risk. The use of modern immunosuppression therapies have improved the life-expectancy of the kidney graft; however, there is a high prevalence of diabetes, cardiovascular disease and obesity (3, 4). It has been established that recipients of KTx increase their physical activity level in the subsequent years after transplantation due to improved quality of life; however, within that time they do not reach the level of physical activity of those of age-matched healthy controls (5). A reason for this is that despite the reversal of many of the prevailing uraemic symptoms following KTx, functional capacity remains compromised due to a combination of prior deconditioning, uraemic myopathy, muscle atrophy and muscle pathology as a result of immunosuppression therapy (6, 7).

Weight gain is a significant and real issue for kidney transplant recipients (8, 9). Obesity remains a widespread issue for KTx recipients with an estimated two thirds of the population being overweight or obese (8). Research suggests that patients who gain more than 15% of their initial weight during the first year after receiving a kidney transplant, they have a higher chance of dying from conditions not related to their kidney function within ten years (9). Although weight gain and maintaining a programme of activity are real concerns for KTx recipients, they are not routinely offered specialist physical activity or weight management programmes in the UK. There are some community schemes for exercise and weight management available. However kidney transplant patients report they are not always understanding of the specific issues surrounding kidney transplantation. Extra appointments, travel time, and return to work where highlighted as barriers to participate in our supervised kidney transplant study (10). Robust research reviews suggest that online behavioural weight management interventions can help people regulate food intake and activity, and on average can lead to clinically meaningful weight loss (11, 12). Therefore there is a need to create an online weight management and physical activity tool, specific to KTx recipients, imbedded with cognitive behavioural therapy and motivational interviewing methods to address post-transplant weight gain. I would like to create this app with input from the research team, kidney transplant patients, and health care professionals (HCP's) working in the transplant team at a South London Teaching Hospital.

### 2.1 Primary Objective

To create a patient focused online weight management and physical activity tool for new transplant recipients called "exertion".

### 2.2 Secondary Objectives

a) To explore the current themes through qualitative data collection:

- Components of the "exertion" resource that are helpful/ unhelpful
- Any difficulties/ barriers to using the "exertion" application

- Any difficulties/ barriers to participating in the study?
- Strengths of the "exertion" resource
- Weaknesses of the resource
- Patient experience and learning using the online resource
- Transplant health care professional experience and knowledge reviewing the online resource

# 3 STUDY DESIGN

This study is a qualitative study and intervention planning study to create and refine an online resource for weight management in new kidney transplant recipients, which will be named "exertion".

## 3.1 Objectives and hypothesis:

The aim of this qualitative study is to use qualitative methods to create and refine a weight management, exercise/ physical activity online resource for patients with kidney transplant recipients.

This study involves data collection via:

- Think-aloud interviews- 5 KTx patients and 2 HCP working in the transplant team will have recorded think aloud interviews using the resources. Other participants will be exposed to the resource during a routine lab session.
- Semi-structured interviews of transplant HCP's and KTx recipients.
- Demographic data including age, gender, occupation, smoking history, medical history, medication lists and baseline body weight (kg).
- Website/ resource log in data
- Field notes and observations from Think Aloud interviews, lab sessions and semi-structured interviews

We aim to recruit 10 new kidney transplant recipients and 5 transplant health care professionals to explore the following themes through 'Think-Aloud' interviews:

- The functionality of the "exertion" online resource for KTx recipients
- The functionality of the "exertion" online resource from a HCP perspective
- KTx participants interpretation of the "exertion" modules and resource as a whole
- HCP participants interpretation of the "exertion" modules and resource as a whole
- Thought processes involved to use the "exertion" application
- Recommendations from participants
    - Likes/dislikes
    - Barriers/ easier to use sections
- Highlight individual differences in the use of the "exertion" resource

We aim to explore the following themes through semi-structured individual interviews and focus groups:

- What components of the online resource (exertion) are helpful/ unhelpful from a kidney transplant perspective
- What components of the online resource are helpful/unhelpful from a kidney transplant HCP perspective
- Are there any difficulties/ barriers participating in the study?
    - And are they what were expected or different?
- Patients experiences and learning using the online application, and when the changes were noticed
- Anything missing/ they would recommend adding to the application.

**Trial duration per participant:** One study visit.

**Estimated total trial duration:** 9 months in total to create resource and have it reviewed by patients and health professionals (3 months to create, 3 months to test and 3 months to refine).

## 3.2 The "exertion" Online Resource

The "exertion" (exercise in renal transplant online) resource will be created by the research team, including physiotherapists and dietitians working in renal specific weight management, with technical software support from SPIKA Company. This is a single centre study at King's College Hospital recruiting 10 kidney transplant recipients and 5 health care professionals from the transplant clinical team. As this study will involve patient interviews and qualitative data, ethical approval will be sought.

The resource will include individually tailored physical activity (PA) (e.g.: walking and cycling), recorded using a pedometer or smart phone apps. PA will be based on current guidelines recommending a minimal amount of 1000 kcal/week expended for health benefits, with optimal benefits associated with 1500-2000kcal/ week. Dietary information from the existing weight management programme at King's College Hospital (KCH) will be accessible to the patients online, including resources like "managing cravings", "goal setting" and "problem solving". The intervention will involve monthly web-based sessions that will start at 6 weeks post transplantation and continue until 12 months post-transplant surgery. For the purpose of this current study, participants will only have access to the online application in a one of session to review and refine the resource. It is clinical practice at our centre for KTx recipients to be cleared to resume structured physical activity post ureteric stent removal which occurs approximately 6 weeks post-surgery.

The packages will focus on modelling prescribed PA and healthy eating advice, and will involve cognitive behavioural techniques to support behavioural change. Recognised behavioural change techniques will be used which will include goal setting, evaluating outcome expectancies and values, self-regulation action planning), and behaviour monitoring will form the core principles. The sessions will also aim to increase treatment self-efficacy

(physical activity) and reduce fear avoidance (using basic acceptance and commitment therapy principles). Tailored feedback will include encouragement and virtual rewards if maintaining weight. Weight gain will trigger initial referral to an automated recovery package. This package will be built into the interventional platform and automatically activate given an increase in weight. The nature of this package is to ensure that following weight gain, the patient remains engaged with this interventional programme and will provide additional behavioural support. The online tool will be accessible either online, or via a smart phone or tablet as a health application (app).

We plan for the resource to allow participants to select modules to work through on a monthly basis over a 12 month period. Behavioural change tools and resources will be embedded within the "exertion" resource. For this current study, participants will access the online exertion resource at a one off supervised research visit. Participants will not have exposure or access to this online resource outside this study visit. The main modules will include information and interactive text on the following areas:

1. Managing cravings and prednisolone
2. Goal setting for activity and food planning
3. Portion sizes and the NHS healthy plate
4. Patient examples of strategies to plan activity (physical activity planning)
5. Patient examples of strategies to eating out/ holidays with low fat diets (food planning)
6. Reading food labels and making healthy food choices
7. Identifying barriers
8. Problem solving
9. Relapse prevention
10. Planning for the future

To ensure the modules are interactive, participants will be asked questions relating to:

- Number of steps and self-reported physical activity levels
- Weight, height, BMI
- Portion sizes
- Individual SMART goals regarding food and activity. The participants will be asked if they have achieved these set goals.
- Problem solving questions for activity and food
- Rating the importance and confidence in ability to make changes to food an activity using a VAS (visual analogue scale)

## 4 STUDY SCHEDULE

### Assessments:

After written consent is received, participant's demographic baseline information at entrance to the trial will be recorded. 5 of the KTx recipients and 2 of the HCP will undergo 'Think-aloud' interviews to assess the usability of the exertion resource. Usability is defined as how

easily someone can use and interact with the online system without any formal training (13). 'Think-Aloud' interviews are a qualitative research technique that assesses how the user interacts with the system and a sample of five can uncover 80% of usability problems and issues (13). 'Think-aloud' interviews provide a valid source of data concerning participant thinking as the participant is asked to vocalise as they perform a task, supervised by the researcher (14). Therefore in this study, the main researcher will record verbatim from participants as they talk out loud whist accessing and using the exertion resource. The researcher will also record field observation notes during the think aloud interviews. Verbal speech and site log in data will be recorded from these sessions. We estimate these interviews will take 60-90 minutes.

The remaining participants (5 KTx and 3 HCP), will have the same amount of time reviewing the resource at the start of the session (60-90 minutes). After the 'Think-aloud' interviews or review of resources, participants will complete a one-on-one semi-structured interview to review their thoughts and experiences on using the exertion resource. Please refer to summary of study flow diagram on page 5 and schedule of assessment (Table 1) below. Having the semi-structured interviews on the same day as the 'Think-aloud' interviews or the reviewing of the resource will minimise patient burden and recall bias.

**Table 1- Schedule of Assessment**

| Procedure | Recruitment | Visit 1 |
|---|---|---|
| Screening and informed written consent | X | |
| Medical history and demographics | | X |
| 'Think-Aloud' interviews:<br>- 5 KTx<br>- 2 HCP<br>- Estimate 60-90 minutes total | | X |
| Exposure to the resource lab sessions<br>Estimate 60-90minutes total | | X |
| Semi structured individual interviews<br>(n=9 KTx, n=5 HCP) | | X |

## 4.1 Distress protocol

As participants will be discussing exercise and food intake whilst using the online resource and during the semi-structured interviews the team have devised a distress protocol (modified from Distress Protocol for qualitative data collection, C.Haigh and G. Witham, Department of Nursing Manchester Metropolitan University).

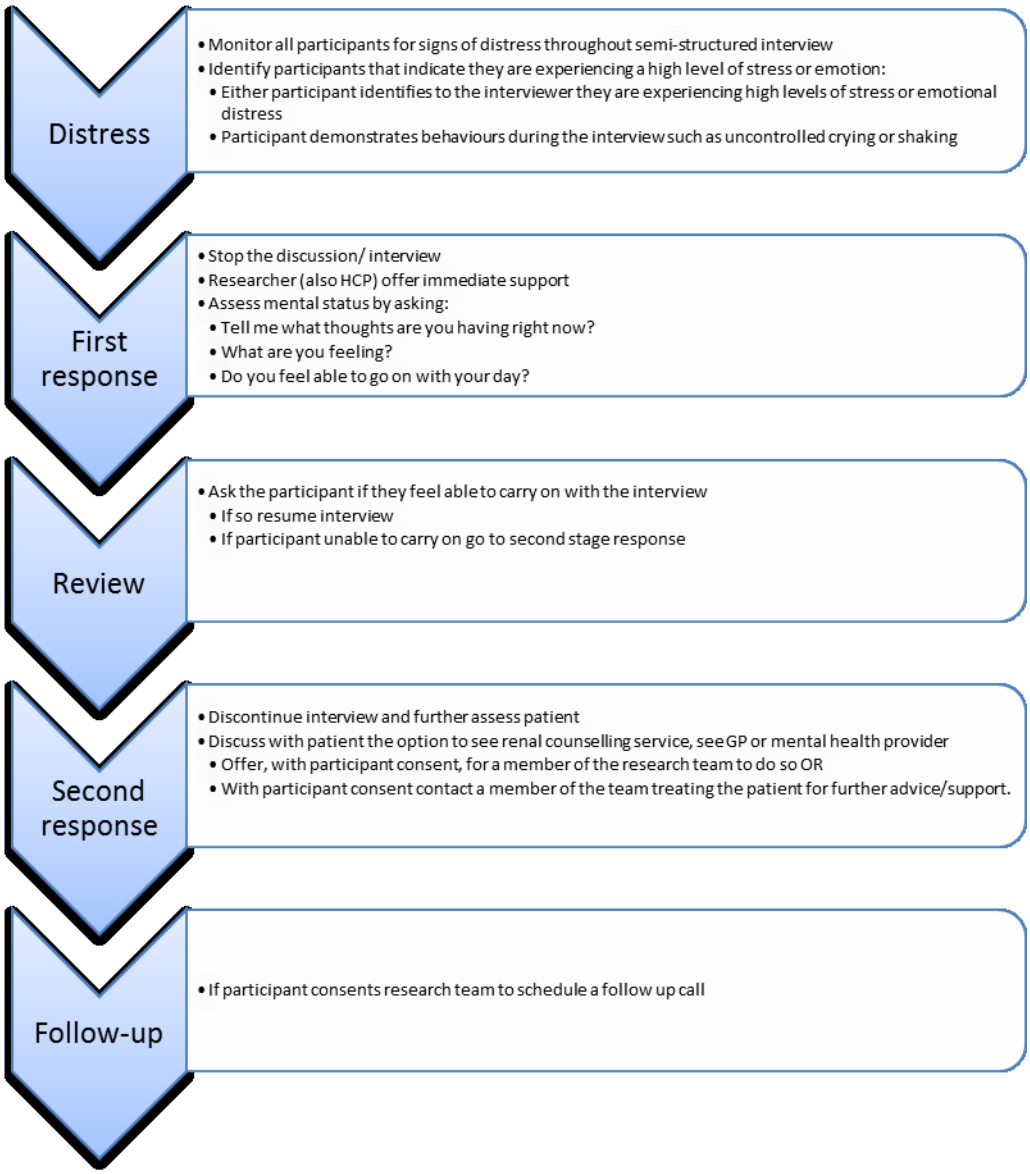


Figure 2. Distress Protocol

## 5 CONSENT

Patients will be screened and identified by clinicians working in the transplant team, and also the main researcher (EC). Potential participants will initially be provided with patient information sheet (the current Research Ethics Committee (REC) and Health Research Authority (HRA) approved version) and a covering letter explaining the trial to them and inviting them to participate in the trial. The research team will meet the potential participants face to face during their clinical visit to offer the patient information letter and cover letter. They will have time to consider the trial and decide whether or not they wish to take part, and to discuss the trial with their family and friends if they would like to. If they are non-english speakers, they will be offered the opportunity to discuss the study in detail and ask any questions via the language line phone translation service. Transplant staff members will also be approached and provided with the information sheet, cover letter and ample time to consider consenting to the trial (a minimum of 24 hours).

At their next clinic appointment, potential KTx participants will have plenty of time to discuss the trial further and to have any questions that they may have about the trial answered from a member of the research team. The nature and requirements of the trial will be carefully explained. The investigator will explain that there is no obligation for a potential participant to enter the trial, that trial entry is entirely voluntary, and that it is up to the potential participant to decide whether or not they would like to join. It will also be explained that they can withdraw at any time during the trial, without having to give a reason and that their decision will not affect the standard of care they receive. Any reasons for non-participation will be recorded if the information is volunteered.

Participants if willing to participate will be consented as per the GCP guidelines. Only adults above the age of 18, with capacity to consent will be accepted into the study. Non-english speakers will be consented via language-line phone translation service. The participant and responsible clinician will sign the informed consent form and the responsible clinician will perform a final confirmation of eligibility. Informed consent will be obtained before any trial-related procedures are undertaken. A copy of the signed informed consent form will be given to the participant. The original signed form will be retained at the study site in the Investigator Site File and a copy placed in the medical notes. A copy will also be sent to the Chief Investigator of the study. With KTx participant's prior consent, their General Practitioner (GP) will also be informed of their participation of the study.

# 6 ELIGIBILITY CRITERIA

Participants will be included based on the following inclusion and exclusion criteria. Those who are ineligible, or decline to participate will be captured on the secure and encrypted recruitment and screening log.

## 6.1 Eligibility criteria for the KTx recipient participants (n=10)

### 6.1.1 Inclusion criteria:

- Adult patient (18 years+)
- male or female
- Able to provide written informed consent
- < 3 months post-transplant. NB. Our team has decided to recruit patients within the first three months post transplants as most patients at our centre are not cleared to start a formal physical activity or exercise plan until they have ureteric stents removed which usually occurs at 6 weeks post-transplant surgery.
- Access to Internet connected computer, smart-phone or tablet. NB. Our team has completed a waiting room survey and our patients often use internet to view their clinical blood results through "renal patient view", therefore do not perceive internet access as a barrier to this study.
- A Body Mass Index (BMI) greater than or equal to 18.5 (healthy range).

### 6.1.2 Exclusion criteria:

- Age < 18 years of age
- Pregnancy

- Unstable medical conditions such as angina, uncontrolled hypertension or diabetes, congestive cardiac failure, active myocarditis, cardiac arrhythmia, co-morbid catabolic condition, psychiatric illness.
- Participated in a structured exercise or physical activity intervention in the last three months
- BMI of less than 18.5 (classified as underweight)
- Significant cognitive impairment preventing them from engaging with online interactive material

## 6.2 Eligibility criteria for the Transplant Health Care Professionals (n=5)

### 6.2.1 Inclusion criteria:

- A nephrologist, kidney doctor, nurse or member of the multi-disciplinary team who actively work with kidney transplant patients at King's College Hospital
- Adult above 18 years of age
- Able to provide written consent
- Access to Internet connected computer, smart-phone or tablet.

### 6.2.2 Exclusion criteria:

- Pregnancy
- Unstable medical conditions such as angina, uncontrolled hypertension or diabetes, congestive cardiac failure, active myocarditis, cardiac arrhythmia, co-morbid catabolic condition, psychiatric illness.

# 7 RECRUITMENT

## 7.1 Selection of Participants

All participants will be recruited from King's College Hospital renal outpatients. Potential participants will be identified when presenting for their routine post-transplant hospital clinic visits by the transplant clinical team. Patients who fulfil the inclusion criteria will have their eligibility confirmed by the research team. Each patient must meet all of the inclusion criteria, and none of the exclusion criteria at entry to the trial. After confirming eligibility, eligible patients will be approached by an appropriately trained member of the research team who routinely work in the transplant clinic, to ascertain interest in entering the study. This individual (likely to be either the PI or CI of the study) will give a comprehensive verbal explanation of the trial (explaining both the investigational and standard treatment options and highlighting any possible benefits or risks relating to participation). Time for questions throughout the discussion will be given and questions adequately addressed. Potential participants will also be given a written information sheet about the trial and be given sufficient time (providing they have received the patient information sheet and had at least 24 hours to read and fully understand the implications of the trial) to consider the study

information prior to deciding whether to take part. Participants that agree to enter the study will then be asked to consent to undergo study assessments. If the participant is willing to take part then they will be asked to sign the consent form with a member of the research team countersigning. Screening logs will be kept on the secure "renal physio" drive and will be encrypted for confidentiality. All eligible and ineligible patients, plus those declining to participate will be logged on the secure screening log.

Throughout the trial duration, participants will be encouraged to ask questions and will be reminded that they can withdraw at any time without their clinical care being affected. No payment is to be offered to the participants taking part in the trial.

# 8 STATISTICAL METHODS

## 8.1 Sample Size

We will interview a purposive sample of KTx patients to include a range of gender and age. We will aim to also recruit a purposive sample of kidney transplant HCP. 'Think-aloud interviews produce large amounts of rich data and it is suggested that site 80% of usability problems are identified with 5 think aloud interviews. Therefore this research team aims to do think aloud interviews on 5 KTx recipients and 2 HCPs.

Individual semi-structured interviews will utilise appropriate topic guides that will be developed and discussed with the patient advisory group, and the steering group. We will continue with individual interviews until we reach data saturation, there is no new data, no new themes, no new coding and we are able to replicate the study (15, 16).

## 8.2 Statistical Analysis

Baseline demographics of the patients will be described using summary statistics. Continuous variables will be summarised using the mean and standard deviation (SD) if approximately normally distributed. Continuous variables that are not normally distributed will be summarised using the median and IQR.

Qualitative analysis: Data will be collected through in-depth feedback about our online intervention materials; field notes, individual interviews and 'Think-aloud' interviews. 'Think-aloud' interviews will be used to elicit participants' reactions to sessions of the online intervention; participants will be observed and asked to comment aloud on reactions to every aspect of the different sessions. Semi-structured interviews will explore participants' overall impressions of the online intervention. These qualitative techniques will allow for themes and sub-themes to emerge. The website will be designed to record user entries, and observational field notes about participants' use of the intervention will also be collected. Individual interviews will be transcribed verbatim and analysed using an inductive thematic analysis approach (17), informed by techniques of grounded theory (15), including line-by-line open coding grounded in data and constant comparison of all instances of codes. Deviant case codes will be employed to ensure that perspectives that diverge from dominant trends are not overlooked.

## 8.3 Randomisation procedures

There is no randomisation in this study.

## 9 PATIENT AND PUBLIC INVOLVEMENT (PPI)

Patient and public involvement is crucial for developing and evaluating this resource. Our renal care group is fortunate to have a group of patients from across the Chronic Kidney Disease trajectory in our research group. They have reviewed all associated study documentations to ensure it is appropriate for patients. This group of patient experts will also assist in reviewing lay summaries for dissemination of research.

PPI is crucial to this project to create and refine a resource for the patients by transplant patients and members of the transplant HCP team.

## 10 FUNDING

The research team has been awarded £25,000 to create the "exertion" resource through the King's College Hospital charity fund. The team are in the process of applying to the Allied Health Professional Kidney Research UK (KRUK) Fellowship. If successful, this fellowship would cover the student's salary, study fees. If the team are unsuccessful in securing the KRUK grant, this study will be absorbed by the renal rehab team with adjusted time-lines.

## 11 DATA HANDLING AND MANAGEMENT

All paper data recording sheets will be stored in lockable filing cabinets at the renal rehab team office for 5 years. Documents will also be archived using the secure iron mountain software. Electronic data spreadsheets will be kept on the private renal rehab team drive and will be password protected. All patient indefinable details (name, address, hospital number) will be removed in place of trial ID numbers.

All staff involved in this research project will ensure data is handled with strict confidentiality in line with local trust policies. Data will be reviewed regularly by the student, and monitored by the supervisors. The lead researcher (EC) will transcribe all interviews. Information gathered from the online resource will be anonymised and protected by a secure log in feature.

## 12 PEER AND REGULATORY REVIEW

This study has been peer reviewed within KCH, by an independent and relevant peer reviewer/committee, the renal research governance board on the 11th of October 2017. The Sponsor has accepted these reviews as adequate evidence of peer review.

The study was deemed to require regulatory approval from the following bodies (list). Each approval will be obtained before the study commences.

- HRA
- REC

## 13 MONITORING AND AUDITING

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Chief Investigator will inform the sponsor should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

## 14 INDEMNITY ARRANGEMENTS

KCH will provide NHS indemnity cover for negligent harm, as appropriate and is not in the position to indemnify for non-negligent harm. NHS indemnity arrangements do not extend to non-negligent harm and NHS bodies cannot purchase commercial insurance for this purpose; it cannot give advance undertaking to pay compensation when there is no negligence attributable to their vicarious liability. The Trust will only extend NHS indemnity cover for negligent harm to its employees; substantive and honorary, conducting research studies that have been approved by the R&I Department. The Trust cannot accept liability for any activity that has not been properly registered and Trust approved. Potential claims should be reported immediately to the R&I Office.

## 15 ARCHIVING

During the study, all data will be kept securely and confidentially at the Renal Physio office. After the study has ended, paper data recording sheets, the Trial Master file and patient consent forms will be kept locked and secure for 5 years. All documents will be archived at a long term storage facility (Iron Mountain) for 5 years. Data spreadsheets will be encrypted, name and contact details removed, and stored on a private renal physio team folder with limited access.

## 16 PUBLICATION AND DISSEMINATION POLICY

The research team plans to disseminate the study research findings in the following settings:

- Conference presentation of study process and resource design of "exertion" at either the American Society of Nephrology conference and the British Renal Society Conference
- Conference presentation of study results at either the American Society of Nephrology conference or the British Renal Society Conference
- Publication of the resource design of "exertion" resource
- Publication of the study findings

## 17 REFERENCES


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## Appendix 1: PROTOCOL VERSIONS

| Version No | Version Date | Detail the reason(s) for the protocol update |
|---|---|---|
| 1.0 | 31.10.2017 | Original protocol involved two phases: 1) designing resource and 2) Feasibility Randomised Controlled Trial to further test online resource. As per guidelines by the South-London REC committee, the research team has separated this study into separate applications. |
| 2.0 | 11.01.18 | NA this is the current version of the protocol of the qualitative study to design the exertion resource |
| 3.0 | 06.03.18 | Changes as per suggestions from the REC and HRA |