ISRCTN87066351 https://doi.org/10.1186/ISRCTN87066351

Physical activity opinions in kidney patients

Submission date
07/10/2015

Recruitment status
No longer recruiting

Registration date
23/03/2016

Overall study status
Completed

Last Edited
25/04/2023

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic kidney disease (CKD) is a long-term condition where the kidneys do not work effectively. Patients with CKD have a very high risk of developing heart problems, losing muscle mass and experiencing poor mental health and a reduced quality of life. Being more active and taking part in exercise has the potential to improve all of these factors and is recommended in national guidelines as being an important part of treatment for CKD. Despite this patients with CKD tend to lead very inactive lifestyles, the reasons for which have not been widely investigated in the UK population. Our research has demonstrated that regular moderate aerobic exercise (e.g., walking) and strength training using weights are both highly beneficial for people with CKD. We now need to develop effective strategies to help kidney patients be more active. Our overall aim is to develop a motivational/educational programme specifically for CKD that will encourage patients to increase their physical activity levels. However, we first need to understand our patients' current activity habits and their attitude to the prospect of change in this aspect of their lifestyle. It will be critical to find out about the perspectives and needs of the patients themselves at an early stage of development. We also need to consult patients about their preferred methods for delivering the programme.

Who can participate?
Adult CKD patients.

What does the study involve?
This study consists of three distinct parts: 1, 2 and 3. In part 1 we carry out a survey consisting of a series of short and widely-used questionnaires to find out about the participants' current exercise habits and their attitude to physical activity.
In part 2 we use group and individual discussions to explore in much greater depth the attitudes towards and perceptions of exercise amongst kidney patients and outpatient clinic staff. We also consult patients about their preferred methods for delivering the programme. We then incorporate the findings into the design and testing of the motivational programme to help kidney patients get more active. In part 3 the findings from part 2 are used in collaboration with patient and expert representatives to develop interventions designed to promote physical activity for kidney patients. Group-based and individual discussions between kidney patients and researchers are then used to explore opinions regarding the content and delivery of these

interventions. The findings are then used to modify the programmes in conjunction with an expert panel. We then create a working model of the intervention that will be tested in further studies.

What are the possible benefits and risks of participating?
There are no direct benefits for the participant taking part in this research. We hope that the results of the study will help us to develop a fit-for-purpose behaviour change intervention that will help future kidney patients become more active and hence increase their chances of having a better quality of life. The only disadvantage of taking part is that participants will need to fill out a survey and potentially attend either a focus group/interview. This will theoretically take up to a few hours of their time depending on what part of the study they participate in. We will reimburse any travel expenses incurred in taking part in this research study.

Where is the study run from?
1. University Hospitals of Leicester
2. Nottingham University Hospitals NHS Trust
3. Derby Hospitals NHS Trust
4. Kettering General Hospital NHS Foundation Trust
5. Lancashire Teaching Hospitals NHS Foundation Trust
6. St Georges Healthcare NHS Trust
7. United Lincolnshire Hospitals NHS Trust
8. East & North Herts NHS Trust
9. Northampton General Hospital NHS Trust

When is the study starting and how long is it expected to run for?
July 2012 to August 2017.

Who is funding the study?
British Renal Society (UK).

Who is the main contact?
Dr Alice Smith
ac500@le.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Alice Smith

Contact details
UoL Academic Unit
Leicester Kidney Exercise Team
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW
+44 (0)116 258 4346
aa50@le.ac.uk

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Increasing physical activity in chronic kidney disease: the patient perspective

Acronym
QCKD

Study objectives
People with kidney problems often suffer from poor quality of life and many health problems. Research has shown that taking regular exercise can be very beneficial for their health and wellbeing, but they tend to lead rather inactive lives. There may be many reasons for this, and in order to help the patients overcome their fears or problems and benefit from the opportunity to exercise we need to fully understand the patients' points of view. This project is designed to find out how our patients feel and think about taking up exercise and becoming more physically active, so that we can develop programmes that will make it easier for them.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Northampton, 13/06/2012

Study design
Mixed methods study consisting of three parts: a physical activity and opinions survey, an exploration of patients motivations and barriers to exercise, and the refinement of a physical activity behaviour change intervention.

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Chronic kidney disease across all stages of disease progression including: patients who do not require renal replacement therapy, patients who undergo a form of dialysis treatment and patients who have received a renal transplant.

Interventions
This is an observational study. Participants are approached whilst attending their routine nephrology appointment or dialysis session and invited to fill in the physical activity survey. Participants are asked for their consent for a researcher to access their clinical records to record relevant clinical information. All participants who complete the survey are informed about the

qualitative part 2 study. If participants express an interest their contact details are taken by the researcher. Subsequently the researcher will then send a patient information sheet and invitation letter outlining the details of the qualitative study to the participant via the post. If the participant is willing to take part the researcher arranges a suitable time with them to attend a focus group or an interview. Focus groups are used initially to identify topics of interest among the group and inform the development of interview topic guides. Interviews are then conducted to explore individual beliefs, motivations and barriers towards exercise. The findings of this work are used to inform the development of a motivational and educational session designed to increase physical activity. For part 3 participants are recruited from routine nephrology clinics or dialysis treatment sessions and from the database of patient contact forms that was built up during the first two stages of the study. Participants are then invited to attend small group discussions or one to one discussions with a researcher to explore the content of the behaviour change intervention in order to ensure that the materials are engaging and acceptable for the patient.

Intervention Type
Behavioural

Primary outcome(s)
Part 1: The five validated questionnaires comprising the Leicester Kidney Patient - Physical Activity Questionnaire Survey (LKP-PAQ survey) are all short, consisting of a few questions each:
1. Duke Activity Status Index (DASI) : a widely-used measure of physical capability
2. GP Activity Questionnaire (GPPAQ): developed by the DoH to provide a simple, 4-level Physical Activity Index (PAI) reflecting an individual's current physical activity. This was chosen over other recognised physical activity questionnaires because of its brevity (most are lengthy and some require an interview) and its applicability over a wide age and health status range
3. Leisure Time Exercise Questionnaire (LTEQ): for those respondents who participate in exercise, assesses the amount of exercise undertaken (from which a metabolic equivalent [METS] estimation can be calculated) and also identifies preferred activities
4. Stage of Change Questionnaire: identifies the respondents' state of readiness to adopt a more active lifestyle according to the Transtheoretical Model of Change
4. Self-Efficacy Questionnaire: identifies the respondents' confidence in their ability to adopt a more active lifestyle, which is a major determinant in the success of changing behaviour.

For Parts 2 and 3 the outcomes are qualitative information acquired from semi-structured interviews and focus groups. Each participant takes part on one occasion.

Key secondary outcome(s))
Part 1:
Free text section at end of survey form - we have provided space for the respondent to elaborate on their thoughts and feelings around exercise and how they would prefer rehabilitation to be delivered.

Relevant information required for analysis extracted from medical notes.
1. Age
2. Gender
3. Ethnicity
4. Co-morbidities
5. Blood/urine test results
6. Drugs

Parts 2 and 3 do not have secondary outcomes.

Completion date
31/12/2018

Eligibility

Key inclusion criteria
All chronic kidney disease patients will be eligible for the study. For those with a kidney transplant, all patients who received their new kidney more than 12 weeks earlier will be eligible.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Part 1:
Transplant patients who have received a new kidney within the previous 12 weeks will be excluded, as post-operative factors are likely to affect physical activity and confound the results.

Part 2 & 3:
Patients with major contraindication to exercise:
1. Unstable angina or myocardial infarction during the past 6 weeks
2. Severe heart failure (NYHA IIIIV)
3. Severe COPD
4. Severe lower limb orthopaedic problems
5. Severe lower limb neuromuscular disease

Date of first enrolment
07/09/2012

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Leicester
United Kingdom
LE5 4PW

Study participating centre
Nottingham University Hospitals NHS Trust
United Kingdom
NG7 2UH

Study participating centre
Derby Hospitals NHS Trust
United Kingdom
DE22 3NE

Study participating centre
Kettering General Hospital NHS Foundation Trust
United Kingdom
NN16 8UZ

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
United Kingdom
PR2 9HT

Study participating centre
St Georges Healthcare NHS Trust
United Kingdom
SW17 0QT

Study participating centre
United Lincolnshire Hospitals NHS Trust
United Kingdom
LN2 5QY

Study participating centre

East & North Herts NHS Trust
United Kingdom
SG1 4AB

Study participating centre
Northampton General Hospital NHS Trust
United Kingdom
NN1 5BD

Sponsor information

Organisation
University Hospitals Leicester NHS Trust (UK)

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Other

Funder Name
British Renal Society Grant 2011

Alternative Name(s)
BRS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	secondary analysis Association of self-reported physical function with survival in patients with chronic kidney disease	01/02/2019		Yes	No
Results article	secondary analysis results in frail patients	23/09/2020	25/09/2020	Yes	No
Results article		14/11/2019	25/04/2023	Yes	No
Results article	qualitative results	10/01/2022	25/04/2023	Yes	No
Results article	secondary analysis in individuals undergoing haemodialysis and peritoneal dialysis	26/03/2021	25/04/2023	Yes	No
Other publications	qualitative study	01/11/2015		Yes	No