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Programmes to encourage exercise and active lifestyles in kidney disease

Submission date
07/07/2015

Recruitment status
No longer recruiting

Registration date
21/08/2015

Overall study status
Completed

Last Edited
09/07/2020

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
People with kidney problems often suffer from a poor quality of life and many health problems. Research has shown that taking part in regular exercise can be very beneficial for their health and well-being, however we also know that few people with chronic kidney disease are being active enough. We want to explore ways to encourage patients to start being more active, at home or in their community. Other projects where researchers have worked with people with different diseases, have shown that using a self-directed approach, which includes education, goal setting and problem solving, with the support of a health-care professional has helped people start exercising regularly. This approach helped people to gain the necessary knowledge and confidence to become more active and overcome their fears or problems in order for them to keep active. This project aims to develop similar self-directed interventions for kidney patients. We have already designed a first draft version of a programme and now we want to ask patients to try it and tell us what they think. We aim to update the design of the intervention after each round of testing, based on what people tell us does or doesn't work about the design. In this study we will invite kidney patients to take part in a self-directed physical activity programme, where we are aiming for people to increase their daily activity to a level which is suitable for them e.g. up to 30mins, 5 days per week, although we will not ask anyone to attempt exercise levels that are too much for them. At the beginning and the end of the research study we will ask the participant to complete some fitness tests and some questionnaires.

Who can participate?
Any adults with chronic kidney disease or a kidney transplant can take part in this study, as long as their own doctors consider them fit enough to participate. Participants must be able to read and understand the English language enough to give informed consent and to read the educational material supplied.

What does the study involve?
During the study, participants are asked to continue their life in the usual way. They should follow their usual recommended diet, and take their usual medicines as prescribed. Participants are asked to go to the research centre for four visits that are flexible and scheduled at their convenience. At Visit 1, they are asked to complete some simple fitness tests and fill in some questionnaires. Visit 1 takes between 1 and 3 hours. Visit 2 is the motivational counselling and

education session, which takes about 1 to 3 hours. This is either delivered as a group or as an individual depending on the design of the project for testing at that point. At the session participants are given some written and illustrated material, which we go through during the session, and which is theirs to keep and take home afterwards. The session is conducted by a trained member of the research team. In the session, we talk about :
•Kidney disease and the participants health
•Exercise and physical activity and the reasons they can help to improve participants health and well-being
•How participants might use exercise and physical activity in their own lifestyle
After visit 2 participants are asked to gradually increase how much physical activity or exercise they do, for the next 6-12 weeks. They are given a pedometer to wear on the waistband of their clothing whilst they are awake. During the study, participants are asked to record how much physical activity and how many steps they do each day, and how hard it is. They are then contacted by telephone regularly throughout the intervention period to see how they are getting on. Visit 3 takes place at the end of the study period above (6-12 weeks after the counselling session). Participants are asked to repeat the same fitness tests and questionnaires that they did in Visit 1. Visit 4 is either a focus group or an individual interview, as one of the aims of the project is to hear how each participant got on throughout the study period and how we could improve it. They are asked to attend either a focus group, with other kidney patients, or an individual interview, at a mutually agreed date and time. The focus group will include about 4-8 kidney patients.

What are the possible benefits and risks of participating?
There are no direct benefits to participants of taking part in this research, although we anticipate being more physically active might help them to improve their fitness levels. We hope that the results of the study will help us design improved treatments for other kidney patients in the future. The main disadvantage of taking part is the time commitment involved in the research visits for assessments and the motivational session (4 visits, each between 1-3 hours). As with all physical activity, there is a very small risk of accident or injury during the assessment visits or whilst being physically active. All the tests will be supervised by trained research staff and will take place at a specialist research centre.

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

When is the study starting and how long is it expected to run for?
July 2015 to July 2021

Who is funding the study?
Kidney Research UK

Who is the main contact?
Mrs Heather MacKinnon

Contact information

Type(s)
Public

Contact name
Mrs Heather MacKinnon

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
version 1 17th March 2015

Study information

Scientific Title
Programmes to encourage Exercise and Active Lifestyles in kidney disease: a single-centre, interventional study

Acronym
PEArL

Study objectives
Providing a supportive intervention, either as a group or individually, can promote self-directed physical activity in people with kidney disease and be acceptable to patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee (NRES Committee East Midlands - Nottingham 2), 22/5/2015, ref: 15 /EM/0208

Study design
Single-centre interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Chronic kidney disease

Interventions
The intervention will investigate the use of both group and individual sessions to facilitate engagement in a self-directed physical activity (PA) programme. This project aims to test the intervention design; seek feedback, using semi-structured interviews; and update both the design and content based on the qualitative findings. The initial intervention design represents a 6-8 week PA programme, launched using a motivational education session, and supported by written educational material and follow-up phone calls by health care professionals.

Intervention Type
Behavioural

Primary outcome measure
The primary aim of the trial is to demonstrate patient-acceptability, thus the recruitment, engagement and retention rates are the primary outcome measures.

Secondary outcome measures
Secondary outcome measures include a range measure of physical and functional assessments, including:
1. The Incremental and Endurance Shuttle Walk Tests,
2. Short Physical Performance Battery
3. Body composition
4. Cardiac bio-reactance

A range of questionnaires will be used to measure PA levels, quality of life and symptom burden. The appropriateness of the outcome measures will be evaluated as part of the trial and will vary as indicated based on the participant feedback.

Overall study start date
01/07/2015

Completion date
01/07/2020

Eligibility

Key inclusion criteria
Participants must:
1. Be >18 years of age
2. Have a diagnosis of Chronic Kidney Disease or have a kidney transplant
3. Be able to provide written consent, read the supported written material and engage in the motivational/educational session
4. Not be considered unfit by their own clinician due to physical impairment, co-morbidity or any other reason for any element of the protocol

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12

Key exclusion criteria
Participants will be excluded if:
1. <18 years of age
2. Are unable to provide written consent, read the supported written material or engage in the motivational/educational session
3. Are considered unfit by their own clinician due to physical impairment, co-morbidity or any other reason for any element of the protocol

Date of first enrolment
01/07/2015

Date of final enrolment
01/07/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester
Leicester Kidney Exercise Team

University of Leicester Academic Unit
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University Hospitals of Leicester

Sponsor details
Trust HQ, Blamoral Building Level 3, Leicester Royal Infirmary
Leicester
England
United Kingdom
LE1 5WW
+44 116 258 4109
RDAdmin@uhl-tr.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Charity

Funder Name
Kidney 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
To be confirmed at a later date.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No