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Exercise Training in Chronic Kidney Disease

Submission date
14/01/2014

Recruitment status
No longer recruiting

Registration date
21/02/2014

Overall study status
Completed

Last Edited
09/08/2019

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
Kidney disease is increasingly common and now affects about 8% of the population. When the kidneys don't work properly, patients often suffer from a number of problems, including muscle weakness, extreme tiredness and increased risk of developing heart disease. Our research has shown that the muscles can be improved by regular muscle building exercise, and walking (aerobic) exercise can help to keep the heart healthy. The aim of this study is to find out whether a combination of muscle-building exercise and aerobic exercise can provide benefits to both the muscles and the heart in people with kidney disease.

Who can participate?
Adults aged 18 and over with a chronic kidney disease (Stages 3b-5) and living in the Leicestershire area.

What does the study involve?
Participants will attend the hospital for some tests to measure their fitness and their current health, including Magnetic Resonance Imaging (MRI) Ultrasound scans of the leg muscles, a heart function test, a blood sample and some questionnaires. Participants will then wear a small wrist device for one week to measure their usual activity levels. For the next six weeks, participants will carry on with their usual daily lives, after which they will return to the hospital to repeat the same tests as before. The participants will then start a 12-week course of supervised exercise classes for about 1 hour, three times a week. Participants will be randomly allocated to either just do aerobic-type exercises such as walking and cycling or to do a mixture of aerobic exercises and leg muscle-building strength exercises with weights. Before the first exercise class, participants will have a small muscle biopsy (sample) taken from the thigh muscle, and this will be repeated the following day after the exercise session. At the end of the 12-week course of exercise classes, the participants will return for another set of health and fitness tests and another muscle biopsy. The results will tell us about how aerobic and muscle-building exercise affects kidney patients, and will help us to advise people with kidney disease about the best types of exercise for them.

What are the possible benefits and risks of participating?
There are no direct benefits of taking part in this study, although we hope that the participants will get fitter by taking part in the exercise classes. Ultimately, taking part in the study will help to provide better care for kidney patients in the future. Any clinically important results will be

passed on to the patients own GP (doctor). As with all physical activity, there is a very small risk of accident or injury during the exercise tests and classes, but all exercise will be supervised by specialist research staff and will take place on hospital premises with resuscitation equipment available and trained staff on hand. Taking blood samples from the arm may cause slight pain or bruising afterwards. For the muscle biopsies, the patient will be given an injection of local anaesthetic, which may cause some slight discomfort. The biopsy itself is not painful, but the area may ache for a while afterwards. There is a very low risk of infection or bleeding at the site of the biopsy.

Where is the study run from?
The study will be run at Leicester General Hospital. The MRI and ultrasound scans will be done at the Glenfield Hospital in Leicester, UK.

When is the study starting and how long is it expected to run for?
The study started in December 2013. Recruitment of kidney patients to take part in the study is expected to continue for about 3 years. After this, blood and muscle samples will be analysed in the laboratory for another 2 years. We expect the study to be completed by December 2018.

Who is funding the study?
Leicester-Loughborough Nutrition, Diet and Lifestyle Biomedical Research Unit, UK.

Who is the main contact for the study?
Dr Alice Smith
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Contact information

Type(s)
Scientific

Contact name
Dr Alice C Smith

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT01061008

Secondary identifying numbers
Protocol version 1 dated 1st August 2013

Study information

Scientific Title
Exercise Training in Chronic Kidney Disease

Acronym
ExTra CKD

Study objectives
This study is designed to determine if delivering aerobic and resistance exercise together in a pragmatic rehabilitation programme can replicate the benefits seen when these forms of exercise were previously investigated separately, or if when combined the two modes of exercise interfere with each other and no benefit is received.

We hypothesise that a 12-week course of thrice-weekly supervised exercise classes comprising a combination of cardiovascular and resistance exercise will significantly improve muscle strength, mass and metabolism compared with cardiovascular exercise alone in patients with advanced pre-dialysis kidney disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Northampton, 22/10/2013, ref 13/EM/0344

Study design
Randomised study

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 contact Dr Alice Smith, aa50@le.ac.uk a patient information sheet

Health condition(s) or problem(s) studied

Chronic kidney disease

Interventions
Randomised study of supervised cardiovascular exercise versus supervised cardiovascular plus resistance exercise, with a 6 week usual activity run-in period for all participants.

12 week course of supervised exercise classes, duration approximately 1 hour, 3 times a week, consisting of either cardiovascular exercises alone or a combination of cardiovascular and lower body resistance exercises. Exercise intensity will be tailored to the individual and progressed through the 12 week course as individually appropriate.

Intervention Type
Behavioural

Primary outcome measure
Muscle strength (total weight lifted during training sessions and estimated 1 repetition maximum of quadriceps extension) measured at 6 weeks, 12 weeks, 18 weeks

Secondary outcome measures
1. Quadriceps Muscle size: Magnetic Resonance Imaging & 3D Ultrasonography. Measured at baseline, 6 weeks, 18 weeks
2. Exercise Capacity: VO2peak. Measured at baseline, 6 weeks, 18 weeks
3. Physical Function: Shuttle walk tests; sit to stand tests. Measured at baseline, 6 weeks, 12 weeks, 18 weeks
4. Daily Physical Activity: 7 day Accelerometry. Measured at baseline, 6 weeks, 18 weeks
5. Body composition: Weight, height, waist circumference. Measured at baseline, 6 weeks, 12 weeks, 18 weeks
6. Arterial Stiffness: Pulse Wave Velocity. Measured at baseline, 6 weeks, 18 weeks
7. Clinical parameters: Extracted from medical records. Measured at baseline, 6 weeks, 18 weeks
8. Muscle metabolism: Muscle biopsy. Measured at 6 weeks, 18 weeks
9. Plasma markers of inflammation and oxidative stress, Venous blood sample. Measured at baseline, 6 weeks, 18 weeks
10. Quality of Life: SF36 and EQ5D questionnaires. Measured at baseline, 6 weeks, 12 weeks, 18 weeks
11. Symptom perception: Chronic Kidney Disease Symptom Score. Measured at baseline, 6 weeks, 12 weeks, 18 weeks
12. Physical Activity habits and attitudes: Leicester Kidney Patient Physical Activity Questionnaire (comprising Duke Activity Status Index; GP Physical Activity Questionnaire; Leisure Time Exercise Questionnaire; Stage of Change Questionnaire; Self Efficacy Questionnaire). Measured at baseline, 6 weeks, 12 weeks, 18 weeks
13. Fatigue: FACIT-Fatigue Questionniare & Visual Analogue Scale. Measured at baseline, 6 weeks, 12 weeks, 18 weeks
14. Appetite: Visual Analogue Scale. Measured at baseline, 6 weeks, 12 weeks, 18 weeks

Overall study start date
02/12/2013

Completion date
01/12/2018

Eligibility

Key inclusion criteria
1. Male and female aged between 18 and 100 years
2. Established Chronic kidney disease (Stages 3b-5)
3. Attending Nephrology outpatient clinics in the Leicester region

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
54

Total final enrolment
41

Key exclusion criteria
1. Age <18 years
2. Unfit for the exercise programme due to physical impairment and significant co-morbidity (unstable hypertension, potentially lethal arrhythmia, myocardial infarction within previous 6 months, unstable angina, active liver disease, uncontrolled diabetes mellitus (HbA1c >9%), advanced cerebral or peripheral vascular disease)
3. Insufficient command of English to give informed consent or comply with the testing and training protocol. If the results indicate that the intervention is useful, future larger studies will include provision for those whose first language is not English.
4. BMI> 40 with waist circumference >102cm for males and >88 for females. Two measures of obesity have been included here to allow for the inclusion of individuals with a high BMI due to a larger muscle mass, as BMI is unable to discriminate between fat mass and fat free mass.

Date of first enrolment
02/12/2013

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University Hospitals of Leicester (UK)

Sponsor details
UHL Trust HQ
Gwendolen House
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
Leicester-Loughborough Nutrition, Diet and Lifestyle Biomedical Research Unit (National Institute of Health Research) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	secondary analysis	01/02/2019	08/05/2019	Yes	No
Other publications	secondary analysis	01/08/2019	08/05/2019	Yes	No
Results article	results	01/06/2018	08/05/2019	Yes	No
Basic results			09/08/2019	No	No
HRA research summary			28/06/2023	No	No