

# Motivation after eXercise in Chronic Kidney Disease

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 03/07/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 05/09/2018	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Kidney disease is a long-term condition where the kidneys are no longer able to work properly. It is increasingly common, affecting around 8% of the population. Symptoms include muscle weakness and extreme tiredness and sufferers can be more at risk of developing heart disease. Research has shown that exercise can benefit many of these complications linked to chronic kidney disease but kidney patients tend to lead very inactive lifestyles. People with other chronic conditions have found supervised exercise class programmes beneficial; however without further support after completing these programmes, many return to a more inactive lifestyle. A motivational session with support telephone calls may help patients to feel more confident and to develop the skills they need to continue exercising at home or in the community.

### Who can participate?

Adults aged 18 and over with a chronic kidney disease and living in the Leicestershire area who have recently completed the Exercise Training in Chronic Kidney Disease Study (ExTra CKD).

### What does the study involve?

Participants are randomly allocated to one of two groups, a motivational group or a normal care group. All patients from both groups undergo tests to measure their fitness and current health including walking tests, sit to stand tests, a heart function test, ultra sound scans of the leg muscle, a blood test and some questionnaires. Participants will also be asked to wear a small wrist device for one week at a time to measure their level of physical activity. In addition, the motivational group have a face to face session to help them set exercise goals and feel more confident and motivated to exercise away from the hospital. These patients will also receive telephone counselling calls in the weeks after completing the exercise programme to see how they are getting on. The results will tell us if a motivational intervention can help patients to maintain their health and fitness levels that they developed in the exercise classes even when this programme comes to an end. This type of study has not been done with CKD patients who are not receiving dialysis in the UK, so we are keen to understand in more depth their thoughts and attitudes towards the exercise classes and the motivational session therefore we will be conducting interviews with some of the patient.

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 become more confident and develop the skills required to continue exercising after taking part in the exercise classes. Ultimately, taking part in the study will help to provide better care for kidney patients in the future by making sure that patients get the correct support after taking part in any exercise rehabilitation programme. 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 but all exercise assessments 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.

Where is the study run from?

The study will be run at Leicester General Hospital, UK. 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?

June 2014 to May 2019

Who is funding the study?

Leicester Kidney Care Appeal (UK)

Who is the main contact for the study?

Dr Alice Smith

Aa50@le.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Alice Smith

### Contact details

UoL Academic Unit

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## **Secondary identifying numbers**

Protocol Version 1 (3rd February 2014)

# **Study information**

## **Scientific Title**

Motivation after Exercise in Chronic Kidney Disease: randomised feasibility study

## **Acronym**

MaX CKD

## **Study objectives**

This study is designed to follow on directly from a 12 week course of thrice-weekly supervised exercise classes based largely on cardiac rehabilitation. The sustainability of healthier lifestyle behaviours after the rehabilitation period ends is often poor and patients may not develop the required confidence and skills needed to continue exercising either at home or in the community.

We hypothesise that continued support via a motivational intervention after the rehabilitation programme will enhance self-confidence and self-management skills, helping patients to sustain their exercise behaviours more so than in control group who will receive no intervention.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

NRES Committee East Midlands Leicester, 24/04/201, ref. 14/EM/0135

## **Study design**

Randomised feasibility study

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Quality of life

## **Participant information sheet**

Not available in web format, please contact Dr Alice Smith, aa50@le.ac.uk for a patient information sheet

## **Health condition(s) or problem(s) studied**

Chronic Kidney Disease

## **Interventions**

Participants will be randomised to normal clinical care or a motivational intervention. The motivational intervention will be a face to face session lasting approximately 45 minutes. The session will utilise a number of behavioural change techniques such as motivational interviewing, goal setting and self-monitoring. These patients will be followed up with supportive telephone calls at 2, 4 and 9 weeks and will have an approximately 10 minute face to face trouble shoot meeting at 6 weeks.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Endurance Shuttle Walk Test (ESWT) a measure of physical capacity or endurance fitness. This will be measured at 6 and 12 weeks.

### **Secondary outcome measures**

1. Quadriceps muscle size: 3D Ultrasonography. Measured at 6 weeks and 12 weeks
2. Physical function: Incremental shuttle walk test; sit to stand tests. Measured at 6 weeks and 12 weeks.
3. Daily physical activity: 7 day accelerometry. Measured at 5 weeks and 11 weeks
4. Body composition: Weight, height, waist circumference. Measured at 6 weeks and 12 weeks
5. Arterial stiffness: Pulse wave velocity. Measured at baseline, 6 weeks and 12 weeks
6. Clinical parameters: Extracted from medical records. Measured at 6 weeks and 12 weeks
7. Plasma markers of inflammation and oxidative stress, venous blood sample. Measured at 6 weeks and 12 weeks
8. Quality of Life: SF36 and EQ5D questionnaires. Measured at 6 weeks and 12 weeks
9. Symptom perception: Chronic Kidney Disease Symptom Score. Measured at 6 weeks and 12 weeks
10. 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 6 weeks, and 12 weeks
11. Fatigue: FACIT-Fatigue Questionnaire & Visual Analogue Scale. Measured at baseline, 6 weeks, and 12 weeks
12. Appetite: Visual Analogue Scale. Measured at baseline, 6 weeks, 12 weeks, 18 weeks
13. Health care usage: measured weekly
14. Self-reported physical activity and intensity: measured daily
15. Patient satisfaction of intervention: measured at 12 weeks.
16. Patient experiences of exercise intervention: explored during first 6 weeks
17. Patient experiences of motivational intervention: explored at 12 weeks.

### **Overall study start date**

25/06/2014

### **Completion date**

31/05/2019

## **Eligibility**

**Key inclusion criteria**

1. Established chronic kidney disease (Stages 3b-5)
2. Completed the ExTra CKD study protocol

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

30

**Key exclusion criteria**

1. Age <18 years
2. Unfit for exercise due to physical impairment or 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.

**Date of first enrolment**

25/06/2014

**Date of final enrolment**

16/08/2017

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

UoL Academic Unit

Leicester

United Kingdom

LE5 4PW

**Sponsor information**

## Organisation

University Hospitals Leicester (UK)

## Sponsor details

Research and Development Office  
Leicester General Hospital  
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-  
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## Sponsor type

Hospital/treatment centre

## ROR

<https://ror.org/02fha3693>

## Funder(s)

### Funder type

Charity

### Funder Name

Leicester Kidney Care Appeal (UK) - partially funded

## 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No

