

# Self-Management Programme for Improving Health through Physical Activity in Chronic Kidney Disease

<b>Submission date</b> 08/12/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/01/2015	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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-management manual, which includes education, goal setting and problem solving, and a motivational counselling session has helped people to start exercising regularly. This approach helped people to gain the necessary knowledge and confidence to take up exercise and overcome their fears or problems in order for them to keep exercising. We want to develop a similar self-management treatment (or intervention) for kidney patients. We have already designed a first draft version of a manual for kidney patients, but we want to know what kidney patients think about it and hear their suggestions for improvements. We will hold focus groups to discuss the manual and the way we propose to use it. We will then make any changes and hold a further focus group to discuss the updated version.

### Who can participate?

Any adults who attend the general nephrology or predialysis clinics at Leicester General Hospital and have no language barriers that would restrict participation in a focus group/interview.

### What does the study involve?

Participants are asked to attend either a focus group with other kidney patients, or a semi-structured interview, at a mutually agreed date and time. This is based on each participant's preference and availability. The focus group includes about 4-8 kidney patients. In the focus group, the manual and how we intend to use to help kidney patients to become more active is discussed. We send the manual to participants to look at in advance of the meeting, with some information about how we think we might use it. We would like to hear participants' views on:

1. The content and layout of the manual
2. Whether you think it would help you or other people
3. Any ways you think we could improve it

4. How we might present it to patients
5. How they might use it
6. What other support might be helpful as well
7. What progress tests or assessments we might do to monitor the effectiveness of the intervention

The focus group is held in a comfortable, private room and takes about 60 to 90 minutes. The discussion is led by two researchers who have no involvement with the clinical care team, and the discussions are only heard by the research team. Participants are only asked to talk about the manual and its use, exercise in general, and related issues. The interviews are held in a comfortable, private room and will take about 45 to 60 minutes. The discussion will be led by two researchers who have no involvement with the clinical care team, and the discussions will only be heard by the research team. Participants will only be asked to talk about the manual and its use, exercise in general, and related issues, using a semi-structured approach and a topic guide. Participants are sent some material to read before the focus group/interview to allow them time to read and think about the content so that they do not feel any pressure to read or comment on information they have never seen before.

What are the possible benefits and risks of participating?

There are no direct benefits for the participant of taking part in this research. We hope that the results of the study will help us develop a self-management intervention that in the future will help 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 attend for the focus group/interview and read the material they have been sent before the meeting. This will take up a few hours of their own time. We will reimburse any travel expenses incurred in taking part in this research study.

Where is the study run from?

Leicester General Hospital (UK)

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

December 2014 to November 2017

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

**ORCID ID**

<http://orcid.org/0000-0002-3530-0471>

**Contact details**

Leicester Kidney Exercise Team  
Academic Unit  
Leicester General Hospital  
Leicester  
Leicester  
United Kingdom  
LE5 4PW

## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

SPARK 1 Protocol version 2 19th November 2014

## **Study information**

**Scientific Title**

Development of a self-directed intervention to facilitate participation in physical activity in people with CKD not requiring Renal-Replacement Therapy: a qualitative study

**Acronym**

SPARK 1

**Study objectives**

This project aims to investigate patient engagement, recruitment and retention in a self-directed exercise programme.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES committee West Midlands - Solihull, 21/10/2014, ref. 14/WM/1187

**Study design**

This research project aims to create, using both expert opinion and patient focus groups /interview, a self-directed exercise intervention for people with chronic kidney disease. It will be a single-centre project.

**Primary study design**

Interventional

**Secondary study design**

**Study setting(s)**

Hospital

**Study type(s)**

Quality of life

**Participant information sheet**

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

Chronic Kidney Disease

**Interventions**

The project aims to develop a self-management intervention to facilitate people to increase their activity levels. To achieve this aim the trial will hold both expert panel meetings and patient focus groups/interviews to derive an educational manual and a self-directed walking programme.

**Intervention Type**

Behavioural

**Primary outcome measure**

The primary output of the study will be a self-management interventions that can be taken forward for testing in a randomised controlled trial.

**Secondary outcome measures**

Qualitative data regarding patient perspective on suitability of intervention for use.

**Overall study start date**

01/12/2014

**Completion date**

30/11/2017

## **Eligibility**

**Key inclusion criteria**

1. Attending nephrology clinic
2. CKD stage 3-4
3. >18 years of age
4. Able to read and understand written and spoken English to a standard where the participant is able to engage in the patient focus group/interview and read supplied material

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

10-15

**Key exclusion criteria**

1. Any form of language barrier that would prevent the participant engaging effectively in a focus group or reading the provided preparatory material

**Date of first enrolment**

06/01/2015

**Date of final enrolment**

31/12/2015

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

United Kingdom

**Study participating centre**

**Leicester General Hospital**

Leicester Kidney Exercise Team

Academic Unit

Leicester

United Kingdom

**Sponsor information****Organisation**

University of Hospitals Leicester NHS Trust

**Sponsor details**

Leicester General Hospital

Gwendolen Road

Leicester

England

United Kingdom

LE5 4PW

**Sponsor type**

Hospital/treatment centre

**Website**

www.leicesterhospitals.nhs.uk

ROR

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

## Funder(s)

### Funder type

Not defined

### 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

It is intended that publications would be submitted to appropriate nephrology, exercise and behaviour change journals and abstracts submitted at appropriate conferences, but this will 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No