

# Online education self-management programme in people with kidney disease

<b>Submission date</b> 15/12/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/12/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/11/2024	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

## Plain English Summary

### Background and study aims

People living with kidney problems (or chronic kidney disease [CKD]) need to look after their own health until they reach the need for dialysis or a kidney transplant, which most patients will never require. Having a healthy lifestyle can help people with CKD live a good quality of life and potentially slow disease progression. However, many people with CKD do not know about their condition, its treatment, or how to look after their health. To manage health effectively, patients need to have the knowledge, confidence and skills to take on this role. This is called 'patient activation'. The researchers have developed an online educational programme aiming to improve CKD patients' knowledge, confidence and skills to look after their own health. The aim of this study is to find out whether this will increase patient activation.

### Who can participate?

Patients aged 18 or older with diagnosed kidney disease who have not had a transplant or who need dialysis treatment. Participants will be invited from different sites around England.

### What does the study involve?

Part A is the main trial, where patients will be randomly allocated into either a group receiving access to the programme, or a control group who will not receive the programme until the end. The main aim is to measure the effect of the programme on patient activation. The researchers will also assess how many people are recruited if patients follow the programme as intended, how many people in both groups drop out, if people fill in the questionnaires as intended, and safety. This part of the study is run online.

Part B is split into two smaller studies; each includes a small sample of those taking part in Part A. Part B1 is a visit to the hospital to assess the participant's physical abilities before and after the programme. Part B2 is an interview (either in person or over the phone) with a researcher, firstly to explore patient thoughts of the programme and how they found taking part.

### What are the possible benefits and risks of participating?

There are no direct benefits of taking part in the study, although it is hoped that the programme will improve participants' knowledge, confidence and skills in managing their own health. There are no risks to taking part. Part A is online, and participants can engage with the programme as they want. Part B involves some simple tests of physical function.

Where is the study run from?  
University Hospitals of Leicester (UK)

When is the study starting and how long is it expected to run for?  
November 2020 to December 2022

Who is funding the study?  
Leicester Biomedical Research Centre (UK)

Who is the main contact?  
Prof. Alice Smith  
aa50@le.ac.uk

**Study website**  
<http://www.leicesterkidneylifestyle.team>

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Alice Smith

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**  
282573

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
IRAS 282573, CPMS 47222

## Study information

**Scientific Title**

Self-Management Intervention through Lifestyle Education for Kidney health

**Acronym**

SMILE-K

**Study hypothesis**

It is hypothesised that a structured online self-management programme - 'My Kidneys & Me' - will increase patient activation levels.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

1. Approved 13/11/2020, East Midlands – Leicester South Research Ethics Committee (Marriott Road, Leicester, LE2 6NT, UK; +44 (0)207 104 8193; Leicestersouth.rec@hra.nhs.uk), ref: 20/EM/0252
2. Approved 19/11/2020, East Midlands - Leicester South Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 1048310; leicestersouth.rec@hra.nhs.uk), ref: 17/EM/0357

**Study design**

Single-blind longitudinal randomized control trial with nested feasibility study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Internet/virtual

**Study type(s)**

Quality of life

**Participant information sheet**

A public available information sheet can be found here: <https://www.leicesterkidneylifestyle.team/study-documents>

**Condition**

Chronic kidney disease

**Interventions**

Patients will be randomised 2:1 into either an intervention group or usual care (control) group. The intervention group will have access to 'My Kidneys & Me' – an online self-management educational programme aimed to increase patient activation and self-management behaviours. The programme consists of educational sessions released weekly for 10-weeks as well as tools

to track physical activity, symptoms, and diet. The usual care group will not have access to the programme, although they will be offered access for 2 years once they have finished in the study. Outcomes will be assessed at baseline, week 10, and week 20.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Patient activation assessed using the Patient Activation Measure (PAM-13) at baseline, week 10, and week 20

## **Secondary outcome measures**

Measured at baseline, week 10, and week 20:

### **Part A:**

1. Disease knowledge measured using the Chronic Kidney Disease Self-Management Knowledge Tool (CKD-SMKT)
2. Quality of life measured using the 12-Item Short-Form Health Survey (SF-12)
3. Symptoms measured using the Kidney Symptom Questionnaire (KSQ)
4. Sarcopenia measured using the SARC-F questionnaire
5. Illness perceptions measured using the Illness Representations Questionnaire (Brief) (IPQ-R)
6. Physical activity measured using the General Practice Physical Activity Questionnaire (GPPAQ)
7. Diet measured using the UK Diabetes and Diet Questionnaire (UKDDQ)
8. Medication adherence measured using the Medication Adherence Report Scale (MARS-5)
9. Healthcare usage measured using the Modified Economic Patient Questionnaire (EPQ)

### **Part B**

1. Anthropometry measured using height, weight, hip and waist circumference
2. Muscle phenotyping using B-mode ultrasonography and myotonometry
3. Gait speed measured using a 4m gait speed test
4. Handgrip strength (HGS) measured using a handheld dynamometer
5. Physical function measured using sit-to-stand-60 test
6. Physical function measured using timed-up-and-go test (TUAG)
7. Physical activity measured using accelerometry

### **Part B2:**

Self-management knowledge, skills, confidence and behaviours, and attitudes towards lifestyle self-management, assessed using semi-structured interviews

## **Overall study start date**

01/11/2020

## **Overall study end date**

31/12/2022

# **Eligibility**

## **Participant inclusion criteria**

1. Individuals aged 18 years or older
2. Established CKD stage 3-4 (eGFR of 15-59 ml/min/1.73m<sup>2</sup>) according to the NICE guidelines

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

432

**Total final enrolment**

465

**Participant exclusion criteria**

Those requiring any form of renal replacement therapy (i.e. any modality of dialysis, or transplantation) or with insufficient command of English or any other precluding factors that prevent ability to give informed consent or comply with protocol

**Recruitment start date**

01/02/2021

**Recruitment end date**

01/02/2022

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

England

United Kingdom

**Study participating centre**

**University Hospitals of Leicester**

Leicester General Hospital

Leicester

United Kingdom

LE4 5PW

**Sponsor information**

**Organisation**

University of Leicester

**Sponsor details**

Leicester General Hospital  
Leicester  
England  
United Kingdom  
LE4 5PW  
+44 (0)116 258 4867  
rgosponsor@leicester.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.le.ac.uk/>

**ROR**

<https://ror.org/04h699437>

**Funder(s)****Funder type**

Research organisation

**Funder Name**

Leicester Biomedical Research Centre

**Results and Publications****Publication and dissemination plan**

1. The protocol will be submitted in January 2021 to a peer-reviewed journal and a link will be made available then.
2. The results are expected to be published in scientific journals and presented at clinical research conferences.

**Intention to publish date**

31/10/2024

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from the research team (Prof. Alice Smith, [aa50@le.ac.uk](mailto:aa50@le.ac.uk)). The type of anonymous data requested will be considered on a case-by-case basis. The researchers expect data to be available in 2023.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	internal pilot results assessing feasibility and acceptability against pre-specified progression criteria	16/11/2022	18/11/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other publications</a>		31/01/2024	06/02/2024	Yes	No
<a href="#">Results article</a>		12/11/2024	15/11/2024	Yes	No