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Online education self-management programme in people with kidney disease

Submission date 15/12/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 18/12/2020	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 15/11/2024	**Condition category** Urological and Genital Diseases	[_] Individual participant data

Plain English summary of protocol

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
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Contact information

Type(s)
Scientific

Contact name
Prof Alice Smith

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
282573

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 282573, CPMS 47222

Study information

Scientific Title
Self-Management Intervention through Lifestyle Education for Kidney health

Acronym
SMILE-K

Study objectives
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

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
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(s)
Patient activation assessed using the Patient Activation Measure (PAM-13) at baseline, week 10, and week 20

Key secondary outcome(s))
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 accelerometery

Part B2:
Self-management knowledge, skills, confidence and behaviours, and attitudes towards lifestyle self-management, assessed using semi-structured interviews

Completion date
31/12/2022

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
465

Key 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

Date of first enrolment
01/02/2021

Date of final enrolment
01/02/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Leicester
Leicester General Hospital
Leicester
United Kingdom
LE4 5PW

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Research organisation

Funder Name
Leicester Biomedical Research Centre

Results and Publications

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). 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?
Results article		12/11/2024	15/11/2024	Yes	No
Protocol article		16/11/2022	18/11/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	internal pilot results assessing feasibility and acceptability against pre-specified progression criteria	31/01/2024	06/02/2024	Yes	No
Other publications		14/05/2025	04/02/2026	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes