

BMJ Open 'Self-Management Intervention through Lifestyle Education for Kidney health' (the SMILE-K study): protocol for a single-blind longitudinal randomised controlled trial with nested pilot study

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ABSTRACT

Introduction Many people living with chronic kidney disease (CKD) are expected to self-manage their condition. Patient activation is the term given to describe the knowledge, skills and confidence a person has in managing their own health and is closely related to the engagement in preventive health behaviours. Self-management interventions have the potential to improve remote disease management and health outcomes. We are testing an evidence-based and theory-based digital self-management structured 10-week programme developed for people with CKD called 'My Kidneys & Me'. The primary aim of the study (Self-Management Intervention through Lifestyle Education for Kidney health (SMILE-K)) is to assess the effect on patient activation levels.

Methods and analysis A single-blind randomised controlled trial (RCT) with a nested pilot study will assess the feasibility of the intervention and study design before continuation to a full RCT. Individuals aged 18 years or older, with established CKD stage 3–4 (eGFR of 15–59 mL/min/1.73 m²) will be recruited through both primary and secondary care pathways. Participants will be randomised into two groups: intervention group (receive My Kidneys & Me in addition to usual care) and control group (usual care). The primary outcome of the nested pilot study is feasibility and the primary outcome of the full RCT is the Patient Activation Measure (PAM-13). The full RCT will assess the effect of the programme on online self-reported outcomes which will be assessed at baseline, after 10 weeks, and then after 20 weeks in both groups. A total sample size of N=432 participants are required based on a 2:1 randomisation. A substudy will measure physiological changes (eg, muscle mass, physical function) and patient experience (qualitative semi-structured interviews).

Ethics and dissemination This study was fully approved by the Research Ethics Committee-Leicester South on the 19 November 2020 (reference: 17/EM/0357). All participants are required to provide informed consent obtained online. The results are expected to be published in scientific journals and presented at clinical research conferences. This is protocol version 1.0 dated 27 January 2021.

Trial registration number ISRCTN18314195.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study will be conducted as a large randomised controlled trial (RCT) and will assess the effect of an online self-management and lifestyle education programme ('My Kidneys & Me') on patient activation levels and subsequent self-management behaviours in people with kidney disease.
- ⇒ The secondary outcomes of the study will assess the feasibility of using such an intervention in this population and explore patient experience of the programme itself.
- ⇒ The nested pilot study will assess the feasibility of the intervention and study design before continuation to a full RCT; progression criteria will be developed with specified targets for progression based on feasibility outcomes.
- ⇒ The use of patient and public involvement in the intervention development and study design will ensure that they are acceptable, suitable and relevant to the target population.
- ⇒ The primary limitation of this study is the potential lack of acceptability of randomisation and assessment.

INTRODUCTION

Chronic kidney disease (CKD) is a long-term condition associated with high morbidity and premature mortality,¹ and has an estimated UK prevalence of ~5%–7%.² In UK, 70% of National Health Service (NHS) expenditure is spent on patients with long-term conditions such as CKD.³ With <1% of time spent in contact with healthcare professionals, many patients are expected to self-manage their condition.³ In CKD, the majority of people are managed in primary care rather than by kidney specialists.⁴ Long-term CKD management requires a high level of patient engagement, both in decision-making and in the implementation of care.⁵ For those with



CKD, this encompasses a spectrum of behaviours ranging from adherence to medication and diet recommendations, maintaining physical activity, recognition and monitoring of risk factors (eg, blood glucose and blood pressure) and self-adjustment of home-care routines.⁶ Self-management interventions aim to facilitate an individual's ability to make appropriate lifestyle changes⁷ and have shown beneficial impacts on various modifiable risk factors relevant to the progression of CKD (eg, proteinuria, blood pressure, exercise capacity).^{7,8} The COVID-19 global pandemic has presented unique challenges for people living with CKD and has further highlighted the need for and importance of self-management.

In order to implement self-management behaviours and participate in healthcare decisions, patients must have knowledge of their condition, and patient education is a crucial pathway to ensuring that individuals can be taught to engage in self-management tasks.⁶ Empirical studies have shown that patient education, including an understanding of CKD, is associated with better outcomes.⁶ Patient activation is the term given to describe the knowledge, skills and confidence a person has in managing their own health⁹ and is closely related to the engagement of preventive health behaviours.⁵ Studies have indicated that activated patients are more likely to attend screenings, check-ups and immunisations, as well as engage in healthy behaviours such as eating a balanced diet.^{10,11} Increased patient activation is associated with improved health outcomes in many long-term conditions.^{12,13} In CKD, lower patient activation is associated with worse cardiovascular disease risk profiles¹⁴ and promoting patient activation in kidney disease care is increasingly being prioritised and has recently emerged as central to legislative policy in the USA¹⁵ and UK.¹⁶ In the UK, National Institute for Health and Care Excellence (NICE) clinical guidance recommends that informational and educational programmes are offered to those with CKD, including information regarding what people can do to manage and influence their own condition. Interventions to increase patient activation are likely to improve self-management behaviour, and consequently this may be a suitable outcome for self-management-based interventions.

A range of barriers have prevented widespread implementation of comprehensive education for people with CKD and a recent systematic review of self-management interventions in CKD found many interventions lack patient engagement in their design, and the majority of interventions do not apply behavioural change theory to inform their development.⁸ As such there remains a need for better and innovative self-management interventions for those with CKD.^{4,8} Digital self-management interventions have the potential to improve remote disease management and health outcomes¹⁷ and are increasingly becoming integrated into self-management to improve behaviour. The COVID-19 pandemic has also presented those with long-term conditions and their healthcare teams an opportunity to innovate and move towards an

increasingly digitalised care, with particular emphasis on supporting patients from their own homes.

Developed in the UK, the structured DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed) diabetes self-management group education programme has recently been shown to improve patient activation in individuals living with diabetes.¹⁸ Based on the same principles, MyDESMOND is a global digital programme to provide ongoing support and guidance.^{19,20} Using the MyDESMOND platform, we developed an evidence-based and theory-based digital self-management programme for patients with CKD called 'My Kidneys & Me'. The programme was developed in conjunction with patients and their families, key stakeholders and a wide range of healthcare professionals including nephrologists, psychologists, physiotherapists, dieticians, exercise scientists and pharmacists. The programme was developed using 'Intervention Mapping', a six-step framework used to guide behaviour change interventions and health education development.²¹ A full and detailed description of the development of 'My Kidneys & Me' can be found in Lightfoot.²²

Objectives and hypotheses

The primary aim of the proposed 'SMILE-K' research study is to assess the effect of a structured online self-management programme—'My Kidneys & Me'—on patient activation levels and subsequent self-management behaviour. Further objectives include assessing the feasibility of using such an intervention in this population and exploring patient experience of the programme itself. We hypothesise that access to 'My Kidneys & Me' will increase patient activation, compared with usual care, in people living with CKD.

METHODS AND ANALYSIS

This protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting recommendations²³ (online supplemental material S1).

Study design overview

A single-blind randomised controlled trial (RCT) with a nested pilot study will be used to assess the effect of the 'My Kidneys & Me' programme. An initial nested pilot study will assess the feasibility of the intervention and study design before continuation to a full RCT is considered. Continuation to the full RCT will be based on a predefined 'stop/go' criteria assessed after n=60 participants have been recruited. The study intervention period will last 20 weeks with outcome measures assessed at baseline (preintervention), week 10 (postintervention) and week 20 (follow-up). A flow diagram showing the participant flow through the study can be found in [figure 1](#).

An optional substudy will occur in parallel with the main study. This will consist of additional objective assessments of body composition, physical activity and physical

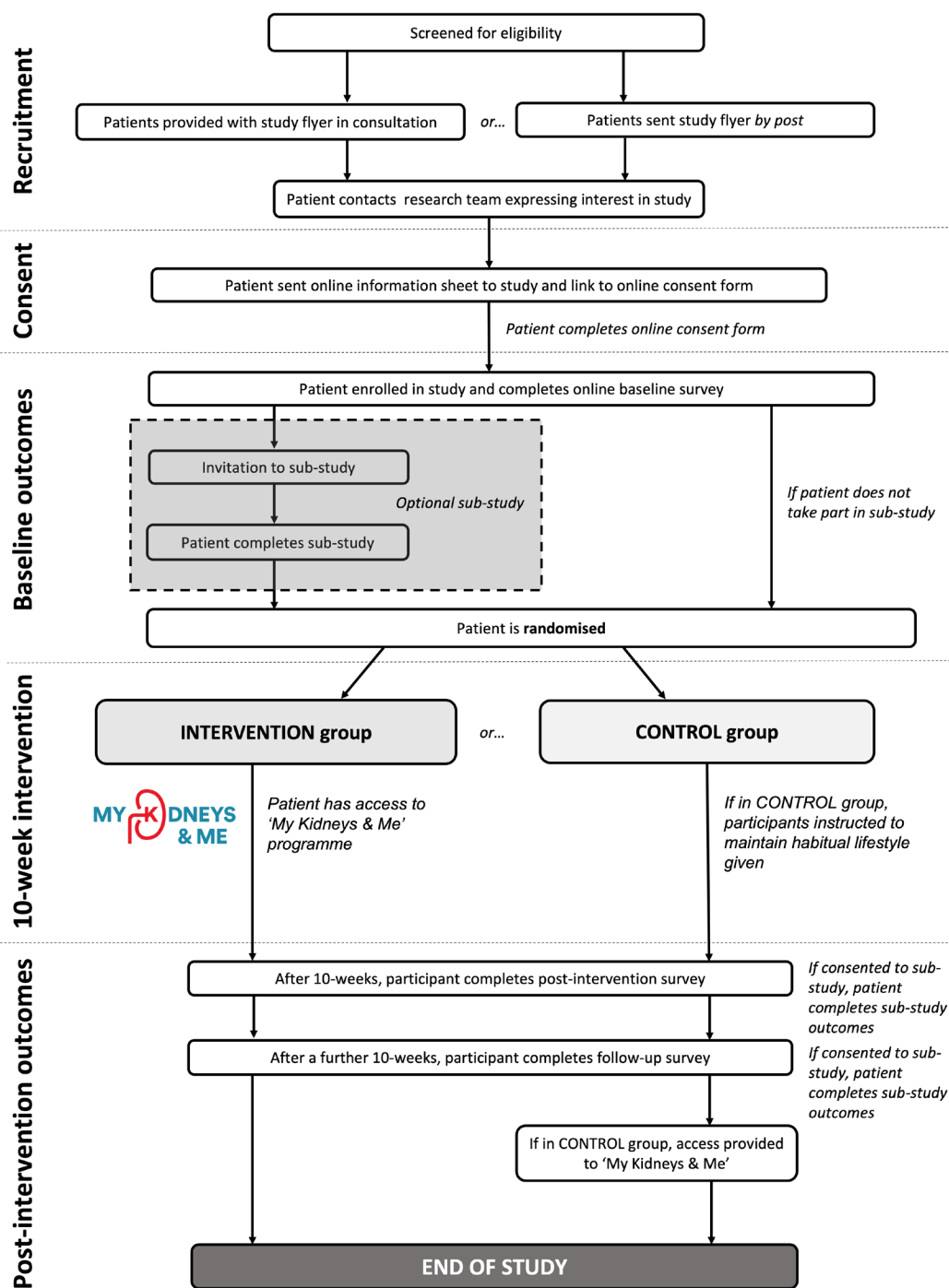


Figure 1 Study flow diagram.

function to the main study outcome protocol, as well as qualitative interviews with participants to discuss their expectations and experiences of the intervention and study protocol.

Eligibility criteria

Individuals aged 18 years or older, with established CKD stage 3–4 (eGFR of 15–59 mL/min/1.73 m²) according to the NICE guidelines will be included. Those requiring any form of kidney replacement therapy (ie, 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 will be excluded. For the substudy, in addition, participants will be excluded if they are pregnant and/or if any element of protocol considered by own clinician or general practitioner (GP) is contraindicated and/or the individual is deemed unfit due to physical impairment, significant comorbidity or other reason (eg, unstable



Figure 2 'My Kidneys & Me' dashboard page.

hypertension, arrhythmia, myocardial infarction <6 months, unstable angina, uncontrolled diabetes mellitus, advanced cerebral or vascular disease).

Recruitment

Participants will be recruited through both primary and secondary care pathways across multiple sites in England. Primary care practices will identify eligible patients and provide them with an introduction flyer and study invitation letter, either during a consultation or via the post. If recruited from secondary care, the flyer will be provided during the patient's routine outpatient clinic visit by the nephrologist. Alternatively, patients may be recruited by postal means. Interested participants are requested to contact the research team by email who will then respond with further detailed information and an online consent form. When participants have consented, they are sent a link to complete the online outcome measures. In eligible patients, further information regarding the substudy is provided. Once the baseline outcome measures have been completed, participants are randomised and provided access to the programme if appropriate. Access will be a secure link that ask participants to register and create a unique username and password. Once created, patients can then access 'My Kidneys & Me' (dashboard shown in [figure 2](#)).

Randomisation

Participants will be randomised into two groups: intervention group and control group. Randomisation will be performed by the research team in a single-blind fashion. Study investigators, clinicians and research staff from external recruiting sites are blinded to the group allocation of their participants. Participants will be stratified based on age (≤ 63 , >63 years) to ensure comparatively

equal representative age characteristics in both groups. These values are based on the median age attained from preliminary unpublished data from two ongoing observational studies in non-dialysis patients with CKD by our group. The control group will not be provided with the intervention during the study and will be asked to maintain their habitual lifestyle activities. The control group will be provided with the intervention on study completion. The intervention group will be provided access to the online 'My Kidneys & Me' intervention.

Intervention

'My Kidneys & Me'

The 'My Kidneys & Me' programme forms part of the award-winning and quality-assured MyDESMOND e-learning platform.^{22 24} The educational sessions provide information about the kidneys, CKD, its treatment and the different ways to self-manage and is written to accommodate for those with low patient activation levels. A summary of the education sessions can be in the My Kidneys & Me development paper.^{22 24} 'How to' booster sessions are interactive educational sessions, which provide instructions on how to perform the self-management behaviours and are released weekly. A summary of these sessions is found in [table 1](#).

The health trackers feature allows patients to self-monitor different aspects of their health that are involved in the self-management of the condition: body weight and measurements, fruit and vegetable intake, symptoms, smoking, cholesterol and blood pressure. These allow patients to manually update their trackers and see their progress over time through graphs and charts. Similarly, the 'Activity' feature allows patients to track their physical activity, although this is broken down into different

Table 1 Summary of the ‘How to’ booster sessions

‘How to’ session	Summary of session	Duration of session (minutes)
1. Get started	This is an introduction about the ‘How to’ sessions and explains what can be expected from them. This will be available from the start.	5
2. Set my own goals	The first ‘How to’ session introduces patients to what goals are, why they are important, how to create their own personalised goals and how to use an action plan. It is recommended that patients first read the ‘Kidney disease and general health’ and ‘Reducing my health risks’ educational sessions so that they can identify which areas they may want to set their own goals in.	25–30
3. Move more and be active	This session includes how to set an activity goal, how to break up sedentary time, how to do aerobic activity and how to maintain activity levels. It is recommended that patients first read the ‘Moving more and being active’ educational session.	15–20
4. How to keep my muscles healthy through strength training	This ‘How to’ session provides instruction on how to safely take part in strength training exercises and how this could help them. It is recommended that patients first read the ‘Keeping my muscles healthy’ educational session.	15–20
5. Take control of my health	This session looks at taking medications and managing other conditions such as diabetes and hypertension. It is recommended that patients first read ‘Kidney disease and general health’ and ‘Reducing my health risks’ educational sessions.	15–20
6. Get the most from my healthcare	This session covers information about why attending healthcare appointments is important, how to make the most out of appointments and how to decide which healthcare professional they may want to talk to for different areas so that they can share treatment decisions. It is recommended that patients first read ‘Treatment options available’ which includes information about their healthcare team and what appointments are for.	15–20
7. Eat well	This session covers how to make healthier food choices and adapt recipes. It is recommended that patients first read the ‘Eating a healthy balanced diet’ educational sessions.	20–25
8. Manage my symptoms	This session includes how to recognise and keep track of symptoms so that they can modify their lifestyle accordingly and speak to their healthcare professional if needed. It is recommended that patients first read ‘Reducing my health risks’ and ‘Managing my symptoms’ educational sessions as this explains the common symptoms of CKD.	10–15
9. Improve my sleep quality	The penultimate session covers how to set sleep goals, improve sleep quality and monitor sleep. It is recommended that patients first read ‘Improving my sleep quality’ educational session.	10–15
10. Look after my well-being	The final session focuses on how to balance daily life with CKD and how to manage illness-related stress. This also includes the importance of social support and how to talk to others. It is recommended that patients first read the ‘Looking after my well-being’ educational sessions.	15–20

CKD, chronic kidney disease.

forms of activity. Patients can track how many steps they have walked and for how many minutes and can challenge others or invite up to five of their own friends and family to join these challenges. The patients can track this by either synchronising the programme with their activity tracker (eg, Fitbit) or they can enter their steps manually. They can also use a bespoke tracker created for ‘My Kidneys & Me’ to record their strength training progress and resources (eg, instructional videos) will be available online. The ‘Decision maker’ feature is a tool to help patients create and monitor their own health-related goals, as this works through a series of questions to help patients identify which goals are most important to them and how they can achieve these by overcoming identified barriers.

Outcome measures

The primary outcome of the nested pilot study is feasibility, and the primary outcome of the full RCT is the Patient Activation Measure (PAM-13).

Nested feasibility outcomes

Before progression to the full RCT, we will assess feasibility outcomes on the first n=60 participants recruited. Based on these outcomes, a decision will be made to continue with the trial based on prespecified progression criteria. These progression criteria will be developed with input from stakeholders in the study, researchers and patients. The following feasibility outcomes will be assessed:

1. *Recruitment rate*: the number of eligible patients and number consented will be recorded. Monthly

recruitment rate and the time taken to recruit 25%, 50%, 75%, and 100% patients will be recorded.

2. *Acceptability of randomisation and assessment procedure:* acceptability of randomisation (and stratification variables) and procedures will be determined by comparison of randomised group characteristics, and by measuring loss to follow-up and by exploring patient' views about their participation in the research.
3. *Programme usage and adherence to intervention:* adherence will be assessed by the completion of sessions, and the use of the goal setting and health tracking features. We will also assess patterns and frequency of programme usage.
4. *Attrition rate:* the number of dropouts (attrition rate) will be recorded.
5. *Missing data:* quantity of missing data (eg, questionnaire return rate, outcome measures not completed)
6. *Patient experience:* this will be attained through qualitative interviews in a subset of patients.

Primary study outcome

The primary outcome of the full RCT is the PAM-13, the most widely used instrument for measuring patient

activation⁹ which was piloted in the NHS through the UK Renal Registry, and has been validated²⁵ and recommend for use in those with kidney disease.^{15 25} The PAM-13 is a validated tool of 13 questions which assesses a patient's knowledge, skills and confidence in managing their own health. The PAM-13 has demonstrated good internal consistency as well as adequate reliability and validity,^{9 26} including in those with kidney disease.²⁵ Answers are weighted and combined to provide a score on a scale from 0 to 100. The PAM allows respondents to be categorised into one of four levels with lower levels indicating low activation and higher levels indicating high activation. The PAM-13 will be assessed among a battery survey of other questionnaires that will be delivered online using Jisc Online Surveys (University of Leicester). As per SPIRIT recommendations, the timepoints for each outcome can be found in [table 2](#).

Secondary outcomes

Alongside a bespoke self-reported demographic questionnaire, other validated questionnaires in the online survey, which capture different aspects of self-management and lifestyle behaviours that are addressed in 'My Kidneys & Me', include:

Table 2 Outcome measure timepoints

Item	Scale/test	Baseline	Week 10	Week 20
Main study*				
Demographics	–	X	–	–
Patient activation	PAM-13	X	X	X
Knowledge	CKD-SMKT	X	X	X
Health status	SF-12	X	X	X
Symptoms	KSQ	X	X	X
Sarcopenia	SARC-F	X	X	X
Illness perception	IPQ-R	X	X	X
Physical activity	GPPAQ	X	X	X
Diet	UKDDQ	X	X	X
Medication adherence	MARS-5	X	X	X
Healthcare use	EPQ	X	X	X
Physical function	STS-60	X	X	X
Clinical data	Full blood count, U&Es	X	X	X
Substudy†				
Anthropometry	Height, weight, BMI, waist and hip circumference	X	X	X
Muscle phenotyping	BIA, ultrasonography	X	X	X
Physical function	Gait speed, HGS, STS-60, TUAG	X	X	X
Physical activity	Accelerometry (7 days)	X	X	X
Qualitative component	Semistructured interview	X	X	X

*Main study outcomes delivered online to all patients.

†Substudy outcomes assessed in a subset of patients. Qualitative interviews may be performed at any of the timepoints depending on participants' voluntary participation and/or their status in the study.

BIA, bioelectrical impedance analysis; BMI, body mass index; CKD-SMKT, Chronic Kidney Disease Self-Management Knowledge Tool; EPQ, Modified Economic Patient Questionnaire; GPPAQ, General Practice Physical Activity Questionnaire; HGS, handgrip strength; IPQ-R, Illness Representations Questionnaire (Brief); KSQ, Kidney Symptom Questionnaire; MARS-5, Medication Adherence Report Scale; PAM-13, Patient Activation Measure; SF-12, 12 Item Short Form Health Survey; STS-60, Sit-to-stand-60; TUAG, Timed-up-and-go' test; U&Es, Urea and electrolytes; UKDDQ, UK Diabetes and Diet Questionnaire.

1. *Chronic Kidney Disease Self-Management Knowledge Tool (CKD-SMKT)*: The CKD-SMKT is a validated 11-item questionnaire, which assesses kidney disease patients' knowledge of various key self-management behaviours and kidney health.²⁷
2. *12-Item Short Form Health Survey (SF-12)*: the SF-12 is a multipurpose short form survey with 12 questions. The SF-12 assesses patients mental and physical functioning and overall health-related quality of life (QoL).²⁸
3. *Kidney Symptom Questionnaire (KSQ)*: the KSQ assesses the frequency, intrusiveness and total impact of a range of 13 common kidney disease-related symptoms. This questionnaire has been validated by our group²⁹ and used widely in the literature.³⁰
4. *SARC-F questionnaire*: the SARC-F questionnaire includes five components—strength, assistance walking, rise from a chair, climb stairs and falls. SARC-F scores range from 0 to 10 and a score ≥ 4 is predictive of sarcopenia.³¹
5. *Illness Representations Questionnaire (Brief) (IPQ-R)*: the IPQ-R is a widely accepted measure of illness representations. These components are identity, cause, timeline, consequence and controllability/cure. The questionnaire consists of three parts: an identity scale, a structure scale, and a causal scale.³²
6. *General Practice Physical Activity Questionnaire (GPPAQ)*: the GPPAQ was developed by the WHO and Department of Health detailing a 4-level Physical Activity Index reflecting an individual's current physical activity. The GPPAQ is a validated measure of physical activity behaviour in CKD.³³
7. *UK Diabetes and Diet Questionnaire (UKDDQ)*: the UKDDQ is a 25-item questionnaire designed to assess diet and dietary behaviours. Respondents are asked to identify how often they consumed certain foods (vegetables, fruits, sugary drinks, processed meat) over that last month.³⁴ Responses will be scored as per previous research.³⁵ This questionnaire is sensitive to changes following an intervention.³⁶
8. *Medication Adherence Report Scale (MARS-5)*: the MARS-5 is a non-disease specific questionnaire used to measure adherence to medications and has been previously used in CKD. This comprises of five questions regarding changing medication dosage, forgetting to take medication, consciously stopping taking medication, skipping medication, and using less than prescribed.³⁷
9. *Modified Economic Patient Questionnaire (EPQ)*: we will use a modified version of the 'EPQ' to assess participants' use of inpatient and outpatient services and data on non-hospital-based health and social care use at all assessment points.³⁸

When the participant consents to the study, the researcher will access their clinical records and extract information such as blood and urine results to gather information of kidney function, proteinuria, iron status and lipid profiles. We will record prescribed medication. Self-reported comorbidities will be checked against those recorded in the medical notes.

Substudy

In an optional substudy, the following additional physical assessments will be performed during a visit to a hospital site:

1. *Anthropometry*: height, weight, body mass index and waist and hip circumference will be measured in line with established procedures. Resting heart rate and blood pressure will be assessed using a standard sphygmomanometer device.
2. *Muscle phenotyping*: muscle and fat mass/size/thickness, and body fat per cent will be measured using a free-standing bioelectrical impedance analysis (BIA) monitor and B-mode ultrasonography of the rectus femoris muscle. These are painless, non-invasive methods for measuring body composition. Our group has recently validated our BIA device against dual-energy X-ray absorptiometry,³⁹ while ultrasonography can be used to assess sarcopenia in CKD.^{40 41}
3. *Gait speed*: the participant is asked to walk a 4 m course at their 'usual' walking speed, with a walking aid if normally used.⁴²
4. *Handgrip strength (HGS)*: HGS will be assessed using a handheld dynamometer (Jamar Plus+Digital). Participants will be asked to hold the dynamometer with their shoulder at 0° flexion and elbow at 90° flexion. Participants will be asked to squeeze the dynamometer handle maximally for 3 s. The peak force output (kg) from the three attempts from both the dominant and non-dominant hand will be recorded.⁴³
5. *Sit-to-stand-60 test*: sit-to-stand (STS) tests are a good measure of functional ability and have been used extensively in patients with CKD. Our group has extensive use and knowledge of this test, and published reliability and validation data for it.⁴⁴ The patient starts from a seated position on a hard, upright chair, with the feet flat on the floor and the knees bent at 90°. For the test, the patient simply stands up fully and then sits down again to the starting position, without using the hands (one repetition). The STS-60 test involves completing as many STS cycles as possible in 60 s. Participants will also be asked to record a STS-60 score as part of the online survey. Minimal guidance via an instruction sheet will be provided for participants, but no other instructions (ie, monitoring via a video call) will be utilised.
6. *Timed-up-and-go' test (TUAG)*: the TUAG assesses mobility and requires dynamic balance. The participant will be asked to rise from a chair, walk 3 m, turn around a cone, and sit back down.⁴²
7. *Accelerometry*: to accurately measure objective physical activity, patients will wear a wrist accelerometer (GENEActiv) for a 7-day period before the intervention and post-intervention.^{33 45}

Familiarisation of objective physical performance measures will be performed before baseline assessments. In order to assess any potential differences in administering the questionnaires online, participants in the sub-study

will also be asked to complete the same questionnaires via paper format.

In the substudy, semistructured interviews will be held with a researcher trained in qualitative methodology. Individual interviews will last between ~30 and 60 min. Interviews will take place in private area. For those unable to attend a face-to-face interview, interviews may also be performed via telephone using a secure recording device as used currently in other studies by our group. Patients recruited may be interviewed on at least one occasion (eg, before and/or after the intervention). Up to three interviews will be conducted with participants depending on their voluntary participation and/or their status in the study: (1) preintervention and/or (2) postintervention (at 10 weeks) and/or (3) after the follow-up phase (at 20 weeks). Topics in this interview will include current self-management knowledge, skills, confidence and behaviours and attitudes towards lifestyle self-management. Topics of the subsequent interviews will include experiences of the intervention, the quality of the content, the quality of the delivery method, reasons for non-adherence with the intervention, and healthcare usage.

Patient and public involvement

A full description of how patients and their families were involved in the development of the programme can be found in Lightfoot.^{22 24} In summary, a study patient steering group was formed consisting of 10 individuals living with kidney disease and two family members. An initial priority setting workshop determined key topics of interest to this group, including lack of educational support from healthcare professionals. Following this, we developed an educational booklet which was code-signed using our patient steering group. This booklet was disseminated to local primary care practices where individuals provided feedback on the content. The information in this booklet was then adapted for digital use and was termed 'My Kidneys & Me' by the patient group. We also performed semistructured interviews with patients around self-management and the use of educational resources. Key examples of feedback from patients included the following: (1) to provide a symptom tracker to enable self-monitoring of symptoms; (2) include a separate session on sleep; (3) include a separate session on well-being, emphasising the importance of looking after mental health; (4) use of myth and fact quizzes as a way to test knowledge; and (5) state how long sessions should take in the introduction. Once 'My Kidneys & Me' was developed, members of the steering group were provided with access to the programme to provide initial comment. The patient steering group assisted with the selection of questionnaires for the study, and reviewed the final questionnaire survey to ensure that it was acceptable. Throughout the study, the steering group will be used to develop a suitable and relevant topic guide to explore participants attitudes towards self-management and the impact these have on their lives. The group will

also be used to interpret initial and final findings. In addition, the patient steering group will support the development of the lay summary outputs to be disseminated to patients and the public.

Data analysis

Sample size calculation

With PAM-13 as the primary outcome in the full RCT, a total sample size of $N=432$ participants are required based on a 2:1 randomisation ($n=288$ in the intervention group and $n=144$ in the control group). This was based on previously published PAM-13 data by our group¹⁴ and on the required power ($\beta=0.8$; $\alpha=0.05$) to detect a minimal clinically significant difference of 4 points in the PAM-13,^{46–48} and an expected attrition rate of 25%. For the initial nested pilot study, a pragmatic sample size of $n=60$ participants ($n=40$ in the intervention group and $n=20$ in the control group, based on 2:1 randomisation) will be used. We aim to recruit at least 10 patients into the optional sub-study.

Statistical analysis

Participant demographics and clinical characteristics will be analysed using descriptive statistics. The primary outcome is the PAM-13, where answers are weighted provide a score on a scale from 0 to 100. As recommended by Twisk *et al*,⁴⁹ estimates of treatment effect will be assessed by longitudinal analysis of covariance. In this method, the outcome variable measured at the different follow-up measurements (postintervention at week 10, follow-up at week 20) is adjusted for the baseline value of the outcome. Analysis will be performed using 'intention-to-treat' (ITT) analysis. In an ITT approach, patients are analysed by how they were randomised regardless of their actual compliance with treatment or intervention. For patient-reported outcomes missing data items will be handled according to established protocols for the validated surveys. Additional post-hoc analysis will be performed to determine if differences exist in PAM score changes between those with low and high PAM scores.

In the substudy, interview recordings will be professionally transcribed verbatim. The precise analytical methodology used may change based on the nature of the data collected, however thematic analysis will be used as an initial foundation for data analysis as it provides a systematic model for managing and mapping the data. Analysis will follow recognised steps (eg, familiarisation, initial and confirmation of coding (using NVivo), defining themes). In an integrative strategy, any available quantitative data will be used to inform the qualitative analysis.

Considerations

This study aims to evaluate the effect of an evidence-based and theory-based digital self-management structured 10-week programme developed for patients with CKD called 'My Kidneys & Me' on patient activation (PAM-13). The use of a nested pilot study to assess the feasibility of the intervention and study design before continuation to a full RCT is a strength of the study. This will enable us

to make necessary adjustment and changes if the feasibility data suggest that participants do not engage with the intervention or that outcome measures are not being completed. Despite including the patient steering group in the selection of questionnaires and review of the final questionnaire survey, there is potential that the questionnaire survey may risk overburdening the participants and affect missing data and evaluation accuracy. Should the nested pilot study indicate poor questionnaire completion rates, we will revise the breadth of the outcomes collected and simplify the questionnaire survey content to improve participant acceptability.

To minimise the risk of bias (selection, performance and detection), the study is a single-blind RCT. While a higher level of blinding is often preferred to further reduce the risk of bias,⁵⁰ due to the nature of the intervention being tested in this study, it is not possible to blind participants to the intervention. However, one method that can be used to reduce selection bias in an RCT is adequate allocation concealment⁵¹ to prevent intentional and unintentional assignment of participants to either of the study groups.⁵⁰ Group allocation will be random and stratified by age.

An improvement of '4-points' in PAM-13 score is considered the minimal clinically important difference (MCID),^{46–48} thus we used the required power to detect this alongside previous published data by our group on PAM-13. The MCID of PAM-13 is generic and not specific to CKD, however, we aim to identify the MCID of PAM-13 in CKD using data from the full RCT if feasible. While there is evidence to suggest that patient activation has important associations with health outcomes, including in CKD^{52–54} and, interventions aiming to improve patient activation are meagre.⁵ Interventions aimed at increasing patient activation are often designed for people with other long-term conditions such as diabetes and hypertension, and to our knowledge, there are no published interventions designed to specifically target patient activation, particularly assessed using the PAM-13, in those living with CKD.

Ethics and dissemination

To carry out this study, we will consider the Good Clinical Practice guidelines of the local governance organisations (University of Leicester and University Hospitals of Leicester NHS Trust) thus guaranteeing the protection of the rights, the safety and the well-being of the participants of the trial in compliance with the principles of the Declaration of Helsinki, as well as the credibility of the data obtained in the clinical trial. All participant data entered into the 'My Kidneys & Me' will be managed through the MyDESMOND platform. Data entered as part of the online outcomes are managed by Jisc Online Surveys under a University of Leicester license. A full informative sheet explaining the study in detail, the voluntary nature of the research and the procedure for the protection of their personal data will be provided along with the online consent form. Patients will be given the opportunity to

contact the researchers with any questions prior to the informed consent. The informed consent obtained from study participants will be online.

This study was fully approved by the Research Ethics Committee (REC)-Leicester South and Health Research Authority (HRA) on the 19 November 2020 (reference: 17/EM/0357). The results are expected to be published in scientific journals and presented at clinical research conferences in 2024. Findings will be disseminated to patients and the wider kidney and healthcare community via social media platforms, interest groups, recruiting sites and institutions associated with the research team. Any subsequent changes to the study protocol will be reviewed by the REC and HRA through appropriate amendments. Any significant protocol changes will be stated on the ISRCTN Registry. The study was prospectively registered as ISRCTN18314195.

Summary

'My Kidneys & Me', an online self-management and lifestyle education programme, aims to increase patient activation and promote self-management behaviours. If this is achieved, it is anticipated that the intervention will achieve its distal aims of improving patient QoL, physical function, and symptom burden while experiencing fewer hospital admissions and saving costs to the NHS.

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