ISRCTN84422148 https://doi.org/10.1186/ISRCTN84422148

Investigating lifestyle factors in kidney disease

Submission date 25/05/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/06/2018	**Overall study status** Completed	
Last Edited 03/12/2024	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
People with kidney disease (KD) have a loss of kidney function. Poor kidney function is related to other health problems such as diabetes and high blood pressure. Patients also suffer from poor physical functioning, low levels of physical activity, and increased levels of disability. This makes doing everyday activities difficult and reduces their quality of life. Patients have many symptoms such as muscle wasting, severe tiredness, and pain. KD patients are required to make self-imposed changes to their lifestyle to accommodate their diagnosis. This includes changing their diet and taking medication. Many public health recommendations emphasize the importance of a 'healthy lifestyle'. This could include stopping smoking, eating better, and doing exercise. These are 'modifiable' factors (i.e. we can change them) and have been shown to help improve the health of KD patients. These factors are simple targets for potential intervention. However, further research is needed to identify the important lifestyle factors impacted by KD, as well as understanding the needs of the patient.
This study aims to investigate the role and differing impact of KD and basic lifestyle factors on patient's physical function, symptoms, healthcare usage, and muscle function. It will also explore the patient 'living experience' of KD and the impact and role of lifestyle.

Who can participate?
Adults aged 18 years or over with kidney disease

What does the study involve?
The study is divided into 3 parts. In Part A, at least 200 patients fill in a series of questionnaires designed to measure and identify lifestyle determinants and factors associated with living with KD. Part B (optional part) further explores and details patient's body composition (such as fat and muscle mass, muscle quality), physical function and strength, potential markers in the blood, and physical activity levels. These measures and tests are conducted at the hospital.
Part C (optional part) will involve an interview, also conducted at the hospital, in which participants are asked about their health and their experience of living with a kidney condition, but in an informal discussion setting.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in this research. However, the results will be extremely useful to help us understand why people with kidney conditions can suffer from a variety of health problems and symptoms.

The main disadvantage of taking part is the time commitment involved filling in the questionnaires found in the survey pack in Part A, and additional visits to the hospital in Parts B and C.

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

When is the study starting and how long is it expected to run for?
January 2018 to May 2023

Who is funding the study?
Investigator initiated and funded - supported by an NIHR Senior Investigators Award

Who is the main contact?
Professor Alice Smith
alice.smith@leicester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Alice Smith

ORCID ID
http://orcid.org/0000-0002-9234-9060

Contact details
Kidney Lifestyle Team Leader
University Hospitals of Leicester
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW
+44 (0)116 258 4346
kidneyhealth@uhl-tr.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2

Study information

Scientific Title
Investigating lifestyle determinants of muscle and physical function, and the impact on patient experience and support needs in kidney disease

Acronym
DIMENSION-KD

Study objectives
Hypothesis generating study with three primary objectives:
1. Investigate the role and differing impact of KD and basic lifestyle factors on patient's physical function, symptoms, healthcare activation, and muscle function.
2. Qualitatively explore the patient 'living experience' of KD and the impact and role of lifestyle on patient QoL, physical functioning, and health status.
3. Explore the association between dietary intake with body composition, physical function /strength, symptoms, and blood markers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Leicester Central Research Ethics Committee, 24/05/2018, ref: 18/EM/0117

Study design
Three part prospective observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Kidney disease (KD)

Interventions
DIMENSION-KD is a observational (i.e. no treatment or intervention) cross-sectional (i.e. a 'snapshot' of participants) study which aims to establish the effect and associations of kidney disease and different patient characteristics, such as body composition, lifestyle factors, such as diet and physical activity, and investigate the impact on their quality of life and physical functioning.

Only patients with a kidney condition can take part (i.e. their kidney function is below 90 ml/min /1.73m2 or ~90%). They are recruited from secondary care (i.e. those whom see a specialist kidney doctor).
The study consists of three parts (two of which are optional):
Part A involves patients completing a questionnaire pack assessing symptoms, physical function, physical activity, dietary intake, and quality of life). There are 9 questionnaire in total. Patients can take them away and fill them in at home. We aim to recruit at least 200 patients into Part A.

Part B involves an optional additional visit to the renal research area in the hospital for further measures. If a separate visit to the research unit is scheduled, travel/parking expenses will be reimbursed. All assessments in Part B are optional and the exact tests performed will depend on the patients schedule and ability. We aim to recruit at least 30 patients into Part B.
Patients completing Part B complete the survey pack from Part A if not already completed. This provides clinical and demographic data.
In Part B, patients have their height, weight, and waist:hip circumference tested. They have their muscle and fat mass measured using bioelectrical impedance analysis (in which they have to stand on a special scale). A more detailed measure of their muscle is taken using an ultrasound scan of their leg and arm muscle. For this the patient simply needs to lie down on a hospital bed whilst the scan is performed. The ultrasound scan gives us information on your muscle size, but also its quality (such as how much fat is the muscle and how the muscle is organised). Whilst patients are having the ultrasound scan, we will also test some other properties of the muscle including how stiff or elastic (stretchy) it is. This is tested using a device called a myotonometery. It is applied to the skin in the same place as the ultrasound scan. It has a small non-sharp point at the end that ‘taps’ the skin several times very quickly in less than half a second.
Next, we test your physical function, strength, and fitness capacity. For all of the tests described below, patients have a practice go. For the ‘timed-up-and-go’ test we ask the patient to rise from a chair, walk 3 metres, turn around a cone, and sit back down. We time how long this takes them. This helps us measure their strength, ability to get out of a chair, walking speed, balance, and agility. For the ‘sit-to-stand-60’ test we ask the patient to rise from the same chair as used above, but instead of walking around a cone, we ask them to sit back down, then stand back up as many times as they can in 60 seconds. For this test they must try and keep their feet flat on the floor and arms crossed.

The next tests form something called the ‘short physical performance battery’ or SPPB for short. This collection, or ‘battery’, of tests is used all over the world to assess physical function. It involves 3 tests (walking speed, balance, and the ‘sit-to-stand-5’ test).

Following on from the balance tests in the SPPB, we also assess balance using a special board that the patient stands on. We ask them to stand as still as possible with eyes open for a period of 30 seconds. We repeat this 3 times. The board can assess how their ‘postural stability’. To assess fitness levels, we ask the patient to walk for 6 minutes back and forth around two cones along a flat corridor. This test is called the ‘6-minute walk test’. For this test, we ask them to walk as far as they can in the 6 minutes. During this test we ask them to wear small device on the back of your leg. This is about the size of a small box of matches, and can measure the amount of oxygen being used by the muscles. It is completely painless and non-invasive.

Along with the physical function tests above, we also assess strength. We assess the strength of the lower body (i.e. your legs) using two pieces of equipment. The first is called a Biodex dynamometer. The second is called the Fysiometer. This utilises the same board as the balance test above, but this time it is placed on an angle and patients push as hard as they can against it with their legs. To test upper body strength, we assess hand grip strength. To do this we ask them to squeeze as hard as they can on something called a handheld dynamometer.

Patients also wear an accelerometer to measure physical activity levels. Patients wear a special watch on their wrist for 7 days. It is waterproof and they do not have to take it off. During this visit we will also take a small blood sample (30ml or ~2 tablespoons). We use this to look at routine blood markers (e.g., your kidney function, haemoglobin, etc.) but also some additional things like lipid profile (e.g., cholesterol levels) and iron levels. With consent, some of the blood is stored in the hospital for analysis at a later date. During this visit, we also ask participants to complete a couple of questionnaires. One of which is filled in at home (24-hour diet diary).

Part C involves an optional additional visit to the renal research area in the hospital for further measures. If a separate visit to the research unit is scheduled, travel/parking expenses are reimbursed. We aim to recruit at least 15 patients into Part C.
Patients completing Part C complete the survey pack from Part A if not already completed. This provides clinical and demographic data.
In Part C, we conduct a 'semi-structured interview' with the patient. This means we ask them certain questions about their health, but it is informal and the discussion may also involve other things they want to talk about or feel are important. Specifically, we are interested in the patient perspective and experience of 'living' with a kidney condition and the impact it has on lifestyle. We focus particularly on symptom experience and the impact of lifestyle factors on reduced quality of life, physical functioning, and health status. We use answers and responses from Part A (and Part B if possible) to guide this discussion.

All interviews take place with an experienced researcher trained in this form of research. Interviews are one-on-one, and take place in a private area at Leicester General Hospital where other interviews are regularly conducted by our group. To ensure we can give our full attention, all interviews are digitally recorded, professionally transcribed verbatim (written up), and anonymised.

Intervention Type
Not Specified

Primary outcome measure
1. Investigate the role and differing impact of KD and basic lifestyle factors on patient's physical function, symptoms, healthcare activation, and muscle function.
2. Qualitatively explore the patient 'living experience' of KD and the impact and role of lifestyle on patient QoL, physical functioning, and health status.
3. Explore the association between dietary intake with body composition, physical function /strength, symptoms, and blood markers.

Secondary outcome measures
1. Explore the association between mechanical and viscoelastic characteristics of the quadriceps and bicep muscle with physical functioning.
2. Validate the Biodex dynamometer against the Fysiometer for the assessment of lower limb strength in patients with KD.
3. Further exploratory investigation will take place as necessary/appropriate (i.e. if/when new information becomes available), however all investigation will aim to explore lifestyle-based determinants of physical function, muscle health, and disease management, with a basis that this information will help us guide and design lifestyle-based interventions to improve the important and most pertinent factors.

Overall study start date

01/01/2018

Completion date
01/05/2023

Eligibility

Key inclusion criteria
1. Diagnosed kidney disease patients
2. Willing and able to give informed consent and comply with the study protocol
3. Male or female
4. Aged 18 years or above

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
At least 200

Key exclusion criteria
1. Age <18 years
2. Any other significant disease or disorder which, in the opinion of the patient's own clinician, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study
3. Inability to give informed consent or comply with the protocol for any reason

Date of first enrolment
01/07/2018

Date of final enrolment
30/04/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust

Sponsor details
Research Office. Level 3 Balmoral Building
Leicester Royal Infirmary
Leicester
England
United Kingdom
LE1 5WW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
Investigator initiated and funded - supported by an NIHR Senior Investigators Award

Results and Publications

Publication and dissemination plan
Findings will be disseminated in peer reviewed scientific journals, internal reports, conference presentation, patient involvement posters, flyers, newsletters etc. We will disseminate findings using our numerous social media pages (e.g., Facebook and Twitter).

Intention to publish date
01/05/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Alice Smith, alice.smith@leicester.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Qualitative results from the DIME-CV sub-study of the DIMENSION-KD	24/12/2021	12/01/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	a survey-based longitudinal sub-study	18/01/2024	08/08/2024	Yes	No
Other publications	psychometric properties of the Patient Activation Measure in CKD using study data	11/06/2021	08/08/2024	Yes	No
Other publications	qualitative sub-study of DIMENSION-KD	25/04/2022	08/08/2024	Yes	No
Results article		15/04/2021	08/08/2024	Yes	No
Results article	Lifestyle Determinants	14/11/2022	08/08/2024	Yes	No
Results article	Multimorbidity prevalence	21/02/2023	08/08/2024	Yes	No
Results article	Physical function and activity, symptoms and diet	09/04/2021	08/08/2024	Yes	No
Other publications	Comparison of Dietary Patterns and Daily Food Intake Across Kidney Disease Stages in England: An A-Posteriori Cluster Analysis	11/07/2024	03/12/2024	Yes	No
Other publications	Muscle power and physical dysfunction: A model for tailoring rehabilitation in chronic kidney disease	03/07/2021	03/12/2024	Yes	No
Other publications	Navigating the COVID-19 infodemic in those living with kidney disease: access and trust in health information sources and the association with anxiety and depression	15/10/2021	03/12/2024	Yes	No
Other publications	Novel Assessment of Viscoelastic Skeletal Muscle Properties in Chronic Kidney Disease: Association with Physical Functioning	14/09/2023	03/12/2024	Yes	No
Other publications	Patient and staff experiences of remote kidney healthcare: lessons learnt from COVID-19	06/10/2021	03/12/2024	Yes	No
Other publications	The Codevelopment of “My Kidneys & Me”: A Digital Self-management Program for People With Chronic Kidney Disease	14/11/2022	03/12/2024	Yes	No
Other publications	The association of micro and macro worries with psychological distress in people living with chronic kidney disease during the COVID-19 pandemic	22/10/2024	03/12/2024	Yes	No
Other publications	The validity of the ‘General Practice Physical Activity Questionnaire’ against accelerometery in patients with chronic kidney disease	02/12/2020	03/12/2024	Yes	No

Other publications	Utility of Ultrasound as a Valid and Accurate Diagnostic Tool for Sarcopenia	11/08/2020	03/12/2024	Yes	No
Plain English results			03/12/2024	No	Yes