

Office use only.

Study ID _____



Investigating lifestyle determinants of muscle and physical function, and the impact on patient experience and support needs in kidney disease (**DIMENSION-KD**)

IRAS Project ID: 242263

Chief Investigator: Professor Alice Smith

PART C

PATIENT INFORMATION SHEET

Invitation to participate

You are being invited to take part in a research study called **DIMENSION-KD Part C**. Before you decide to take part, it is important for you to understand why this study is being done and what it involves. This information sheet is designed to help you decide whether you would like to participate in this study.

Please **take time to read** the following information carefully and discuss it with friends, relatives, or your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Please feel free to keep this information sheet for your own records.

Thank you for your time

If you have any questions, please contact the research team on:

Professor Alice Smith **Dr Thomas Wilkinson**
Leicester Kidney Lifestyle Team, University of Leicester Academic Unit,
Leicester General Hospital, Leicester, LE5 4PW
✉ dimekd@uhl-tr.nhs.uk

What is the purpose of the research study?

Around 1 in 10 people in the UK have some form of a kidney condition. Having a problem with your kidney(s) does not just affect your body's ability to clean the blood, people also suffer from troublesome symptoms and feel tired and weak which can make normal daily activities more difficult. Having a kidney condition can have big changes on people's lifestyle such as their diet and the amount of physical activity they do.

We are carrying out a programme of research to better understand what causes these problems and to find ways that people with kidney conditions can improve their own health and wellbeing by adjustments to their lifestyle.

There are a number of different parts to this study. Some parts are surveys and some involve an interview with a researcher. Different people will do the different parts of the study, you do not have to do them all.

In **Part C**, which you are invited to take part in, we are interested in exploring perspectives and experiences of people living with a kidney condition. This includes the impact it has on your life, your beliefs about patient self-management, your lifestyle habits, what support you need or may have used and experiences with lifestyle interventions.

Using this important information, we can begin to explore what problems affect people with kidney conditions most, and what potential issues are responsible for this. In the future, we can then try to change these factors to improve the lives of people with kidney conditions.

Why have I been invited?

We are asking you to take part because you have a kidney condition (i.e. your kidney function is impaired), and you are aged over 18 years old. We are asking a wide range of people with kidney conditions.

Do I have to take part?

No you do not, it is up to you whether you decide to participate or not. If you would like to take part, then please contact the research team using the contact details on the front of this information sheet. If you consented to being contacted in the Part A survey pack, a researcher will also be in touch soon to discuss these optional parts with you.

Keep this information sheet for your records.

If you do not wish to take part, you do not need to respond to the letter or email.



Please note that even if you say you are interested in taking part in Part C, we may not contact you if we have lots of volunteers.

What will happen to me if I take part?

Part C of this study involves a one-to-one phone call, or a face to face meeting at an appropriate venue if suitable, where we will contact a “semi-structured” interview with you. This means we will ask you certain questions about you and your views on your health and living with a kidney condition. It is informal and the discussion may also involve other things you want to talk about or you feel are important. We will not insist that you talk about anything you prefer not to discuss, and you can choose not to answer any of the questions without giving a reason. This call (or visit) usually lasts around 30-60 minutes and will be held at a convenient time for you.

All interviews will take place with an experienced researcher trained in this form of research. **Interviews will be digitally recorded**, professionally transcribed verbatim (written up), anonymised, and translated where necessary.

Your name or any other personal identifiable information will not be used in the analysis. We may use direct quotes of what you said in future publications, but it will not be possible to identify you.

If you have only been approached to take part in Part C, we will also ask you a few questions about yourself, i.e. demographic characteristics, and about your views and competencies about taking care of your health (13-item questionnaire), along with filling in the online consent

If you travel for this interview, we will happily reimburse any petrol and parking costs. We can also arrange a taxi free of charge. The interview will be held at a time to suit you.

What are the possible disadvantages and risks of taking part?

The main disadvantage of taking part is the time commitment involved in the phone call (or visit) for the interview. We estimate this will take up to 1 hour.

Remember, for face to face interviews, we will reimburse your travel expenses (mileage) and car parking for this visit. If you wish, we can also arrange a taxi to pick you up and take you home. You will not have to pay for this taxi.

What are the possible benefits of taking part?

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.

What happens when the research study stops?

Any clinical care you may be receiving will continue unchanged.

What if something goes wrong?

It is very unlikely that you would be harmed by taking part in this type of research study. However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you should ask to speak to [insert study team /phone] who will do their best to answer your questions. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact Patient Information & Liaison Service at

pils.complaints.compliments@uhl-tr.nhs.uk.

The Firs, c/o
Glenfield Hospital,
Grobby Road,
Leicester.

LE3 9QP

Freephone: 0808 1788337

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against University Hospitals of Leicester NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Will my taking part in this study be kept confidential?

We take your confidentiality very seriously. All information that is collected about will be kept **strictly confidential**. Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it. The information we obtain from your medical records will be used for this research only and not for any other purpose.

All data is stored securely at the University Hospitals of Leicester NHS Trust and no one else, other than the research team, will have access to it. With your permission, your own GP will be notified of your participation in the study.

Any online forms will be completed using a website called 'Jisc Online Surveys'. 'Jisc Online Surveys' is certified to ISO 27001– the recognised information security standard. (<https://www.jisc.ac.uk/about/certification>). 'Jisc Online Surveys' is licenced by the University of Leicester. All 'Jisc Online Surveys' user and respondent data is stored in the EU – for more information see: <https://www.onlinesurveys.ac.uk/help-support/online-surveys-security/>.

Data may be accessed by authorised individuals from the Sponsor, regulatory authorities or host NHS organisation (e.g. University Hospitals of Leicester NHS Trust) for monitoring and audit purposes.

All data management procedures will conform to University Hospitals of Leicester NHS Trust policy (<http://www.leicestersresearch.nhs.uk/wp-content/uploads/2017/03/SOP-S-1031-UHL-V4-Feb-17-signed.pdf>).

What will happen to any data collected during the research?

As stated above, all data collected will be labelled with an anonymous code and it will not be possible to identify you personally. Any data collected are part of a research programme and any results will not be used as a basis for diagnosis or treatment, either now or in the future.

In line with University Hospitals of Leicester NHS Trust procedures, data will be stored for 5 years following the end of the trial.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to dimekd@uhl-tr.nhs.uk

What will happen to the results of the research study?

We expect the results of the research to become available from 2022. We will publicise the results in posters and leaflets in clinical areas so you can read them while you are there, and we will write a report about them in our Kidney Research Newsletter. If you would like us to send you a written report of the results, or if you would like to receive our Kidney Research Newsletter, please ask the researcher or contact the research team using the details on the front cover.

The results will also be published in a medical journal(s). All information will be anonymised so you will not be identified in any report or publication.

Who is organising and funding the research?

The research is being organised by the Leicester Kidney Lifestyle Team at the John Walls Renal Unit, Leicester General Hospital and is led by Professor Alice Smith, Professor of Lifestyle Medicine at the University of Leicester and University Hospitals of Leicester NHS Trust.

Any research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be reviewed by an NHS Research Ethics Committee before it can go ahead. This study has been reviewed by the East Midlands - Leicester Central Research Ethics Committee. A favourable opinion means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision.



Yes, I would like to take part, what do I do?

1. Contact us directly at dimekd@uhl-tr.nhs.uk (or by mail, as per information below)
2. A researcher will contact you and answer any questions you may have
3. If you are happy to go ahead, we will provide a link to an online consent form for you to complete
4. We will then arrange a suitable date and time for your interview
5. The researcher will telephone you at the agreed time for your interview
6. You can change your mind at any time without giving a reason



No, I am not interested, what do I do?

Nothing. Thank you for reading. Either tick the corresponding box on the form at the back of the Part A survey pack, or please recycle the documents you have been given, or return them to the researcher. We can then reuse them in the future.

The treatment and standard of care you receive from the NHS will not be affected if you decide not to take part or to withdraw.

Contact for further information

If you would like any further information about this study please contact the research team below, or speak to your GP.

DIMENSION-KD
Leicester Kidney Lifestyle Team,
University of Leicester Academic Unit,
Leicester General Hospital,
Leicester,
LE5 4PW

✉ dimekd@uhl-tr.nhs.uk

Thank you for reading.
