



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 E

Online Survey

INFORMATION SHEET

version 2, dated 12.09.2022

 **Please read before filling in the survey** 

Invitation to participate

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it involves. This information sheet is designed to help you decide whether you would like to participate in this online survey study.

Please **take time to read** the following information carefully and discuss it with friends, relatives and 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:

**Leicester Kidney Lifestyle Team, University of Leicester Academic Unit,
Leicester General Hospital, Leicester, LE5 4PW**

Tel **0116 258 4346**

✉ dimekd@uhl-tr.nhs.uk

<https://www.leicesterkidneylifestyle.team/>

Around 1 in 10 people in the UK have some form of a kidney condition. Having a problem with the kidney(s) does not just affect the body's ability to clean the blood, people also suffer from troublesome symptoms and often feel tired and weak which can make normal daily activities more difficult. Having a kidney condition can have big effects 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.

Part E of this study involves an online survey. The survey includes several simple questionnaires that measure a range of symptoms, lifestyle factors such as sleep and how often you access "green or blue space". "Green and blue space" refers to natural environments such as gardens, parks, woodland and countryside (green space) and rivers, canals, lakes and the seaside (blue space).

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

We are asking people with a kidney condition to fill in the survey, and also people who are close to them but DO NOT have a kidney condition as far as they know ("Significant Others"). Comparing the survey responses of these two groups of people will help us to understand how kidney problems affect sleep and lifestyle.

Why have I been invited?

We are asking you to take part because :

- **EITHER** 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, including those on dialysis or with a kidney transplant, and those who have a kidney condition but do not need dialysis or a transplant
- **OR** you are aged over 18 years old and you a relative or close friend (a Significant Other) of someone with a kidney condition, but as far as you know, you do not have a kidney problem yourself. We are interested in your responses to the survey because your lifestyle may be similar in some ways.

This will help us to identify which lifestyle issues are affected by kidney problems, and which by other factors unrelated to the kidneys.

Do I have to take part?

No you do not, it is up to you whether you decide to participate or not. If you decide to take part, then you simply need to complete the online consent form and survey here : <https://leicester.onlinesurveys.ac.uk/dime-e-survey>

Once you have done this, click on the SUBMIT button at the end of the survey and your responses will be returned to the study team.

You can keep this information sheet for your records.

If you do not wish to take part, please recycle any paper documents you received. 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.

What will happen to me if I take part?

The DIMENSION-KD study is made up of several separate parts (A-E). You are currently reading the information sheet for **Part E**. You can find more about **Parts C** and **D** below. The other parts have now finished and are closed.

Part E involves filling in the online consent form and survey and then clicking on the Submit button at the end which will send your responses back to the research team.

If you have a kidney condition, we will ask you for some information so that your hospital kidney care team can access your clinical records and extract some of the information from your most recent blood and urine test results.

If you do not have a kidney condition, you will not be asked for this information and no one will access any of your clinical records

If you do not fill in the consent form or click on the Submit button at the end of the survey, you will not be included in the study and no information about you will be recorded

The online survey has two parts – the Consent Form and the Part E Survey.

It firstly contains a consent form which we would like you to complete to confirm that you understand what the study involves and that you agree to take part.

Once you have completed the consent form, you will move on to the Part E survey questions, which include :

- some simple questions about **yourself and your health**
- a series of **questionnaires** that are used in health research (see below). Most of the questionnaires ask you to select your answers in tick boxes. Some of them also provide free text boxes where you can type your answer.
 - **Short Form-12 (SF-12)**
This is a commonly used questionnaire which assess how your health affects your quality of life
 - **Patient Activation Measure (PAM)**
This questionnaire is designed to find out about your knowledge, skills and confidence in managing your own health and care
 - **GP Physical Activity Questionnaire**
A brief questionnaire to assess your physical activity levels
 - **Kidney Symptom Questionnaire**
A questionnaire about some of the symptoms which often affect people living with a kidney condition. We are interested in all the symptoms you experience, whether or not they are caused by your kidney condition. We would also like participants who do not have a kidney condition to fill in this questionnaire as the symptoms are quite common in the general population too.
 - **The Depression, Anxiety and Stress Scale (DASS-21)**
This questionnaire is designed to find out about your levels of depression, anxiety and tension/stress.
 - **Questions about green and blue space**
How close you live to green/blue space, how often you use it and what you do there
 - **Pittsburgh Sleep Quality Index (PSQI)**
A questionnaire about how well you sleep
 - **Sleep Hygiene Index (SHI)**
A questionnaire about your sleep habits

It takes about 20-30 minutes to complete the whole Consent Form and Survey Form.

What about Parts C and D?

During the consent form and at the end of the Part E Survey, we will ask you whether you wish to take part in either Part C or Part D of the DIME-KD study, which involve having a discussion with a researcher to talk in more detail about some of the topics in the survey. Part C is for people with a kidney condition, and Part D is for people who do not have a kidney condition. Both parts are optional. If you may be willing to talk to a researcher by telephone (or in person if you live locally to Leicester), the survey provides a space to enter your email address. We will then contact you with further information and you can decide whether you want to take part. If you do go ahead, the discussion will be conducted at a date and time to suit you.

Please note that even if you do provide your email address so we can contact you about talking to a researcher, we may not be able to do so if we get too many people. Therefore please do not worry if we don't contact you.

What are the possible disadvantages and risks of taking part in the Part E survey?

The main disadvantage of taking part is the time commitment involved filling in the questionnaires found in this survey, as it includes quite a lot of questions. Most of the questions are short and you just tick one box to answer them, although a few are a bit longer. Remember you can take as long as you want to fill them in, and you do not have to do them all in one go. There is an option to finish the survey later.

We would like you to try and answer every question but understand that some of the questions may be a bit personal. If there is a question you would prefer not to answer, then you can leave this blank. **All your responses are kept strictly confidential.**

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 how sleep patterns and access to green space affects people with a kidney condition and how best to plan to help in the future.

If you would like to receive feedback from the study, please contact the research team using the details on the front cover.

What happens when the research study stops?

Any clinical care you may be receiving will continue unchanged.

If you have a kidney condition, with your consent, we will access your medical records for 3 years. This will be once a year from the time you return the survey (i.e. 3 times in total). Over those 3 years, we will look at how many times you needed to visit the hospital, if/how long you needed to stay for, how your kidney condition and related health is progressing, and whether or not something major happened (such as the need for dialysis, any severe health problem (e.g., heart attack), or death). We will use this information to test whether any of these events could be predicted by your answers on the questionnaires. If so, we could use this information to detect people earlier who might be more at risk in the future.

If you do not have a kidney condition, we will not access your medical records at all.

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

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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 you 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. If you have a kidney condition, we ask you to provide identification details so we can identify which hospital you are from and access your correct medical records. If you do not have a kidney condition, we do not ask you for such details and we will not access your medical records.

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.

Both the online consent form and survey questionnaires 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
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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.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name, contact details, and responses to the questions you provide. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

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 on 0116 258 4346
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 2023. We will write a report about them on our website : <https://www.leicesterkidneylifestyle.team/> and share them on social media channels such as Twitter @leicskidney

If you would like us to send you a written report of the results, please contact the research team using the details at the front cover of this document

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. University Hospitals of Leicester NHS Trust is the sponsor.

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. Please go to the online survey here :
<https://leicester.onlinesurveys.ac.uk/dime-e-survey>
2. Click 'Next' at the bottom of the Introduction page
3. Fill in the consent form
4. Complete the survey
5. Click the SUBMIT button at the end of the survey



I am no longer interested, what do I do?

Nothing. Thank you for reading. Please recycle any paper documents you have been sent.

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
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University of Leicester Academic Unit,
Leicester General Hospital,
Leicester,
LE5 4PW

Tel **0116 258 4346**

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Thank you for reading.

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