

A pilot feasibility study of an online Self-Management Intervention through Lifestyle Education for Kidney health (SMILE-K)

IRAS Project ID: 282573 Chief Investigator: Professor Alice Smith

Part B2 (Interview) Online Patient Information Sheet

Thank you for taking part in our SMILE-K research study and agreeing to test our online 'My Kidneys & Me' lifestyle education programme.

As part of the larger research study (called Part A), we are asking a small number of participants to take part in a smaller sub-study. We are calling this smaller sub-study, Part B. This involves a telephone interview about your health. This additional Part B is completely voluntary and if you do not wish to take part, will not affect your involvement in the larger study testing the online programme.

You are being invited to take part in Part B, this smaller sub-study, because 1) you have a kidney condition (i.e. your kidney function is reduced) and 2) because you have consented to take part in Part A of the research study. Before you decide whether to take part or not, it is important for you to understand why this additional sub-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 part of the study.

Please take time to read the following information carefully and discuss it with friends, relatives and your GP or doctor if you wish. Ask us if there is anything that is not clear or if you would like more information.

Once you have read this information sheet, if you are interested please fill in the Part B2 online consent form using the link in the email that was sent. If you do not wish to take part, then your involvement in the main part of the study (Part A) will continue as normal. This means that you could go on and complete the online questionnaires if you have not already done so.

Thank you for you for your time.

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

Leicester Kidney Lifestyle Team, Leicester General Hospital, Leicester, LE5 4PW

✉ mykidneysandme@uhl-tr.nhs.uk

What is the purpose of this additional sub-study (Part B)?

Whilst online questionnaires are easy to fill in and provide important information, they do not give us the full picture of your experience with the program. By asking participants in an informal 'interview', it will help us understand better your kidney condition, health, and your experiences of self-managing your health. If you have been given access to the programme, we will also ask you about your experiences with the online 'My Kidneys & Me' programme.

If you change your mind at any time, then you are free to withdraw at any time. You can withdraw from the study by contacting us at any time. Contacting us to tell us you wish to withdraw means we will no longer send you other documents and surveys as part of the study. It also allows us to determine who is not using the programme because they are no longer in the study, or because they have not used it. If you do withdraw, with your consent, we will keep any data you may have provided up to that point. If you lose capacity (e.g., become ill that you can no longer continue) to take part in the study, then you will be withdrawn from the study. Again, with your consent, we will keep any data you may have provided up to that point. The treatment and standard of care you receive from the NHS will not be affected if you decide not to take part or withdraw.

Why have I been invited to Part B?

We are asking you to take part because you have a kidney condition (i.e. your kidney function is reduced), you are aged over 18 years old, and you have consented to take part in Part A of the SMILE-K research study.

Do I have to take part in Part B? Does it affect my involvement in Part A?

No, you do not. It is up to you whether you decide to participate or not. If you do decide to take part, then you simply need to fill in the consent form which you can access by clicking the link in the email.

If you do not wish to take part, then your involvement in the main part of the study (Part A) will continue as normal. This means that you could go on and complete the online questionnaires if you have not already done so. If you consent to Part B, we will let your GP know in writing.

What will happen to me if I take part in Part B?

1 Step 1.
Firstly, read this information sheet carefully. If you would like to take part, complete the online consent form that can be accessed by clicking the link in the email we sent you. If we do not hear from you within 7-days we will assume you do not wish to take part and your involvement in Part A will continue as normal.

2 Step 2.
Once you have contacted us, we will contact you to arrange a date and time to conduct an interview by telephone. This interview may take up to 1 hour.

3 Step 3.
Part B involves an informal discussion with one of our experienced researchers. We call this a 'semi-structured interview'. This means we will ask you certain questions about your health and views of the programme, but it is relaxed, and the discussion may also involve other things that come up and you want to talk about or that you feel are important. This conversation will focus on your kidney condition, how your health affects your ability to perform daily activities, how you cope with your condition, and what ways you have tried to improve your health. We will also ask you about your involvement in the study – this could include things like how you found the online programme, what you used it for, how you would improve it etc.



This one-on-one informal discussion will take place over the telephone. This interview may last up to 1 hour. The interview will take place at a time and date that suits you. To ensure we can give you our full attention, all interviews will be recorded using an encrypted digital recorder. After the interview, the interview will be written up by a professional transcriber. This transcriber will be external to the research team and has all the relevant security and data protection agreements with the University of Leicester to undertake this work. No recordings are stored on the recorder and are transferred straight away once we finish the interview with you. We need to keep the recordings as we may need to go back to them when we are analysing the data. As such, original recordings, once taken off the recorder, are stored on our secure hospital and university servers. Your name or any other personal identifiable information will not be used in the transcripts or the analysis, and we will only use your unique patient ID number to label the recording. We may use direct quotes of what you said in future publications, but it will not be possible to identify you.



4 Step 4.
If you were asked to be interviewed before starting We may ask you to be interviewed again for a second time after 10-weeks regardless of what group you are in (either CONTROL or INTERVENTION). This will be around the same time we ask you to complete the online questionnaires in Part A.

5 Step 5.
10-weeks later, we may ask you to be interviewed again for the third and final time after 20-weeks regardless of what group you are in. This will be around the same time we ask you to complete the online questionnaires in Part A.

What are the possible disadvantages and risks of taking part?

The main disadvantage of taking part is the time commitment involved when being interviewed – these will take around 30-60 minutes depending on how much you have to say. You do not have to answer any questions you do not wish to, and all your responses are kept strictly confidential.

What are the possible benefits of taking part?

There are no direct benefits expected by taking part in this research. What you share with us will be extremely useful to help us understand to what extent 'My Kidneys & Me' is beneficial for people's health.

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 the research team 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@uhl-tr.nhs.uk



08081 788337



The Firs, C/O Glenfield Hospital, Groby Road, Leicester, LE3 9QP

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).

How will we use information about you?

We will need to use information collected from any answers you provide to questions we may ask, and information we collect about you during the different assessment tests for this research study. This information will include your name, hospital number, contact details, and date of birth. 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 unique ID number instead.

We will keep all information about you safe and secure. 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. All electronic data collected as part of the study is stored securely at the University Hospitals of Leicester NHS Trust and University of Leicester and no one else, other than the research team, will have access to it. Data may be accessed by authorised individuals from the Sponsor (University of Leicester), 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. These can be found at: <http://www.leicestersresearch.nhs.uk/wp-content/uploads/2017/03/SOP-S-1031-UHL-V4-Feb-17-signed.pdf>

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 will happen to any data collected during the research?

As stated above, all data collected will be labelled with an ID number and it will not be possible to identify you personally. Any data collected are part of a research programme 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.

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. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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/ or <https://le.ac.uk/ias/data-protection>

by sending an email to ✉ mykidneysandme@uhl-tr.nhs.uk

To speak to the sponsor's (University of Leicester) Data Protection Officer (Elisabeth Taoudi, Data Protection Officer and In-House Commercial Lawyer, University of Leicester, University Road, Leicester, LE1 7RH), or please email ✉ ias@le.ac.uk or ring ☎ 0116 229 7945

What will happen to the results of the research study?

We expect the results of the research to become available from 2023. 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 and on our website. A summary of the results of the study will be sent to all participants who want it and you can indicate if and how you want to receive these on the consent form. 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) and presented at medical conferences/meetings. 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, the Leicester Diabetes Centre, and the Leicester Biomedical IRAS: 282573 SMILE-K_Part B2 (Interview) Online Patient Information Sheet_Version 2.0_05.12.2021

Research Centre. The study is led by Professor Alice Smith, Professor of Lifestyle Medicine at the University of Leicester. The study is sponsored by the University of Leicester.

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 South 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.

What next?



Yes, I would like to take part in Part B, what do I do?

1. Please complete the online consent form which can be accessed by clicking [HERE](#) or via the link in the email sent.
2. We will contact you to arrange a time and date suitable for you to have the interview over the phone/via videoconferencing.



I am not interested in Part B what do I do?

Nothing. Thank you for reading. 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.

If you have not done so already, please complete the rest of the online questionnaires for Part A of the study. Once you have done this, we will be in contact with you in regard to the rest of the study.

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 or doctor.



Leicester Kidney Lifestyle Team, Leicester General Hospital, Leicester, LE5 4PW

✉ mykidneysandme@uhl-tr.nhs.uk

Thank you for reading.