

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 B (Local) 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 (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 several visits to the hospital for some additional tests and an 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 contact the research team using the contact details below or email: mykidneysandme@uhl-tr.nhs.uk. If we do not hear from you in 7-days, we will contact you (using the contact details provided in Part A) to follow up any interest. If you do not wish to take part in this part of the research study, your participation in the main study won't be affected.

Thank 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

☎ 0116 258 4346

✉ mykidneysandme@uhl-tr.nhs.uk

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

We would like to thank you for already agreeing and consenting to take part in our SMILE-K research study. We are using online questionnaires in the main study (Part A) so that lots of people from over the country can take part without having to visit a hospital for testing as you might normally do in a research project. Whilst online questionnaires are easy to fill in, they do not give us the same information that more detailed tests can as they rely on what people tell us. Doing more detailed physical tests in some participants gives us extra information that we would not be able to measure using a questionnaire. This information might include measures of strength, physical function, and muscle size. We may also use this time to discuss with you in an informal 'interview' format 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.

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 contact us via email: mykidneysandme@uhl-tr.nhs.uk. If we do not hear from you after 7-days, we will contact you via email to follow-up any interest.

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 should complete the online questionnaires if you have not already done so.

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

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

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, contact us on: mykidneysandme@uhl-tr.nhs.uk. If we do not hear from you after 7-days, we will contact you via email to follow-up any interest. If you are not interested in this part, then let us know and your involvement in Part A will continue as normal.

2 Step 2.
Once you have contacted us, we will arrange a date and time for you to come to Leicester General Hospital. This visit may take up to 2 hours. We will happily reimburse any petrol and parking costs incurred. In order to be reimbursed, original receipts (e.g., parking tickets) must be provided. We can also arrange a taxi free of charge.

3 Step 3.
Part B of the study is divided into two parts – Part B1 and Part B2. You can choose to take part in both parts or either Part B1 or B2. Part B1 will take around 45 minutes and Part B2 up to 1 hour.

Part B1

When you arrive at the hospital you will sign a consent form for Part B1. We will then perform several physical tests of your health. These will include:

Your height, weight, BMI, and waist and hip circumference which will be measured in a private research area. These will be performed by a trained researcher and in line with established procedures. Your heart rate and blood pressure will be assessed using a standard inflatable cuff as you would normally have this done at your GP practice etc. These assessments will take ~10 minutes.

We will then measure the amount of muscle and fat in your body. For this we will use a technique called 'bioelectrical impedance analysis' (or BIA for short) using a small painless electrical current while you stand barefoot on a set of special scales and hold onto two handles. Due to a transmitting device that is part of the equipment, if you have a pacemaker, we will not do this test with you. This assessment will take ~10 minutes.

We will also perform an ultrasound scan on your right leg to let us look at your muscles. For the leg scan, we will ask you to lie or sit on a hospital bed. You will be asked to bring shorts as the scan is measured at the top of the leg (the thigh – between the hip and knee). If you do not own shorts, we can provide a pair to borrow or a hospital gown to wear. All scans are conducted by a member of the research team in a private room. We will apply a small amount of gel to the ultrasound probe. This may be a little cold when pressed against your skin. We will take several 'photographs' (or images) of the muscles and tendons in your leg. For each muscle, we will take at least 3 'photographs' of the muscle. This is to make sure they are similar and accurate. The ultrasound scans will give us information on your muscle and tendon size and quality. Information on the muscle size will be provided at the end of your involvement in the study. The ultrasound is completely painless and non-invasive. It takes around 10-15 minutes.



The ultrasound scan is taken around half-way up your upper leg. This will be marked in washable marker pen.



The scanner is then placed lightly against the skin where the images will be taken.

Whilst you 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 myotonometry. 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. We will do this on both the leg and arm. For this test, we will test both sides of the body. It is completely painless and non-invasive.

We will ask you to walk 4 metres at your usual walking speed. You can use a walking aid if that is what you are used to. This assessment will take a maximum ~5 minutes.

To test your upper body strength, we will assess your handgrip strength. To do this we will ask you to squeeze as hard as you can on something called a handheld dynamometer. We will ask you to have 3 attempts with each arm. You will get a small rest in-between. This assessment will take ~5 minutes.

For the 'timed-up-and-go' test we will ask you to rise from a chair, walk 3 metres, turn around a cone, and sit back down. We will time how long this takes you. This will help us measure your strength, ability to get out of a chair, walking speed, balance, and agility. This assessment will take ~5 minutes.

For the 'sit-to-stand-60' test we will ask you to rise from the same chair used above, but instead of walking around a cone, we will ask you to sit back down, then stand back up as many times as you can in 60 seconds. For this test you must try and keep your feet flat on the floor and your arms crossed. This assessment will take ~5 minutes.

For all the physical tests (e.g., the ones where we are asking you to move around), we will give you a practice go so you are happy with what is being asked of you.

Whilst asking people using a questionnaire is generally an OK way to measure how much exercise and physical activity they do, the most accurate way is using a form of wearable technology – a special watch that measures how much you move around in the day and night; a bit like a 'Fitbit' or similar device. We will ask you to wear the watch on your wrist for 7-days. We will give it to you when you come in for assessment visits and you can either post it back to us (we can give you a prepaid envelope) or bring it back to us. The watch is waterproof so you can shower and bathe in it. You do not have to take it off at all, and we would like you to wear it whilst you are asleep too.

During this visit we will also ask you to complete paper versions of the questionnaires that you have been asked to fill out online (in Part A). This is to make sure that people are completing the online versions of these questionnaires the same way they would if they were on paper. The paper survey pack may take up to 1 hour to complete. You can take this home to fill in and we will provide a stamped addressed envelope for you to send it back in the post for free.

Once you have completed all these tests at the hospital you are free to go home. We will ask you to complete the online questionnaires in Part A if you have not yet done so.

If you also wish to take part in Part B2 we will ask you to stay for another ~1 hour. Part B2 is described below.

Part B2

Part B2 involves an informal discussion with one of our 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 have you 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 may take place at the hospital, your own home, or over the telephone. This interview may last up to 1 hour and if you attend in person will take place in a private area where other interviews are regularly conducted by our group. We will happily reimburse any petrol and parking costs incurred. In order to be reimbursed, original receipts (e.g., parking tickets) must be provided. We can also arrange a taxi free of charge. The interview will take place at a time and date that fits with you. All interviews will take place with an experienced researcher trained in this form of research.

When you arrive at the hospital you will sign a consent form for Part B2. If you wish to be interviewed over the phone, then we will send you a link to an online consent form. This will be similar to the one you filled in for Part A.

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 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.
We will ask you to attend the hospital again for a second time after 10-weeks regardless of what group you are in (either CONTROL or INTERVENTION). You will repeat Part B1 and/or B2 again. This visit may take up to 2 hours if you do both Part B1 and B2. We will happily reimburse any petrol and parking costs incurred. In order to be reimbursed, original receipts (e.g., parking tickets) must be provided. We can also arrange a taxi free of charge. 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 will ask you to attend the hospital again for the third and final time after 20-weeks regardless of what group you are in. You will repeat Part B1 and/or B2 again. This visit may take up to 2 hours if you do both Part B1 and B2. We will happily reimburse any petrol and parking costs incurred. In order to be reimbursed, original receipts (e.g., parking tickets) must be provided. We can also arrange a taxi free of charge. 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 in Part B1 is the time commitment involved attending the hospital for the visits – this could be up to 1 hour each time. Some of the physical function and strength tests we do are maximal in effort (i.e. we ask you to try your hardest), and therefore may feel quite hard and uncomfortable when doing them. We will give you plenty of rest between tests and attempts, and you can stop them at any time. Remember, all the tests we do are used across the world in research. Our group and the researchers involved in the study have lots of experience in doing them with patients. The main disadvantage of Part B2 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. If you only wish to do Part B2 and do not wish to physically attend the hospital, we can arrange to do the interview over telephone or via videoconferencing. If you do both Parts B1 and B2, each visit could last up to 2 hours.

What are the possible benefits of taking part?

There are no direct benefits expected by taking part in this research. However, the results 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.complaints.compliments@uhl-tr.nhs.uk



0808 1788337



The Firs (CO), 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 as part of the tests and 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.

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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
or by ringing us on ☎ 0116 258 4346

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?

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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 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 email us on mykidneysandme@uhl-tr.nhs.uk
2. We will contact you to arrange a time and date suitable for you to undertake Part B1 and/or Part B2.



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. Alternatively, you can email us on mykidneysandme@uhl-tr.nhs.uk

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

☎ 0116 258 4346

✉ mykidneysandme@uhl-tr.nhs.uk

Thank you for reading.