

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 A Online Patient Information Sheet

Thank you for contacting us asking for further information on our SMILE-K research study and our online 'My Kidneys & Me' lifestyle education programme.

You are being invited to take part in a research study because you have a kidney condition (i.e. your kidneys do not work as well as they should). Before you decide whether to take part or not, 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 study or not.

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, please click on the second link in the email to fill in the consent form online.

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

✉ mykidneysandme@uhl-tr.nhs.uk



Summary of the research

'My Kidneys & Me' is an interactive online lifestyle education programme for people with a kidney condition to help provide the knowledge, skills, and confidence to look after their own health. 'My Kidneys & Me' is being tested in a research study (called SMILE-K) to find out how people use the programme and how long they use it for over the 20-week study period.

You have been invited to take part because you have a reduced kidney function, and your doctor feels that you may benefit from the 'My Kidneys & Me' programme.

The study involves having access and use of the 'My Kidneys & Me' for 20 weeks and filling in online surveys at 3 different time-points (the start, after 10 weeks, and after 20 weeks). The surveys will ask you about your health, knowledge, skills, and lifestyle so we can track any changes.

Regarding the 'My Kidneys & Me' programme, we are interested in how, why, when, or whether people use the programme and how they engage with the different features. As such, it is up to you how much you use it and what for. We want people to use it for what works best for them – that may be logging in each day and working your way through the interactive learning sessions, or it may be using the health trackers each week to monitor an aspect of your health such as your blood pressure. It is up to you how and when you use the programme. There is no right or wrong way.

There are no direct benefits expected by taking part in this research. However, we hope that you find the programme interactive, educational, and useful in managing your health. It is up to you how you use the programme, if at all. The feedback we get will help us develop and improve the programme in the future.

Any clinical care you may be receiving will continue unchanged. Once you have registered for the 'My Kidneys & Me' programme you will have access for a period of 2 years.

Information about all aspects of the study is detailed below. The next page is a hyperlinked contents page for this information sheet. This means that you can click on any of the links to read more about that topic.

If you have any questions or would like more information, please email the 'My Kidneys & Me' team at: ✉ mykidneysandme@uhl-tr.nhs.uk

Please click on the topics below to take you to the relevant page for more information.

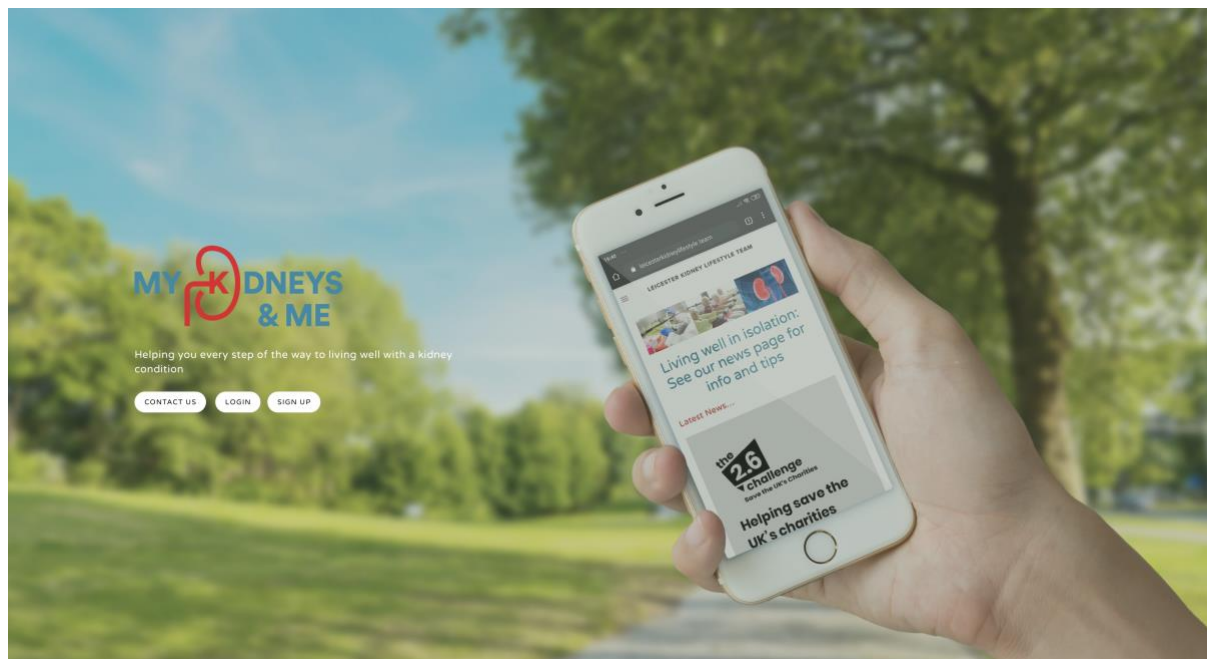
- What is the purpose of the SMILE-K research study?
- Why have I been invited?
- Do I have to take part?
- What will happen to me if I take part?
- What does the 'My Kidneys & Me' programme involve?
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What is the purpose of the SMILE-K research study?

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, it can cause different symptoms such as tiredness, weakness, and joint pain.

People living with a kidney problem need to look after their own health until they reach the need for dialysis or a kidney transplant, which most patients will never require. Living a healthy and active lifestyle can help people with kidney problems live a good quality of life for as long as possible, lower the effect of symptoms and potentially slow the progression of the condition. However, many people with a kidney problem do not know about their condition, its treatment, the importance of looking after their own health, or practical ways to look after their own health. To manage health successfully, people need to have the right knowledge, confidence and skills.

With the help of researchers, doctors, dieticians, psychologists, patients and their relatives, and other healthcare professionals we have developed a new online lifestyle education programme called 'My Kidneys & Me'. The programme can be accessed on your computer, phone, or tablet.



This programme has been developed aiming to improve people with kidney problems' knowledge, confidence and skills to look after their own health. More about the programme can be found later on in this information sheet, however in summary, the online programme contains different features such as interactive learning sessions that cover a range of topics

such as 'kidney disease', 'diet', and 'physical activity', health trackers, and the ability to set your own health goals.



The 'My **Kidneys & Me**' programme is part of the larger MyDESMOND e-learning platform which has been developed by the Leicester Diabetes Centre, University Hospitals of Leicester NHS Trust, and the University of Leicester. More information about MyDESMOND can be found here: <https://www.mydesmond.com/home/> and on the NHS Digital website: <https://www.nhs.uk/apps-library/mydesmond/>

We are looking for people with kidney problems to test the 'My **Kidneys & Me**' programme over 5 months (20 weeks). We will also ask you to complete some questionnaires before and after to see what effect it may have. We will also ask you to give us a feedback on how we can improve it in the future – this will be in the form of some questions completed as part of the survey pack sent out at the end of the study. The information collected will also help tell us if we are able to test the programme in a larger study.

Why have I been invited?

We are asking you to take part because you have a kidney condition (i.e. your kidney function is reduced) and you are aged over 18 years old. We are asking a wide range of people with kidney conditions. Your GP or doctor may have given or sent you the information flyer because they believe you may benefit from having access to the 'My **Kidneys & Me**' programme.

Do I have to take part?

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 using the other link in the email. Once you have done this, we will contact you via email with a link to the first set of online survey questionnaires. If you do not wish to take part, please delete this email. You do not have to tell us directly you no longer want to take part.

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.

You can still take part in this study if you are taking part in another research study. However, this will depend on the other type of research. Please let us know if you are taking part in any other research studies and we will discuss this with you in further detail.

If you do decide to take part, with your permission, your GP will be informed you have decided to participate in the study.

What will happen to me if I take part?

1 Step 1.

Firstly, read this information sheet carefully. If you would like to take part, complete the online consent form and fill in the questions on the form at the end (which can be found by clicking the link in the email).

Once we receive your consent form, the research team will access your clinical records and extract the following information:

- | | |
|-------------------------------------|---------------------------------------|
| - Age | - Other health conditions |
| - Sex | - Recent blood and urine test results |
| - Ethnicity | - Socioeconomic status |
| - Primary cause of kidney condition | - Blood pressure |
| - Smoking habits | - Body mass index (BMI) |
| - Clinical outcomes | - Current medications |
| - Healthcare usage | |

Some of this information will also be asked in the survey (see below). Please note, if you do not fill in the consent form, we will not access any information about you.

2 Step 2.

Once you have filled in and completed the online consent form, we will send you an email with a link to the first set of survey questionnaires. This email will also contain your unique study ID number. You will need to enter this, along with your initials, when filling in the surveys as this will help us when linking your answers together. This survey is completed online. The survey contains simple questionnaires about you and your health. All these questionnaires have been especially chosen as they measure different aspects of your health and are used frequently in

medical research in patients with kidney conditions across the world. For most of the questionnaires, you simply need to select the box you most think applies to you. Some of the questions might not seem relevant to you, or you might feel they ask the same things as another. Please try and answer them regardless.

The survey will take up to 1 hour to fill in. You do not have to fill the survey in all at once and can save your progress by clicking on the 'Finish later' button at the bottom of every page. These are the questionnaires that are included:

1. Basic information – We will ask you some simple questions about yourself such as your age, ethnicity, occupation, and health. We will also ask you about your height and weight.
2. Patient Activation Measure (PAM) – This questionnaire is designed to find out about your knowledge, skills and confidence in managing your own health and care.
3. Chronic Kidney Disease Self-Management Knowledge Tool (CKD-SMKT) – This questionnaire asks you about how well you can manage your kidney problems.
4. 12-Item Short Form Health Survey (SF-12) – This questionnaire asks for your views about your health and how it affects what activities you can do.
5. Kidney Symptom Questionnaire (KSQ) – This questionnaire will ask you about any symptoms you have as a result of your kidney condition.
6. SARC-F – This questionnaire will ask you about your strength, mobility, and how well you can walk, stand from a chair, climb stairs and if you have fallen over recently.
7. Illness Representations Questionnaire (Brief) (IPQ-R) – This questionnaire asks you about symptoms and other health conditions you have.
8. GP Physical Activity Questionnaire (GPPAQ) – This questionnaire will ask you about your physical activity levels.
9. UK Diabetes and Diet Questionnaire (UKDDQ) – This questionnaire asks you about your diet.
10. Medication Adherence Report Scale (MARS-5) – This questionnaire asks you about the medications you take.
11. Health usage questionnaire – This questionnaire asks you about your recent use of the healthcare service.

As part of the survey we will also ask you to we would like to assess your physical function by asking you to do as many sit-to-stands as possible in 1 minute. This is optional and you do not have to do it if you do not wish. We recommend that you do this test in the company of someone else – this can be a friend or family member. This is to make sure you are safe but also they can help use the stopwatch. The test involves sitting on a chair with your hands across your chest. Start a timer/stopwatch for 1 minute. There are many online timers you can use, or you can use your phone. This test is used across the world in lots of different people with health conditions, including kidney conditions. The test is simple and safe. However, if you do not wish to do the test then you do not have to. Further instructions will be found at the appropriate section of the online survey.



3

Step 3.

Once you have completed the online survey, you will be randomised into one of two groups:

- 1) a CONTROL group or;
- 2) the INTERVENTION group.

We will inform you which group you are in by email. The randomisation will be done by the research team using a computer programme.

If you are randomised into the CONTROL group, you will experience your usual care as it would be if you were not in the study. We will ask you to maintain your normal lifestyle, normal physical activity levels, and normal diet. You will be asked to record/note any major changes in lifestyle and health over this period. Please do not worry about potentially missing out if you are in this group, you will be provided with a link to the full programme at the end of the study. You will have access to this for 2 years if you sign up within a month of finishing the study.

If you are randomised into the INTERVENTION group, you will be provided with a link to the 'My Kidneys & Me' programme along with a unique verification code to access it. As stated before, the 'My Kidneys & Me' programme is part of the MyDESMOND e-learning platform hosted by the Leicester Diabetes Centre and University of Leicester. When you have inputted the verification code you will be taken to a registration page where you will be asked to create a username and password. These will be your login details for the programme. If you do not register within 7 days after receiving your code, an automated reminder email will be sent.

As the 'My Kidneys & Me' programme is part of the larger MyDESMOND e-learning platform, before completing the registration, you will be asked to agree to the MyDESMOND 'Terms and Conditions', 'Privacy Policy', and 'Accessibility Compliance Statement' before continuing. If you wish to view these now, these statements can be found in Appendix 2 at the end of this document or by clicking [HERE](#). It is important to know that these terms and conditions apply to the whole MyDESMOND programme, of which some features are not relevant to the 'My Kidneys & Me' programme. The MyDESMOND platform is designed for those with diabetes so some of words used in these documents may not be relevant for you.



Once you have registered, you will receive an automated 'Welcome' email from the programme. When you log-in for the first time, you will be taken to a 'Welcome' page explaining the features of the programme and how to navigate around.

You can log-in at any time to the 'My Kidneys & Me' programme from the 'My Kidneys & Me' front page by clicking on the 'Log-in' function. You will be asked to enter the username and password you created. The programme is available on any device that can run a web browser such as a computer, laptop, tablet, or mobile phone. If you forget your username and/or password, you can request a reminder to be sent to the email you used to sign up with.

Further information about the programme and its features can be found below.

4 Step 4.
After 10-weeks we will send you an email with a link to the survey questionnaires for a second time. You will need to enter your ID and initials as part of the survey. This is designed to test if having access to the programme has had any effect on your health. The survey is the same as before, except we will not ask you about your basic information again (e.g., your age, ethnicity etc.). You will be asked to fill in the survey regardless of what group you are in. If we do not receive your survey within 14-days of it being sent out, we will send you one reminder email.

5 Step 5.
After another 10-weeks we will send you an email with a link to the survey questionnaires for the third and final time. You will need to enter your ID and initials as part of the survey. Once you have filled in the survey questionnaires for the third time your involvement in the study is over. If we do not receive your survey within 14-days of it being sent out, we will send you one reminder email.

If you are in the INTERVENTION group, you will have access to the programme for a period of 2 years. If you are in the CONTROL group, after you have filled in the survey for the third time, we will provide you with a link to access the programme. You will also have access to this for 2 years once you register.

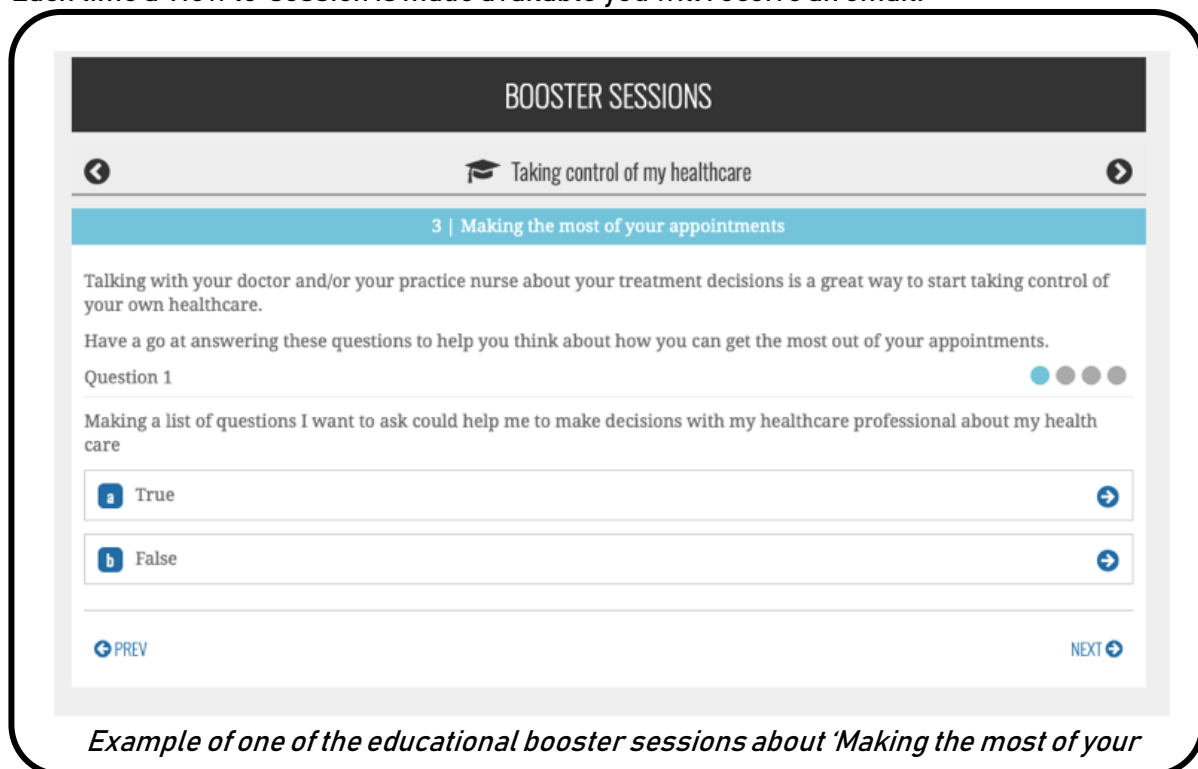
What does the 'My Kidneys & Me' programme involve?

'My Kidneys & Me' is an interactive online lifestyle education programme which has been developed to improve people with kidney problems' knowledge, confidence and skills to look after their own health. The programme consists of five main features:



Educational sessions
'How to' sessions
Health trackers
Decision maker
Activity

The educational sessions provide information about the kidneys, different kidney problems, its treatment and the different ways to self-manage having a kidney problem. The 'How to' sessions are interactive educational sessions, which provide instructions on how to look after your health. There are 8 'How to' sessions. These are released weekly after the second week. Each time a 'How to' session is made available you will receive an email.

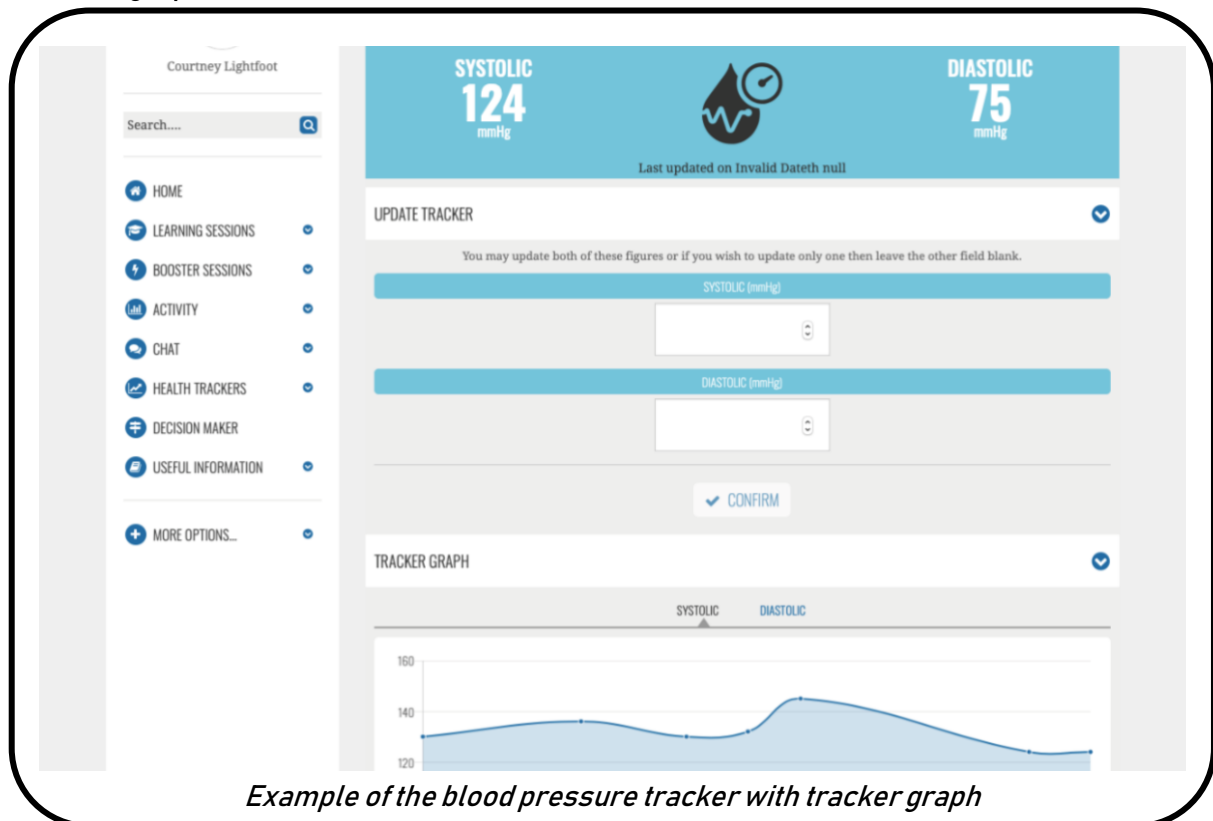


Example of one of the educational booster sessions about 'Making the most of your (healthcare) appointment with interactive questions

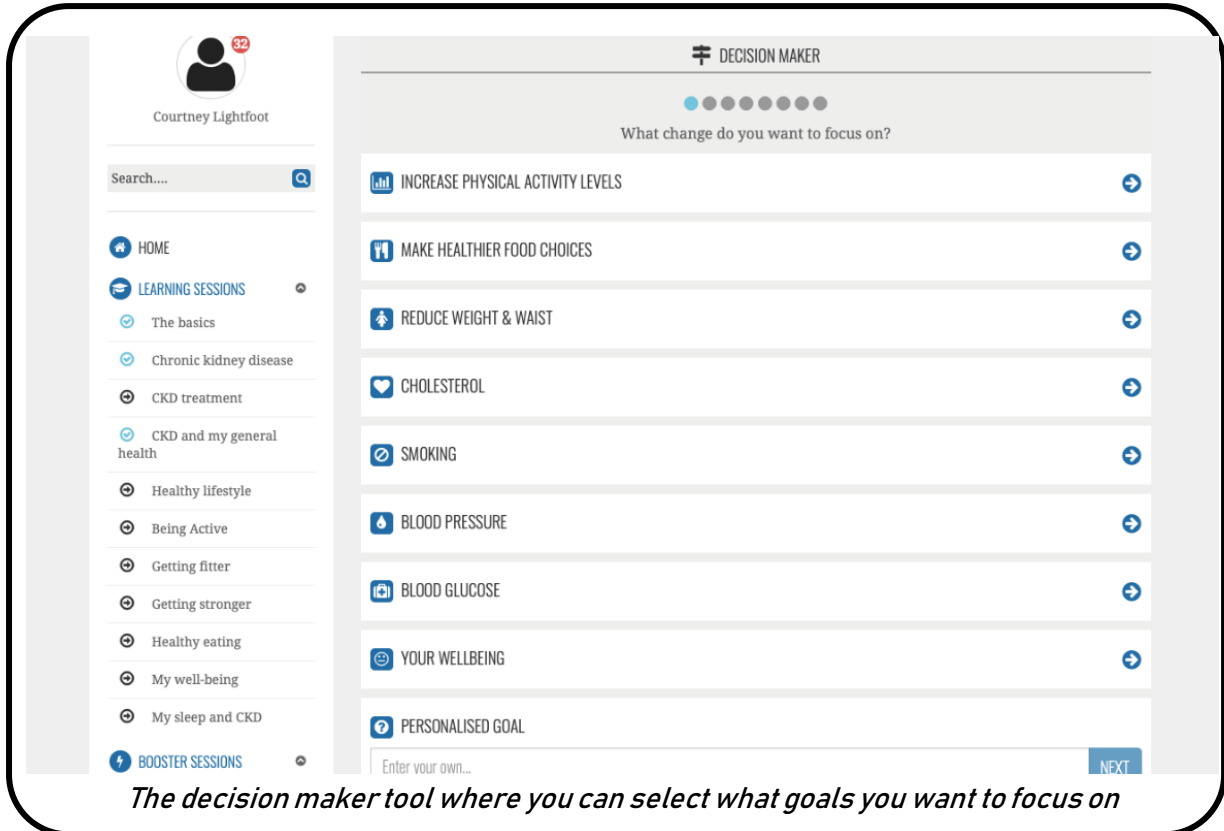
The health trackers feature allows you to track different aspects of your health. These will help you manage your health. The different trackers are:

Your physical functioning
Your body weight and measurements
Your fruit and vegetable intake
Your symptoms
Your smoking
Your cholesterol
Your blood pressure

These allow you to manually update your progress over time. Your progress will be shown via different graphs and charts.



The 'Activity' feature allows you to track your physical activity. You can track how many steps you have walked and for how many minutes. You can also challenge others or invite up to five of your own friends and family to join these challenges using a 'buddies' link. You can also connect your Fitbit or Google Fit devices and accounts, or you can enter your steps manually if you use another device. You can also use this feature to track your strength training progress. The 'Decision maker' feature helps you create and monitor your own health related goals.



Once you have registered for the programme you can log-in and use the programme how you wish. There are no limits to how many times you can log in and use the different features.



Please note, the main purpose of the 'My Kidneys & Me' programme is to provide information to users with kidney problems within the UK. All information provided via the 'My Kidneys & Me' programme is general information which can never be treated as being a substitute for professional health care. Do not rely upon any of the general information provided via the site for medical diagnosis or treatment. You must always consult with your doctor about personal health concerns.

If this is Part A, does this mean there are other parts of the study?

The main part of the study (i.e. testing the programme) is Part A. A small number of patients are being asked to complete other additional parts of the study. The researcher may contact you about this if you are suitable and may give you some further information via email.

What are the possible disadvantages and risks of taking part?

The main disadvantage of taking part is the time commitment involved filling in the survey questionnaires three times throughout the 20-week period. The pack is made up of several questionnaires. Most of them are short and have only a few questions. Some are longer. 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. You do not have to complete the survey in one go – you can return to the survey at any time to finish it. You will need to click on the 'Finish Later' button at the bottom of any page to do this.

Regarding the 'My Kidneys & Me' programme, we are interested in how, why, when, or whether people use the programme and how they engage with the different features. As such, it is up to you how much you use it and what for. We want people to use it for what works best for them – that may be logging in each day and working your way through the interactive learning sessions or it may be using the health trackers each week to monitor an aspect of your health such as your blood pressure. It is up to you how and when you use the programme. There is no right or wrong way to use it.

What are the possible benefits of taking part?

There are no direct benefits expected by taking part in this research. However, we hope that you find the programme interactive, educational, and useful in managing your health. It is up to you how you use the programme, if at all. The feedback we get will help us develop and improve the programme in the future.

What happens when the research study stops?

Any clinical care you may be receiving will continue unchanged. As stated, once you have registered for the 'My Kidneys & Me' programme you will have access for a period of 2 years.

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).

Your data and data protection

Information about the online software and platforms we are using in this study can be found in Appendix 1 and 2, or by clicking **HERE**.

In summary, throughout the SMILE-K study, you will be asked to provide information about yourself through two different online programmes:

- 1) 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/>.

Further information on 'Jisc Online Surveys' can be found in Appendix 1, or by clicking **HERE**.

- 2) The 'My Kidneys & Me' online programme is hosted on the MyDESMOND platform (<https://www.desmond-project.org.uk/>) as stated previously. This is an internationally established e-learning platform developed by the Leicester Diabetes Centre, University Hospitals of Leicester NHS Trust, and University of Leicester. MyDESMOND is regulated by the NHS Improvement and the Care Quality Commission.

Further information on MyDESMOND can be found in Appendix 2, or by clicking [HERE](#).

How will we use information about you?

We will need to use information from any answers you provide to questionnaires or other questions we may ask, from your medical records, 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. If you agree to take part in this study you will have the option to take part in future research using your data saved from this study. 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.

As described in Appendix 2, our website uses Google Analytics, a service which transmits website traffic data to Google servers in the United States, and which we then use to make the site work and to understand how it is being used. Google Analytics does not identify individual users or associate your IP address with any other data held by Google. We use reports provided by Google Analytics to help us understand website traffic and webpage usage.

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 as part of the 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 entered as part of the study (e.g., into the surveys) will be stored for 5 years following the end of the trial.

We keep information on your 'My Kidneys & Me' account for 24 months if the account remains active. If the account is deactivated or unused all information is archived after six months, and permanently deleted after 24 months. This is so that we meet our compliance obligations, and in case you want to use the service again in the future.

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.

Remember, you are responsible for all activity that takes place with your account. This includes what information you input into the programme. Any information you put into the 'My Kidneys & Me' WILL NOT be used for the purpose of research.

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 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 enough information on which to make an informed decision.

What next?

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

1. Please click on the other link in the email we sent you. This will take you to the online consent form. You can also click [HERE](#) to be taken to it.
2. Fill in the answers on the consent form and sign the consent form by writing your FULL name and the date you filled it in on.
3. Once we have received your consent form, we will send you an email with a link to the first set of questionnaires to complete.

 I am no longer interested, 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.

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