ImpRoving the Reporting of ITch using AccelerometERs in kidney patients (IRRITATE)

Participant Information Sheet (PIS)

You are being invited to take part in a research study to explore if people with chronic kidney disease (CKD) who suffer from itch find it acceptable and feasible to use wrist-worn activity trackers, or accelerometers, to support symptom assessments. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take the time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Feel free to ask us about anything that is not clear or if you would like more information. Thank you for taking the time to read this.

ABOUT THE RESEARCH

➢ Who will conduct the research?

The project is being carried out by Dr Sabine van der Veer (senior lecturer) and Mrs Sudershan Pillay and Albert Wells (medical students) at the Centre for Health Informatics, School for Health Sciences, University of Manchester.

➢ What is the purpose of the research?

Over one in three people with kidney disease are bothered by itchy skin. Itch often disturbs sleep, which in turn is linked to an increased risk of depression and dying. This means that we need timely and accurate assessment of these symptoms to prevent worsening of outcomes down the line. However, both itch and sleep problems remain underreported and undertreated, partly because it relies on patients reporting these symptoms to their kidney team.

The purpose of this study is to explore whether we can use accelerometers to support monitoring of itch and related sleep problems in people with kidney disease. Accelerometers are wrist-worn devices that track bodily activities, and you only have to wear them in order to collect data. Accelerometers can detect disturbed sleep and scratching activity, but it is still unclear whether kidney patients find it acceptable and feasible to use accelerometers for collecting symptom data. We also do not know if accelerometers could support or even replace kidney patients' self-reported itch and sleep problems.

The results of this project will inform if and how accelerometers could support itch and sleep monitoring in people with kidney disease. We hope that in the future this will help to manage symptoms better and will improve patients' experience and quality of life.

You have been invited to take part because you contacted the research team directly to express your interest in participating. In total, we plan to recruit a maximum of 45 people with chronic kidney disease who are suffering from itchy skin.

Will the outcomes of the research be published?

The results will be published in academic journals, at scientific conferences, and on the project's website (https://www.herc.ac.uk/research_project/irit-a/). Published results will never include information that might identify you as an individual.

Who has reviewed the research project?

The project has been reviewed and approved by the University of Manchester Proportionate Research Ethics Committee.

What would my involvement be?

What would I be asked to do if I took part?

If, after reading this information sheet, you are still interested in participating, we will call you for a screening to check if you meet the criteria for taking part. A researcher will contact you via email to ask for your phone number and what time would be convenient for you.

- If you do not meet the criteria or decide not to take part, we will only record the date and outcome of your screening, and how you heard about the study. All other screening data will be destroyed immediately in line with with the University's guidelines.
- If you meet the critera and decide to take part, we will ask you to complete an online from to give your written consent for participating in the study.

Once you have consented to take part, you will receive an accelerometer and a data collection booklet at your home address by postal mail. The booklet has a written instruction about what you need to do, and a member of the research team will book in an onboarding session with you to talk you through it and answer any questions you may have. They will also ask for some personal information, such as your age, ethnicity, postcode and if you are right or left-handed. Together, the session will take no more than 30-45 minutes. To plan the session, we will check with you what day/time would suit you and if you prefer to be contacted via zoom or by phone.

After the session, we will ask you to wear the accelerometer on your non-dominant wrist for seven nights in a row, from the moment you go to bed to the moment you wake up. The accelerometer is waterproof, so you can keep it on at all times, but there is no need to wear it during the day if you don't want to. In addition, we will ask you to keep a sleep and itch log (included in the booklet) for each night you wear the accelerometer. Completing one sleep and itch log will take you less than 2 minutes.

After one week of wearing the accelerometer and completing the logs, you can return the booklet together with the accelerometer to the research team by postal mail using the provided stamped envelope. Around the same time, we will email you a link to an online questionnaire. The questionnaire is about your sleep quality and itch severity over the past week, and about your experience of wearing the accelerometer. Completing the questionnaires online will take you approximately 30 minutes.

If the strap of the accelerometer causes skin irritation or discomfort, you can simply stop wearing the accelerometer and return it to the research team as normal. We will still ask you to complete the online questionnaire.

The researchers will not share any information collected as part of the study with your care team. This means that taking part in this study cannot directly benefit or otherwise affect your care, but by participating, you will help to improve how symptoms of kidney disease are managed in general.

➢ Will I be compensated for taking part?

After we have received the accelerometer, completed booklet and completed online questionnaires from you, you will receive a £20 shopping voucher to thank you for your time and contribution.

➢ What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. You should only consider taking part if you think you can wear the accelerometer comfortably and without problems. If you are unsure about this, for example because you have a fistula or may need one in the future, please contact your renal centre for advice.

You can let the research team know via email if you want to participate or when they contact you. If you do decide to take part, you will be given this information sheet to keep and asked to sign an online consent form. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify which data is yours. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

Data Protection and Confidentiality

➢ What information will you collect about me?

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically, we will need to collect:

- Name and contact details;
- Age, gender, ethnicity and if you are right or left-handed;
- Postcode (to derive information on the relative deprivation of the area you live in);
- If you are on dialysis or have a kidney transplant;
- How severely you have been affected by itchy skin over the past week;
- Accelerometer data on your sleep;
- Your self-reported sleep quality, itch severity, and experience of wearing the accelerometer.

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

What are my rights in relation to the information you will collect about me?

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including accelerometer data.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research.

Will my participation in the study be confidential and my personal identifiable information be protected?

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way.

Only researchers at The University of Manchester will have access to your personal information. To ensure confidentiality, we will provide you with an assigned ID number only known to the research team. Only the research team will have access to the key that links this ID number to your personal information. We will use this ID instead of your name to store your data (known as pseudonymised) whenever possible. All data will be stored in electronic format. Any identifiable data (e.g. your name and contact details) will be stored separately from your pseudonymised data. We will destroy your:

- Screening and contact details as soon as we have received and processed your accelerometer and booklet data, and have sent you the shopping vouchers.
- Completed paper participant booklets as soon as we have scanned them into electronic format
- Consent form two after publication of the research
- Pseudonymised data five years after publication of the research.

Please note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

Additional information in relation to COVID-19

Due to the current COVID-19 pandemic, we have made some adjustments to the way in which this research study will be conducted that ensures we are adhering to the latest government advice in relation to social distancing as well as taking all reasonable precautions in terms of limiting the spread of the virus. You should carefully consider all of the information provided below before deciding if you still want to take part in this research study. If you choose not to take part, you need to inform research team. If you have any additional queries about any of the information provided, please speak with a member of the research team.

➢ Are there any additional considerations that I need to know about before deciding whether I should take part?

We are not asking you to attend the hospital outside of your routine clinical consultations, and no face-to-face contact is required for taking part in the study.

The accelerometer will be handled by a researcher before sending it to you. In some cases, an accelerometer may be used for data collection in someone else before you. Although the risk of spreading coronavirus via the accelerometer is low, we have taken special measures to further minimise this risk.

➢ What additional steps will you take to keep me safe while I take part?

- We will use disinfectant to soak the straps and to whipe the accelerometers before sending them to you via the post.
- The researcher who prepares the mailing of your accelerometer will wash their hands in line with handwashing guidelines and wear face covering throughout the preparation.
- We will minimise the occasions where an accelerometer is used for data collection in more than one participant as much as practically possible.
- In case the same accelerometer has been used by someone else before you, we will leave at least 72 hours between receiving the accelerometer from the previous participant before preparing it and sending it to you.
- The participant booklet will include instructions for how you can clean the accelerometer yourself in the period you are using it for data collection, should that be needed.

➢ What if the Government Guidance changes?

Changes to government guidance will not impact on the study because all contact between you and the research team will be via post, phone or zoom.

➢ What if I have additional queries?

If you have any remaining questions or concerns, do not hesitate to contact the research team using the contact details on the next page.

What if I have a complaint?

➢ Contact details for complaints

If you have a complaint that you wish to direct to members of the research team, please contact:

DR SABINE VAN DER VEER, the chief investigator, in first instance, v**ia email sabine.vanderveer@manchester.ac.uk or phone 0161 306 7767**.

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact:

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information Tel 0303 123 1113

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the chief investigator.

DR SABINE VAN DER VEER

UNIVERSITY OF MANCHESTER

☎ **0161 306 7767**

✉ **sabine.vanderveer@manchester.ac.uk**