Recorded Exercise, Activity, and Cardiovascular Tracking for Kidney transplant Impact and Decision-making (REACT-KID)

Participant Information Sheet

Before you decide to take part in this study it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. A member of the team can be contacted if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Purpose of the study

Patients with kidney failure are faced with a choice between dialysis for the rest of their lives or a kidney transplant. Although for many patients, a transplant works out better, for others dialysis may be the best option. This is an important decision, and it is not always clear which choice will be right for each patient.
We are looking at whether wearing a smartwatch device at home for a few days can give us extra information about a patient's daily physical activity levels and heart rate ranges. This information may contribute to the decision making and may predict potential outcomes from each treatment option.

Why have I been chosen?

All patients planned to be listed for transplantation under the care of Cambridge University Hospitals are invited to take part.

Do I have to take part?

Taking part in the study is entirely voluntary, and **if you decide not to participate this will not affect your care in any way, now or in the future nor will participating in the study affect your care as a patient.** If you change your mind at any point, then all you have to do is let the study team know.

What will happen to me if I take part?

When you attend your transplant assessment clinic appointment, we will discuss the study with you and, if you are happy to take part, we will ask you to sign a consent form, a copy of which is attached. You will be asked to complete a short questionnaire about your quality of life and

a short test of memory and thinking. We will show you how to wear a Garmin smartwatch device on your wrist, and ask you to wear it continuously for one week from the clinic appointment while you go about your usual activities. The device will automatically store information on your movement (accelerometry) and heart rate. You will be asked to return the device in a pre-paid, addressed envelope that we will provide. If you go on to receive a kidney transplant, we may ask you to repeat the questionnaire and wear the device for another one-week period following a clinic visit four months after the operation, then return it as before.

Please note that although the device collects information about your movement and heart rate, this data is not monitored by clinicians in real time. The research team will not receive live alerts or be able to respond to any health events while you are wearing the device.

If you feel unwell at any point you should seek medical care as you normally would. Wearing the device does not replace routine medical care, and no clinical team will be monitoring your health based on the data collected. You are not liable for the device if any damages occurs during the period of wearing the device.

Will I receive any payment for taking part?

No, it will not be possible to provide payment for taking part.

Are there possible disadvantages and/or risks in taking part?

In some instances, you could experience itchy skin or develop a little rash from wearing the wrist strap. This could be because the strap or your wrist is damp. Try drying your skin and the smartwatch. However, if the itchiness continues, please take off the smartwatch and return it to the researcher in the prepaid padded envelope provided. If the itchiness does not go away on its own then use a small amount of proprietary HC45 cream (E45 moisturiser plus 1% hydrocortisone cream), which you can buy from a pharmacy without prescription.

Please note, we take care to thoroughly disinfect both monitors before and after use and take further precautions for safe handling and packaging. The monitors and wrist straps will not be damaged if disinfectant wipes are used.

If you have any questions or problems, please do not hesitate to contact the research team.

This is a study to explore and learn. The data measured by the smartwatch will not change the care you get, now or in the future. You will not be able to see the data collected on the device during the study.

There will probably be no direct benefit to you by participating in this study. However, in the future it may benefit you or other patients like you.

What will happen to the results of the research project?

The results of the study will be presented at conferences and written up in journals. The findings will be shown for groups of individuals. If we ever show individual results, your personal details will be removed so that no one can tell who you are.

You will be asked to indicate whether you wish to receive a summary of the findings of the study when you complete the consent form. The summary will be sent out after the results have been published in a research journal. This will be at the end of the study (Autumn 2027). You may opt to receive the results either by post or by email. You may change your mind about whether you would like to receive the summary at any time during the study by letting a member of the study team know.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers, who will do their best to answer your questions - you can do this by contacting Stephen Marsh by email at stephen.marsh9@nhs.net

What can I do if I have any complaints or concerns?

If you wish to complain or have any concerns about any aspect of the way you have been treated during this study then you should immediately inform the Chief Investigator (Prof. Gavin Pettigrew) via gavin.pettigrew1@nhs.net

Alternatively you can contact your local Patient and Advice Liaison Services (PALS)

Telephone: 01223 216756

Email: cuh.pals@nhs.net

Who is organising and funding the research?

This study is organised by scientists at the University of Cambridge, with study coordination provided by the Cambridge Epidemiology & Clinical Trials Unit at the MRC Epidemiology Unit. The research will be conducted with support from clinic staff involved in patient care. The Chief Investigator is Prof. Gavin Pettigrew. The study is funded by the NIHR Cambridge Biomedical Research Centre and jointly sponsored by Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge, who will also act as joint data controllers.
The results from the study will also form part of the doctoral research (PhD) of Mr Stephen Marsh, who is a member of the research team and involved in the day to day coordination of the study. He is listed as a contact on this information sheet.

Ethical review of the study

The project has been reviewed and approved by the Seasonal Research Ethics Committee (REC) and Health Research Authority (HRA).

Insurance

Cambridge University Hospitals NHS Foundation Trust, as a member of the NHS Clinical Negligence Scheme for Trusts, will accept full financial liability for harm caused to participants in the study caused through the negligence of its employees and honorary contract holders. There are no specific arrangements for compensation should a participant be harmed through participation in the study, but no-one has acted negligently.

The University of Cambridge will arrange insurance for negligent harm caused as a result of protocol design and for non-negligent harm arising through participation in the study.

Data Protection

How will we use information about you?

We will need to use information from you, your medical record, and the Garmin device for this research project. This information will include your

- NHS number
- Name
- Contact details.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

Access to your information for monitoring and audit.

To make sure that the study is being carried out to the required standards, your medical records and the information collected for the study may be looked at by authorised individuals from Cambridge University Hospitals NHS Foundation Trust, the University of Cambridge (as joint sponsors), or regulatory authorities. This means that people outside your direct care team may need to see identifiable information about you. These checks will be carried out under strict confidentiality rules and only for the purpose of ensuring that the research is being conducted 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.

Cambridge University Hospitals NHS Foundation Trust (CUH) and University of Cambridge are joint sponsors for this study based in the United Kingdom. The joint- sponsors of this research are responsible for looking after your information. We will share your information related to this research project with the following types of organisation:

- University of Cambridge

- Cambridge University Hospitals NHS Foundation Trust

In addition, data collected from the Garmin device will be processed using the Fitrockr platform, a secure health research platform that allows us to access high-resolution data from the smartwatch. This platform is used widely in health research across the NHS and academic institutions.

The Garmin devices will be pre-configured by the research team with a study ID only. No personal identifiers (e.g. name, contact details, GPS location) will be stored on the device or shared with Garmin or Fitrockr. All data are stored on secure, GDPR-compliant EU-based servers (located in Germany), and only authorised research staff at the University of Cambridge will access the data for analysis.

We will keep all information about you safe and secure by:

- only using information that we need for the research study;
- letting very few people know your name or contact details, and only if they really need it for this study;
- keeping your data safe and secure;
- following all privacy rules;
- making sure no-one can work out who you are from the reports we write.

International transfers
Your data will not be shared outside of the UK.

How will we use information about you after the study ends?

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.
We will keep your study data for a maximum of one year after the study has finished. The study data will then be fully anonymised and securely archived or destroyed.

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.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- by asking one of the research team
- by sending an email to stephen.marsh9@nhs.net
- at www.hra.nhs.uk/patientdataandresearch
- On the "How we use your personal information (for medical research participants) page on the University website: https://www.information-compliance.admin.cam.ac.uk/data-protection/research-participant-data
- or by email to the Data Protection Officer at: cuh.gdpr@nhs.net

Contact for further information

Should you require any further information about the study, kindly contact Stephen Marsh by email at stephen.marsh9@nhs.net

Thank you very much for taking the time to read this information