A study of Wrist Worn Accelerometery to characterise the physical activity of patients with End-Stage Renal Disease (W-WARD2 study).

We would like to give you the opportunity to participate in a research study.

Please read through this information leaflet and then one of the research team will have a further chat with you to answer any questions you may have.

Why do we think this is an important study?

The kidneys are important at getting rid of toxins and excess water from the body. If they fail, then these toxins and the excess water builds up within your body. As you know, we treat kidney failure by either giving patients a new kidney (a transplant) or by removing the toxins and fluid from the body by dialysis.

In Cambridge, we aim to personalise the care we give to our patients with kidney failure. As such, we have recently started measuring the physical function of our patients with kidney failure, who either already require dialysis or may need dialysis in the future. We are currently doing this in a number of ways including measuring how strong your grip is, assessing your walking and asking you questions about how difficult you find certain activities.

In the future, we think that this will allow us to target treatments to help improve your physical function and potentially identify any problems you experience earlier.

We are aware that our current approaches to measure your physical activity and function have limitations and in particular may over- or underestimate the level of your physical activity in your daily lives. For this reason we are keen to see if we can get a better picture of your habitual levels of physical activity by asking you to wear an activity monitor (called an accelerometer) on your wrist at home for a week at two time points 6 months apart.

Why have I been invited to take part?

You have either started dialysis or may require it in the future.

Do I have to take part?

You are free to choose whether to participate or not. This will not affect your care in anyway. If you change your mind at any point, then all you have to do is let us know.

What will happen to me if I take part?
If you agree to take part, we will measure your physical function as we do in all patients, but you will also then be asked to wear the activity monitor for 7 days continuously. At the end of 7 days, we will ask you to post the monitor back to us using a pre-paid envelope that we will provide, or if instructed by your clinic team, bring the monitor back with you at your next clinic visit. We will ask you to wear this activity monitor a second time 6 months after your first wear.

Other than that, researchers will just keep an eye on how you are doing by looking at your medical records, i.e. you do not need to make any special trips to see us.

Will I receive any payment for taking part?
It will not be possible to provide payment for taking part.

What are the possible risks taking part?
We do not believe that there are any significant risks in taking part.

Occasionally people have described mild skin irritation from wearing the monitor. In the unlikely event that you experience this, you will be given advice to take the device off and report it to the research team.

What are the possible benefits of taking part?
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 happens if I don't want to carry on with the study?
If you decide that you no longer want to take part, you can withdraw from the study at any time. No further data will be collected, though any data already collected will be used in the study analysis.

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 Mev Alsop or Regin Lagaac at Cambridge Dialysis Centre on 01223 400 180.

Complaints
If you remain unhappy and wish to complain formally, you can do this through the standard NHS complaints procedures – to do this you should contact the Patient Advice and Liaison Office (PALS) near the main Addenbrooke's Hospital entrance, by email: cuh.pals@nhs.net or by phone: 01223 216756. In addition, you can also contact the head of department at the MRC Epidemiology

Unit, University of Cambridge, Prof. Nick Wareham by telephone: 01223 330315 or email: nick.wareham@mrc-epid.cam.ac.uk

Harm

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 Cambridge University Hospitals NHS Foundation 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).

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.

Will my taking part in this study be kept confidential?

In this research study we will need to use information from your medical records. This information will include your medical history, your medications, your physical function test results (the assessments performed in clinic), routine measurements made in the clinic (blood pressure, heart rate etc) and results of your routine blood tests and scans.

We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. You will be assigned a unique code when you consent to take part in the study. This code will be used to label all data collected during the study and is used in place of personal information. People will use this information to do the research or to check your records to make sure that the research is being done properly. Personal identifiable information, such as your contact details and NHS number will be kept separate from any other data we collect and will be stored on secured network drive.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. Cambridge University Hospitals NHS Foundation

Trust (CUHNFT) and University of Cambridge are joint sponsors for this study based in the United Kingdom. CUHNFT and the University of Cambridge will be using information from you to undertake this study and will act as joint data controllers. This means that both organisations are responsible for looking after your information and using it properly. CUHNFT will keep identifiable information about you for 20 years after the study has finished and it will then be destroyed. With your permission, information we collect will be stored anonymously at the MRC Epidemiology Unit, University of Cambridge for analysis using the unique code only.

At the end of the study, we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write.

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

- www.hra.nhs.uk/information-about-patients/
- https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information
- By email the Data Protection Officer at: cuh.gdpr@nhs.net
- Or by asking one of the research team using the details below.

What will happen to the results of the research study?

We will publish and publicise the outcome of this study to help other dialysis centres, but all included data would be completely anonymous. This may include in scientific and medical journals (both in print and on-line) and presenting our findings to other medical professionals at conferences.

We will also ask your patient bodies (including Cambridge Kidney Patient Association) to disseminate our findings via their social media platforms.

Who is funding this research?

This study is supported by the National Institute for Health Research Biomedical Research Centre Cambridge for this study.

Who has reviewed the study?

This study has been reviewed by an independent group of people, the Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. The study has been given a favourable opinion by Brighton and Sussex Research Ethics Committee.

Further information and contact details

If you would like further information about any aspect of this research, you should talk to one of the research team whose names are below:

The research team are Dr Kirsten Rennie, Mr Subhankar Paul, Mr James Richards, Mr Gavin Pettigrew, Dr Sanjay Ojha, Dr Matthew Butler and Dr Victoria Keevil.

They can be contacted via Mev Alsop or Regin Lagaac at the Cambridge Dialysis Centre on 01223 400 180 or by writing to Mr Subhankar Paul at Cambridge Dialysis Centre, Unit E, Beadle Trading Estate, Ditton Walk, Cambridge, CB5 8PD or email: subhankar.paul@nhs.net

Further information about the study can be found on the study webpage https://www.mrc-epid.cam.ac.uk/research/studies/w-ward