UK Dialysis Cognition Study (UKDC).

The background and purpose of the research

We are asking for your help with this important research study. This study will compare the change in cognitive function between people starting haemodialysis or peritoneal dialysis. Cognitive function is the brain's ability to remember, learn and reason. Taking part in this study is **strictly your choice**. Your treatment will not be changed in any way if you choose not to take part in this study.

This study is called the **UK Dialysis Cognition Study (UKDC)**. We will collect medical data on 320 people starting haemodialysis or peritoneal dialysis. Your dialysis centre is taking part in this study. This study is funded by Baxter (now Vantive) This is a healthcare company. University Hospitals Birmingham NHS Foundation Trust are sponsoring (backing) this study.

The study is organised by the University Hospitals Birmingham NHS Foundation Trust. A research company called Arbor Research Collaborative for Health (Arbor Research) will be in charge of data organisation and analysis. Arbor Research is a non-profit company in the United States and has worked on a similar study in the UK called DOPPS (Dialysis Outcomes Practice Pattern Study). This study has been ongoing since 1996. This study has provided important information which helped improve the care of dialysis patients.

We know cognitive function may slowly go down after the start of dialysis treatment. This UKDC study will help us to better understand the pattern of change in cognitive function in people like you. This will help us to come up with new ways to help people on dialysis in the future.

What would taking part involve?

You were picked to take part in this study because you are starting dialysis for kidney failure. We will ask for your permission to collect data about you. Data from your medical history will be collected mainly from your medical record. We want to collect data at the time you join the study and again every six months for the length of the study (2025-2028). You would take part in this study for up to 24 months.

We would collect data about your dialysis treatment, medical condition, lab values, hospital visits, medications, and other parts of your medical care. We will also ask you to collect 24hr urine samples at the start of your dialysis, and then up to four times over the duration of the study. The data you provide will help us understand how your dialysis treatment affects your cognition. This research study will not help you directly,

but it will help us better understand the change in cognitive function in people on dialysis. In future, the findings may help people with kidney failure to choose the right type of dialysis for themselves.

We would also ask you to do Patient Questionnaires and a cognitive function test. You will do these when you join the study and again after 3, 6, 9, 12 and 24 months. These surveys will ask your opinion about your life and experiences on dialysis. This information is very important to us. Your participation in this research is voluntary. This means it is your choice whether to take part or not. Your care will not change if you choose not to take part in this study.

Your treatment will not change when you take part in this study. This is because the study only involves us collecting data about you. We will not start a new treatment.

Confidentiality and using your data

How will we use information about you?

We will need to use information from you from your medical records for this research project.

This information will include your name and NHS number. 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 code number instead.

University Hospitals Birmingham NHS Foundation Trust is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Arbor Research (USA)

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

- Anonymising all your personal details

International transfers

We may share or provide access to data about you outside the UK for research related purposes to:

- Plan data analysis
- Publication plans

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Arbor Research (USA)

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law by doing the following:

- They must follow our rules about keeping your information safe.

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 10 years. 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 medical records. 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, including the specific mechanism used by us when transferring your personal data out of the UK by asking one of the research team members

What are the risks of taking part?

There are no risks to your health with taking part in this study. Strict measures are in place, so all the data collected about you remain confidential. Data provided to researchers by Arbor Research will not be identifiable to you. Any collection, storage and transfer of data involve a general risk of re-identification This risk is small but cannot be completely excluded,

Capacity

If you lose capacity during your time in the UKDC study, the local study team will consult a consultee. This is someone who knows you well but is not acting in a professional or paid role. This could be a relative/guardian or friend. Your appointed consultee will be provided with an approved information leaflet and declaration form to complete.

Right to Withdraw:

Your care will not change if you decide you want to stop taking part in this study at any time. We would not collect any new data about you. Data about you that has already been collected may still be used. Please let your Research Nurse or Doctor know if you want to stop taking part in this study. If you lose the ability to make decisions for yourself we will no longer collect new data. We would also not ask you to do more questionnaires or cognitive function tests. We would discuss with a family member or friend of yours about using the data we would have already collected on you.

Questions:

If you have any questions, please talk with your dialysis centre. You may also contact Dr ……., the Principal Investigator of UKDC at your hospital by email at …… or phone on ……..

If you wish to contact someone not involved in the study, please contact:

Patient Advice and Liaison Service (PALS), University Hospitals Birmingham NHS Foundation Trust

Telephone: 0121 371 3280

Email: PALS@UHB.nhs.uk