TONiC
Trajectories of Outcome in Neurological Conditions

IRAS Ref - 268738

Participant Information Sheet

Linking other studies and health information to, and collecting supplementary information and samples for the TONiC study

Thank you for your interest in our research. This sheet will explain the background behind our research, why we are doing this work, and how you could be involved. Please take time to read the following information carefully. If you are in any way unsure or have any questions, please do not hesitate to ask. Take time to decide whether or not you wish to take part.

What is the research about?

The TONiC study is helping us to understand the factors that determine quality of life in neurological conditions and you have contributed to what is now a very large and successful national study.

Linking our TONiC information to the information obtained from blood, saliva or other human tissue samples would be a very powerful way to understand some of the more fundamental questions in neurological conditions such as what are the **environmental, biological** and **genetic** factors that determine disease severity?

Environmental factors including air pollution levels and sunlight exposure can be obtained by knowing the location (postcode if possible) of where you spend most of your time (live and work).

Biological factors can reveal how your body is reacting to the neurological condition or its treatment and can be identified by testing blood. There are also likely to be biological factors that show how the brain and spinal cord are reacting to disease that can only be seen in the spinal fluid. A spinal fluid sample could be given by having a lumbar puncture and if you needed one for your NHS care we will ask your consent to keep the leftover fluid rather than discard it. Another important biological factor is the type of bacteria living in your gut; to analyse this, we would need a sample of urine and/or faeces and information on your diet and medication obtained by a questionnaire.

Genetic factors can be analysed from blood from a blood test, the cells in a cheek swab, or the cells in the spinal fluid obtained by lumbar puncture. Specialist testing can determine if there are particular genes that influence disease severity. We can also investigate if your health condition and lifestyle are influencing your genes. Samples that you have donated may also be used as comparison samples for other diseases.

By reading this leaflet and considering consenting to this research, you are NOT agreeing to provide all these samples. We are explaining the type of research to be done. We will discuss with you exactly which samples and you can decide if you want to donate them.

Why have I been invited?

We are asking you to be involved because you have completed one or more questionnaire pack(s) for the TONiC study.

You may be interested in helping the study to answer the important question of what influences disease severity by providing the highest quality supplementary information in the form of new blood samples, stool sample or even consider donating a spinal fluid sample.

Do I have to take part?

No, you don't. It is entirely up to you to decide whether you would like to be involved in our research. There is no penalty for not taking part and if you do agree to take part you can still withdraw at any time without stating a reason. A decision to withdraw, or a decision not to take part, will not affect the standard of care you receive.

What does my participation involve?

We may ask you to complete additional questionnaires and provide samples which may include blood, stool, mouth swab or spinal fluid (collectively called bio-samples).

It is possible to consent to all, some or none of the following parts in order to:

1) complete a questionnaire on diet (e.g. nutritional supplement drinks, vitamins, foods), and an environment questionnaire asking about where you have lived and worked and your occupation (if any);

2) provide a blood or saliva sample for analysis. The blood sample is taken by application of a tourniquet to the arm and then inserting a needle into a vein at the elbow or back of the hand. It is highly likely that you will be familiar with this test from routine NHS care. Alternatively, the blood may be obtained from a simple finger-prick, such as people with diabetes routinely do for themselves at home to check blood sugar;

3) provide a stool sample obtained at home or a urine sample. You may already have done a test like this, from your GP or as part of routine screening;

4) provide a genetic sample which would be either a blood test or a mouth swab (a cotton bud simply drawn along the cheek inside the mouth or a saliva sample obtained by you spitting into a tube, which can be done at home);

5) provide a cerebrospinal fluid (CSF) sample by having a lumbar puncture procedure (if you are already having one as part of routine care); a blood sample will also be required to accompany the CSF. Analysis of the spinal fluid may involve extracting genetic information from any cells contained in the fluid. Lumbar punctures are routinely done by all neuroscience centres and you would be given full information prior to making any arrangements to proceed.

Non-genetic and genetic blood samples would be drawn at the same time, should you have consented, in order to keep the number of blood tests to a minimum. We will normally collect samples when you are attending hospital for your routine clinic visit. We are inviting you to donate samples for research and will not be paying you to participate.

What will happen to any samples that I donate, and the data generated from samples?

Your samples will be stored in a biobank for ten years, registered against a study number and without identifiable information attached. After this time, your samples will be destroyed unless ethical approval is granted to continue with the research. We are required to explain to you what would happen in the unlikely event that you lose capacity to provide research consent at some point in the future. If in future you lose capacity, we will continue to store the samples you donated and the information you have already provided. We will continue to use them according to the choices you made when you did have capacity to make decisions. Samples may be removed from the biobank and sent to laboratories in other parts of the UK or rest of the world and analysed by academic or commercial scientific organisations who are working with the TONiC group; these organisations may be outside the UK. The samples will only be used for healthcare research. We will not give any of these collaborators any personal details which could identify you.

The data generated from your samples will be held until the research analysis is complete; it will be protected by UK data protection laws (UK GDPR). Your data may be accessed by academic and commercial organisations within and outside of the EU, who will be required to obey UK and EU data protection law and process your data in accordance with this consent, with the appropriate safeguards in place to do so.

What will happen to the results generated from my samples?

It is now accepted practice that the anonymous results are shared in order to obtain the maximum scientific benefit from samples, so we will archive a copy of the data in a recognised data storing database (such as the European Genome-phenome Archive). The data could be used by other researchers to help people with your illness, other diseases, or on non-disease related but relevant issues (such as developing new methods of analysis). No personal identifying data (name, address etc.) is ever shared with any other researchers or any data storing database, and the data in the database is anonymous.

We will not feedback to you any of the results we obtain analysing your samples, because you are donating these samples for research and not for clinical diagnostic testing – samples for clinical diagnostic testing are subject to very strict rules for accuracy. Also, if you decide, following discussion with your clinical team, that you wish to be referred for clinical genetic testing you would have access to counseling about possible implications of the results before and after testing. The results of research testing will not routinely be added to your NHS records; however, if we identify something from your blood sample that has a high risk of affecting your health and is treatable or preventable we may feed this back to your family doctor and/or hospital consultant.

Will my treatment be affected by my participation?

No. Whether you choose to take part or not, your care in hospital will not be affected now or at any time in the future.

What are the benefits of taking part?

This research will not directly influence the care and services that you will receive. However, we hope that the information that you give to us will help us to better understand important factors associated with quality of life and disease severity in neurological conditions and to improve services for patients in the future.

What are the risks of taking part?

No risk is expected from completing the environmental or diet questionnaire.

Blood testing carries a risk of bruising or bleeding from the venepuncture site and it could be painful. Sometimes, it is not possible to draw blood back through the needle, in which case the blood test can be either re-attempted or abandoned.

Before deciding about lumbar puncture, you would be given full information from the team who would do this procedure for you.

Your rights

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

Will my taking part be kept confidential?

Yes. To carry out our work we will need to maintain a computer record about you, which will be stored in line with the General Data Protection Regulations (UK GDPR). Personal data (data that can identify you) will be used by the TONiC study group. Personal data may be shared with external research organisations, such as universities and commercial companies in this country and abroad for scientific research purposes. We will not share information that can be used to identify you. We will share the minimum information required for an understanding of the sample you have donated; for example, some blood levels might be normal in older people but abnormal in young people, we would provide the year of birth of the donor and not the actual date of birth.

We may need to contact your GP and/or your hospital consultant; or link to your medical records electronically using the NHS Clinical Practice Research Datalink (or an equivalent system).

All those involved in handling information about you, or any other data relating to you, such as that arising from the analysis of your samples, have a duty of confidentiality to you as a research participant. Your identity will not be disclosed to third parties.

The Walton Centre NHS FT is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

The Walton Centre NHS FT will keep identifiable information about you for 10 years. This will include your name, NHS number, DOB and address. This information will not be passed to a third party, we are keeping it so we could make contact if there was a result that has a high risk of

affecting your health and is treatable or preventable so your GP or consultant should arrange further tests.

Can I withdraw from the study?

Yes, you are free to withdraw from the study at any time without stating a reason.

If you withdraw from the study, we will keep the information about you that we have already obtained. The information that you have already provided, including any bio-samples you donated in the past which have already been banked and/or analysed, will be retained. If a sample has not yet been processed, you can request that it is destroyed. To safeguard your rights we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at https://www.finders-study.org/data-sharing or by contacting the TONiC office on 0151 5563565 /0151 556 3693.

Who is doing the study?

The senior researcher of the study is Professor Carolyn Young from the Walton Centre NHS Foundation Trust.

Who has reviewed the study?

It has been reviewed by an independent NHS research ethics committee and internally by the Walton Centre Research & Development Committee.

What if something goes wrong?

If you have any questions or concerns at any stage of your involvement in this research project, please feel free to discuss these with the research team. We will do our best to resolve any problems quickly. If you are still unhappy and wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service (NHS) complaints mechanisms are available to you. Further details and advice can be found on the NHS website or by contacting your local Patient Liaison Service (PALS) or you can contact the Information commissioner's office on 0303 123 1113.

We do not foresee any risk of harm to you during this study. However, if you are harmed in any way by taking part in this research project you should be aware that there are no special compensation arrangements. If you are harmed due to someone else's negligence, you may have grounds for legal action but you may have to pay for this yourself.

Where can I get more information from?

If you have any further questions or would like some more information, please feel free to contact 0151 556 3693 or by email tonic@thewaltoncentre.nhs.uk or see the website at https://www.finders-study.org/. The team will be happy to discuss any concerns and to answer your questions. If your query relates to the use of your data, the team will pass your query onto the Data Protection Officer (DPO@thewaltoncentre.nhs.uk).

Thank you for taking the time to read this information sheet!