



IRAS Ref - 88372

Participant Information Sheet

Phase 5 - Linking other studies and health information to the TONiC study

What is the research about?

The TONiC study is allowing 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.

The size of the TONiC study means that there is a chance that you may have already taken part in another study of your neurological condition, such as a genetics study or may have donated spinal fluid samples to a tissue biobank, or may be approached in the future to take part in such studies. Linking our TONiC information to other existing studies would be a very powerful and efficient way to understand some fundamental questions such as what are the **environmental, biological** and **genetic** factors that determine disease severity?

Most people who have participated in TONiC will have had hospital-based tests such as MRI scanning for either diagnosis or disease monitoring. Similarly, some will have had spinal fluid collection (lumbar puncture). Linking the information on your neurological condition from the TONiC study to NHS MRI scans and treatment information may also facilitate important research into the factors predicting disease severity.

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 and may already have participated in another study to which we are interested in linking or may participate in other such studies in the future.

Do I have to take part?

It is entirely up to you to decide whether you would like to be involved in our research.

What does my participation involve?

Taking part in this project requires no *active* participation. We are asking your permission to link information which has already been collected.

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

- 1) allow biomedical researchers to link their data/data derived from samples that they already hold on you to your TONiC questionnaires or to link TONiC questionnaires to future studies in which

you may participate (you are not obliged to enrol in any such future studies) and this may involve sharing completely pseudonymised TONiC data with commercial companies outside the UK or EU who may be needed for data analysis, this data will not contain any information that could traditionally identify you, e.g. your name or DOB;

- 2) allow TONiC researchers to review your hospital records for any relevant test results and treatment information (including MRI images to be analysed by the TONiC study group);
- 3) allow us to keep your details (such as NHS number and contact details) beyond the end of the TONiC study, so that you could be approached, including in the future, by us or other research groups working with us, should any new research questions arise. You would be under no obligation to take part in any potential studies; we are asking permission to hold your details so that we could ask you about studies which may be of interest to you.

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 use the information you have already provided in keeping with the choices you made when you did have capacity to make decisions. Information that you have already given us could be used in new studies relying on analysing data that is already collected, but you would usually not be able to join a future study.

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.

What are the risks of taking part?

Since no *active* participation is required, no risks are expected.

Your rights

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways 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 (GDPR).

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).

Linking your information between studies would be typically performed by matching your NHS number and then using your name, date of birth and postcode to double check that the link is correct. Use of this identifiable personal information will be kept to an absolute minimum by as few

researchers as possible for the strict purpose of allowing the link to be made; from then on anonymous study numbers/codes will be used.

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 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 five years after the study has finished. Your data will have a study number, and only the hospital where you joined the study and/or the TONiC team at the Walton Centre will be able to match the study number to your identity. Your pseudonymised data may be kept for the duration of the scientific research being carried out by The Walton Centre and its commercial research partners. This continual analysis is necessary for scientific research being carried out by The Walton Centre and its research partners because as changes and advances emerge over time, the data collected may gain new significance. The minimum level of your data necessary for this research is processed. This data will only be processed for the purposes outlined in this leaflet, and with appropriate levels of security in place.

The Walton Centre NHS FT will collect information about you for this research study from other studies and/or hospital records. This information will include your name and NHS number and health information, which is regarded as a special category of information. We will use this information to 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.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or outside the UK or EU; it will be protected by UK data protection laws (GDPR). Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about opportunities to participate in research including those in future beyond the end of this study. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

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. To safeguard your rights we will use the minimum personally-identifiable information as possible.

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).

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 5563565 or 0151 556 3693 or by email wcf.tonic@nhs.net . If your query relates to the use of your data, the team will pass your query onto the Data Protection Officer at the Walton Centre.