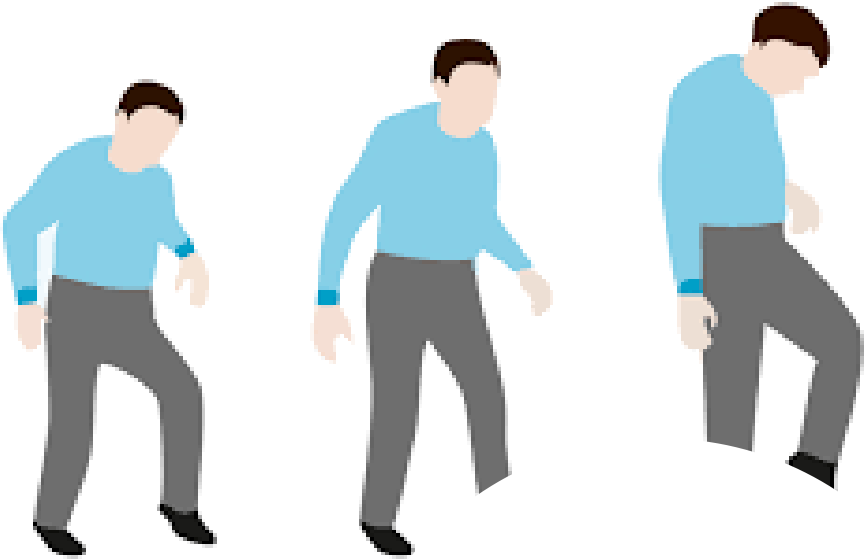




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PATIENT
INFORMATION
BOOKLET

Ataxia Study

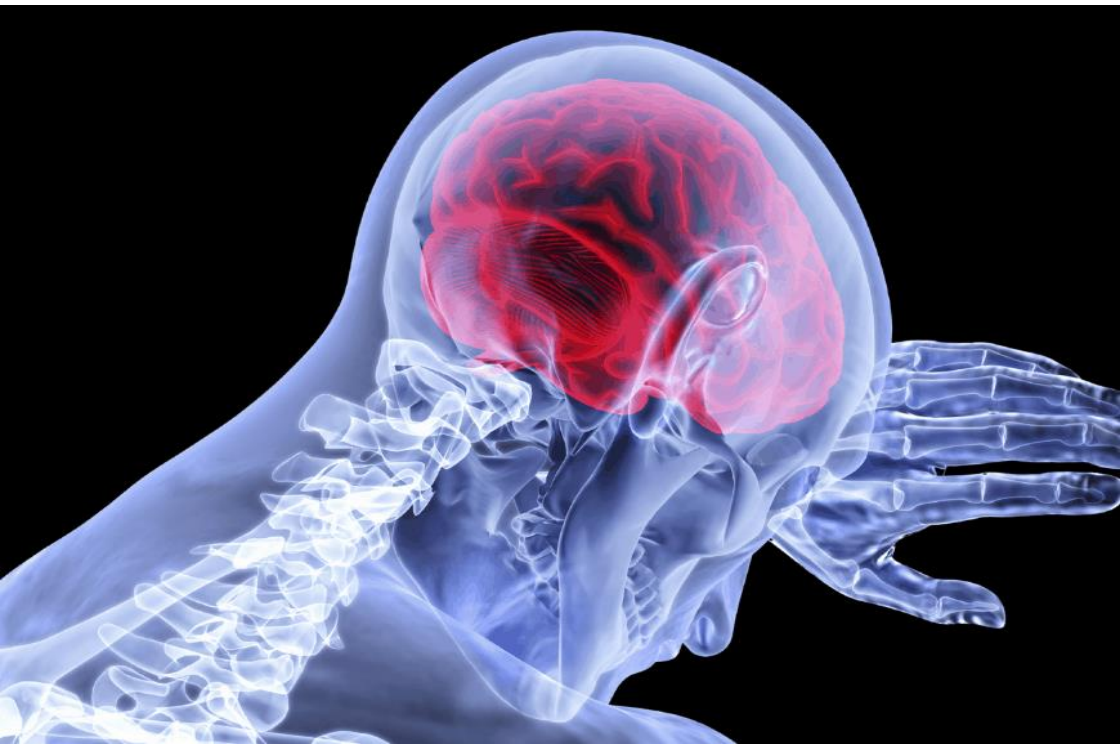
Participant Leaflet

Participant information leaflet

Illness Perceptions, Illness Uncertainty, Coping and Psychological Adjustment in individuals with Genetic Ataxias

You are being invited to take part in a research study to be carried out by Deirdre Murphy, Psychologist in Clinical Training alongside Neuropsychologist, Dr. Garret McDermott and Consultant Neurologists, Prof. Sinead Murphy, Prof. Richard Walsh and Dr. Petya Bogdanova-Mihaylova in the National Ataxia Clinic in Tallaght University Hospital. Before you decide if you want to take part, please read the information in this leaflet carefully.

Take time to ask questions – don't feel rushed or under pressure to make a quick decision. You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. Talk to others about the study if you wish. Contact us if you have any questions or there is something you would like more information on.



Part 1 – The Study

Why is the study being done?

Genetic ataxias are a rare set of conditions. Previous research has shown that living with genetic ataxias can have an impact on how an individual feels and their quality of life.

We want to understand more about your experience of living with genetic ataxia, the level of uncertainty you experience in relation to your illness, and the ways in which you cope with this. In turn this will help us to help other patients.

Why am I being asked to take part?

You have been asked to take part in this study because you have a diagnosis of genetic ataxia.

Do I have to take part? What happens if I say no? Can I withdraw?

No. It is entirely up to you to decide whether or not to take part in this study. If you choose not to take part in this study, or if you decide to withdraw your consent to participate, there will be no repercussions. Your decision to participate or withdraw from this study will not impact the service you receive in any way.

How will the study be carried out?

This study will look at whether you experience uncertainty in relation to your illness, how you cope with the difficulties you experience and if these factors impact on your quality of life and mood. In order to do this, you will be asked to complete an online survey.

What will happen to me if I agree to take part?

You will be provided with a link to an online survey. This survey will include questions about the symptoms you experience, the uncertainty you may experience in relation to your illness, your quality of life and your mood. The survey should take no more than 40 minutes to fill in. You can access this survey from any laptop, computer or mobile phone, at any time that suits you. You do not have to complete the survey in one sitting. If you would like support filling in the survey, I will contact you by phone to arrange a telephone call or video call using Microsoft Teams to complete the survey. It is estimated that approximately 150 people will be recruited for this study. After you finish the survey, you will be asked if you consent to being contacted again later to discuss these themes in more detail in a one-to-one interview on Microsoft Teams.

Are there any benefits to me or others if I take part in the study?

We do not anticipate any direct personal benefits from taking part in this study. However, we hope that the information we gather as part of this study will help researchers and clinicians better understand the experiences of our patients living with genetic ataxias. We also hope that it will help us design services to support people with genetic ataxias, like you, to manage the uncertainty associated with the condition.

Are there any risks to me or others if I take part in the study?

The survey is not designed to be distressing or upsetting. However, you will be asked to reflect on your situation, and it is possible that some people may become upset. If you feel upset or worried after completing the survey you may discuss this with the researcher. Alternatively, we would encourage you to contact your GP about support that may be available, or to call one of the helplines listed below

- Samaritans: 116 123
- AWARE: 1800 80 48 48

Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?

The information provided in this study will be analyzed collectively and as such individual results will not be available.

If you would like a copy of the results of the research, you can contact me on the email above I will share them with you.

This study will be written up in report form and submitted to Trinity College Dublin School of Psychology as part of the course work for my Doctorate in Clinical Psychology. The results of the study may also be submitted for publication in a scientific journal and may be presented to fellow researchers and practitioners via conference presentations and posters. Your participation will not be identified in any report/publication.



Part 2 – Data Protection

What information about me (personal data) will be used as part of this study? Will my medical records be accessed?

Your medical records will not be accessed for this research study. You will be asked to provide demographic and health-related information.

What will happen my personal data?

Your privacy is very important to us. All personal information collected as part of the study will be treated in strictest confidence. Your personal data will never leave the European Economic Area.

You will be asked to provide your name and contact details at the beginning of the survey. When your responses are downloaded for analysis, your name and contact details will be removed and replaced with a unique code so that your information is de-identified.

De-identified survey responses will be moved to a password-protected document and stored on the secure TCD One Drive system.

De-identified survey responses will be stored for seven years on a secure TCD One Drive in line with TCD protocol. This data will then be destroyed in line with TCD protocols.

Who will access and use my personal data as part of this study?

The research team will have access to the de-identified survey data (see contact details in Part 5). The information from this study will be written up as part of the course work for the Deirdre Murphy's Doctorate in Clinical Psychology. The results of the study may be submitted for publication in a scientific journal and may be presented to fellow researchers and practitioners via conference presentations and posters.



Will my personal data be kept confidential? How will my data be kept safe?

You will be asked to provide your name when completing the survey. This will be replaced with a unique ID code once your data is downloaded from the survey host. Only the researcher, Deirdre Murphy, and supervisors Dr. David Hevey and Dr. Garret McDermott will have access to your code. This unique ID code will be used when analysing your data.

Your data will be stored in password-protected documents and stored on a secure TCD One Drive file. You may be receiving this information via the National Ataxia Clinic. I am asking clinicians to pass this information on to individuals attending the clinic, however, they will not know who chooses to take part.

This study will be written in report form and will not contain any identifiable information.

What is the lawful basis to use my personal data?

The lawful basis for the processing of your personal data for the interview is Consent, in accordance with Article 9 of GDPR. This means that you will have to complete a consent form stating that you understand and agree to provide your personal data before you can take part in the study.

What are my rights?

You have the right to:

- Access your data and receive a copy of it
- Withdraw from this study at any time up to the point of data analysis in January 2022 without providing any reason. After this point it will not be possible to extract individual data. Withdrawing your consent from this study will not have any impact on the service you receive.

Part 3 – Costs, Funding & Approval

Will it cost me anything if I agree to take part?

No, there is no cost associated with participation in this study. You will not receive payment or reimbursement for your participation in this study. All investigators are HSE employees and are thus covered under the HSE Clinical Indemnity Scheme.

Who is funding this study? Will the results study be used for commercial purposes?

This research has not received any funding.

Has this study been approved by a research ethics committee?

This study has been granted ethical approval from Tallaght University Hospital / St. James's Hospital Joint Research Ethics Committee and The School of Psychology Research Ethics Committee, Trinity College Dublin.

Part 4 – Future Research

Will my personal data and/or biological material be used in future studies?

No. De-identified data collected in this study will be stored securely for seven years on a secure TCD One-Drive in accordance with TCD procedures. After this period, this data will be destroyed in accordance with TCD policy. Your data will not be used in any future research studies.

Part 5 – Further Information

Where can I get further information?

If you have any questions, please email Deirdre Murphy at murphd79@tcd.ie and she will be happy to answer any questions.

The following contact details for research team members are also available for your information.

- Dr. Garret McDermott (Principal Investigator) Principal Clinical Neuropsychologist, Tallaght University Hospital.
Tel: +353 1 414 4599, E-mail: Garret.McDermott@tuh.ie
- Dr. David Hevey (Co-investigator), Psychology Head of School, Trinity College Dublin.
Tel: +353 1 896 3914 E-mail: HEVEYDT@tcd.ie
- **Data Controller(s):** Trinity College Dublin & Tallaght University Hospital
- **Data Processors:** Deirdre Murphy & Dr. David Hevey, Trinity College Dublin.
- **Data Protection Officer:** dpo@tuh.ie

What happens if I wish to make a complaint?

Under GDPR, if you are not satisfied with how your data is being processed, you have the right to lodge a complaint with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie.

Will I be contacted again?

After you have taken part in this research you will not be contacted again, unless requested by you. You can contact me at any stage of the study at murphd79@tcd.ie.