

**Validity of the Distress Thermometer in identifying distress in people with Parkinson’s Disease**

Patient information sheet

Version 6, 04.07.19

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| **Chief Investigator:** Dr Breda Cullen, Clinical Psychologist | **Research Supervisors:** Dr Sharon Mulhern and Dr Breda Cullen |
| **Trainee Clinical Psychologist**: Bronagh Reynolds |  |

You are being invited to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

**What is the research about?**

This study is designed to investigate whether the Distress Thermometer is an accurate way of identifying distress specific to people with Parkinson’s Disease. The Distress Thermometer is a one item, an eleven-point visual scale (0-10) with higher scores indicating higher levels of distress. If the Distress Thermometer is found to be valid in this context, this will provide important evidence to support its use with people with Parkinson’s Disease in the Movement Disorder Clinic and wider services. This study is being undertaken as part of the fulfilment for an academic qualification (Doctorate in Clinical Psychology).

**Who is being asked to take part?**

We are asking people with a diagnosis of Idiopathic Parkinson’s Disease to take part in the study.

**Why have I been invited?**

You have been invited to take part in this research because you have a diagnosis of Idiopathic Parkinson’s Disease, are registered with a Movement Disorder Consultant in the Movement Disorders Clinic and are aged 18 years or over.

**What will taking part involve?**

Consenting to participate in this study means that you will be asked to complete some brief questionnaires. In total this should take 20-25 minutes and can be completed at the Movement Disorder Clinic where a private room has been arranged.

Alternatively, if you wish to take part in the study but are unable to stay after your appointment at the clinic, the questionnaires may be given to you along with a pre-paid postage envelope. This means that you can complete the questionnaires at home and post them back to the research team. A home visit can also be arranged after your appointment if this is preferable, where the researcher will visit you at home to allow you to complete the questionnaires.

As well as completing the questionnaires, we will also request your permission for the researchers to access your medical records, to collect further background information regarding your diagnosis (name of diagnosis, date of diagnosis and current medications).

It should also be noted that it is current practice that all individuals attending the movement disorder clinic are asked to complete a Distress Thermometer prior to their appointment. This exists as part of routine care and would occur regardless of whether you decide to participate in this research.

If at any point you lose the capacity to consent during the study, you would be withdrawn from the study and no further clinical or non-clinical interventions or procedures would be carried out and no new data would be collected. Questionnaires already completed or partially completed may be retained and used for the purposes for which consent has already been given, provided they are effectively anonymised and no longer identifiable to the research team or any other persons to whom access will be given.

**What are the possible benefits of taking part?**

We do not expect there to be any specific benefits to yourself by taking part. In general, research improves our knowledge of how best to identify people’s difficulties and what tools are most appropriate to assess for difficulties, including distress. Your participation will help increase our knowledge in this area with regards to the use of the distress thermometer in Movement Disorder Clinics.

**Are there any disadvantages or risks to taking part?**

Although we do not expect that participating in this study will cause you any distress, if you express distress when speaking to the researcher or through your responses on the study questionnaires, we will help you to access appropriate support if needed. This would involve passing on some information to the Parkinson’s disease team, in line with usual procedures.

**Do I have to take part?**

No. It is up to you to decide whether to take part. This study is completely voluntary. You do not have to take part if you do not want to.

**What happens if I decide not to take part?**

Nothing. Taking part is entirely up to you. If you do not wish to take part, it will not affect any treatment that you currently receive and will not affect any future care you may require. Also, if you decide to take part, you can change your mind and withdraw from the study at any time, without giving a reason, and without it affecting your care either now or in the future.

**Will my information be kept confidential?**

All the information you provide will be kept confidential and the research questionnaires will only be identified by code, not your name. The consent forms and study data will be stored on NHS Ayrshire and Arran premises and will be accessible only to researchers who are directly involved with the research, or other authorised staff for audit purposes. Electronic information will be stored on secure NHS or University of Glasgow computer systems. Any information stored on University computers will be anonymised, with the code linking to identifiable information held separately to ensure confidentiality of data.

If you share information that makes the researcher concerned for your safety or the safety of other people, we may be required to tell others involved in your care (e.g. your GP).

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. 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 possible.

You can find out more about how we use your information at https://www.nhsaaa.net/data-protection-notice/

Also, the research team may share anonymised data in future with other researchers elsewhere, such as on the Enlighten Research Database.

**What will happen to the results of the research study?**

The results will be compiled in a report completed as part of an academic qualification (Doctorate in Clinical Psychology). They may later be published in a scientific journal and through other routes to ensure that the public are also aware of the findings. You will not be identified in any report/publication arising from this study. If you wish to be informed of results from the present study, please tick the relevant box on the consent form to opt-in. A summary of the results will be sent to you once the research is completed.

**Who is organising the research?**

The study is being undertaken in partial fulfilment of an academic qualification at the University of Glasgow and is organised by the Chief Investigator (Dr Breda Cullen) and research supervisor (Dr Sharon Mulhern) and Trainee Clinical Psychologist (Bronagh Reynolds).

The University of Glasgow is the sponsor for this study based in the United Kingdom. We will be using information from you 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 University of Glasgow will keep identifiable information about you for 2 years after the study has ended.

**Who has reviewed the study?**

The study has been reviewed by the University of Glasgow to ensure that it meets standards of scientific conduct. It has also been reviewed by North of Scotland Research Ethics Committee 1, and the NHS Ayrshire and Arran Research and Development Department.

**What will happen if there is a problem or if I want to make a complaint?**

If you have any concerns about the study or the way it is conducted, or if you wish to complain about any aspect of this study, please contact Prof. Tom McMillan, Mental Health and Wellbeing, Gartnavel Royal Hospital, Admin Building, 1st Floor, 1055 Great Western Road, Glasgow, G12 0XH, or the Research and Development Department, NHS Ayrshire and Arran on 01563 825850.

The normal NHS complaint mechanisms will also be available to you. NHS Ayrshire and Arran Complaints Team: 01292 513620

**Contact for further information about the study**

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| Bronagh Reynolds | Dr Breda Cullen | Dr Sharon Mulhern |
| Mental Health and Wellbeing  Admin Building, 1st Floor, Gartnavel Royal Hospital  1055 Great Western Road  Glasgow G12 0XH  0141 2113912 | Mental Health and Wellbeing  Admin Building, 1st Floor, Gartnavel Royal Hospital  1055 Great Western Road  Glasgow G12 0XH  0141 2113912 | Psychology Department  Horseshoe Building  Ayrshire Central Hospital  Kilwinning Rd,  Irvine  KA12 8SS  01294 322057 |

**Thank you for reading this Participant Information Sheet**

Reply Slip

Please bring this page with you to your appointment and hand to a staff member

Please tick the box to indicate your reply

I am interested in discussing this study with the researcher at the clinic

YES

NO

Your name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_