Preliminary development of a psychological formulation tool for people with Functional Neurological Disorder

The University of Manchester: Kathryn Harper, Dr. Richard Brown
The University of Sheffield: Professor Markus Reuber
Sheffield Teaching Hospitals NHS Foundation Trust: Cordelia Gray, Aimee Morgan-Boon

Participant Information Sheet (PIS): Experts by Experience Group Discussion

You are being invited to take part in a research study which aims to develop a psychological formulation tool for assessing the psychological characteristics and needs of people with FND. The research is being conducted as part of a Doctorate in Clinical Psychology at The University of Manchester being undertaken by Kathryn Harper. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

➤ What is the purpose of the research?

Functional Neurological Disorder (FND) is when someone experiences symptoms (e.g., fits, problems moving, loss of sight), but tests suggest that their brain is functioning normally. These problems can be very distressing and hard to understand. We know that people with FND are not all the same and we want to understand more about their differences. Professionals have suggested that there are many different sub-groups of people within FND. We want to identify what these sub-groups are like. We also plan to develop a new tool that would help professionals assess people with FND and decide which sub-group they are in. This will help people with FND get the right treatment for their needs.

➤ What will I be asked to do if I agree to take part?

If you agree to take part, you will be asked to attend a group discussion on the video-conferencing platform Zoom. The group would consist of people with FND (we call these “experts by experience”) and one or two members of the research team. The discussion will last 1.5 to 2 hours and will explore your views about characterising different groups of people with FND. The group will be audio-recorded via an encrypted University of Manchester audio device (therefore not recorded on Zoom) and the content will be transcribed by Kathryn Harper for later analysis.
More detailed information about the research is provided below. **If you decide that you would like to take part, please email Kathryn.Harper@postgrad.manchester.ac.uk** and Kathryn will send you a consent form to complete.

**Further information about the project**

- **Will I be compensated for taking part?**

  There is no financial reward for participating in this study. However, it is an opportunity to express your views about how to help people with FND, which may contribute to the future care of people with the condition.

- **Are there any risks to taking part?**

  The discussion will focus on FND and how it can be understood and treated. We will discuss this in general terms and will not ask you any direct questions about your own experience of FND. Nevertheless, this is obviously a very personal topic for people with FND and there is a chance that you will find it upsetting to talk about. You may also find it hard hearing other peoples’ views about this. If you think you would become very upset talking and hearing about FND then you may prefer not to take part. Other than that, we do not think there are any risks to participants.

  If you do decide to take part and find the topic distressing you can leave at any time and request to talk to one of the focus group facilitators who will offer you an individual zoom session or a telephone conversation following the group. You can request this by emailing Kathryn Harper or by private messaging her or the co-facilitator on the Zoom platform. Both facilitators are trainee clinical psychologists and have experience with supporting people who are experiencing distress.

  Alternatively you can telephone the Samaritans on 116 123 who offer a safe place for you to talk at any time without any cost.

- **Will the outcomes of the research be published?**

  The research will be written up as a research paper and submitted to a chosen appropriate journal. It will be included in Kathryn Harper’s thesis and may be presented at conferences.

- **Who has reviewed the research project?**

  The project has been reviewed by The University of Manchester Research Ethics Committee and a Research Sub-Committee within the Clinical Psychology Doctorate programme department.

- **Who is funding the research project?**

Version 2; 31/03/2021
A small amount of funding has been provided by the Clinical Psychology Doctorate programme at the University of Manchester.

➢ What happens if I do not want to take part or if I change my mind?

It is entirely up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time without having to give a reason and without detriment to yourself. Prior to taking part you can withdraw by contacting Kathryn Harper. You will then not be contacted again. If you choose to withdraw during the group discussion, you can leave at any time. However, it will not be possible to remove your data from the project once it has been submitted (e.g., you have spoken during the group discussion) – once the discussion has taken place, it will be transcribed and anonymised so people will not know who said what. This does not affect your data protection rights. If you decide not to take part, you do not need to do anything further.

Data Protection and Confidentiality

➢ What information will you collect about me?

In order to participate in this research project we will need to collect information that could identify you, called “personal identifiable information”. Specifically we will need to collect:

Name, age, gender and details about the symptoms you have experienced in relation to FND. Your name will only be used to contact you and it will not be published or disclosed to anyone else.

➢ Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

➢ What are my rights in relation to the information you will collect about me?

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you. Once the discussions have been transcribed, it will not be possible to know who said what and so these transcriptions will not be shared. The transcripts will not include any of your personal data.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research.

➢ Will my participation in the study be confidential and my personal identifiable information be protected?
In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

All data will be collected electronically and stored securely on University servers and on the University of Manchester Research Data Storage Service in accordance with the University of Manchester policies on data protection, the Data Protection Act (2018) and General Data Protection Regulations (GDPR, 2018). No hard copies of data will be collected. The researchers will have access to the University servers through the VPN global connect facility. All data will be encrypted before being stored.

Following the completion of consent forms, participants will be provided with a unique identifier, which will be placed on all data instead of their name; this will ensure their details are kept secure (also known as pseudo-anonymisation). A separate file containing participants corresponding details (e.g., email address) will be stored in an encrypted file on the University RDMS and only accessible to the research team. Consent forms will be stored securely on the RDMS separately from the research data.

The group discussion, conducted via Zoom video conferencing software, will be recorded with a University approved encrypted audio device (i.e., not recorded via Zoom itself). The recording will start after the groups have been given data protection information (such as not to say their names when speaking). The recordings will then be transferred to secure University storage as soon as possible and the original recording on the audio device will be deleted. The recordings will be transcribed by Kathryn Harper and transcripts of the recordings will also be stored on the university storage, and anonymised so people will not know who said what. The stored recording will be deleted once the transcription has been checked against it.

All data will be pseudonymised [in line with University policies, GDPR (2018) and the Data Protection Act (2018)]. The data will be protected, encrypted and regularly backed up and only accessible to the research team.

Anonymised data will be kept for 5 years following study completion.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.
What if I have a complaint?

If you have a complaint that you wish to direct to members of the research team, please contact:

Richard Brown: Richard.J.Brown@manchester.ac.uk

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner’s Office about complaints relating to your personal identifiable information Tel 0303 123 1113

Contact Details

If you have any queries about the study, or if you are interested in taking part, then please contact the researcher(s).

Kathryn Harper: Kathryn.Harper@postgrad.manchester.ac.uk

Richard Brown: Richard.J.Brown@manchester.ac.uk