**Participant Information Sheet**

**Study Title**: Effectiveness and Acceptability of Formulation and Brief-ACT intervention for Functional Neurological Disorders

**Researcher**: Irma Konovalova, Trainee Clinical Psychologist

**ERGO number:** 70341

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others, but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

**What is the research about?**

I am a 3rd/Final year Trainee Clinical Psychologist completing a Doctorate in Clinical Psychology at Southampton University. This research project is part of my Doctoral Thesis. It is sponsored by the University of Southampton. Functional Neurological Disorders is my area of interest and as part of my thesis research, I wanted to contribute to limited but growing area of research.

Functional Neurological Disorder (FND) is a problem with the functioning of the nervous system and how the brain and body send and receive signals. FND has multiple causes that can vary from patient to patient. Each individual with FND can have different combinations and severity of symptoms, including problems with movement, senses and episodes of altered awareness, like seizures and blackouts. Individuals with this condition have long delays in receiving a diagnosis. This can stop individuals from developing an understanding of their condition and accessing appropriate psychological services.

Information from up-to-date research shows that a formulation, explanation of individual’s condition, can improve people’s quality of life and even reduce how often they experience the symptoms. Acceptance and Commitment Therapy (ACT) has been shown to also improve quality of life, mood and how symptom’s affect the person. This therapy aims to help people to live well despite the difficulties they are experiencing. Currently, there is some promising evidence that ACT can help people with FND live a better life. But more research is needed. So far, no one has completed research that explores if formulation and ACT together can be helpful for people who have FND. Therefore, this is the aim of my project.

Specifically, I am investigating if formulation and ACT based intervention can lead to increases in psychological health, emotional processing and Quality of Life. While ACT does not directly aim to get rid of illness symptoms, for example seizures, we want to see if symptoms may reduce anyway.

**Why have I been asked to participate?**

You have been asked to participate in this study because you have a diagnosis of a Functional Neurological Disorder and the treatment that we offer is tailored to this condition. We aim to complete the study with six individuals with FND.

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

You will be invited to take part in a study that will require active participation for 15 weeks. During this time you will be asked to complete some questionnaires and attend psychotherapy sessions at Poole Community Clinic. You will need to attend 5 sessions in total over 15 week period and answer some brief questions every other day throughout this period. After 11 weeks, you will be contacted again a month later. Please read the outline bellow.

Weeks 1 to 4. At the start of week 1 you will complete some questionnaires that approximately will take 30min. Then you will answer some brief questions every other day throughout this period.

Week 5 and 6. You will be invited to attend Poole Community Clinic one day a week during this period. In week 5, we will invite you to a clinical interview, where we ask you to tell us your story and talk about your illness, so we can have a better understanding of it. The first session may take up to 2h. In week 6, we will invite you back to Poole Community Clinic and we will think together about your illness and provide you with the explanation how this illness may have started and what keeps it going. This is standard practice of care. At the end of week 6 we will ask you to complete the battery of questionnaires that will take approximately 30min.

Week 7 and 8. You will not have any therapy sessions. You will only be asked to answer a few brief questions every other day.

Week 9, 10 and 11. You will be asked to attend Poole Community Clinic for an hour once a week to complete Brief Acceptance and Commitment Therapy. In these sessions we will talk about things that are important to you and provide you with some coping strategies to manage the difficulties that you may be experiencing. This treatment would not be normally offered as a standard practice of care. You will be asked to answer a few brief questions every other day.

Week 12 to 15. You will no longer have to come into Poole Community Clinic. You will only be asked to answer a few brief questions every other day. At the end of week 15 we will ask you to complete the battery of questionnaires via online platform Qualtrics that will take approximately 30min. After week 15, you will no longer need to answer routine questions.

Some therapy sessions may need to be audio recorded for monitoring purposes, to ensure that the therapist is sticking to the model they are working with. The recording will be listened to by a Clinical Psychologist/supervisor directly from the recording device and after that immediately destroyed. It will not be transferred or stored for any period of time.

**Are there any benefits in my taking part?**

There may be no benefit to taking part in this study. However, the benefits may relate to you developing a better understanding your condition and developing some new coping strategies. Similar studies have shown that people with Functional Neurological Disorders and similar conditions experienced benefits in psychological wellbeing and quality of life.

Additionally, the study will help improve our current understanding of Functional Neurological Disorders and develop treatments that are tailored to these individuals.

**Are there any risks involved?**

As engaging in any psychological therapy, you will be exploring sensitive or personal issues that may result in some psychological discomfort or distress. These can be addressed in our sessions or alternatively you can discuss this further with your GP. We are anticipating any additional risk and no higher risk than that of standard medical care.

**What data will be collected?**

The information that we will collect will include some personal information (gender identity, age, ethnicity, health data such as diagnosis of FND and other co-morbid physical or mental health diagnoses). The questionnaires will ask you about your mood, thinking and coping styles, quality of life, understanding of your illness and illness symptoms.

Your personal information will be collected by myself, the main researcher, and provided by your referring doctor or clinician, as per standard clinical practice.

The questionnaires will be completed by you via Qualtrics, an online platform. You will be assigned a participant number, so your data cannot be identifiable by anyone else but the research team.

Your personal data will be anonymised and handled securely during collection, analysis, storage and transfer by using encryption and password protected access, or lockable cabinets for hard data. Personal data and consent forms will be kept separate from non-identifiable data.

In order to keep in touch with you, we will need to store your contact details (email address, telephone number) for the duration of the study. This will be no different to standard clinical practice.

All identifiable data including your name and contact details will be destroyed after the completion of data collection.

**Will my participation be confidential?**

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

You will be given a unique ID number when you complete the questionnaire. This will replace your personal details. No-one will read your questionnaire data apart from the research team (which consists of Trainee Clinical Psychologist, a supervisor from the NHS, an assistant psychologist from the NHS, and the supervisor from the university).

The referring clinician and your GP will be notified of your participation in research, as per standard medical care. We would like to share the formulation letter with your GP and referring clinician, as per standard clinical practice. In addition, the only other time we would have to breach confidentiality and speak to your GP or emergency services, if we believe that you are at risk to yourself or to others, or if you are at risk from others.

As part of standard medical care, your medical notes will need to be updated about the intervention you receive. As a result, the main researcher, Trainee Clinical Psychologist, will need to access your medical notes to ensure they are kept up to date.

**Do I have to take part?**

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

If you would like to take part in this research, please notify your clinician who informed you about this study and they will send us a referral letter.

**What happens if I change my mind?**

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights or routine care being affected. If you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only.

Should you wish to withdraw please notify the researcher, Irma Konovalova, or your referring clinician.

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

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

The project will be written up as part of the Doctoral Programme requirements and published in a scientific journal. The copy of the results will be made available to you, should you wish to receive that information.

**Where can I get more information?**

For more information, please contact Irma Konovalova via email I.Konovalova@soton.ac.uk

**What happens if there is a problem?**

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

*You can also contact the research team: Irma Konovalova at* *I.Konovalova@ston.ac.uk**, Dr Birgit Gurr, Consultant Clinical Neuropsychologist, at* *birgit.gurr@nhs.net* *or Dr Warren Dunger, my academic supervisor at* *W.N.Dunger@soton.ac.uk*

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, ‘Personal data’ means any information that relates to and is capable of identifying a living individual. The University’s data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason (‘lawful basis’) to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the ‘Data Controller’ for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for up to 6-12 months after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University’s data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University’s Data Protection Officer (data.protection@soton.ac.uk).

Your data will be pseudonymised, where your data will be linked using a code until the data collection is finished. Only the main researcher, Irma Konovalova, will know the code assignment. Since this study will have a small sample size (approximately 6 participants), some information can be identifiable, but only by the main researchers in the team.

**Thank you for taking the time to read the information sheet and considering taking part in the research.**