



Department

Royal Preston Hospital,
Sharoe Green Lane,
Fulwood,
Preston.
PR2 9HT

Title of Study: **Mixed-Methods Study of Clinical Hypnosis in the Management of Functional Neurological Disorders: Outcomes and Acceptability**

PATIENT INFORMATION SHEET

You are being invited to participate in a research study run by the Functional Neurological Disorder (FND) team at Lancashire Teaching Hospitals NHS Foundation Trust and Lancaster University. Please read the following information carefully before you decide whether to take part in the study or not.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to evaluate a brief hypnotherapy intervention for people with Functional Neurological Disorder (FND). We want to understand how acceptable and useful hypnotherapy is in routine care, and whether people report changes in symptoms, mood, daily functioning, and body awareness. We will also explore people's experiences of receiving hypnotherapy.

WHAT IS THE DIFFERENCE IN TREATMENT?

Taking part in the study will not change your usual NHS care. You are reading this PIS as you have been offered a course of clinical hypnotherapy delivered by trained clinicians in our specialist FND service, as part of your FND care. The main differences from what you would normally do are that **you will be asked to complete an online survey before your first hypnotherapy session, after your last session, and then 4 weeks afterwards**. If you decide not to participate in our study, you can still receive hypnotherapy, but you won't be required to complete any survey. Completing the survey will take about 20 minutes each time, and you will be asked the same questions. This will enable the researchers to compare your answers to the survey and check if hypnotherapy has had any impact on your FND symptoms and overall well-being.

You will be able to complete the survey either at home (as it will be emailed to you by the researchers) or during/after your appointments with a clinician at the FND clinic.

If you choose to take part in the study, you will also be invited to take part in a one-to-one interview about your experience. The interview will be conducted via phone call or video call (using Microsoft Teams), according to your preference. It will be conducted by a trained researcher from Lancaster University, who will ask you about your views and experiences of attending hypnotherapy sessions to improve your FND symptoms and overall wellbeing.

If you want to take part in our study, you can decide to take part in the first stage (completing the surveys before your hypnotherapy sessions, after, and 4 weeks after your last session) **and** in our interview, or you can take part **only in the first stage (completing the surveys), but not in the interview.**

WHY HAVE I BEEN CHOSEN?

You have been chosen because you have been diagnosed with FND and referred to the Lancashire Teaching Hospitals (LTH) FND service for treatment. Following assessment, the LTH clinical team considered you a suitable candidate to explore hypnotherapy as a treatment option.

DO I HAVE TO TAKE PART?

No, it is entirely up to you whether or not you take part in this research study. If you decide not to take part, or if you choose to withdraw at any time, this will not affect the care you receive in any way, including your access to hypnotherapy or any other treatment.

If you agree to take part, you will be asked to provide consent before completing the surveys. You are free to stop taking part at any time without giving a reason. If you withdraw, no new information will be collected from you.

You may request that your data is deleted within two weeks of completing each survey or interview. After this time, your data may have been anonymised and included in the analysis, and it may no longer be possible to remove it.

WHAT WILL HAPPEN IF I TAKE PART?

- You will be asked to provide consent.
- You will complete a survey containing questionnaires about your symptoms, mood, daily functioning and body awareness at three time points: before starting hypnotherapy (baseline), after your final session, and about 4 weeks later (follow-up).
- After finishing hypnotherapy, some people will be invited to a one-to-one interview to talk about their experience. Taking part in an interview is optional.

In this research study, we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study, we will save some of the data in case we need to check it.

We will make sure no-one can work out who you are from the reports we write.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Taking part in this study may not directly benefit you. However, some people with FND have found hypnotherapy helpful in managing their symptoms. By taking part, you will have the opportunity to take part in a study to understand if hypnotherapy can be useful to help people manage their FND symptoms and feel better.

Your involvement may also help us to learn more about how useful hypnotherapy could be for others with FND in the future.

WHAT ARE THE POSSIBLE RISKS OF TAKING PART?

Hypnotherapy is a talking intervention and is generally considered low risk. Some people may temporarily feel tired, light-headed, or emotionally stirred, or may notice increased awareness of bodily sensations. Very occasionally, people with FND may notice a short-term increase in symptoms. If you feel uncomfortable at any point, you can ask to pause or stop. Clinicians delivering the sessions are trained to support grounding and stabilisation, and your usual clinical team remains available.

Taking part in this research involves completing questionnaires about your symptoms, mood, and daily functioning. These questionnaires are commonly used in healthcare and research. Some people may find that answering questions about their symptoms or wellbeing brings up difficult thoughts or feelings. If this happens, you are free to skip any questions or stop completing the survey at any time.

If you take part in an interview (optional), you may be asked to talk about your experiences. You can choose not to answer any questions you do not feel comfortable with, and you can pause or stop the interview at any time.

If you share information that raises concerns about your safety or the safety of others, the research team has a duty to follow safeguarding procedures, which may involve informing appropriate members of your care team.

Taking part in this research will not affect your clinical care, including any hypnotherapy you receive as part of your usual treatment.

There is also a list of resources available that you can contact anytime, should you feel discomfort at any stage of the research process:

- **Emergency services (if you are in immediate danger): Call 999.**

- **NHS 111 (urgent medical advice, 24/7):** Call **111** (free from any phone).
- **Your GP or usual care team:** Contact during working hours for clinical support and next-step guidance.
- **Samaritans (24/7 emotional support):** Call **116 123** (free) or email jo@samaritans.org.
- **Shout (24/7 text support in the UK):** Text **SHOUT** to **85258**.
- **Local NHS urgent mental health helpline:** Available in every area of England; you can call via your local NHS Trust's website or ask NHS 111 to connect you.

Study team (non-emergency, study-related concerns):

- **Chief Investigator – Dr Daniela Di Basilio:** d.dibasilio@lancaster.ac.uk.
Address: Health Innovation One, Sir John Disher Drive, Lancaster University, Bailrigg, Lancaster, LA1 4AT.
- **FND service clinical team at Lancashire Teaching Hospitals NHS Foundation Trust (your usual clinic):** You can request a call-back via the hospital switchboard or your clinic's usual contact route.

If you become distressed during a study interview, tell the interviewer—they will pause/stop and follow the study's safeguarding process. For distress between sessions or outside study activities, please use the urgent options above (999/111) as needed, then let the study team know when you can.

**HOW WILL WE USE INFORMATION ABOUT YOU?
MY PERSONAL INFORMATION BE USED?**

We will need to use information from you and your medical records for this research project. This information may include your name, date of birth, age, diagnosis, contact details, clinic appointment dates, questionnaire responses, and audio recordings/transcripts if you take part in an interview. People from your care team will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead: in order to protect your identity, we will ask you to create a unique identification code (UIC) the first time you complete the survey. We will ask you to keep hold of this code, so that you can use it to complete the survey the second and third time, without using your full name. This code will also be used to identify your interview.

If you lose the code, you will be able to re-create it following the instructions provided the first time: just email the researchers at their email address (please see below) and they will help you to retrieve your code, if you lose it.

Once we have finished the study, we will write our reports in a way that no one can work out that you took part in the study.

We will keep all information about you safe and secure by:

- Storing electronic data (survey responses, interview recordings and transcripts) on password-protected, encrypted NHS or University secure servers.
- Limiting access to your identifiable information to authorised members of the research and clinical teams who need it for the study.
- Replacing your name and other identifying details with a unique identification code (UIC) as soon as possible.
- Keeping any document that links your name to your study code in a separate, secure location with restricted access.
- Encrypting and securely storing audio recordings of interviews and deleting them once they have been transcribed and checked.
- Ensuring that any data shared between Lancashire Teaching Hospitals NHS Foundation Trust and Lancaster University are transferred securely and in line with data-sharing agreements.
- Reporting study findings only in anonymised or aggregated form, so that no individual can be identified.
- Retaining study data only for the period required by research governance policies, after which it will be securely archived or destroyed.

Your data will not be shared outside the UK.

With your permission, we will inform your GP that you are taking part in this study so they are aware as part of your routine care. We will share only essential details (study title, sponsor, the study team's contact information, and the dates of your participation). We will not share your questionnaire answers or interview content unless you ask us to, or if we are concerned about your safety or the safety of others—in which case we may need to contact your GP in line with safeguarding and duty-of-care policies. Choosing whether or not to inform your GP will not affect the care you receive.

HOW WILL WE USE INFORMATION ABOUT YOU AFTER THE STUDY ENDS?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 10 years. The study data will then be securely destroyed.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to stop taking part in the study, please email the study Chief Investigator, Dr Daniela Di Basilio (d.dibasilio@lancaster.ac.uk) and let her know you would like to be withdrawn from the study.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

You can find out more about how we use your information at:

<https://www.hra.nhs.uk/information-about-patients/> or by contacting the Chief Investigator, Dr Di Basilio.

WHAT IF I CHANGE MY MIND ABOUT TAKING PART?

You can choose to withdraw as specified above. Your standard of care will not be affected if you change your mind.

WHO HAS REVIEWED THE STUDY?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the London - [Queen Square Research Ethics Committee \[26/PR/0366\]](#).

WHO SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT AND/OR DURING THE STUDY, OR WISH TO MAKE A COMPLAINT?

If you have a specific concern or query about the research, you can contact the study team at the details below.

Study Chief Investigator:

Dr Daniela Di Basilio, Lecturer in Clinical Psychology and Clinical Psychologist
Division of Health Research
Faculty of Health and Medicine | Lancaster University
www.lancaster.ac.uk

Clinical Psychology
Health Innovation One
Sir John Fisher Drive
Lancaster University

d.dibasilio@lancaster.ac.uk

Principal Investigator (research site lead):

Dr Abhijit Das
Consultant Neurologist
Consultant Neurologist, Royal Preston Hospital
Clinical Lead, Functional Neurological Disorder Service
Sharoe Green Lane North
Fulwood
Preston, Lancashire
PR2 9HT

For a more independent contact, you can contact the Research Governance lead within the Centre for Health Research and Innovation at Lancashire Teaching Hospitals by contacting 01772 522031. You may also wish to talk to the hospital's Patient Advice and Liaison Service (PALS), which provides support to patients, families and visitors. They will be able to help support you if you have any concerns or complaints and are available by phone on 01772 522 972 or by emailing PALS@lthtr.nhs.uk.

If you would like to take part in our study, please click on the 'next button' to see a copy of the Consent Form.