

Hypnotherapy for FND

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

SHORT STUDY TITLE: Clinical Hypnosis for FND

PROTOCOL VERSION NUMBER AND DATE: Version 1.0; Date: 27/03/2026

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

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Date:

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Name (please print):

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Position:

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Chief Investigator:

Signature:

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Dawida Di Basilio

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Date:

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Name: (please print):

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Daniela Di Basilio

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Sponsor	Lancashire Teaching Hospital NHS Foundation Trust (LTHTR)
Joint-sponsor(s)/co-sponsor(s)	N/A
Key Protocol Contributors and Research Team Members	- Dr Daniela Di Basilio (DDB) - Lecturer in Clinical Psychology at Lancaster University, Clinical Psychologist at Lancaster University (UK) - Dr Abhijit Das (AD) - Consultant Neurologist, Royal Preston Hospital (LTHTR), Clinical Lead of the

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	LTHTR Functional Neurological Disorder Service (UK) - Dr Jacqueline Twamley (JT), Academic Research and Innovation Manager (LTHTR), UK - Mr Andrew Saint (AS), DCLINPsy trainee at ancater University (UK) - Miss Lois Minnis (LM), DCLINPsy trainee at ancater University (UK)
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STUDY SUMMARY

Study Title	Mixed-Methods Study of Hypnotherapy in the Management of Functional Neurological Disorders (FND): Outcomes and Acceptability
Internal ref. no. (or short title)	Hypnotherapy for FND
Study Design	Mixed-Methods Feasibility Study
Study Participants	Individuals with a diagnosis of FND supported by the FND service based at LTHTR
Planned Size of Sample (if applicable)	38-40
Planned Study Period	April 2026-January 2027
Research Question/Aim(s)	The following research questions guide the study: 1. What is the effect of clinical hypnosis on psychological well-being (anxiety, depression, and stress), health-related quality of life, and functional neurological symptoms in individuals with FND over time (baseline, post-intervention, and follow-up)? 2. Are any observed therapeutic benefits of clinical hypnosis—across psychological well-being, quality of

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	life, and symptom severity—sustained at follow-up (e.g., 4 weeks post-treatment)? 3. How do individuals with FND experience clinical hypnosis in terms of perceived effectiveness, acceptability, and barriers or facilitators to engagement? 4. How do participants interpret changes in their symptoms or well-being following clinical hypnosis? 5. What recommendations -if any- do they offer for improving the design, delivery, and accessibility of hypnosis-based interventions?
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FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
Lancashire Teaching Hospital NHS Foundation Trust (LTHTR)	In-kind contribution (staff time)

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor for this study is Lancashire Teaching Hospitals NHS Foundation Trust (LTHTR), which assumes overall responsibility for the initiation and management of the study. LTHTR will also act as a research site, facilitating recruitment by providing access to a list of suitable patients for potential inclusion. In collaboration with the research team, the sponsor will be jointly responsible for risk management and assessment throughout the study. The sponsor will not influence the study design, data analysis, interpretation, or dissemination of findings. These elements will be led independently by

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the research team. The sponsor does not have control over the final decision regarding publication or other aspects of dissemination.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

Study Steering Groups

A dedicated group of Public and Patient Involvement (PPI) representatives, all of whom have lived experience of Functional Neurological Disorder (FND), will be actively involved in the study to ensure a co-produced and patient-centred approach. We plan to involve around 2-3 representatives who will provide critical feedback on study processes by:

- 1) Refining the interview script
- 2) Contributing to collaborative analysis of themes derived from interviews
- 3) Provide feedback on the results obtained from the study and how to best convey the 'key messages' emerging from the data
- 4) Provide feedback on the best way to create visual displays of data, to engage with different types of audience.

Regular meetings with the PPI group will be held to maintain their involvement and integrate their insights into different stages of the research. In line with NIHR and HRA guidance, PPI representatives ("experts by experience") will receive payment and expenses for their contributions. All Lancaster University DClinPsy trainees have an allocated budget for PPI activities, so the Research Assistants (RAs - Lancaster University DClinPsy trainees) will use their budget to pay for the experts-by-experience involvement.

While no single national tariff is prescribed, common UK benchmarks are approximately £25 per hour for ad-hoc tasks or meetings (NHS England, 2025). The study team will adopt this guidance when issuing payments, and the research assistants (RAs) leading the quantitative and qualitative strands will seek the necessary University- and course-level approvals before issuing payments.

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PROTOCOL CONTRIBUTORS

The research team comprises several contributors with clearly defined roles to ensure the effective design, conduct, and delivery of the study. Dr Daniela Di Basilio will serve as the Chief Investigator (CI), with overall responsibility for the study's design, coordination, and oversight. Dr Abhijit Das will act as the Principal Investigator (PI) at the research site (Royal Preston Hospital – LTHTR), leading site-specific activities including recruitment and clinical oversight. Dr Jaqueline Twamley will serve as Research Manager (RM) for site activities, supporting the coordination and implementation of the study at Royal Preston Hospital. Lois Minnis and Andrew Saint (RAs) will coordinate data collection and analysis, ensuring consistency and rigour in methodology and interpretation.

The sponsor, Lancashire Teaching Hospitals NHS Foundation Trust (LTHTR), will support the study by acting as a research site and sharing responsibility for risk management and assessment. Patients with lived experience of FND will be involved through a dedicated Public and Patient Involvement (PPI) group. Their contributions will shape data collection and analysis procedures, and they will continue to be engaged throughout the dissemination process.

KEY WORDS:

Functional Neurological Disorder (FND), Hypnotherapy,
Mixed-Methods, Feasibility, Co-production

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STUDY PROTOCOL**Title: Mixed-Methods Study of Hypnotherapy in the Management of Functional Neurological Disorders: Outcomes and Acceptability****1. BACKGROUND****1.1. Functional Neurological Disorder: Definition and Current Clinical Guidelines**

Functional Neurological Disorder (FND) refers to a condition in which individuals experience neurological symptoms, such as seizures, motor dysfunction, or sensory disturbances, in the absence of identifiable structural abnormalities in the brain (NICE, 2023). This disorder, previously referred to by terms such as conversion disorder or hysteria, reflects a complex interplay of neurobiological, psychological, and social factors, and is now conceptualised as a brain network disorder involving disruption of normal neural communication and integration (Raynor & Baslet, 2021; Hallett et al., 2022). FND is heterogeneous in presentation and includes functional seizures, functional movement disorders, functional cognitive disorder, and other sensorimotor manifestations (Bennett et al., 2021; BPS, 2024). It affects individuals across the lifespan and appears to be more prevalent in females under the age of 50 (BPS, 2024). Its prevalence is estimated at approximately 50 to 100 cases per 100,000 individuals, translating to 50,000–100,000 people affected in the UK alone (Finkelstein et al., 2025; Bennett et al., 2021). Furthermore, it is the second most common reason for new neurology outpatient referrals after headaches (Stone et al., 2010), although underdiagnosis and misdiagnosis (e.g., as multiple sclerosis) remain prevalent (Walzl et al., 2022).

The diagnostic process for FND can be lengthy and distressing, with individuals often facing years before an accurate diagnosis. The burden of FND extends beyond the symptoms themselves, with individuals frequently experiencing reduced quality of life, psychological distress, and healthcare inequities, including limited access to specialist services (Keatley & Molton, 2022; McLoughlin et al., 2025; NNAG, 2023). Stigma, disbelief from healthcare professionals, and unclear communication around diagnosis can exacerbate distress and hinder engagement with treatment (McLoughlin et al., 2024).

The recommended management for FND in the UK, according to NICE guidelines (2024b), involves individualised, multidisciplinary care under a biopsychosocial framework. Psychological therapy, particularly Cognitive Behavioural Therapy (CBT), remains the most widely endorsed intervention (NICE, 2024b; Gutkin et al., 2021). CBT approaches typically involve psychoeducation,

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identification of symptom triggers, cognitive restructuring, and grounding techniques to manage stress and dissociation (Bennett et al., 2021; Gilmour et al., 2020). While some studies show CBT's effectiveness in improving seizure frequency or quality of life (e.g., LaFrance et al., 2014; Goldstein et al., 2020), others reveal only modest or short-term benefits, or inconsistent findings across FND subtypes (Goldstein et al., 2021; Gutkin et al., 2021). Evidence comparing CBT to other modalities, such as psychodynamic therapy, remains inconclusive.

Given the limitations of standard psychological treatments, there is growing interest in alternative and adjunctive approaches, such as hypnosis. Clinical hypnosis has been defined as a waking state of awareness (or consciousness), in which a person's attention is detached from his or her immediate environment and is absorbed by inner experiences such as feelings, cognition and imagery. It involves focusing attention and imaginative involvement to the point where what is being imagined feels real (Williamson, 2019). It is a guided process in which a clinician first leads a person into a focused, deeply relaxed state through gentle verbal prompts (a hypnotic induction). In this state, attention becomes more inward and concentrated. The clinician then offers therapeutic suggestions designed to support specific goals, such as changing a habit, reducing anxiety, or reframing unhelpful beliefs (Peter, 2024; Weir, 2024). As our conscious experience is constantly shaped by how the brain blends current information with past memories, beliefs, and expectations, hypnosis creates a context in which that experience can be more flexibly "edited." In this focused state, the brain can become more receptive to new perspectives and patterns, making positive change easier to integrate (Walter et al., 2025).

Historically, hypnosis was used to treat functional neurological symptoms—then often conceptualised as "hysteria" or "hystero-epilepsy"—particularly during periods of war when large numbers of soldiers presented with conversion symptoms such as non-epileptic seizures, paralysis, or sensory disturbances (Fatović-Ferenčić & Kuhar, 2025). Early clinicians employed hypnosis both as a diagnostic and therapeutic tool, aiming to access and modify the psychological processes believed to underlie these presentations. Although the rise of psychoanalysis and later behavioural approaches led to a relative decline in the use of hypnosis in mainstream psychiatry, interest in its clinical applications has re-emerged in recent years, particularly within integrative and trauma-informed models of care (Sanyal et al., 2022).

Contemporary conceptualisations of hypnosis emphasise its role in enhancing focused attention, absorption, and responsiveness to suggestion, which may be particularly relevant for FND, where alterations in attention and agency, and maladaptive predictive processing are thought to

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contribute to symptom generation and maintenance (Edwards et al., 2012; Brown & Reuber, 2016).

Neurocognitive models also suggest that hypnosis may modulate top-down predictive processes and alter the integration of beliefs, expectations, and bodily signals—mechanisms that overlap with leading models of FND (e.g., predictive processing accounts) (Connors et al., 2024). In this sense, hypnosis may provide a structured context in which maladaptive symptom expectations can be revised. Systematic reviews indicate that hypnosis shows promise in reducing functional symptoms, including psychogenic non-epileptic seizures and functional motor symptoms, with some studies reporting maintenance of gains at follow-up (Connors et al., 2024; Moene et al., 2003; Walter et al., 2025). The FND service at Lancashire Teaching Hospitals NHS Foundation Trust has introduced clinical hypnosis service as an adjunctive tool as an NHS service, with promising results (Lukose & Das, 2026).

However, the current evidence base remains methodologically limited. Many studies involve small sample sizes, lack adequate control conditions, or use heterogeneous outcome measures. Randomised controlled trials are scarce, and replication across independent research groups is limited. Furthermore, intervention protocols are often poorly standardised, making it difficult to isolate the active therapeutic components (Sanyal et al., 2022). Importantly, there is a notable paucity of qualitative research exploring patients' lived experiences of hypnosis within FND treatment. This gap is particularly significant given that FND management places strong emphasis on psychoeducation, therapeutic alliance, and the patient's subjective understanding of their symptoms. Hypnosis, which explicitly engages imagination, expectation, and meaning-making processes, may interact closely with these relational and experiential factors. A deeper exploration of patient perspectives could therefore illuminate not only acceptability and feasibility but also the mechanisms through which hypnosis exerts therapeutic effects. [OBI]

In light of this, the current study seeks to explore hypnosis as a relatively novel intervention for FND. Specifically, it aims to investigate the feasibility, perceived effectiveness, and acceptability of hypnosis through a mixed-methods lens, centring the voices of individuals with FND to understand better how they engage with and respond to this form of therapy. This research builds on preliminary positive findings while addressing crucial gaps in patient-focused outcomes and experiential insight.

2. RATIONALE

This mixed-methods study aims to conduct a preliminary evaluation of the perceived effectiveness, feasibility, and usability of clinical hypnosis for individuals with FND. The integration of both quantitative and qualitative strands will enable a comprehensive understanding of clinical outcomes as well as patient perspectives on treatment engagement, acceptability, and perceived change. The findings obtained will inform larger studies on the potential benefits of clinical hypnosis for FND.

3. AIMS AND OBJECTIVES

3.1 Overall aim

To preliminary evaluate the effectiveness, feasibility, and usability of clinical hypnosis as a treatment for individuals diagnosed with Functional Neurological Disorder (FND), using a mixed-methods design.

3.1.1. Quantitative objectives

The quantitative component of the study will specifically aim to:

1. **Assess psychological well-being:**

Determine the impact of clinical hypnosis on key indicators of psychological well-being—namely, levels of anxiety, depression, stress, and health-related quality of life—at three time points: baseline, after a course of 3 fortnightly sessions (6 weeks in total), and follow-up (4 weeks post-treatment).

2. **Measure changes in functional symptoms:**

Evaluate whether there are differences in functional neurological symptoms (e.g., functional seizures, motor disturbances) through a comparison of their frequency and severity before engaging with clinical hypnosis (baseline), after 6 weeks, and at follow-up.

3. **Examine the sustainability of treatment effects:**

To investigate the persistence of any therapeutic benefits by assessing whether

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improvements in psychological well-being, quality of life, and symptom severity are maintained at follow-up.

3.1.2. Qualitative objectives

- To explore participants' experiences of receiving clinical hypnosis, including perceived benefits and barriers to engagement (if any)
- To understand how participants interpret any observed changes in symptoms or well-being in the context of their broader lived experience with FND.
- To identify service users' recommendations for improving the delivery and accessibility of hypnosis-based interventions for the FND population.

4. THEORETICAL FRAMEWORK

This study is grounded in a biopsychosocial and neurocognitive framework known as “predictive processing (Bayesian) framework”. The predictive processing (Bayesian) framework conceptualises the brain as a hierarchical inference system that continuously generates predictions about sensory input and updates these predictions based on prediction error. Perception and action arise from the integration of prior expectations (“priors”) and incoming sensory signals, weighted by their relative precision (Darling et al., 2025; Edwards et al., 2011).

In FND, symptoms are proposed to arise when maladaptive prior expectations about bodily states or movements become excessively precise and dominate sensory evidence. This imbalance leads to the generation of genuine, involuntary symptoms—such as weakness, tremor, or non-epileptic seizures—despite the absence of structural neurological pathology. Disturbances in attentional weighting, agency attribution, and self-monitoring processes further contribute to symptom persistence (Milano et al., 2023).

Clinical hypnosis is theoretically well aligned with mechanisms thought to underlie FND, particularly within predictive processing (Bayesian) frameworks. These models propose that the brain continuously generates predictions about the body and environment based on prior experience and compares them with incoming sensory information (Edwards et al., 2011; Perez et al., 2021). Perception and action normally reflect a balance between prior expectations and sensory evidence. In FND, this balance may become disrupted, such that symptom-related expectations are afforded excessive precision relative to sensory input, leading to the generation of genuine but involuntary symptoms in the

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absence of structural pathology (Pick et al., 2019).

Hypnosis may provide a structured context in which this imbalance can be adjusted. By narrowing attention and enhancing responsiveness to suggestion (Lifshitz et al., 2013; Terhune & Cardeña, 2016), hypnosis can experimentally alter sense of agency and perceived involuntariness (Lush et al., 2020). In predictive processing terms, this may facilitate recalibration of precision weighting between prior expectations and sensory input. Rather than simply suppressing symptoms, hypnosis may therefore engage core neurocognitive mechanisms involved in symptom generation and maintenance. Importantly, predictive models also emphasise that perception and bodily experience are shaped by prior beliefs, contextual meaning, and subjective models of the self (Fobian & Elliott, 2019; Rudrauf et al., 2022). Within FND, symptom generation is understood as arising from maladaptive prior expectations and altered self-representation, highlighting the central role of personal beliefs and lived experience in shaping symptom expression (Brown, 2004; Edwards et al., 2011; Lush et al., 2020). Exploring patients' lived experiences through qualitative methods is therefore theoretically consistent with this framework, as it allows examination of how individuals interpret, experience, and integrate therapeutic change within their own understanding of their symptoms.

4. STUDY DESIGN and METHODS OF DATA COLLECTION AND DATA ANALYSIS

5.1. Study Setting

This study will be conducted at a single specialist clinic located in the North West of the UK – the FND service at Royal Preston Hospital (LTHTR). All participant recruitment and the hypnotherapy intervention sessions will take place through this outpatient service. The site provides experienced clinical staff and private consultation rooms necessary for delivering hypnotherapy sessions and collecting clinical data. No additional centres are involved (single-centre study), which simplifies coordination and ensures consistency in how the intervention is delivered.

The selection of this site also ensures that if any participant requires support (e.g. due to symptom exacerbation), appropriate clinical care is immediately available (please see the 'adverse event report form' for more details). There are no unusual site-specific requirements beyond standard clinic facilities; a quiet, comfortable environment is provided for hypnotherapy. The study setting thus aligns with the research question by facilitating access to FND patients in a real-world clinical context and providing a safe, controlled environment for both intervention and data collection.

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5.2 Sample and Recruitment

5.2.1. Inclusion criteria

Participants must meet all of the following criteria to be included in the study:

- **Diagnosis:** Confirmed diagnosis of FND by a neurologist or specialist in the FND service (e.g. motor or sensory functional symptoms).
- **Age:** Adults aged 18 years or above.
- **Location of care:** Currently a patient at the FND service (Lancashire Teaching Hospitals) or referred to this service for treatment.
- **Consent capacity:** Capable of giving informed consent to participate, and able to comply with study procedures (e.g. completing questionnaires and attending or participating in therapy sessions).
- **Language:** Sufficient proficiency in English to understand the Participant Information Sheet (PIS), give consent, and engage in therapy and interview (as all materials and sessions will be conducted in English).

5.2.2 Exclusion Criteria

Participants will not be eligible for the study if any of the following apply:

- **Serious co-morbid Conditions:** Presence of severe unmanaged physical or mental health conditions that would interfere with participation. For example, an active severe neurological disease other than FND, or severe psychiatric disorders (such as psychosis or significant cognitive impairment) that impair the ability to engage in hypnotherapy or complete questionnaires. These could confound results or pose safety/consent issues.
- **Inability to consent or communicate:** Individuals who lack capacity to give informed consent or who cannot participate in research activities due to communication barriers (e.g. non-English speakers without available translation, or those with severe language or cognitive barriers) will be excluded.
- **Concurrent participation in conflicting research:** Participants enrolled in another interventional clinical trial or research study that could conflict with this intervention's outcomes will be excluded, to avoid confounding effects.

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- Declines hypnotherapy: Patients who, after discussion and/or after trying an initial session of hypnotherapy, are unwilling to undergo hypnotherapy treatment would not be suitable, since the intervention is central to the study.

5.3 Sampling

5.3.1 Size of sample

This study will measure changes in outcomes over three time points (T1, T2, T3) within the same individuals, and the sample size for the quantitative strand will be determined via an a priori power analysis. As hypnotherapy as a treatment for FND is relatively recent, there is no longstanding tradition of recommended sample sizes for hypnotherapy-based interventions. Previous literature on FND for hypnosis mostly includes mid-sized studies with around 40 participants (Moene et al., 2003; Tibben et al., 2024). For this study, the sample size was calculated a priori using the software G*Power (version 3.1), a widely recommended tool for sample size and power calculations across various statistical tests (Faul et al., 2007). A-priori sample size calculations were carried out in G*Power (v3.1) for a repeated measures design with three time points (baseline, post-treatment, and 4-week follow-up). The test family was set to F tests, with the statistical test specified as ANOVA: repeated measures within factors. The alpha level was set at .05 and power at .80, with three measurements, nonsphericity correction set to 1, an expected medium effect size of $f = .25$, and an assumed correlation among repeated measures of .60, based on typical values for self-report symptom scales. More specifically, we assumed a within-person correlation of $r = .60$ between repeated measurements as this is consistent with published test–retest or repeated-measures stability estimates for our study instruments (please see Appendix 1), which all typically range between $r \approx .57$ –.75 in different populations (Arias de la Torre et al., 2023; Fobian & Elliott, 2019), making .60 a conservative, literature-based estimate (Fobian & Elliott, 2019). Under these parameters, G*Power indicated that a total sample of 30 participants would be needed to detect the main effect of time. To account for an expected attrition rate of around 20 per cent between baseline and follow-up, a recruitment target of about 38 to 40 participants will be set.

For the qualitative component (post-intervention interviews), sample size will be determined by the principle of information power, in light of which the more information the sample holds, the lower the number of participants needed (Malterud et al., 2016). Therefore, all participants who consent to the qualitative strand will be considered for interviewing, but it is anticipated that approximately 10–15

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interviews will be adequate to reach saturation. The sample for interviews will thus be a subset of the quantitative sample: those who have completed the hypnotherapy intervention and agreed to share their personal experiences.

5.4. Sampling technique

The selection of participants will use a mixture of purposive and convenience sampling, focusing on individuals who have the characteristics central to the research question (i.e. diagnosed FND patients receiving hypnotherapy – purposive sampling) but are also available and willing to take part (convenience sampling). All eligible patients within the recruitment period will be invited consecutively. This approach aligns with the study's mixed-methods design and pragmatic considerations. It ensures that all participants: (a) have the condition of interest and exposure to the intervention, and (b) are accessible to the researcher through the clinical service. It also reflects the theoretical framework of the study, since FND is relatively rare and requires a specific diagnosis, a targeted sampling is appropriate to gather the most informative cases. The sampling technique optimally utilises limited research resources by focusing on cases that are most pertinent to the research question. The combination of purposive and convenience elements in the sampling strategy is expected to yield a sample that is both appropriate (relevant to FND and hypnotherapy) and practical to recruit, given the clinical setting.

5.5 Recruitment

5.1.1 Sample Identification

Potential participants will be identified through the FND service's records and routine clinical activities. Dr Das (PI), as the FND service lead, will first screen the list of patients diagnosed with FND who are either about to begin hypnosis sessions, or have been invited to engage with clinical hypnosis sessions (and are currently on the waiting list). Once eligible participants are identified, Dr Das will introduce the study in the first instance, either via phone call, mail or during routine clinic visits. If participants are interested in the study and agree (verbally or in writing) to have their details shared with the research team, Dr Das will add them to a list of potential participants. This list will contain their names and contact details (email and/or phone number) and will be shared with CI and RAs (DDB, LM, and AS) via an encrypted folder accessible only to the research team. The RAs (LM and AS) will contact prospective participants on this list via short messages (SMSs) and emails (see document 'Initial Approach and Reminder_Emails', Initial Approach and Reminder_Short Messages').

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The initial email and SMSs will be brief invitations explaining that a research study is evaluating the experiences of people with FND engaging with clinical hypnosis, why they have been identified as potential participants and what they would be asked to do if they took part in the study (i.e., taking part in online surveys and attending a final -optional- interview). Both the email and the initial SMS will ask if the person is interested in learning more. A follow-up phone call may be made (especially if the email is not responded to) to ensure the information is received and to answer any immediate questions. Up to two reminders (via email and/or SMS) will also be sent to potential participants, if the initial email or SMS do not receive a reply.

At this stage, researchers (or Dr Das, if doing the approach) will not yet obtain full consent – they will only seek verbal or written confirmation that the patient is open to receiving detailed study information. If the patient expresses interest, the researcher (LM) will proceed to the next step, which involves sending a REDCap link containing the Participant Information Sheet (PIS) and consent form (CF). REDCap (Harris et al., 2009) was chosen as the electronic data capture tool for this project due to its widespread use in research and its status as approved software for use by LTHTR for research purposes.

After providing informed consent, participants will also be asked to create a unique identification code (UIC), which will allow them to remain anonymous in T2 and T3 and will allow for their data to be 'matched' across the two stages of the study (intervention and interviews). At baseline (T1), they will be asked to indicate their full name when signing the CF, so that the UIC can be 'matched' with participants and can be used (instead of participants' names) in T2 and T3. The use of such log will also allow researchers to delete all records related to a participant (in T1-T3 and also in the interview), should a participant withdraw their consent to the use of the data in any of the stages of the study (T1-T3 and/or interview). Participants will be contacted via email or phone call by one of the RA (LM) after session 3 (T2) and again at follow-up (T3) to complete the survey. On these occasions, participants will be reminded to use their UIC (and will be reminded of their UIC, if needed) when completing the survey.

Participants will not receive any payment or inducement for taking part in the study – their involvement is entirely voluntary.

5.6. Consent

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The consent procedure will proceed as follows: Interested individuals will be sent a hyperlink (via email) to a REDCap form that begins with the PIS, offering a comprehensive document explaining the study in plain language and covering the purpose of the research, what participation involves (for both the quantitative assessments and the optional qualitative interview), the potential risks and benefits, confidentiality of data, and the voluntary nature of participation (including the right to withdraw at any time). Participants will be encouraged to read this carefully. They will also be provided with contact information for the research team should they have any questions or need clarification before proceeding. After reviewing the PIS, the REDCap form will present an electronic CF. This form will allow the participant to confirm consent by responding to a series of yes/no statements (for example, “I have read and understood the Participant Information Sheet dated XX/XX/2025”). Participants will indicate their agreement (by selecting “Yes”) and the REDCap system will securely log the response.

Importantly, the PIS and CF will cover both strands of the study – quantitative and qualitative. Participants will be explicitly asked whether they agree to each component. It is made clear that they may choose to participate in only the quantitative data collection (i.e. just complete the questionnaires and receive the therapy) and decline the interview, or vice versa, or both.

For those who consent to be contacted for an interview, a separate consent process will be initiated. After the participant completes the hypnosis intervention (at the point of discharge or the end of the last session, T2), the researcher designated for qualitative data (AS) will reach out to these participants via email (and/or phone, whichever is the preferred method of contact). Participants will be reminded of what the interview entails (e.g. a 30-60 minute discussion about their experience with hypnotherapy, conducted via telephone or online). If they verbally reconfirm interest, the researcher will email them the PIS related to the interviews again, so they can refresh their understanding of the interview’s purpose and process. Before starting the actual interview, the researcher will obtain verbal consent on record – this will involve the participant verbally stating consent at the beginning of a recorded interview. While videorecording participants’ consent, AS will also complete a written version of the CF, to be saved with the videorecording of the consent to participate – separately from the videorecording of the interview.

Participants’ General Practitioners (GPs) will be informed of their participation in the study by letter (see document: “GP Letter”), with the participant’s consent. The letter will briefly outline the nature of the study, confirm that the participant is receiving clinical hypnosis as part of their existing care, and provide contact details for the research team should the GP require further

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information. No additional clinical responsibilities will be placed on the GP, and only relevant information will be shared.

6. Characteristics of the intervention (clinical hypnosis)

Participants will receive a brief, manualised clinical hypnosis intervention designed for FND, which is already offered by the LTHTR FND service as an adjunctive treatment as part of their standard care (no changes to the standard intervention will be introduced as part of the study). The approach targets mechanisms relevant to FND—such as attentional dysregulation, symptom-focused expectation, autonomic arousal, and sensorimotor incongruence—and will be delivered by an appropriately qualified clinician (Dr Das) with training in hypnosis and experience working with FND. Each session is delivered fortnightly and lasts approximately 45–60 minutes. Sessions follow a consistent structure: (1) brief check-in; (2) Induction - focused-attention and relaxation methods (e.g., eye-fixation, controlled breathing); (3) symptom-focused therapeutic suggestions, metaphor and imagery (e.g., normalisation of movement patterns, enhanced sense of control, seizure-interruption cues, modulation of somatic sensations); (4) Post-hypnotic suggestions and (5) debrief. The intervention is delivered face-to-face in the LTHT FND specialist clinic. As part of the standard clinical hypnosis protocol delivered in the LTHT FND service, patients are also provided with the audio-recordings of their clinical hypnosis sessions, which they are encouraged to use at home to practice between sessions.

Sessions content is tailored to the individual symptom phenotype and formulation while preserving core components. Fidelity will be supported through clinical supervision and MDT meetings regularly attended by Dr Das. Adverse experiences (e.g., distress, marked dissociation) will be managed via standard grounding/stabilisation procedures, and sessions may be paused or stopped if needed, following standard LTHT-approved protocols.

7. Data collection

7.1. Quantitative data collection

The preliminary effectiveness and feasibility of this intervention will be evaluated using an LTHTR-approved online data collection tool (REDCap) (Harris et al., 2009). We will create a REDCap online survey containing the measures included in Appendix 1. These measures will be collected three times: at baseline, before engaging in the first clinical hypnosis session (T1), after session 3 (T2) and

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at follow-up (T3). An additional clinician-delivered measure will be used by Dr Das (as used in his standard clinical practice) to evaluate the symptomatic improvement (or deterioration) using the Clinical Global Impression – Improvement scale (CGI-I) (Busner and Targum, 2007), a brief, clinician-rated tool that asks the treating professional to judge how much a patient's condition has improved or worsened relative to baseline on a 7-point scale (from “very much improved” to “very much worse”).

7.2. Qualitative data collection and analysis

Following the intervention phase, a subset of participants will participate in individual interviews to explore their in-depth experiences with the hypnotherapy treatment. These interviews constitute the qualitative data collection. All participants who indicated consent to the qualitative strand (and reconfirmed willingness at the end of therapy) will be scheduled for an interview at a convenient time. Interviews will be conducted by the researcher leading the qualitative data collection (AS), using a semi-structured format. An interview topic guide with open-ended questions and prompts will be used to ensure key topics are covered (for example, questions about participants' perceptions of hypnotherapy, any changes in symptoms they attribute to the therapy). Interviews will be conducted either via telephone or via a secure online video platform (Microsoft Teams), according to participant preference. Participants will conduct the interview in a comfortable, private setting of their choice. Each interview is expected to last approximately 30 to 60 minutes and will be video-recorded using the recording function of the video platform. The interviewer will also take brief field notes (e.g. noting tone or emotional expressions not evident from audio) to aid interpretation.

Following each interview, the recording will be transcribed verbatim. Transcription will be done by the researcher (AS). Any potentially identifying information mentioned (names, places, etc.) will be removed or replaced with pseudonyms during transcription to protect anonymity. Each participant will be identified via the ID code assigned in stage 1 (intervention), and transcripts will only use these codes.

8. Data Analysis

8.1 Data Analysis – Intervention stage

The quantitative outcomes collected at T1, T2, and T3, both by Dr Das (in-session CGI scale) and remotely via REDCap, will be analysed using appropriate repeated-measures statistical tests. If the data meet parametric assumptions, a repeated measures ANOVA will be conducted to test for

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significant changes over time within subjects. Time (with three levels: pre, post, follow-up) will be the within-subject factor. A significant ANOVA result would indicate an overall time effect, and this will be followed by post-hoc pairwise comparisons (with adjustment for multiple comparisons) to pinpoint where changes occurred (e.g. from T1 to T2, and whether gains are maintained at T3). A recent pilot study (Tibben et al., 2024) on hypnosis for FND used this approach, finding a significant time effect with large effect size using RM-ANOVA. If the data are not normally distributed or the sample size is small, a non-parametric equivalent (such as the Friedman test) will be used, with Wilcoxon signed-rank tests for post-hoc comparisons. Effect sizes (e.g. Cohen's d for paired differences or partial η^2 for ANOVA) will be reported to assess the magnitude of changes. A significance level of 0.05 will be used for hypothesis testing. In addition, baseline demographic and clinical characteristics will be summarised descriptively. No interim analyses are planned, given the small scale. All analyses will be carried out using statistical software (SPSS).

8.1.1. Handling of variable treatment exposure at follow-up

The primary analysis will examine change in outcome measures across T1 (baseline), T2 (6 weeks), and T3 (follow-up) using repeated-measures ANOVA where parametric assumptions are met, or the Friedman test where assumptions are violated, as previously specified.

As hypnotherapy continues as part of standard clinical care, some participants may receive additional sessions beyond the initial 6-week period. Therefore, outcomes at T3 may reflect variable treatment exposure. To address this, the following will be implemented:

- The number of sessions completed by T2 will be recorded.
- The number of additional sessions received between T2 and T3 will also be recorded.
- Total sessions received by T3 will be summarised descriptively.

To account for heterogeneity in treatment exposure at follow-up, exposure-adjusted sensitivity analyses will be conducted. These will include:

1. Including number of sessions (e.g., total sessions by T3 or additional sessions between T2–T3) as a covariate in supplementary analyses; and/or
2. Stratified analyses comparing participants who received no additional sessions after T2 with those who received one or more additional sessions.

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These analyses are intended to aid interpretation of T3 findings and to distinguish maintenance effects following an initial 6-session block from effects associated with continued treatment. The primary repeated-measures analysis will remain unchanged.

8.1.2. Missing data approach

The primary analysis will use all available data at each timepoint. The extent and pattern of missing data will be described. Given the feasibility nature of the study, formal imputation methods will not be routinely applied.

If missing data or variability in treatment exposure renders repeated-measures ANOVA unsuitable, linear mixed-effects models may be conducted as a sensitivity analysis, as these models allow inclusion of participants with incomplete data under a missing-at-random assumption and can incorporate treatment exposure variables.

Last Observation Carried Forward (LOCF) will not be routinely used. Sensitivity analyses may be conducted where appropriate to assess the robustness of findings.

8.2 Data analysis - Interviews

For qualitative data analysis, the study will employ thematic analysis (TA), which was chosen because it offers a flexible yet structured approach to qualitative data that is not tied to any one theoretical perspective (Braun & Clarke, 2021; Clarke, 2021), making it suitable for research on underexplored topics such as novel interventions in FND. Braun and Clarke's well-known six-phase framework will be used to guide the analysis process (Clarke, 2021).

To assist with data organisation during analysis, a qualitative analysis software (NVivo) will be used. Several strategies will be employed to enhance the rigour of the qualitative analysis. First, the researcher (AS) will practice reflexivity – being aware of and bracketing their own potential biases or preconceptions about hypnotherapy, to reduce their influence on data interpretation. Second, to improve credibility, AS will discuss the coding and themes with the Chief Investigator (DDB), experienced in qualitative methods.

8.3. Statistical and qualitative data analysis software

Quantitative data will be analysed using IBM SPSS Statistics (current version available within the host institution at the time of analysis). Data will be entered and stored in a pseudonymised format using participant-generated study ID codes. Prior to analysis, data will be screened for completeness,

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distributional assumptions, and outliers. Descriptive statistics will be calculated to summarise demographic and clinical characteristics, feasibility outcomes (e.g., recruitment, retention), and outcome measures at each timepoint.

Qualitative data (video-recorded interviews transcribed verbatim and anonymised) will be analysed using NVivo (current institutional licence version at time of analysis). NVivo will be used to support systematic coding, data organisation, and theme development. Transcripts will be imported in anonymised form and coded inductively and/or deductively in line with the stated analytic approach (e.g., reflexive thematic analysis). The software will be used as a data management and analytic support tool; interpretation and theme development will remain the responsibility of the research team.

Access to both SPSS datasets and NVivo project files will be restricted to authorised members of the research team and stored on secure University systems in accordance with data governance policies.

9 ETHICAL AND REGULATORY CONSIDERATIONS

This study will obtain ethical approval from the Health Research Authority (HRA) prior to commencement. All research procedures will be conducted in accordance with the approved protocol and any subsequent amendments approved by the HRA. The study will be carried out in full compliance with the principles outlined in the Declaration of Helsinki (2013), including respect for participants, informed consent, and the right to withdraw without consequence.

9.1. Data protection and confidentiality

LTHT is the Sponsor for this study and is responsible for ensuring that the research is conducted in accordance with the UK General Data Protection Regulation (UK GDPR), the Data Protection Act 2018, and NHS information governance requirements. The study is conducted in collaboration with Lancaster University.

9.2. Use of personal data

In order to carry out this research, personal data will be collected, including participants' names and contact details (e.g., email address and/or telephone number), as well as demographic information and limited clinical information necessary to determine eligibility and coordinate participation.

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Personal data will be used solely for the purposes of:

- Contacting participants about the study,
- Arranging survey completion and (if applicable) interviews,
- Linking data across time points (T1, T2, T3),
- Ensuring appropriate governance and oversight of the research.

All identifiable personal data will be stored securely on password-protected, encrypted Lancaster University servers with access restricted to authorised members of the research team only. Personal data (e.g., names and contact details) will be retained only until the end of the study and completion of data analysis. Once the study has concluded and no further contact is required, identifiable personal data will be securely deleted.

9.3. Anonymisation of research data

Survey responses collected via REDCap will initially be linked to participants at baseline (T1) for matching across time points. Once all follow-up data (T2 and T3) have been collected and datasets have been verified, participants' names and direct identifiers will be permanently removed from the research dataset. Dr Das will add the CGI scores directly to the final dataset, so no access to patient records will be needed from any other member of the research team.

Interview recordings will be transcribed verbatim. During transcription, all identifying information (e.g., names, locations, or other potentially identifiable details) will be removed or replaced with pseudonyms. Audio or video recordings will be deleted once transcription has been completed and accuracy has been checked. At that point, the dataset (including anonymised survey responses and anonymised interview transcripts) will no longer contain direct identifiers.

9.4. Retention of anonymised data

Fully anonymised research data (including survey datasets and interview transcripts) will be retained securely for up to 10 years in accordance with LTHTR Trust and Lancaster University research governance policies. This is standard practice to allow for verification of findings, academic publication, and potential secondary analysis. Anonymised data will not contain any information that could reasonably identify individual participants.

9.5. Access to Data

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Access to identifiable data will be strictly limited to authorised members of the research team who require it for the purposes of conducting the study. Anonymised and collated findings will be shared with members of the Public and Patient Involvement (PPI) steering group to support interpretation and dissemination of results. PPI members will only receive anonymised and aggregated data; they will not have access to identifiable personal information.

9.6. Confidentiality

All information collected during the study will be handled confidentially and stored securely as described above. Findings will be reported in anonymised form in academic publications, presentations, and reports, and no individual participant will be identifiable in any outputs. If, during participation, information is disclosed that raises concerns about a participant's safety or the safety of others, the research team may need to share relevant information with appropriate clinical or safeguarding services in line with NHS safeguarding policies. This would be done only where necessary and in accordance with legal and ethical obligations.

9.7 Assessment and management of risk

9.7.1. Risk assessment and management

Lancashire Teaching Hospitals NHS Foundation Trust (LTHRT) will hold overall responsibility for the risk management of this study. Risk assessment and management will be a shared responsibility between LTHRT and the research team, ensuring all potential risks are identified, evaluated, and appropriately mitigated in accordance with NHS policies and relevant ethical guidelines.

9.7.2. Risk analysis

There will be no direct contact between researchers and participants in the quantitative strand of this study, however, should they experience any discomfort or distress in relation to the questions asked in the survey, they will have the opportunity to contact the research team and/or the FND service clinical team, whose contacts will be reported on the PIS, which will be shown on all REDCap survey links that participants will be sent (T1-T3). The RAs will also send a Debrief Email (see document: 'Debrief Email') to all participants after T3, to remind them of the research team's contact

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details and provide details of the sources of support also listed on the PIS (e.g., Samaritans), which they can access freely at any time.

In the qualitative research strand, instead, a more direct risk management plan will be devised. While the overall risk level of the study is anticipated to be low, it is recognised that qualitative research—particularly interviews exploring personal or sensitive experiences—may uncover information with safeguarding implications.

9.7.3. Risk management plan (interview stage)

All research staff involved in the study will be trained in safeguarding procedures and in identifying and responding appropriately to distress or risk disclosures.

a. If a participant becomes distressed:

- The interview will be paused or stopped based on the participant's comfort.
- The researcher will assess immediate risk using a predefined protocol.
- If there is an immediate risk to the participant's safety, the researcher will inform the appropriate clinical or safeguarding lead within LTHRT or the participant's care team.
- The participant will be provided with information about support services and encouraged to contact their GP or mental health provider.
- The incident will be documented and escalated according to institutional safeguarding protocols.

b. If a participant discloses an intention to harm others:

- The researcher will follow safeguarding procedures, reporting the information to the designated safeguarding lead at LTHRT.
- Where necessary, information may be shared with relevant statutory services (e.g. social services, police) in line with the legal duty to prevent serious harm.
- The participant will be informed, wherever possible, about the need to share this information and with whom it will be shared.

c. If a participant discloses abuse or safeguarding concerns involving others (e.g. children or vulnerable adults):

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- The researcher will inform the LTHRT safeguarding team in line with NHS safeguarding policy.
- A formal safeguarding referral will be made where required.
- The research team will not act independently but will follow guidance from the safeguarding lead.

9.7.4. Information sharing and confidentiality

Confidentiality will be maintained throughout the study, with the exception of circumstances where there is a clear safeguarding risk. In such instances, data will be shared on a strictly need-to-know basis, in accordance with NHS information governance and legal obligations. Participants will be informed of these limits to confidentiality during the consent process.

9.7.5. Research Ethics Committee (REC) and other regulatory review & reports

Prior to the commencement of this study, a favourable ethical opinion will be sought from a recognised Research Ethics Committee (REC). This review will include an assessment of the study protocol, informed consent materials, participant information sheets, recruitment advertisements, and any other relevant documentation.

Substantial amendments requiring NHS REC approval will not be implemented until a favourable opinion has been received and all necessary arrangements are in place to implement the changes at research sites. All correspondence with the REC, including initial submissions, approvals, and amendments, will be retained in accordance with sponsor and regulatory requirements. The Chief Investigator (CI - DDB) will be responsible for submitting all required reports to the REC and will keep all correspondence.

10. Access to the final study dataset

Access to the full dataset will be restricted to members of the research team and authorised personnel from LTHRT) who are directly involved in the study. All individuals with access will be bound by confidentiality agreements and will adhere to data protection regulations.

The data will be shared with PPI representatives for the purposes of providing feedback on study findings, interpretations, and relevance. This data will be fully de-identified to ensure that individual participants cannot be identified, in line with ethical and legal standards. All data handling

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will comply with the UK General Data Protection Regulation (UK GDPR), the Data Protection Act 2018, and institutional data governance policies.

11. End of Study

For Phase 1, this will be the final follow-up questionnaire (T3); for Phase 2, the final interview.

12. DISSEMINATION POLICY

12.1. Dissemination policy

The results of the study will be disseminated through publication in peer-reviewed scientific journals and presented at national and international academic and clinical conferences. All manuscripts, abstracts, and presentations will be reviewed prior to submission to ensure consistency with the Final Study Report, protection of participant confidentiality, and adherence to intellectual property and data sharing agreements.

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11. APPENDICES

11.1 Appendix 1- Measures used in the quantitative strand (Clinician-administered and REDCap surveys – T1-T3)

Clinician-administered:

- The **Clinical Global Impression – Improvement scale (CGI-I)** (Busmer & Targum, n.d.) is a brief, clinician-rated tool that asks the treating professional to judge how much a patient's condition has improved or worsened relative to baseline on a 7-point scale (from "very much improved" to "very much worse"). Because it is simple, fast, and applicable across diagnoses, it is widely used in neurological and FND-related practice to provide a standardised, global measure of treatment response in both clinical care and research settings (Pick et al., 2020).

REDCap surveys – T1-T3:

- **Ad-hoc demographic questionnaire** measuring age, gender, ethnicity, marital/relationship status and living situation).
- **Ad-hoc demographic questionnaire** measuring the frequency, intensity and duration of seizures on 6-point Likert scales and open-ended questions (e.g., "thinking about the past month, how many episodes of seizures have you had (on average)?")
- **Ad hoc brief questionnaire** asking (a) how many times, on average, service users have engaged with home-based practice (session audio-recordings) in the 6 weeks of their intervention attendance, and at follow-up (after 4 weeks); (b) how useful they have found engaging with this practice from 0 (not useful at all/no improvement) to 10 (very useful/clear benefits and improvements).
- **Patient Health Questionnaire-8 (PHQ-8)**
An 8-item self-report scale for depressive symptoms, which has been widely used and has proven to have overall high validity and internal consistency across different countries (Arias de la Torre et al., 2023)

Hypnotherapy for FND

- **Generalised Anxiety Disorder-7 (GAD-7)** (Spitzer et al., 2006): A 7-item tool for screening and monitoring generalised anxiety symptoms. Demonstrates excellent reliability (alpha ~0.92), strong sensitivity and specificity, and responsiveness to treatment-related change (Teymoori et al., 2020)
- **Multidimensional Assessment of Interoceptive Awareness (MAIA-2)** (Mehling et al., 2018): a 24-item scale measuring various facets of interoceptive awareness (e.g. noticing bodily sensations, emotional awareness of bodily states, self-regulation, etc.). Several studies have confirmed good psychometric properties of the short version (Scheffers et al., 2024).
- **Pearlin Mastery Scale:** A 7-item scale developed by Perlin & Schooler (Pearlin & Schooler, 1978) to assess the extent to which one feels in control of forces that affect one's life. Each item is rated on a 4-point agreement scale, with higher total scores indicating greater mastery. The scale typically shows acceptable reliability (Cronbach's α ~0.70–0.80) and overall, it is considered a valid and acceptable tool (Eklund et al., 2012).
- **Patient Health Questionnaire-15 (PHQ-15)** (Kroenke et al., 2002): A 15-item questionnaire widely used to assess somatic symptom severity (Leonhart et al., 2018). FND patients often report physical symptoms (pain, fatigue, gastrointestinal issues, etc.), and the PHQ-15 is frequently used to quantify this somatic symptom burden. Recent work highlighted that it has adequate internal consistency (α ~0.80) and is sensitive to changes in symptom severity (Kroenke et al., 2002; Leonhart et al., 2018).
- **Work and Social Adjustment Scale (WSAS)** (Mundt et al., 2002): A 5-item scale evaluating functional impairment in work, home management, social leisure, private leisure, and family relationships. It has been used in FND studies to evaluate people's overall functioning (Guy et al., 2024) , and it is considered a valid and reliable measurement (Thandi et al., 2017).