RESEARCH PROTOCOL

Feasibility and Acceptability of Body Signal Integration Training for Functional Neurological Disorder: A case series

Contents

1) RESEARCH TEAM & KEY CONTACTS

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2) INTRODUCTION

The current study will use a systematic case series design to pilot a manualised intervention for individuals with a diagnosis of Functional Neurological Disorder (FND). The study will recruit 8 participants and measure their FND symptoms, psychological wellbeing and

satisfaction with the treatment package delivered. Baseline measures will be collected during a pre-treatment meeting. Intervention will involve 6-8, 1-hour sessions delivered online via videocall. The intervention will aim to improve body perception by getting participants to 'tune into' (pay attention to) their body using different methods and in different physical and emotional states. The study will assess whether the treatment package is acceptable to participants and feasible to deliver. The study will also gather preliminary data around any changes in FND symptoms and psychological wellbeing to see if the intervention has the potential to improve clinical outcomes.

It is expected that the intervention delivered will be feasible and acceptable to deliver and successful in reducing participants' FND symptoms. If this is the case, it would benefit both the participants of the study and people with FND in the future.

3) BACKGROUND

Functional Neurological disorder is a problem with the functioning of the nervous system and how the brain and body communicate with one another (Pick, Goldstein , Perez, & Nicholson, 2019). Individuals with FND often exhibit the subjective clinical features of neurological conditions (e.g., seizure, paralysis, movement disorders and cognitive dysfunction), but there are objective signs that the symptoms are not caused by neurological damage or disease. 10-20% of patients seen in neurology clinics have FND (Pick, Goldstein , Perez, & Nicholson, 2019). In addition to neurological symptoms, individuals with FND often experience associated symptoms such as memory difficulties, headache and fatigue, which are distressing and impact on social/occupational functioning. This affects overall quality of life (Pick, et al., 2020). Psychological adversities (e.g., stressful life events and interpersonal difficulties) are also important risk factors in FND. They are often associated with poorer quality of life, increased symptom severity and reduced resilience (Pick et al., 2019). As such, psychological therapy forms a key aspect of treatment in this area.

The exact mechanisms that underlie FND symptoms are not yet fully understood. There has been an increased emphasis on theories of emotion processing and interoceptive difficulties. It has been hypothesised that individuals with FND may experience a deficit in interoception which affects the integration of signals from the body and mind (Yogarajah, 2019). This causes problems with the identification stage of emotion regulation (Gross, 2015). This combination of emotion processing and interoceptive deficit contributes directly to the generation of FND symptoms. Support for this model of FND comes from studies that have found reduced interoceptive awareness in individuals with FND (Yogarajah, 2019). Additionally, individuals with FND frequently report difficulties in emotional functioning such as, anxiety, depression and affect dysregulation (Williams , Reuber, & Levita, 2020).

In addition to difficulties with emotion processing there is research on the relationship between dissociation and FND. Dissociation in FND refers to a range of phenomena such

as emotional numbing, memory and identity impairments as well as bodily symptoms. It is thought that individuals with FND may have a predisposition towards dissociation and this contributes (via impairments in interoception) to the generation and severity of FND symptoms (Pick, et al., 2020).

Current psychological models used to treat FND are Cognitive Behavioural Therapy (CBT), Psychodynamic therapies and hypnosis. These interventions usually focus on coping with the impact of FND symptoms and improving quality of life. Due to the growing body of evidence suggesting that individuals with FND struggle with interoception, emotion identification and dissociation there is the potential to develop new therapies that target these mechanisms directly. Additionally, there may be a resistance in individuals with FND towards psychological accounts of their symptoms (O'Connell, et al., 2020). Interventions targeting body perception may be more accepted due to an emphasis on physical and cognitive awareness. With that in mind, the current study aims to evaluate the acceptability, feasibility and efficacy of a 6-8 session treatment package designed to improve mind-body integration in individuals with FND.

The designed intervention is derived from the Integrative Cognitive Model (ICM) of medically unexplained symptoms and Psychogenic Non-Epileptic Seizures (Brown, 2004; Ven den Bergh, Witthoft, Petersen, & Brown, 2017; Brown & Reuber, 2016). This model suggests that conscious body perceptions are interpretations of bottom-up signals influenced by top-down factors such as attention, beliefs, fears and emotional states. The model suggests that Functional Neurological Disorders are distortions in body awareness that arise when normal bodily signals are misinterpreted as noxious, due to a combination of top-down factors and the bodily signals themselves being weak. The intervention targets several factors identified as important in this model, including imprecise bodily signals, poor emotion recognition and regulation, anxious beliefs and fears about symptoms and symptom-focussed processing. The intervention aims to sharpen signals from the body by reducing avoidance and misinterpretation of those signals and thereby improve body perception and interoceptive accuracy. If acceptable, feasible and effective, the intervention would contribute to the literature for the Integrative Cognitive Model of FND and inform future interventions for individuals with FND.

4) STUDY OBJECTIVES

4.1 Primary Question/Objective:

The primary aim of this study is to develop and begin testing the acceptability and feasibility of a 6-8 session treatment package aimed at improving mind-body integration in a series of people with FND. This will be measured using adherence to therapy, patient satisfaction and acceptability measures.

4.2 Secondary Question/Objective:

The secondary aim is an initial evaluation of the efficacy of the piloted treatment package including impact on psychological distress, core FND Symptoms and quality of life.

5) STUDY DESIGN & PROTOCOL

5.1 Participants

Eight participants will be recruited for the current study from FND charities. Participants will be aged 18 and above with a diagnosis of Functional Neurological Disorder as evidenced by a letter from a medical doctor confirming the diagnosis. Recruitment involves the use of an equality and diversity strategy to maximise the chance of recruiting a sample that is ethnically diverse.

5.2 Study Intervention and/or Procedures

Treatment:

- Participants will be offered 8, 1-hour, online sessions, delivered weekly via Microsoft Teams. The intervention will focus on developing skills to improve attunement to the signals from the body to the brain.
- The sessions will involve engaging in various exercises tuning into the body under different circumstances. Participants will be asked to tune into how particular objects feel in their hands. Participants may be presented with short clips or stories to make them feel a little happy or sad and then will be asked to tune into how the body feels in response to them.
- These sessions will be recorded via Microsoft Teams and selected aspects of them will be observed by the principal researcher and their clinical supervisor to ensure therapy quality.
- Participants will be asked to complete weekly measures online via Qualtrics survey platform in the 10-15 minutes prior to their session commencing. Assessment measures (CORE-10, FND symptoms questions, EuroQol Dimension and a measure of adverse reactions to the therapy) will be completed weekly. Any adverse reactions will be addressed in the beginning of the session.
- In the final session of treatment, all the preliminary measures will be repeated along with the measures of satisfaction in therapy and intervention acceptability.
- Following the final session of treatment, a date to complete a one-month follow up will be arranged with the participant.

Follow-Up:

- One month following the end of psychological therapy, a session will be attended remotely via Microsoft Teams by participants.

- During this session, all pre-treatment, weekly and post-treatment measures will be re-administered including questionnaires measuring satisfaction with therapy.

5.3 End of study

The end of the study will be defined as when the last participant has completed their last follow-up session and completed the follow-up measures. At this point, plans that have been approved by the UREC for the use of data collected in the course of the study will be reviewed. Following the study completion, analysis and write-up, the results of the study will be disseminated to the participants that have consented to be contacted for this purpose.

6) STUDY PARTICIPANT0053

6.1 Inclusion Criteria:

Participants will eligible to participate if they:

• Are currently experiencing FND symptoms, as measured on items 34-47 on the SOMS-7 questionnaire (excluding seizures and hallucinations). The study is aiming to investigate the feasibility of an intervention for individuals with FND.

• Have a confirmed diagnosis of FND (through letter from medical doctor) to ensure participants have a diagnosis of FND and are therefore the target audience for the intervention

• Are willing and able to participate in remote therapy. The intervention will be delivered remotely so participants must be willing to engage with remote therapy.

• Are able to converse in English proficiently without support from a link worker. The study will not be using interpreters and so an ability to converse proficiently in English to be able to engage with the intervention is needed.

• Are residing in the UK for the duration of the study, this is so the trial therapist would be able to develop an informed crisis and risk management plan for participants should they experience any negative effects from therapy or express any risks during the course of the intervention.

6.2 Exclusion Criteria:

Participants will not be eligible to participate in the study if they:

- Are currently undergoing any other psychological therapy

- Have previous experience of a mindfulness-based intervention targeting FND. The intervention tested utilises a mindfulness-based approach, so previous experience of this

would affect the acceptability of the intervention if participants have already engaged in something similar.

- have symptoms of epilepsy and/or loss of consciousness, as treatment sessions will be provided remotely and this impacts on our ability to support and manage risks of individuals that may lose consciousness in a session.

- have symptoms of psychosis (as assessed on the Comprehensive Assessment of At-Risk Mental State, CAARMS), as individuals with both FND and psychosis symptoms would make the sample non-homogenous. Furthermore, individuals with active psychosis are likely to experience more serious adverse reactions and may struggle to engage in the treatment package offered.

- have a diagnosis of Personality Disorder, as they are more likely to experience more serious adverse reactions and may struggle to engage in the treatment package.

- have active plans of self-harm and/or suicide. Potential participants will be asked to complete the risk items on the CORE-OM and will be interviewed around these. This is to ensure the safety of participants engaging in novel therapy and to manage the risks of any potential adverse side-effects of therapy

- Have a history of prior suicide attempts, to manage the risks of causing negative side effects of therapy

- Have any difficulties with alcohol or substance misuse, as this would make the sample non-homogenous. Furthermore, difficulties with alcohol and substance use could impact on ability to engage in the treatment package and also this population could experience more serious adverse reactions.

- Have active symptoms of Post Traumatic Stress Disorder (PTSD) i.e., having current symptoms of nightmares and flashbacks. This population would be more at risk of adverse effects and would make the sample non-homogenous.

- Have symptoms of an eating disorder. This would make the sample non-homogenous and this population would be more at risk of adverse effects.

6.3 Recruitment:

Recruitment:

- Participants will be recruited via advertisements by FND charities. Members of the charities that have an interest in the study will be able to access the information sheet via a link on the website of the charity. Members will be able to register their interest in the study by completing an initial screening questionnaire and providing an email address through which they can be contacted

- The information sheet contains information about the study, the rationale for the study and information about what the treatment will entail and what participants will be asked to complete during the study.
- The initial screening questionnaire aims to screen out individuals who do not meet the eligibility criteria for the study and those who may be more at risk of experiencing adverse effects from the intervention.
- A preliminary meeting will be arranged with the potential participant; this will take place via Microsoft Teams due to the study recruiting from charities across the country. During this meeting, the inclusion/exclusion criteria will be discussed, information in the information sheet will be reiterated and it will be checked that participants have a good understanding of this information. Participants will be given information in both written and verbal format about giving consent to the study. Consent will be taken by the principal researcher using an online form.
- There is no time-frame within which participants must consent and no participant will be enrolled in the study until they have voluntarily given consent.
- Participants will be offered the opportunity to withdraw their consent at any time.
- Participants will also be asked to give consent to be contacted following the study to receive feedback on the results of the study, this is entirely optional for participants. Participants will be supported throughout the process of consenting and there will be no rush or pressure place on participants to give consent until they are ready.
- Following consent to participate in the study, participants will be asked for the contact information for their local GP, social support and local crisis service. This is to inform the generation of a safety plan which will be completed with the participant, which will include an agreed protocol for if something unexpected occurs during therapy. Additionally, a letter will be sent to participants GPs to inform them of their participation in the study.
- Participants meeting all criteria and having completed the safety plan will complete baseline measures: CORE 34, 5 questions assessing FND symptoms, the Screening for Somatoform Symptoms 7 (SOMS-7) and the Work and Social Adjustment Scale (WSAS).
- Following completion of baseline measures, the first remote session to deliver the psychological intervention will be arranged with the participant.

6.4 Participants who withdraw consent [or lose capacity to consent]:

Participants are able to withdraw consent at any time without giving any reason as participation in the research is voluntary, without their care or legal rights being affected. If a participant wished to withdraw their consent, the principal researcher will request verbal consent for the data already collected to be used for the purposes of the project only and no further data will be collected. If the participant would like to withdraw their full consent, including any previous data collected for the purposes of the project, the principal researcher

will support this in withdrawing any data that has not yet been anonymised. Any data that has been anonymised will not be able to be withdrawn from the study.

7) OUTCOME MEASURES

The aim of the study is to determine the feasibility, acceptability and preliminary effectiveness of the intervention designed. The benefits of answering this question would be that participants may experience improvement in their FND symptoms and potential improvement in quality of life as a result of this. Additionally, if the outcomes of the intervention are positive, this could inform future research conducted and further development of the designed intervention which would be able to help other individuals with FND in the future.

8) DATA COLLECTION, SOURCE DATA AND CONFIDENTIALITY

Personally identifiable data will be collected about participants including their name, address, contact details, details of registered GP. Data around participants' FND symptoms, mental health and quality of life will also be collected and stored. These will be collected via interview and questionnaires delivered via Qualtrics survey. Treatment sessions will also be audio and video recorded to be monitored for quality in Clinical Supervision.

Therapy sessions will be recorded using Microsoft Teams using the Principal Investigator's University of Manchester Teams account. Following the session, recordings will immediately be transferred on to the principal researcher's University of Manchester secure P-Drive. Recordings will be deleted as soon as possible following the principal researcher receiving clinical supervision on the sessions recorded. Sessions will be stored on a University drive in mp4 format using password protection which will only be known by the research team. The research team will monitor to ensure that videos are password protected and are only being accessed for the purpose of supervision. The password will contain a minimum 7 characters, have a mixture of upper- and lower-case letters, symbols and numbers. The recording will be checked and then deleted from Teams. Consent forms and safety plans will be saved on the Research Data Storage system. The file name will be saved with a date of consent and allocated a number to protect confidentiality and ensure no file names are the same (i.e. DD_MMM_YYYY_P_1 or DD_MMM_YYYY_CL_1). Participants will be asked to complete measures throughout baseline, treatment and follow-up. These will be administered via Qualtrics survey. Participants will complete surveys under Unique ID codes and the data received from participants will therefore be stored under their Unique ID codes. Data from Qualtrics surveys will be stored on the P-Drive under the anonymised ID codes.

9) STATISTICAL CONSIDERATIONS

9.1 Statistical Analysis

To assess the primary aim (acceptability and feasibility), we will measure adherence to treatment, safety (adverse reactions) and attitude to intervention. We will conduct descriptive statistical analysis of: therapy completion rates, sessions attended, measures completed, adverse events and participant satisfaction with the therapy.

In order to assess the secondary hypothesis (efficacy of treatment) we will chart individual participant FND symptoms and clinical measures during the baseline and treatment phases to determine any change in these variables over the course of treatment. We will calculate Rate of Change Index (RCI) and Clinically Significant Change (CSC) for the various outcome measures to determine if the change seen is statistically reliable and clinically meaningful.

9.2 Sample Size:

The appropriate sample size for a case series is variable depending on the type of study conducted and the depth of data yielded. Carey and Boden (2003), suggest that a case series can explore as few as two or three cases. This study will recruit 8 participants with a view to at least 6 participants completing the intervention. This ensures a larger sample than the minimum recommended in critical guides.

10) MONITORING AND QUALITY ASSURANCE

The current study will be utilising clinical and research supervision to manage quality. Clinical supervision will be provided weekly during the intervention stage of the study. Supervision will follow an agenda which covers quality issues. Adherence and adverse events/reactions will be recorded and put in the study master file. Supervision will also be used to ensure all paperwork and governance is completed weekly.

11) SAFETY CONSIDERATIONS AND ADVERSE EVENTS

The study is offering participants a novel treatment package focussing on improving the communication between body and brain through 6-8 sessions of psychological therapy. As with any novel psychological intervention, there is the potential that the intervention could cause an increase in symptoms or increase psychological distress. In order to protect participants from harm, adverse and serious adverse reactions will be monitored for all participants, including any changes in symptoms and risks to self or others. The research team will make every effort to prevent adverse reactions from happening. Further detail on the protocols is included in the Ethical Considerations section.

12) PEER REVIEW

The current study was proposed to the University of Manchester Research Subcommittee Panel A in June 2022 for independent review. The panel provided feedback and amendments to the proposed study, these recommendations and feedback were then taken on board and a subsequent letter and proposal was submitted to the Research Subcommittee for further review. The Committee then wrote a letter stating that the research proposal has

been independently reviewed and that it is considered to meet necessary scientific and methodological standards.

13) ETHICAL AND REGULATORY CONSIDERATIONS

13.1 Approvals

List the approvals that will be in place for your study and framework/principles to be followed during the study.

University Research Ethics Committee approval will be obtained before commencing research. The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2017.

13.2 Risks

The study is offering participants a novel treatment package focussing on improving the communication between body and brain through 6-8 individual sessions of psychological therapy.

Prior to commencing treatment, participants GP' (with consent from participant) will be sent a letter advising them that the participant has agreed to participate in the study and engage with novel psychological intervention for FND. A protocol for managing risks throughout the study has been generated and includes the procedures for if participants disclose information containing risks to themselves or others (including contacting participant GP, signposting to additional support for participants). Any risks, adverse reactions or serious adverse reactions will be taken to clinical supervision and discussed with the research team.

The intervention for the study will be delivered by a Trainee Clinical Psychologist (principal researcher) under the close supervision of the Primary Academic Supervisor (who is a qualified Clinical Psychologist). In the event of a participant experiencing serious adverse reactions to the treatment delivered, a protocol will be activated whereby the research team will consider stopping the trial. The research team will consider withdrawing treatment from participants not experiencing serious adverse reactions following evaluating severity of risks. Decisions around proceeding or stopping the trial will involve an independent academic from within the Division of Psychology and Mental Health at the University of Manchester. Any decisions around stopping the trial will take into account the impact on other participants and risks of this will be mitigated accordingly (through offering additional generic support, signposting to support and alternative non-direct counselling or support). Whilst the principal researcher has developed protocols to manage and mitigate any risks to participants, we have no reason to believe this therapy will carry any higher risk than any other therapy that is regularly offered to individual's with FND. Any adverse event, reaction, serious adverse event or reactions occurring for participants will be logged and documented and the outcome of decision making around each reaction will also be logged and stored in order to monitor the overall wellbeing of participants in the study. The information sheet will also emphasise that the intervention offered is a novel treatment that is aiming to gather initial evidence as

to its effectiveness, this is to fully inform participants of the nature of the intervention being delivered and manage expectations around its effectiveness so that participants can make informed choices around consenting to participate. Furthermore, at the end of the intervention, the principal researcher will discuss future options with participants including signposting to further support services as appropriate.

There is the potential as with any psychological intervention that the principal researcher could become distressed or affected by the delivery of intervention. This will be mitigated by the principal researcher being closely supervised by a qualified Clinical Psychologist throughout the delivery of intervention. No other risks to researchers have been identified

14) STATEMENT OF INDEMNITY

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

15) FUNDING AND RESOURCES

The University of Manchester, Doctorate in Clinical Psychology Programme has a budget allocated for trainees to utilise for research projects. Trainees are given a budget of up to £400 allocated at the discretion of the ClinPsyd research sub-committee. This budget has been allocated to compensate participants for the time taken to complete measures throughout the study. The current project has been approved by the subcommittee for a budget of £360 to be allocated as follows:

100% completion of measures - £45 voucher
90% or more completion - £40 voucher
75% or more completion – £30 voucher
60% or more completion - £20 voucher
50% completion - £15 voucher

The study aims to recruit 8 participants, should all participants complete therapy and complete 100% of measures this will total £360 of compensation in the form of shopping vouchers.

16) PUBLICATION POLICY

We will seek to publish the research in a journal in order to disseminate findings within the academic community. We will also seek to present our findings to the charities recruited from on their websites in addition to providing a summary of results for the Charity and

individual participants of the study. Findings may also be presented at conferences and academic meetings.

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