# Formulation informed brief acceptance and commitment therapy for functional neurological disorder

Submission date	Recruitment status	Prospectively registered
18/08/2023	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2023	Completed	Results
Last Edited	Condition category	Individual participant data
11/09/2023	Nervous System Diseases	Record updated in last year

#### Plain English summary of protocol

Background and study aims

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

Information from up-to-date research shows that a formulation, or explanation of an individual's condition, can improve people's quality of life and even reduce how often they experience the symptoms. Acceptance and Commitment Therapy (ACT) has been shown to also improve quality of life, mood and how symptoms affect the person. This therapy aims to help people to live well despite the difficulties they are experiencing. Currently, there is some promising evidence that ACT can help people with FND live a better life, but more research is needed. So far, no one has completed research that explores if formulation and ACT together can be helpful for people who have FND. This study is investigating if formulation and ACT-based intervention can lead to increases in psychological health, emotional processing and quality of life. While ACT does not directly aim to get rid of illness symptoms, such as seizures, the researchers want to see if symptoms may reduce anyway.

#### Who can participate?

Adults (18 years of age and over) with a formal diagnosis of Functional Neurological Disorder

#### What does the study involve?

It will require active participation for 13 weeks. During this time participants will be asked to complete some questionnaires and attend psychotherapy sessions at a local clinic. The study will involve five sessions and will require participants to answer some brief questions every other day throughout this period. After 11 weeks, participants will be contacted again a month later.

What are the possible benefits and risks of participating?

There may be no benefit to taking part in this study. However, the benefits may relate to developing a better understanding condition and developing some new coping strategies. When engaging in any psychological therapy, people may experience some psychological discomfort or distress. We are not anticipating any additional risk and no higher risk than that of standard medical care.

Where is the study run from?

Dorset Healthcare University NHS Foundation Trust (UK)

When is the study starting and how long will it run for? November 2021 to July 2023

Who is funding the study? University of Southampton (UK)

Who is the main contact?

1. Irma Konovalova, ik1n20@soton.ac.uk

2. Dr Warren Dunger

# Contact information

#### Type(s)

Public

#### Contact name

Miss Irma Konovalova

#### Contact details

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# Additional identifiers

# EudraCT/CTIS number

Nil known

#### **IRAS** number

311583

## ClinicalTrials.gov number

Nil known

# Secondary identifying numbers

IRAS 311583

# Study information

#### Scientific Title

Effectiveness and acceptability of formulation and Brief-ACT intervention for functional neurological disorder

### **Study objectives**

The primary objectives were to establish the effect of a Formulation Informed Brief Acceptance and Commitment Therapy (F-ACT) intervention on symptom interference, measured as distress and impact on engagement in daily activities, and psychological health, emotional processing, quality of life, psychological inflexibility and understanding of functional neurological disorder (FND).

The secondary objective was to examine if the intervention benefits FND illness symptom reduction, specific to patient presentation.

#### Ethics approval required

Ethics approval required

#### Ethics approval(s)

Approved 04/11/2022, North West - Greater Manchester Central Research Ethics Committee (3rd Floor Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8057, +44 (0)207 104 8244, +44 (0)207 104 8004; gmcentral.rec@hra.nhs.uk), ref: 22/NW /0320

#### Study design

Single-case experimental design

# Primary study design

Interventional

# Secondary study design

Non randomised study

# Study setting(s)

Community

# Study type(s)

**Treatment** 

# Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

# Health condition(s) or problem(s) studied

Functional neurological disorder (FND)

#### **Interventions**

The intervention consisted of two parts. The first part included the development of a collaborative biopsychosocial formulation with the participant, to help them gain a better

understanding of their illness, following a clinical interview. The second included three Acceptance and Commitment Therapy (ACT) sessions, based on three functional units (Triflex) that aim to increase psychological flexibility.

The study will require active participation for 13 weeks. During this time participants will be asked to complete some questionnaires and attend psychotherapy sessions at a local clinic. The study will involve five sessions and will require participants to answer some brief questions every other day throughout this period. After 11 weeks, participants will be contacted again 1 month later.

#### Intervention Type

Behavioural

#### Primary outcome measure

The following questionnaires were completed at baseline, following the formulation intervention, following the ACT-based intervention and at the end of the follow-up period:

- 1. Quality of life (QoL) measured using the Work and Social Adjustment Scale (WSAS)
- 2. Emotional processing measured using the Emotional Processing Scale (EPS)
- 3. Psychological health measured using a 34-item Clinical Outcomes in Routine Evaluation Outcome Measure (CORE-OM)
- 4. Psychological inflexibility measured using the Acceptance and Action Questionnaire (AAQ-II)
- 5. Illness perception and understanding of the condition measured using the Brief Illness Perception Questionnaire (BIPQ)

#### Secondary outcome measures

Symptom frequency was measured by a self-rated question "Over the last few days: (1) how often have you experienced the symptoms of your illness". It was rated on a 10-point Likert scale ranging from 0 (no symptoms) to 10 (many severe symptoms). It was completed every 2 days throughout the length of the study.

#### Overall study start date

08/11/2021

# Completion date

04/07/2023

# Eligibility

## Key inclusion criteria

- 1. Adults aged 18 years and above
- 2. Capable of giving informed consent
- 3. FND diagnosis confirmed by a neurologist
- 4. Sufficient English to engage in therapy
- 5. Not currently engaged in another psychotherapy or FND treatment

# Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Upper age limit

100 Years

#### Sex

Both

#### Target number of participants

6

#### Total final enrolment

6

#### Key exclusion criteria

- 1. Primary diagnosis of intellectual disability
- 2. Severe mental ill health requiring inpatient treatment or potentially affecting trial participation (e.g., suicidality, acute psychosis, active or extensive self-harm)
- 3. A diagnosis of a complex regional pain syndrome, dissociative identity disorder, or posttraumatic stress disorder of high severity with significant dissociation

#### Date of first enrolment

07/11/2022

#### Date of final enrolment

31/03/2023

# Locations

#### Countries of recruitment

England

**United Kingdom** 

## Study participating centre

Dorset Healthcare University NHS Foundation Trust

Sentinel House 4-6 Nuffield Road Nuffield Industrial Estate Poole United Kingdom BH17 ORB

# Sponsor information

#### Organisation

University of Southampton

#### Sponsor details

Highfield Campus Southampton England United Kingdom SO17 1BJ +44 (0)2380 595058 rgoinfo@soton.ac.uk

#### Sponsor type

University/education

#### Website

http://www.southampton.ac.uk/

#### **ROR**

https://ror.org/01ryk1543

# Funder(s)

## Funder type

University/education

#### **Funder Name**

University of Southampton

#### Alternative Name(s)

University of Southampton UK

#### **Funding Body Type**

Government organisation

#### Funding Body Subtype

Universities (academic only)

#### Location

United Kingdom

# **Results and Publications**

#### Publication and dissemination plan

Planned publication in a high-impact journal and as a doctoral thesis

# Intention to publish date

31/12/2023

# Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

# IPD sharing plan summary

Data sharing statement to be made available at a later date