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Formulation informed brief acceptance and commitment therapy for functional neurological disorder

Submission date
18/08/2023

Recruitment status
No longer recruiting

Registration date
12/09/2023

Overall study status
Completed

Last Edited
11/09/2023

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
University of Southampton
Highfield Campus
Southampton
United Kingdom
SO17 1BJ
N/A
I.Konovalova@soton.ac.uk

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 0RB

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