Emotion perception and expression in patients with a functional neurological disorder

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Somatic symptom and related disorders
Study type	Observational invasive

Summary

ID

NL-OMON51084

Source
ToetsingOnline

Brief title
EMIN-FND

Condition

- Somatic symptom and related disorders

Synonym
Conversion disorder, functional neurologic disorder

Research involving
Human

Sponsors and support

Primary sponsor: Elisabeth-Tweesteden ziekenhuis
Source(s) of monetary or material Support: Het onderzoek wordt gesponsord door het topklinisch centrum voor lichaam;geest en gezondheid;van GGz Breburg

Intervention

Keyword: Anger, Conversion disorder, Emotion, Functional neurological disorder

Outcome measures

Primary outcome

The main study parameter for the first objective is emotional incongruence. Emotional incongruence is quantified by the difference between self-reported emotion describing an unpleasant interpersonal interaction compared to an observable nonverbal expression of emotions. Observable nonverbal emotions will be quantified using facial expression of negative emotions using software-based analyses of digitized video recordings (FaceReader). This study will specifically focus on the emotion of self-reported and nonverbally expressed anger. The main study parameter for the secondary objective is the clinical course of FND-symptoms in patients with FND. The clinical course will be determined by the Clinical Global Impressions (CGI)-scale as primary outcome, and symptom status, quality of life and referral for FND-related intervention as secondary outcome measures. For the ancillary objectives, participants will also complete questionnaires to assess background psychological measures and the electronic patient records will be used to obtain clinical information relevant to FND.

Secondary outcome

Secondary study parameters for primary objective 1 will be:

- The congruency between the clinician observed anger and patient-reported anger will be measured by the clinical interview and the referring physician form assessed at T0.

- The Anger-EMIN scores during the other phases of the interview, assessed at T0.

Secondary study parameters for primary objective 2 will be:

- Quality of life assessed using the Short Form 12 (SF-12) and the Mental health-Quality of Life (MH-QoL) questionnaires.

- The levels of pain and fatigue as measured by the Numeric Rating Scale for Pain and Fatigue (NRS-PF).

- Referral for psychological or psychiatric treatment, as measured by the results of the *Assessment of treatments received by the patient* at 12 months follow-up (T3).

- Symptoms of depression, measured by the Patient Health Questionnaire-9 (PHQ-9) assessed at T0-T3.

- Symptoms of anxiety, measured by the Generalized anxiety Disorder-7 (GAD-7) assessed at T0-T3.

Study description

Background summary

Functional neurological disorder (FND) is common in clinical practice, with prevalence estimates of 16% in neurology outpatient settings. The aetiology and predictors of the clinical course of FND are insufficiently understood. Prior research indicates that psychological factors related to emotion perception and expression contribute to the development of FND, particularly anger-related emotions. The present study investigates the role of the mismatch between the patients* self-expression of emotions and observable nonverbal emotions from facial expression as related to FND and its clinical course during a one-year follow-up.

Study objective

The primary objectives are to: (1) Examine whether emotional incongruence (i.e., the mismatch between self-reported emotion and observed emotion from facial expression) is more common in patients with FND than non-FND control groups (healthy controls and patients with neurological disorders); and (2) determine whether emotional incongruence is predictive of the clinical course of FND. The secondary objective is to establish clinical and psychosocial correlates of emotional incongruence in patients with FND.

Study design

This is a cross-sectional between-groups design (primary objective 1), combined with a longitudinal design (primary objective 2) including four assessments during a follow-up of one year.

Study burden and risks

Patients are asked to come to the hospital for a one-hour visit within two weeks after being diagnosed with FND (either at the emergency department or at a neurology outpatient visit). During the first research visit, patients will be interviewed for 30 minutes and complete questionnaires (30 min); an additional 10 min is reserved for informed consent and other study-related assessments as described in the study protocol. After 3, 6 and 12 months, follow-up assessments will be made using questionnaires (30 min) and measures of behavior (20 min). Patients are also asked for permission to review their medical records and contact of their primary care physician to document health care utilization (relevant to primary objective 2). This is an observational longitudinal study and no pharmacological agents or devices will be used. The risk for worsening of FND-symptoms due to participation in this study is low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with FND:
- Age >= 18 years
- Diagnosis of FND
- Diagnosis is made by a neurologist
- Diagnosis is based on, at least, clinical history and neurological examination
Participants of all ethnic backgrounds, both female and male patients will be enrolled in this study. There is no upper age limit.

Healthy controls (control group 1)
- Age >= 18 years
- Not having a psychiatric disorder
- Not having a neurologic disease
Participants of all ethnic backgrounds, both female and male patients will be enrolled in this study group.

Neurological control group (Spinal disc herniation (SDH) / Migraine, control group 2)
- Age >= 18 years,
- Diagnosis of:
o Spinal disc herniation, based on clinical symptoms and matching MRI-images
o Migraine, formal diagnosis according to the Dutch guidelines. Diagnosis is made by neurologist
Participants of all ethnic backgrounds, both female and male patients will be enrolled in this study group.

Exclusion criteria

A potential participant will be excluded from participation in this study if one or more of the following criteria applies:
• A known diagnosis of autism spectrum disorder (ASD) because, according to the DSM-5, verbal and non-verbal communication is often not well integrated in ASD, and this may interfere with the measurement of Anger-EMIN.
• Psychotic disorder. Rationale: the negative symptoms of a psychotic disorder involve a reduction of emotional expression which may interfere with the results.
• Impairment interfering with performing the tasks needed for the study (e.g., blindness, aphasia, severe tremor).
• Not fluent in the Dutch language. Rationale: all questionnaires and tests are provided in Dutch. Participants who do not understand the Dutch language cannot participate.
• Life expectancy of less than one year.
• Refusal to informed consent.

A medical history of neurological disorder, a previous episode of functional neurological complaints or another medical disorder is not exclusionary for the FND group.

4.3.2 Healthy controls
A potential healthy control participant who meets any of the following criteria will be excluded from participation in this study:
• Exclusion criteria as applied for FND.

4.3.3 Spinal disc herniation (SDH) / Migraine controls
A potential neurological control participant who meets any of the following criteria will be excluded from participation in this study:
• Exclusion criteria as applied for FND.
• A current or prior diagnosis of FND.
• Patients who daily use opiates or benzodiazepines

A non-recent diagnosis of migraine and spinal disk herniation is not exclusionary because the FND-group can also include patients who do not have a first episode of FND.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-06-2021
Enrollment:	190
Type:	Actual

Ethics review

Approved WMO Date:	08-03-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	28-07-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-03-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL76176.028.20