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Pain perception and its influences in functional neurological disorder

Submission date
17/02/2025

Recruitment status
Recruiting

Registration date
18/02/2025

Overall study status
Ongoing

Last Edited
03/03/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Functional neurological disorder (FND) symptoms may arise from changes in brain function rather than disease processes with structural damage to the nervous system. One key idea in understanding FND is that the brain plays an active role in shaping perception, movement, and bodily sensations. By understanding how the relevant psychological and physiological factors shape pain experience in FND, this study hopes to gain insights into the mechanisms behind symptom generation and identify new strategies to support patients.

Who can participate?
Adults aged between 18 and 65 years old can take part. One group includes people diagnosed with FND, and the other group consists of non-clinical (healthy volunteer) controls with no major medical or mental health condition.

What does the study involve?
Participants will be recruited via community adverts and charities. Participants will take part in a single lab session where mild electrical pulses are applied to test pain perception. The capacity for pain modulation will be tested introducing a pain modulatory device. Participants will also complete questionnaires about pain, anxiety, and other psychological factors.

What are the possible benefits and risks of participating?
The study helps improve understanding of FND and pain perception. There are no direct health benefits for participants. The main risk is temporary discomfort from the mild electrical pulses.

Where is the study run from?
The study is conducted at the Institute of Psychiatry, Psychology & Neurosciences (IoPPN), King's College London, UK

When is the study starting and how long will it run?
October 2024 to December 2025. The study will start recruiting in February 2025 and will be concluded by December 2025, or earlier, if the target sample of 80 participants is reached.

Who is funding the study?
The Felgenhauer Foundation for the Promotion of Young Neuroscientists (Felgenhauer Stiftung zur Förderung junger Neurowissenschaftler) and the German Research Foundation (Deutsche Forschungsgemeinschaft, DFG) fund the study. The study is carried out at King's College London.

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Pain perception and its modulation in functional neurological disorder

Acronym
FNDNO

Study objectives
This experimental study investigates the pathophysiologic mechanisms of functional neurological disorder and pain perception.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/12/2024, Health Faculties (Blue) Research Ethics Subcommittee of King's College London (3rd Floor, 5-11 Lavington Street, London, SE10NZ, United Kingdom; -; rec@kcl.ac.uk), ref: HR/DP-24/25-45681

Study design
Mixed-methods controlled factorial-group study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Laboratory, University/medical school/dental school

Study type(s)
Other

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

Interventions
This project employs a mixed, controlled, factorial group design with the between-subject factor group (functional neurological disorder (FND) versus non-clinical controls (NCC)) and the within-subject factors modulation condition (ON versus OFF). Target sample size N = 80, with n = 40 per group. Groups will be matched for sex, age, and, if possible, socioeconomic status.

The experiment will include four phases. Experimental pain will be induced with mild electrical pulses (Digitimer, DS8R) and the effect of endogenous pain modulation will be tested by introducing a pain modulatory device. The modulation condition will be randomised at the trial level in phases 2-4 but there will be no experimenter blinding to group allocation (FND versus NCC). All participants will undergo the same experimental protocol.

The pain stimulation trials in the different conditions (modulation ON versus OFF) in phases 2, 3 and 4 will be pseudo-randomised at the trial level.

Intervention Type
Behavioural

Primary outcome measure
The following primary outcome measures are assessed using a Visual Analogue Scale (VAS) between 0-100 repetitively measured in the single lab visit during phases 2 and 4:
1. Pain intensity after each pain stimulus in each phase
2. Prior pain expectation at the beginning of each phase and again after every block of 4 pain stimuli within a phase
3. Prior pain expectation certainty at the beginning of each phase and again after every pain stimuli within a phase

Secondary outcome measures
The secondary outcome measures are all assessed during the single lab visit:
The following outcomes are repetitively measured, once before phase 2 and once before phase 4:
1. Prior anxiety measured using a Visual Analogue Scale (VAS) between 0-100 at the beginning of each phase
2. Prior anxiety certainty measured using a Visual Analogue Scale (VAS) between 0-100 once at the beginning of each phase
3. State anxiety measured using the State-Trait Anxiety Inventory (STAI) (short 6-item-version: STAI-6) once at the beginning of each phase
4. Psychometric and health-related variables will be measured using the following questionnaires once in the single lab visit :
4.1. Functional Neurological Symptoms Questionnaire (FNSQ)
4.2. Brief illness perception questionnaire (B-IPQ) 6
4.3. Widespread Pain Index (WPI)
4.4. Pain Frequency Intensity and Burden Scale (P-FIBS)
4.5. Patient Health Questionnaire (PHQ-8)
4.6. Somatosensory amplification scale (SSAS)
4.7. Pain Vigilance and Awareness Questionnaire (PVAQ)
4.8. Generalized Anxiety Disorder (GAD-7 Anxiety) 13
4.9. Brief Autism-Spectrum Quotient, AQ-10+SM-4
4.10. Brief Dissociative Experience Scale (B-DES)
4.11. Fear of Pain Questionnaire – short (FPQ-9)
4.12. Pain Catastrophizing Scale (PCS)
4.13. Brief Suggestibility Scale (BSS)

Overall study start date
01/10/2024

Completion date
31/12/2025

Eligibility

Key inclusion criteria
For non-clinical (healthy) controls
1. Aged from 18-65 years old
2. Fluency in English to understand the study instructions

For participants with lived experience of FND:
1. Aged from 18-65 years old

2. Fluency in English to understand the study instructions
3. Diagnosis of Functional Neurologic Disorder (FND) as defined in ICD-10 (FND with motor or sensory symptoms (ICD-10 F44.4 and 44.6), seizures (F44.5), or mixed symptoms (F44.7) or according to the diagnostic classification of DSM-5

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
For all participants:
1. Diagnosis of major comorbid cardiovascular (e.g., heart disease)
2. Medical electrical implants, e.g., a pacemaker or implanted pumps, having implanted metals in the nondominant hand or arm, where the electrical pulses are applied
3. Pregnancy
4. Practical reasons against study participation: Physical symptoms / disability impairing ability to participate (e.g., severe/constant tremor, bilateral upper limb paralysis, multiple daily seizures)
5. Presence of a skin condition, scarring/tattoos on the left volar forearm at site of stimulation
6. Significant pain on the non-dominant volar forearm where pulses are to be applied during the 3 days before testing
7. Any aversion to receiving mild electrical pulses
8. Any aversion to experiencing pain during the experiment

For non-clinical controls:
To ensure the definition as non-clinical controls: Diagnosis of FND; active major physical or mental health disorder

For participants with lived experience of FND:
To minimize the risk of the experiment and avoid distortion on the physiological pain perception and/or would impair the ability to participate: active severe psychiatric disturbance (e.g., psychosis, alcohol, or substance dependence) or neurological (e.g., epilepsy, multiple sclerosis, Complex Regional Pain Syndrome (CRPS) in the tested arm) disorder that would either confound the findings or impair the participant’s ability to participate

Date of first enrolment
20/02/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Psychiatry, Psychology and Neurosciences, King's College London
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Sponsor information

Organisation
King's College London

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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Deutsche Forschungsgemeinschaft (German Research Foundation)

Alternative Name(s)
German Research Association, German Research Foundation, DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Funder Name
Felgenhauer-Stiftung (Felgenhauer Foundation)

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed during the current study will be stored in a publicly available repository (Open Science Framework, OSF, https://osf.io/).
• The type of data stored: Tabular data
• Timing for availability: Data will be made available with the publication of the results in a peer-reviewed journal. No planned time limit for availability after publication.
• Whether consent from participants was required and obtained: Consent for participation, including sharing of anonymised data on a public repository, will be collected.
• Comments on data anonymization: All data will be anonymized, no sensitive and identifying data will be shared.

IPD sharing plan summary
Stored in publicly available repository