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Yoga therapy for functional neurological disorder

Submission date
06/02/2025

Recruitment status
No longer recruiting

Registration date
13/02/2025

Overall study status
Ongoing

Last Edited
01/04/2025

Condition category
Nervous System Diseases

[ ] 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) is characterised by neurological symptoms, such as limb weakness or non-epileptic seizures, that cannot be explained by identifiable neurological pathology. Issues with bodily awareness, like sensing internal bodily signals (known as interoception) might contribute to the development or maintenance of FND symptoms. Difficulties in emotional awareness and regulation are also considered to be key factors contributing to FND. Brain scanning studies have revealed disruptions in brain networks responsible for processing bodily sensations and emotions. These insights highlight the potential of mind-body approaches, like yoga, to help manage the disorder.
Somatic yoga, which uses gentle movements, breathing exercises, and mindfulness, aims to enhance the connection between mind and body. Evidence suggests that yoga-based therapies can improve physical and emotional well-being. For instance, research shows that yoga can reduce stress, improve mood, and positively influence overall well-being by balancing physiological and psychological processes. Some initial research has reported positive outcomes for individuals with neurological conditions, including enhancements in brain function and neuroplasticity. Studies have demonstrated that yoga can be an effective adjunct therapy for neurological issues, supporting better brain connectivity and function. Additionally, yoga interventions have shown promise for a range of mental health disorders, contributing to reduced anxiety and depression and improved emotional regulation. A recent case series demonstrated that a tailored yoga intervention was associated with reduced symptom severity and better overall quality of life for people with FND.
Despite these encouraging findings, there are still significant research gaps. Specifically, we need more evidence on how somatic practices, such as yoga therapy, might influence the brain-body connection, including bodily awareness and emotional regulation processes in FND, and whether such approaches might result in improved symptoms, general functioning, and quality of life in people with the diagnosis.
This study seeks to address these gaps and contribute to a better understanding of effective interventions for FND. It will explore the feasibility, acceptability and potential benefits of a novel somatic yoga intervention, tailored for people diagnosed with FND.

Who can participate?
Patients with FND who are currently affected by motor, seizure and/or sensory symptoms, who

are over 18 years old, who do not have additional neurological diagnoses, and who do not currently experience severe mental health symptoms. Participants must not be currently undergoing another similar intervention during their participation in the study.

What does the study involve?
Participants will be randomly allocated to either the somatic yoga programme or to a music relaxation programme. All participants will attend an initial in-person laboratory testing session at the start of their participation and a final laboratory session after the 6-week study period. At these visits, participants in the yoga programme group will complete an individual yoga session with a yoga therapist, whereas participants in the music programme group will complete a music relaxation session.

Between these sessions, participants in the yoga group will take part in guided, individualised weekly somatic yoga sessions conducted online and will also receive a customised manual to support regular home practice. The music programme group will be asked to undertake self-guided focused, music relaxation sessions, with a manual and playlists provided by the research team. The therapist will contact participants weekly to monitor their wellbeing.
The programmes will be evaluated using self-report questionnaires at the start, middle and end of the intervention, as well as at 3-month follow-up. Lab-based measures will taken at the start and end of the programmes. Participants will also be invited to participate in brief interviews at the end of the study to obtain feedback on their experiences.

What are the potential benefits and risks of taking part?
All participants who complete the study will receive the yoga intervention or the music relaxation programme. As such, participating in this project will provide participants with a new experience which may be beneficial to them. However, these benefits cannot be guaranteed.
There are few risks involved in this study. However, it is possible that participants might experience mild discomfort or FND symptoms during the yoga sessions. We will ensure that movements are gentle and adaptable to participants' needs, and they will be encouraged to stop or modify any activity that feels uncomfortable. Participants will be able to take a break at any time.
It is also possible that some of the questionnaires might touch upon potentially sensitive or distressing topics, including aspects of physical and mental health, and difficult life events. The laboratory sessions might be challenging and/or unfamiliar to some participants, which could result in some degree of discomfort. Participants will have the option to decline any part of the study without giving a reason, and they will also be reminded of the right to withdraw from the study, or any aspect of it, at any time. If a participant experiences any distress or discomfort, support will be provided by the research team.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
November 2024 to September 2025

Who is funding the study?
King's College London (UK)

Who is the main contact?
1. The research team, yoga4fnd@kcl.ac.uk
2. Dr Susannah Pick, susannah.pick@kcl.ac.uk

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
Somatic yoga therapy for functional neurological disorder: a feasibility study

Acronym
Yoga4FND

Study objectives
This study explores the feasibility, acceptability and potential benefits of a novel somatic yoga intervention, tailored for people diagnosed with functional neurological disorder (FND).
This study will assess feasibility by examining engagement and completion rates, in addition to obtaining participants' feedback on their experiences of the intervention and the study procedures.
This study will also examine whether the intervention has the potential to reduce FND

symptoms and improve bodily awareness, emotional processing and reactivity, as well as overall well-being and functioning in this group.
It is hypothesised that the yoga intervention will be associated with greater improvements in these areas, as well as better regulation of the body’s autonomic responses, such as heart rate and stress reactions, compared to the music relaxation control programme.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/03/2025, King's College London Health Faculties High Risk Research Ethics Committee (King's College London, Research Ethics Office, 3rd Floor, 5-11 Lavington St., London, SE1 0NZ, United Kingdom; +44 (0)20 7836 5454; rec@kcl.ac.uk), ref: HR/DP-24/25-46075

Study design
Single-centre open-label feasibility randomized controlled trial (interventional)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Functional neurological disorder (FND)

Interventions
Current interventions as of 01/04/2025:

Participants will be randomised on a 1:1 basis using an online randomisation tool to either the somatic yoga programme (active) or to a music relaxation programme (control). All participants will attend an initial in-person laboratory testing session at the start of their participation and a final laboratory session after the 6-week study period. At these visits, participants in the yoga programme group will complete an individual yoga session with a yoga therapist, whereas participants in the music programme group will complete a music relaxation session.

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The programmes will be evaluated using self-report questionnaires taken at the start, middle and end of the programmes, in addition to a 3-month follow-up. Lab-based measures will be taken at the start and end of the interventions. Participants will also be invited to participate in brief interviews at the end of the study to obtain feedback on their experiences.

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The programmes will be evaluated using self-report questionnaires and lab-based measures taken at the start and end of the programmes. Participants will also be invited to participate in brief interviews at the end of the study to obtain feedback on their experiences.

Intervention Type
Other

Primary outcome measure
Feasibility:
1. Recruitment: The number/proportion of eligible participants who consent to participate in the study by 30/06/2025
2. Adherence: The number/proportion of scheduled intervention sessions attended and completed
3. Withdrawal: The number/proportion of enrolled (consented) participants who withdraw from the study prior to completion
4. Adverse events: The number and nature of adverse events reported during study participation
5. Acceptability: Qualitative measures of perceived benefit of intervention, barriers and facilitating factors, experiences of study procedures

Secondary outcome measures
Current secondary outcome measures as of 01/04/2025:

Assessed at the start, middle and end of the intervention (weeks 1, 3 and 6) and at 3-month follow-up:
1. FND symptom severity measured using the Clinical Global Impression-Improvement Scale; Functional Neurological Symptom Questionnaire
2. Physical symptoms measured using the Patient Health Questionnaire – 15; Somatoform Dissociation Questionnaire – 20
3. Psychological symptoms measured using the Patient Health Questionnaire – 8; Generalized

Anxiety Disorder – 7; Multiscale Dissociation Inventory; Positive & Negative Affect Schedule; Clinician Administered Dissociative States Scale
4. Health-related quality-of-life measured using the 36-item Short Form survey
5. General functioning measured using the Work & Social Adjustment Scale
6. Autonomic symptoms measured using the Body Perception QuestionnaireShort Form
7. Interoceptive awareness measured using the Multidimensional Assessment of Interoceptive Awareness
8. Emotional processing measured using the Toronto Alexithymia Scale – 20
9. Interoceptive accuracy measured using the modified Schandry heartbeat tracking task

Measured at the start and end of the intervention (weeks 1 and 6-8):
10. Autonomic activation measured using electrocardiography; electrodermal activity recording
11. Emotion regulation measured using the computerised affective images task
12. Cognitive control measured using CANTAB Connect automated tests

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Previous secondary outcome measures:

Assessed at the start and end of the intervention (weeks 1 and 6):
1. FND symptom severity measured using the Clinical Global Impression-Improvement Scale; Functional Neurological Symptom Questionnaire
2. Physical symptoms measured using the Patient Health Questionnaire – 15; Somatoform Dissociation Questionnaire – 20
3. Psychological symptoms measured using the Patient Health Questionnaire – 8; Generalized Anxiety Disorder – 7; Multiscale Dissociation Inventory; Positive & Negative Affect Schedule; Clinician Administered Dissociative States Scale
4. Health-related quality-of-life measured using the 36-item Short Form survey
5. General functioning measured using the Work & Social Adjustment Scale
6. Autonomic symptoms measured using the Body Perception QuestionnaireShort Form
7. Interoceptive awareness measured using the Multidimensional Assessment of Interoceptive Awareness
8. Emotional processing measured using the Toronto Alexithymia Scale – 20
9. Interoceptive accuracy measured using the modified Schandry heartbeat tracking task
10. Autonomic activation measured using electrocardiography; electrodermal activity recording
11. Emotion regulation measured using the computerised affective images task
12. Cognitive control measured using CANTAB Connect automated tests

Overall study start date
01/11/2024

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Normal or corrected eyesight

3. Fluency in English language
4. A primary diagnosis of FND* with motor symptoms, seizures, sensory symptoms or mixed symptoms

*FND diagnosis will be validated by asking the participants to provide proof of diagnosis in the form of an existing medical letter from a qualified healthcare professional

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Comorbid diagnosis of major cardiovascular (e.g., heart disease), psychiatric (e.g., active psychosis, severe alcohol or substance use disorder) or neurological (e.g., epilepsy, multiple sclerosis) disorder that would either confound the findings or impair the participant's ability to participate
2. Physical symptoms/disability impairing ability to perform tasks or attend the in-person therapy sessions (e.g., severe tremor, upper/lower limb paralysis, seizure frequency >10 per day)
3. Functional cognitive symptoms only
4. Currently undergoing another body-based intervention for FND*

*Participants already engaging in body-based (e.g., yoga, acupuncture) or music-based therapies (self- or therapist-guided) will be asked to abstain from these sessions during this study. If unfeasible, participants will be excluded from the current study.

Date of first enrolment
01/02/2025

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
Department of Psychological Medicine
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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Government

Funder Name
Institute of Psychiatry, Psychology and Neuroscience, King's College London

Alternative Name(s)
Institute of Psychiatry, Psychology & Neuroscience, King's College London, Institute of Psychiatry, Psychology & Neuroscience, Institute of Psychiatry, Psychology and Neuroscience, Institute of Psychiatry, Psychology & Neuroscience at King's College London, Institute of

Psychiatry, Psychology and Neuroscience at King's College London, IoPPN, King's College London, IoPPN

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of the study will be summarised in one or more articles that will be submitted for publication in scientific journals and may be presented at conferences. The results will also form parts of internal reports (MSc dissertations). Participants will not be identified in any published report or article. A brief summary of the results will be sent to participants on request. However, each individual person’s results will not be provided.

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available on request to Dr Susannah Pick (susannah.pick@kcl.ac.uk)

IPD sharing plan summary
Available on request