

Yoga therapy for functional neurological disorder

Submission date 06/02/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/02/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/09/2025	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

Contact name

Dr Susannah Pick

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Other

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.

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 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.

Previous interventions:

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.

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 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(s)

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

Key secondary outcome(s)

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 Questionnaire Short 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

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
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10. Autonomic activation measured using electrocardiography; electrodermal activity recording
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12. Cognitive control measured using CANTAB Connect automated tests

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

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

United Kingdom

England

Study participating centre

King's College London

Department of Psychological Medicine
Institute of Psychiatry, Psychology & Neuroscience
16 De Crespigny Park
London
United Kingdom
SE5 8AZ

Sponsor information

Organisation

King's College London

ROR

<https://ror.org/0220mzb33>

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

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