

Specialist physiotherapy for functional motor disorder

Submission date 26/03/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/03/2018	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/04/2025	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Functional motor disorder (FMD), also known as conversion disorder, is a common disorder affecting movement. Symptoms include weakness, tremor, spasms and difficulty walking. The problem is part of the spectrum of neurological symptoms that are not caused by a recognisable disease process and relates to a disturbance in motor (movement) control and sensory perception. People with FMD suffer disability and distress equivalent to people with neurodegenerative disease such as Parkinson's disease. The prognosis of FMD is considered poor and current treatment options are limited. Physiotherapy is widely considered an important part of treatment, but there is limited evidence to support its use. A specialised physiotherapy treatment programme has been developed for people with FMD which showed promising results in a number of small studies. This study will test whether the specialist physiotherapy programme is better than standard care at reducing disability caused by FMD and whether the treatment could save the NHS money.

Who can participate?

Patients aged 18 and over with FMD

What does the study involve?

Participants are randomly allocated to receive either the specialised physiotherapy programme or standard care. The specialist physiotherapy consists of nine sessions completed over 3 weeks and a follow-up session. The treatment includes education about FMD, learning ways to control movement, and developing a long-term plan to help symptoms improve. Standard care involves a referral to local community physiotherapy for strength, balance and walking exercises. Participants are followed up after 6 and 12 months by completing 11 questionnaires either by post, telephone, or an online form using a secure internet application. The number of hospital contacts is also recorded for participants in each group.

What are the possible benefits and risks of participating?

The main benefit of taking part in the study is that participants receive a care plan that conforms to best practice recommendations. This includes a comprehensive explanation of the diagnosis of FMD by their neurologist. This is widely considered the first important step in treatment. The care plan also includes a referral to physiotherapy that states the diagnosis of FMD.

Physiotherapists often report that patients with FMD are referred to their service without being told their diagnosis. The participant will be followed up by their neurologist. The physical risks associated with the physiotherapy are minimal. The physical treatment strategies involve practicing normal movements such as standing up, sitting down, stepping, walking and going up and down stairs. Exercises are usually performed at a low intensity. Falling is a potential risk in people with reduced balance. However, physiotherapists are experienced at assessing falls risks and preventing falls, as this forms part of normal physiotherapy practice. Chronic pain and fatigue are common in people with FMD. Participation in physiotherapy can potentially exacerbate chronic pain and fatigue. This however would be transient. There is a small risk that participating in the intervention may cause psychological distress. While patients with FMD often have higher rates of anxiety and depression, psychiatric illness and a past history of psychological trauma are not as common in patients with FMD as once thought.

Where is the study run from?

1. St George's University Hospital
2. Western General Hospital
3. Sheffield Teaching Hospitals NHS Foundation Trust
4. The Walton Centre NHS Foundation Trust
5. North Bristol NHS Trust
6. Nottingham University Hospitals NHS Trust
7. Dorset County Hospital NHS Foundation Trust
8. NHS Tayside
9. Salford Royal NHS Foundation Trust
10. Kings College Hospital

When is the study starting and how long is it expected to run for?
May 2018 to February 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Glenn Nielsen

Study website
<https://www.physio4fmd.org/>

Contact information

Type(s)
Scientific

Contact name
Dr Glenn Nielsen

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

36950

Study information

Scientific Title

A randomised controlled trial of specialist Physiotherapy for Functional Motor Disorder (Physio4FMD)

Acronym

Physio4FMD

Study objectives

Functional motor disorder (FMD), also known as conversion disorder, is a common disorder affecting movement. Patients typically present with weakness, tremor, spasms and difficulty walking. The problem is part of the spectrum of neurological symptoms that are not caused by a recognisable disease process and relates to a disturbance in motor control and sensory perception. People with FMD suffer disability and distress equivalent to people with neurodegenerative disease such as Parkinson's disease. The prognosis of FMD is considered poor and current treatment options are limited. Physiotherapy is widely considered an important part of treatment, however there is limited evidence to support its use.

The trialists have developed a specialised physiotherapy treatment programme for people with FMD which showed promising results in a number of small studies. This trial will test whether the specialist physiotherapy programme is better than standard care at reducing disability caused by FMD and whether the treatment could save the NHS money.

Ethics approval required

Old ethics approval format

Ethics approval(s)

London – Surrey Borders Research Ethics Committee, 21/03/2018, ref: 18/LO/0486

Study design

Randomized; Interventional; Design type: Treatment, Education or Self-Management, Physical, Rehabilitation

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Functional motor disorder

Interventions

The trialists will perform a randomised controlled trial across several UK hospitals, comparing the specialist physiotherapy programme with standard care. Patients who are diagnosed with FMD by a neurologist will be invited to take part. Those who consent will be randomised to receive either our specialised physiotherapy programme or standard care. The specialist physiotherapy consists of 9 sessions completed over 3 weeks and a follow up session. The treatment includes education about FMD, learning ways to control movement, and developing a long-term plan to help symptoms improve. Standard care involves a referral to local community physiotherapy for strength, balance and walking exercises. Participants will be followed up at 6 and 12 months after enrolment by completing 9 questionnaires sent by post or over the telephone. We will also compare the number of hospital contacts recorded by the NHS for participants in each group.

Intervention Type

Other

Primary outcome measure

SF36 Physical Function domain; Timepoint(s): 12 months post randomisation

Secondary outcome measures

1. Health related quality of life is assessed using the Short Form 36 v2 at baseline, 6 months and 12 months
2. Mobility is assessed using the Functional Mobility Scale at baseline, 6 months and 12 months
3. Understanding and illness beliefs are assessed using the Revised Illness Perception Questionnaire at baseline, 6 months and 12 months
4. Anxiety and depression are assessed using the Hospital Anxiety & Depression Scale (HADS) at baseline, 6 months and 12 months

5. Fatigue is assessed using a single question rating fatigue on a 5-point scale (from no fatigue to extreme fatigue) at baseline, 6 months and 12 months
6. Employment and return to work is assessed using the Work Productivity & Impairment Questionnaire at baseline, 6 months and 12 months
7. Subjective measures of health service use are assessed using the Client Service Receipt Inventory (CSRI) at baseline, 6 months and 12 months
8. Objective measures of health service use are assessed using Hospital Episode Statistics (HES) and equivalent data from NHS Scotland. Data for the 12 months prior to randomisation will be compared to data for the 12 months post randomisation
9. Quality adjusted life years will be calculated using the EQ-5D-5L Questionnaire, assessed at baseline, 6 months and 12 months
10. Cost-effectiveness of Specialist Physiotherapy compared to treatment as usual will be assessed at 12 months, in a comprehensive health economic analysis, using the CSRI to collect health service use, validated using HES data and the EQ-5D-5L to calculate Quality Adjusted Life Years

The following outcome measures were added on 14/09/2018:

11. Participant's perception of change at 6 and 12 months post randomisation will be assessed using the 5-point Clinical Global Impression Scale of Improvement (CGI-I)
12. The influence of the number of somatic symptoms reported at baseline assessment on treatment outcome at 6 and 12 months post randomisation will be measured by the Extended Patient Health Questionnaire-15
13. The impact of specialist physiotherapy compared to treatment as usual on the participant's confidence that their diagnosis of FMD is correct at 6 and 12 months post randomisation, using a 10 point scale

Overall study start date

01/05/2018

Completion date

16/02/2023

Eligibility

Key inclusion criteria

1. New or returning patients presenting to participating outpatient neurology clinics and neurology inpatients
2. The patient has a "clinically definite" diagnosis of FMD according to the Gupta and Lang diagnostic classification criteria (Gupta and Lang 2009)*
3. Aged 18 or over
4. Diagnostic investigations have come to an end
5. The patient is accepting of the intervention
6. Motor symptoms must be sufficient to cause significant distress or impairment in social, occupational or other important areas of functioning (subjectively described by the patient), independent of other comorbidities

* Gupta A, Lang AE. Psychogenic movement disorders. Curr Opin Neurol 2009;22:430–6. doi: 10.1097/WCO.0b013e32832dc169

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 264; UK Sample Size: 264. In August 2021, the trial was extended to increase the sample size to accommodate for the impact of the COVID-19 pandemic. A new target range of 357 to 387 was set.

Total final enrolment

355

Key exclusion criteria

1. The recruiting neurologist deems the patient to have severe psychiatric co-morbidity, including factitious disorder, self-harm, anxiety and depression, which would interfere with the patient's ability to participate in physiotherapy**
2. The patient has an organic diagnosis which explains the majority of their symptoms or disability
3. pain, fatigue or dissociative seizures that would interfere with their ability to engage in the trial physiotherapy intervention
4. Disability to the extent that the patient requires assistance for toileting
5. The patient is unable to attend 9 sessions of physiotherapy over a 3 week period, within 6 weeks of initial neurology consultation
6. Ongoing unresolved compensation claim or litigation
7. The patient has no fixed address or is seeking rehousing through their council for disability access reasons
8. Unable to understand English sufficiently to complete questionnaires
9. The patient has a documented learning disability that prevents them from answering questionnaires independently
10. The patient lacks capacity to give consent

** The decision to exclude a patient due to psychiatric comorbidity is a clinical decision made by the neurologist, rather than a decision based on a screening tool or questionnaire. We believe that no single screening tool or questionnaire would serve this purpose (due to the range of potential psychiatric problems. Additionally, there is insufficient data on which to base cut-off scores to exclude patients on any particular questionnaire. The recruiting neurologists involved in the trial are consultants in neurology, selected for their experience in managing patients with FMD and patients with psychiatric comorbidity.

Date of first enrolment

01/09/2018

Date of final enrolment

31/01/2022

Locations

Countries of recruitment

England

Scotland

United Kingdom

Study participating centre

St George's University Hospital

Department of Neurology

Atkinson Morley Wing

Blackshaw Road

London

United Kingdom

SW17 0QT

Study participating centre

Western General Hospital

Department of Clinical Neurosciences

Edinburgh

United Kingdom

EH4 2XU

Study participating centre

Sheffield Teaching Hospitals NHS Foundation Trust

Royal Hallamshire Hospital

Glossop Road

Sheffield

United Kingdom

S10 2JF

Study participating centre

The Walton Centre NHS Foundation Trust

Lower Lane

Fazakerley

Liverpool

United Kingdom

L9 7LJ

Study participating centre

North Bristol NHS Trust

Southmead Hospital
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre

Nottingham University Hospitals NHS Trust

Queen's Medical Centre Campus
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre

Dorset County Hospital NHS Foundation Trust

Williams Avenue
Dorchester
United Kingdom
DT1 2JY

Study participating centre

Dorset County Hospital NHS Foundation Trust

Williams Avenue
Dorchester
United Kingdom
DT1 2JY

Study participating centre

Salford Royal NHS Foundation Trust

Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre

Kings College Hospital

Kings College NHS Foundation Trust

Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Freeman Road Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation

St George's, University of London

Sponsor details

c/o Miss Motunrayo A Taiwo
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United Kingdom
-

Sponsor type

University/education

ROR

<https://ror.org/040f08y74>

Funder(s)

Funder type

Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/31/63

Results and Publications

Publication and dissemination plan

The trialists intend to publish the trial protocol by 01/05/2019. The protocol will soon be available on the NIHR Portfolio website: <https://www.journalslibrary.nihr.ac.uk/programmes/hta/163163/#/>. The trialists intend to publish the main trial findings in a high-impact peer reviewed journal.

Intention to publish date

30/09/2023

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/10/2019	23/10/2019	Yes	No
Statistical Analysis Plan	COVID impact, mitigating strategies and statistical analysis plan	24/03/2023	04/04/2023	No	No
HRA research summary			28/06/2023	No	No
Results article			22/05/2024	Yes	No
Other publications	Economic analysis	01/04/2025	07/04/2025	Yes	No