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Specialist physiotherapy for functional motor disorder

Submission date
26/03/2018

Recruitment status
No longer recruiting

Registration date
27/03/2018

Overall study status
Completed

Last Edited
18/11/2026

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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 supports 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

Contact information

Type(s)
Scientific

Contact name
Dr Glenn Nielsen

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Additional identifiers

Protocol serial number
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 supports 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

Primary study design
Interventional

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

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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 years 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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

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
United Kingdom

England

Scotland

Study participating centre
St George’s University Hospital
Department of Neurology
Atkinson Morley Wing
Blackshaw Road
London
England
SW17 0QT

Study participating centre

Western General Hospital
Department of Clinical Neurosciences
Edinburgh
Scotland
EH4 2XU

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Royal Hallamshire Hospital
Glossop Road
Sheffield
England
S10 2JF

Study participating centre
The Walton Centre NHS Foundation Trust
Lower Lane
Fazakerley
Liverpool
England
L9 7LJ

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-Trym
Bristol
England
BS10 5NB

Study participating centre
Nottingham University Hospitals NHS Trust
Queen's Medical Centre Campus
Derby Road
Nottingham
England
NG7 2UH

Study participating centre

Dorset County Hospital NHS Foundation Trust
Williams Avenue
Dorchester
England
DT1 2JY

Study participating centre
Dorset County Hospital NHS Foundation Trust
Williams Avenue
Dorchester
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DT1 2JY

Study participating centre
Salford Royal NHS Foundation Trust
Stott Lane
Salford
England
M6 8HD

Study participating centre
Kings College Hospital
Kings College NHS Foundation Trust
Denmark Hill
London
England
SE5 9RS

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

Sponsor information

Organisation

St George's, University of London

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

Individual participant data (IPD) sharing plan

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?
Results article			22/05/2024	Yes	No
Protocol article		21/10/2019	23/10/2019	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Economic analysis	01/04/2025	07/04/2025	Yes	No
Other publications	Embedded qualitative study	16/11/2026	18/11/2026	Yes	No
Statistical Analysis Plan	COVID impact, mitigating strategies and statistical analysis plan	24/03/2023	04/04/2023	No	No
Study website		11/11/2025	11/11/2025	No	Yes