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Optimising pelvic floor muscle training to improve quality of life outcomes for individuals with progressive multiple sclerosis and incontinence

Submission date
08/04/2015

Recruitment status
No longer recruiting

Registration date
08/04/2015

Overall study status
Completed

Last Edited
15/06/2016

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is a neurological condition that affects the nerves in the brain and spinal cord. These nerves are usually protected by a layer of protein called myelin. In MS, the body's immune system mistakes myelin for a foreign body and attacks it. The myelin becomes damaged and can be partially or completely lost. This results in scars, known as lesions or plaques, and can disrupt the electrical signals from the brain travelling along the nerve fibres to the rest of the body. The nerve fibres themselves can also become damaged over time. The symptoms of MS are wide ranging and vary considerably in severity. They include semi or complete blindness, fatigue, difficulties in balance and co-ordination and spasticity. Bladder and bowel symptoms are common among both men and women with MS. Urinary and faecal incontinence can occur as individual symptoms or in combination with each other but are usually evaluated and treated independently. Pelvic floor muscle training (PFMT) is known to improve these symptoms in people without MS but less is known about its effects on MS patients. The aim of this study is to assess the feasibility of investigating PFMT to improve urinary and faecal incontinence in MS patients.

Who can participate?
Patients aged 18 or over with MS and urinary and/or faecal incontinence

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are given supervised PFMT for 12 weeks led by a physiotherapist. Those in group 2 undergo the same programme for 12 weeks but unsupervised.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Southmead Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2015 to April 2017

Who is funding the study?
Multiple Sclerosis Society (UK)

Who is the main contact?
Dr Nikki Cotterill

Contact information

Type(s)
Scientific

Contact name
Dr Nikki Cotterill

Contact details
Bristol Urological Institute
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BS10 5NB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18358

Study information

Scientific Title
Optimising pelvic floor muscle training to improve quality of life outcomes for individuals with progressive multiple sclerosis and incontinence: a feasibility study

Acronym
OPTIMISE

Study objectives

The aim of this study is to explore the feasibility of addressing the limitations in existing studies investigating pelvic floor muscle training (PFMT) to improve urinary and faecal incontinence in both men and women with primary and secondary progressive multiple sclerosis (MS) in order to develop a definitive trial. The main areas to be addressed are: eligibility, recruitment and retention rates, practicalities in delivery and experience of the intervention for participants, and data regarding the proposed outcome measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 18/02/2015, ref: 15/SW/0009

Study design
Randomised; Interventional; Design type: Prevention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Neurological disorders; Subtopic: Neurological (all Subtopics); Disease: Nervous system disorders

Interventions
1. Self-led arm: Identical programme of pelvic floor muscle training to that in the supervised arm but this group will be self-led
2. Supervised arm: Supervised pelvic floor muscle training group exercise programme conducted weekly for twelve weeks, led by a physiotherapist
Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

Intervention Type
Behavioural

Primary outcome measure
Feasibility of the trial; Timepoint(s): Completion of the study.

Secondary outcome measures
N/A

Overall study start date
10/03/2015

Completion date
11/04/2017

Eligibility

Key inclusion criteria
1. 18 years or older, NHS patients
2. Primary or secondary progressive MS diagnosis
3. UI, FI or both for at least three months
4. Participants who complete ICIQ-UI Short Form and report some incontinence (“About once a week or less often” to “All the time” to item 3 - ICIQ--UI Short Form), and/or,
5. Participants who complete ICIQ--B and report some incontinence (“Most of the time” to “Never” to items 9, 10 or 11 - ICIQ--B 04/08)
6. Cognitive capacity to complete assessments and treatment protocol (Mini Mental State Examination >8)
7. Stable disease over previous 3 months
8. Ability to contract pelvic floor muscles (perineometer response >0)
9. Participants taking LUTS medications can participate if they have been taking the medication at a stable dose for at least three months prior to study enrolment
10. Participants taking Loperamide or bowel relaxation medications can participate if they have been taking the medication at a stable dose for at least three months prior to study enrolment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

Key exclusion criteria
1. MS relapse including escalation of symptoms or requiring hospitalization, during the three months prior to the study
2. Introduction of new MS therapies or medications during the three months prior to the study
3. Symptomatic urinary tract infection
4. Indwelling urinary catheter if only reporting urinary incontinence (can be included with catheter if presenting with faecal incontinence for the trial)
5. Pregnancy
6. Vaginal delivery or caesarian section in previous twelve months
7. Pelvic organ prolapse that is visible beyond the intra--oitus on relaxation or cough.

8. Incontinence surgery if undertaken for presenting symptoms (if presenting with faecal incontinence for the trial and incontinence surgery has been undertaken for urinary cause they can be included, and vice versa)
9. Red flag bowel symptoms such as bleeding or recent unexplained change in bowel habit.

Date of first enrolment
10/03/2015

Date of final enrolment
11/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Urological Institute
Southmead Hospital,
Southmead Road,
Westbury-On-Trym
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Trust Headquarters
Beckspool Road
Frenchay
Bristol
England
United Kingdom
B16 1JE

Sponsor type
Hospital/treatment centre

ROR

https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
Multiple Sclerosis Society

Alternative Name(s)
Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society UK, Multiple Sclerosis Society UK, MS Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No