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

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|-------------------|---|---|--|--|
| 08/04/2015 | | ☐ Protocol | | |
| Registration date | Overall study status Completed Condition category Nervous System Diseases | Statistical analysis plan | | |
| 08/04/2015 | | Results | | |
| Last Edited | | Individual participant data | | |
| 15/06/2016 | | 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 Southmead Hospital Southmead Road Westbury-On-Trym Bristol United Kingdom BS10 5NB

Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

N/A

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |