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Balance right in multiple sclerosis

Submission date
19/09/2016

Recruitment status
No longer recruiting

Registration date
29/09/2016

Overall study status
Completed

Last Edited
10/10/2023

Condition category
Nervous System Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is one of the most common diseases of the central nervous system (brain and spinal cord). Healthy nerves are coated in a fatty casing (myelin sheath) which helps messages to travel quickly and smoothly along nerves. When a person is suffering from MS, the immune system, which normally helps to protect against infection, attacks the myelin sheath, stripping it from the nerves (demyelination). This demyelination means that messages cannot travel along the nerves effectively, causing a range of symptoms including problems with balance and coordination and weakness in the arms or legs. Secondary progressive MS (SPMS) is a form of later stage MS, where already severe symptoms become progressively worse. Patients with SPMS describe their worsening mobility (ability to walk and move around) to be the most difficult symptom, and falls are very common. Whilst falls prevention programmes are available in the NHS for the elderly, evidence suggests that these are unsuitable for people with MS. The researchers have therefore developed a 13 week manualised and personalised exercise and education programme titled 'BRiMS' to help prevent falls and improve mobility and quality of life. The aim of this study is to find out the acceptability of the BRiMS programme to find out whether a large-scale study looking at its effectiveness would be possible.

Who can participate?
Adults with SPMS with a history of falls in the South West or Ayrshire regions.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group continue to receive their usual care throughout the study. This can differ between different patients and regions but generally involves occasional appointments with a variety of health professionals (such as physiotherapists, occupational therapists, GPs, MS nurse specialists, neurologists, and rehabilitation consultants). Those in the second group receive their usual care as well as taking part in the BRiMS programme. This involves a thirteen week personalised program of exercise and education designed to lower the risk of falls. The programme includes a one-to-one assessment session, a home visit and three group sessions alongside a home programme of exercise and education activities. The programme is supported throughout by online interactive resources and input from an experienced physiotherapist. At the start of the study and then again after 12 and 25 weeks, participants complete a number of questionnaires in order to find

out the best way of measuring the effectiveness of the program for a large-scale study. Following completion of the study, some participants are also invited to share their experiences of taking part by giving an interview over the telephone.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
Derriford Hospital and five other NHS hospitals in England and Scotland (UK)

When is the study starting and how long is it expected to run for?
May 2016 to April 2018

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

Who is the main contact?
1. Mrs Margie Berrow (public)
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2. Dr Jenny Freeman (scientific)
3. Dr Hilary Gunn (scientific)

Contact information

Type(s)
Public

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Central Portfolio Management System (CPMS)
31798

Study information

Scientific Title
A guided self-management programme to reduce falls and improve quality of life, balance and mobility in people with secondary progressive Multiple Sclerosis: a feasibility randomised controlled trial

Acronym
BRiMS

Study objectives
The aim of this study is to test the feasibility of and aid the planning of an anticipated multi-centre randomised controlled trial to compare a 13 week manualised and personalised exercise and education programme (entitled 'BRiMS') plus usual care with usual care alone in improving mobility and quality of life and reducing falls in people with secondary progressive MS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West – Exeter Research Ethics Committee, ref: 16/SW/0266

Primary study design
Interventional

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Neurological disorders, Primary sub-specialty: Multiple sclerosis; UKCRC code/ Disease: Neurological/ Demyelinating diseases of the central nervous system

Interventions
Participants will be randomised in a 1:1 ratio in blocks of 10 either to a manualised 13-week education and exercise programme (BRiMS) plus usual care (Intervention) or to usual care alone (Control).

Intervention group: Participants will be invited to participate in the BRiMS programme alongside their usual care. The BRiMS programme is delivered as a 13-week therapy-led personalised education and exercise intervention, structured to maximise the development of self-efficacy and support participant engagement. BRiMS addresses modifiable fall risk factors such as poor balance and mobility and enables self-management by the use of individualised mobility, safety and falls risk management strategies. The programme includes a one-to-one assessment session, a home visit and three group sessions alongside a home programme of exercise and education activities. The programme is supported throughout by online interactive resources and input from an experienced physiotherapist.

Control group: Participants will continue to receive their usual clinical care alone. Usual care is likely to vary significantly between participants and regions, but typically involves occasional appointments with a variety of health professionals (for example physiotherapist, occupational therapist, general practitioner, MS nurse specialist, neurologist, rehabilitation consultant). Multi-disciplinary interventions are usually short term, since resource restrictions limit the provision of long-term maintenance therapy. Specialist falls programmes for older people exist in most locations across the UK, however, these are seldom accessed by people with MS. Some programmes specifically exclude those with neurological conditions from attending, and have lower age restrictions which present further barriers. The trial will record the content of usual care for all participants at each follow-up assessment.

Participants in both groups will be assessed at baseline, 13 and 25 weeks.

Intervention Type
Other

Primary outcome(s)

Selection of an appropriate primary outcome measure for the full scale trial is undertaken through blinded assessments of the MS Walking Scale-12vs2.0, EuroQoL EQ5-D5L and MS Impact Scale-29vs2.0 at baseline, 13 and 25 weeks.

Key secondary outcome(s)
1. Patient and clinician reported outcomes related to falls and injury rates will be measured by the self-reported fortnightly falls patient diaries for the duration of the study
2. Activity level will be measured by activity monitors worn for 1 week at baseline, 13 and 25 weeks
3. Walking will be assessed by the self-report MSWS-12 questionnaire and an objective clinician-rated measure of walking capacity - the two-minute walk test (2MWT) carried out at baseline, 13 and 25 weeks
4. Balance will be assessed by The Mini-Balance Evaluation Systems Test (Mini-BEST) and the Functional Reach Test (FRT, forwards and lateral) carried out at baseline, 13 and 25 weeks
5. Fear of falling will be measured with the 16-item self-report Falls Efficacy Scale (International) (FESi) at baseline, 13 and 25 weeks
6. Community integration will be measured using the self-report Community Participation Indicators (CPI) questionnaire at baseline, 13 and 25 weeks

Completion date
30/04/2018

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of secondary progressive MS (SPMS) as determined by neurologist's opinion
2. Aged 18 years or older
3. Willing and able to understand/comply with all trial activities
4. Expanded Disability Status Scale (EDSS) ≥ 4.0 ≤ 7.0 ie: those people who at best have difficulty waliking 500 metres without aid or rest; and at worst are unable to walk more than 5 metres even with an aid
5. Self-report two or more falls in the past six months
6. Willing and able to travel to and participate in BRiMS group sessions in local centres and to commit to undertaking their individualised home-based programme
7. Access to a computer or tablet and to the internet

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex

All

Total final enrolment
56

Key exclusion criteria
1. Patient report of relapse or having received steroid treatment within the last month
2. Any recent changes in disease-modifying therapies. More specifically patients will be excluded if:
2.1. They have ever had previous treatment with Alemtuzemab (Lemtrada / Campath)
2.2. Ceased Nataluzimab (Tysabri) in the last 6 months
2.3. Within three months of ceasing any other MS disease-modifying drug
3. Participated in a falls management programme (e.g. for older people) within the past six months
4. Co-morbidities which may influence the ability of individuals to participate safely in the programme or likely to impact on the trial (e.g. uncontrolled epilepsy)

Date of first enrolment
09/01/2017

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Derriford Hospital
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PL6 8DH

Study participating centre
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Study participating centre
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Study participating centre
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TR15 3ER

Study participating centre
Royal Cornwall Hospital
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TR1 3LQ

Study participating centre
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Kilwinning Road
Irvine
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KA12 8SS

Sponsor information

Organisation
Plymouth Hospitals NHS Trust

ROR
https://ror.org/05x3jck08

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2019	21/06/2019	Yes	No
Results article		04/01/2021	10/10/2023	Yes	No
Protocol article	protocol	27/07/2017		Yes	No
Abstract results	preliminary results presented at Rehabilitation in Mutiple Sclerosis (RIMS) Conference	01/05/2018	22/03/2019	No	No
Abstract results	preliminary results presented at the Physiotherapy UK Conference 2018	01/01/2019	22/03/2019	No	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes