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SUMS: Standing up in people with multiple sclerosis

Submission date	Recruitment status	[_] Prospectively registered
03/02/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
03/02/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/08/2022	Nervous System Diseases	

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 disabilities, such as walking problems and immobility. Being able to stand upright is highly valued by most people, both mentally and physically. Standing frames are commonly used by people with spinal cord injury (SCI) who are unable to stand unaided. These frames provide support to enable even severely disabled patients to stand safely. Regular use has been shown to reduce complications of immobility (such as pressure sores and muscle wasting) and boost feelings of wellbeing. Many people with MS develop severe walking problems and so spend much of their day sitting down. The associated complications impact on quality of life and result in increased healthcare needs. These problems can be minimised if physical activity is increased, however without easy access to a frame, people must travel to a rehabilitation/MS centre to stand which can be both expensive and time consuming. Using a standing frame at home may offer a solution which reduces the economic and social costs for the patient and NHS. The aim of this study is to test the effectiveness of a home-based standing programme with a frame in people who are severely disabled by their MS.

Who can participate?
Adults with MS who require assistance to walk more than 20 metres or who are restricted to a bed or wheelchair.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive two, home-based, hour-long therapy sessions, during which time they are taught how to use the standing frame, followed by six 15-minute telephone consultations. The participants are encouraged to stand in the frame for 30 minutes, three times a week. In order to offer further support, participants are given user-friendly information leaflets and DVDs. Participants in the second group continue to receive usual care. At the start of the study and then again after 20

and 36 weeks, participants in both groups complete a number of questionnaires and assessments in order to test if their motor (movement) abilities and quality of life have improved.

What are the possible benefits and risks of participating?
Participants may benefit from an increased level of physical activity and improvements to movement and mood as a result of regularly standing in the frame. Risks of taking part are small but some participants may experience some increased fatigue, muscle stiffness or soreness because muscles that may not have been moved in a long time are being used.

Where is the study run from?
Peninsula Allied Health Centre (Plymouth University) and at least 30 other health centres catering for people with MS across Devon, Cornwall and East Anglia (UK)

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

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

Who is the main contact?
Dr Jennifer Freeman
jenny.freeman@plymouth.ac.uk

Study website
https://plymouth.ac.uk/research/sums

Contact information

Type(s)
Public

Contact name
Dr Jennifer Freeman

Contact details
Peninsula Allied Health Centre
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PL6 8BH
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
163803

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 18999, IRAS 163803

Study information

Scientific Title
A multi-centre randomised controlled trial to assess the effectiveness and cost effectiveness of a home-based self-management standing frame programme plus usual care versus usual care in people with progressive multiple sclerosis (MS) who have severely impaired balance and mobility

Acronym
SUMS

Study objectives
The aim of this study is to investigate the clinical and cost effectiveness of a home-based self management standing programme in people who are severely physically impaired with multiple sclerosis (MS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West – Frenchay, 13/05/2015, ref: 15/SW/0088

Study design
Randomised; Interventional; Design type: Treatment

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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Neurological disorders; Subtopic: Neurological (all Subtopics); Disease: Multiple Sclerosis

Interventions
Participants are randomly allocated to one of two groups.

Intervention group: Participants will be asked to stand in an Oswestry standing frame for 30 minutes three times per week for a total of 16 weeks during a 20 week period. This method of supported standing, uses a robust wooden frame to provide support through the use of straps at the knees, hips and ankles (www.oswestry-frames.co.uk). The treating physiotherapist will teach the participant and carer safe use of the standing frame over 2 face-to-face sessions in the participant's home (~60 minutes/session). They will be taught exercises, stretches and balance activities to undertake using the frame. To complement this and optimise adherence, an information booklet and DVD will provide advice on how to intensify the programme, a detailed description/schema of the exercises, advice on safety issues, and "frequently asked questions". To further optimise adherence these face-to-face sessions will be supported by weekly telephone support (~15 minutes) for 4 weeks, and then monthly for the following 2 months. Calls will focus on facilitating individuals to set and achieve personal targets. As is routine clinical practice, the therapist's contact name and telephone number will be provided should any queries arise.
Individuals may take up to four weeks to become re-accustomed to an upright position. A 20 week period has therefore been allocated for achieving the desired intensity of standing activity as participants will not have been used to prolonged standing and may fatigue. This further allows for time when the participant is unable to use the frame (illness, holidays, etc.), as highlighted by our user discussion groups.

Control group: Participants receive usual physiotherapy care only. Although usual care varies between individuals, it rarely involves regular physiotherapy intervention either within the community or hospital. Intervention is generally limited to a few visits, typically reacting to presenting problems (e.g. practising transfer skills, providing mobility aids) rather than promoting long-term preventative self-management..

Participants in both groups are followed up at 20 and 36 weeks.

Intervention Type
Other

Primary outcome measure
Motor function is measured using the Amended Motor Club Assessment at baseline, 20 and 36 weeks.

Secondary outcome measures
1. Bowel and Bladder Control is measured using the self report Bladder and Bowel Control Scales at baseline, 20 and 36 weeks
2. Falls frequency is determined at baseline, 20 and 36 weeks
3. Knee extensor strength is measured using dynanometry at baseline, 20 and 36 weeks
4. Length of hip flexors are measured using goniometry at baseline, 20 and 36 weeks
5. Quality-adjusted life-years (QALY) are measured at baseline, 20 and 36 weeks
6. Quality of Life is measured using the 29-item MS Impact Scale and the EURoQOL 5D-5L at baseline, 20 and 36 weeks
7. Respiratory capacity is measured using spirometry to measure forced expiratory volume (FEV) at baseline, 20 and 36 weeks

8. Sitting balance is measured using the Modified Functional Reach in Sitting at baseline, 20 and 36 weeks
9. Spasm Frequency is measured using the Penn Spasm Frequency Scale at baseline, 20 and 36 weeks

Overall study start date
01/01/2015

Completion date
31/03/2018

Eligibility

Key inclusion criteria
1. Individuals diagnosed with primary or secondary progressive MS according to McDonald's criteria
2. Aged 18 years or over
3.Willing and able to consent to participate
4. Scoring 6.5-8.0 on the Expanded Disability Status Scale (EDSS), i.e. people who "require bilateral assistance to walk 20 metres or less" to those "restricted to bed or wheelchair"
5. Ability of the home / family to accommodate the standing frame
6. Able to get into a standing frame independently or with assistance from a carer
7. Agreement of another person (e.g. carer) should assistance be necessary for the standing programme
8. Willing and able to travel to local assessment centres for blinded outcomes assessment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 140; UK Sample Size: 140; Description: 70 people will be randomly allocated to the usual care group and 70 to the standing frame plus usual care group.

Total final enrolment
140

Key exclusion criteria
1. Any recent changes in disease modifying therapies (more specifically if they have ever had Campath, are within past 6 months of ceasing Nataluzimab, or are within 3 months of ceasing any other MS disease modifying drug)
2. Have relapsed/received steroid treatment within the last month

3. Are currently, or during the past 6 months have undertaken a regular standing frame programme(more than once a week)
4. Have a history of osteoporotic-related fractures
5. Have comorbidities which contraindicate standing in the frame (e.g. foot ulceration, uncontrolled epilepsy) or likely to impact on the trial (e.g. chronic jaundice, heart disease, age related multiple co-morbidities)
6. Currently participating in another clinical trial (rehabilitation or pharmacological)

Date of first enrolment
01/09/2015

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Peninsula Allied Health Centre
Plymouth University
Derriford Road
Plymouth
United Kingdom
PL6 8BH

Study participating centre
Peninsula Community Health
Unit 2 Harleigh Road
Bodmin Business Centre
Bodmin
United Kingdom
PL31 1AQ

Study participating centre
Newquay Hospital
St Thomas Road
Newquay
United Kingdom
TR7 1RQ

Study participating centre
Royal Cornwall Hospital
2 Penventinnie Lane
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
Camborne Redruth Community Hospital
Barncoose Terrace
Redruth
United Kingdom
TR15 3ER

Study participating centre
Liskeard Community Hospital
Clemo Road
Liskeard
United Kingdom
PL14 3XD

Study participating centre
Newton Abbot Hospital
West Golds Road
Newton Abbot
United Kingdom
TQ12 2TS

Study participating centre
Paignton Hospital
Church Street
Paignton
United Kingdom
TQ3 3AG

Study participating centre
Totnes Hospital
Torbay and Southern Devon Health and Care NHS Trust
Coronation Road

Totnes
United Kingdom
TQ9 5GH

Study participating centre
Dartmouth Hospital
South Embankment
Mansion House Street
Dartmouth
United Kingdom
TQ6 9BD

Study participating centre
Mount Gould Local Care Centre
Therapy Unit
200 Mount Gould Road
Plymouth
United Kingdom
PL4 7PY

Study participating centre
Ivybridge Reablement Team
5 Olafs Chapel
Puslinch Farm
Yealmpton
United Kingdom
PL8 2NN

Study participating centre
Bideford Hospital
Abbotsham Road
Bideford
United Kingdom
EX39 3AG

Study participating centre
Tyrrell Hospital
Ilfracombe Community Rehabilitation
St Brannock's Park Road

Ilfracombe
United Kingdom
EX34 8JF

Study participating centre
Axminster Hospital
Axe Valley Community Rehabilitation team
Chard Road
Axminster
United Kingdom
EX13 5DU

Study participating centre
Tiverton and District Hospital
Kennedy Way
Tiverton
United Kingdom
EX16 6NT

Study participating centre
Multiple Sclerosis Therapy Centre
West Grange
Clyst Heath
Exeter
United Kingdom
EX2 7EY

Study participating centre
Royal Devon & Exeter Hospital
Wonford Road
Exeter
United Kingdom
EX2 6DW

Study participating centre
Lucerne Residential Home
40-42 Chudleigh Road
Exeter
United Kingdom
EX2 8TU

Study participating centre
Tavistock Community Rehabilitation Team
DCC Offices
Abbey Rise
Whitchurch Road
Tavistock
United Kingdom
PL19 9AS

Study participating centre
Swaffham Community Hospital
Sporle Road
Swaffham
United Kingdom
PE37 7HL

Study participating centre
Dereham Community Hospital
Northgate
Dereham
United Kingdom
NR19 2EX

Study participating centre
Wymondham Health Centre
18, Bridewell Street
Wymondham
United Kingdom
NR18 0AR

Study participating centre
Kelling Community Hospital
Old Cromer Road
High Kelling
Holt
United Kingdom
NR25 6QA

Study participating centre

North Walsham Community Hospital
Yarmouth Road
North Walsham
United Kingdom
NR28 9AP

Study participating centre
MS Therapy Centre
Iceni Way
Norwich
United Kingdom
NR6 6BB

Study participating centre
Norwich Community Hospital
Bowthorpe Road
Norwich
United Kingdom
NR2 3TU

Study participating centre
Disability Resource Centre
4, Bunting Road
Bury St Edmunds
United Kingdom
IP32 7BT

Study participating centre
Newmarket Community Hospital
56 Exning Road
Newmarket
United Kingdom
CB8 7JG

Study participating centre
The Kirkley Centre
154 London Road
Lowestoft
United Kingdom
NR33 0AZ

Study participating centre
Bluebird Lodge
100, Mansbrook Boulevard
Stowmarket
United Kingdom
IP3 9GJ

Study participating centre
Felixstowe Community Hospital
Constable Road
Felixstowe
United Kingdom
IP11 7HJ

Sponsor information

Organisation
Plymouth Hospitals NHS Trust

Sponsor details
Neurology
The John Bull Building
Derriford Hospital
16 Research Way Derriford
Plymouth
England
United Kingdom
PL6 8BU

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
1. Planned dissemination of results via journal articles, newsletters, conference presentations, user discussion groups, and the study website.
2. Planned publication in MS lay newsletters and magazines (e.g. MS Trust “Open Door” and MS Society “Research Matters” newsletters)
3. Planned presentation at national and international conferences

Intention to publish date
31/05/2018

Individual participant data (IPD) sharing plan
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IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2019	16/07/2019	Yes	No
Results article	qualitative results	28/10/2020	30/10/2020	Yes	No
Protocol article	version 1	05/05/2016	17/08/2022	Yes	No
Statistical Analysis Plan		17/01/2018	17/08/2022	No	No
HRA research summary			28/06/2023	No	No