

# SUMS: Standing up in people with multiple sclerosis

<b>Submission date</b> 03/02/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/02/2016	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/08/2022	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> 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 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

Plymouth University

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Plymouth

United Kingdom

PL6 8BH

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jenny.freeman@plymouth.ac.uk

## **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](http://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 dynamometry 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?
<a href="#">Results article</a>	results	01/08/2019	16/07/2019	Yes	No
<a href="#">Results article</a>	qualitative results	28/10/2020	30/10/2020	Yes	No
<a href="#">Protocol article</a>	version 1	05/05/2016	17/08/2022	Yes	No
<a href="#">Statistical Analysis Plan</a>		17/01/2018	17/08/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No