PARTICIPANT INFORMATION SHEET

SUMS: A multi-centre randomised controlled study to assess the effectiveness of a home-based self-management standing frame programme in people with progressive MS.

Invitation to participate
We would like to invite you to participate in a new research study. Before you decide whether or not to participate, it is important that you understand why the research is being done and what it will involve. This information sheet explains the background and aims of the study. Please take time to read it carefully and discuss it with family and friends or your own physiotherapist, doctor or nurse if you wish. If there is anything that is unclear, or if you would like more information, please ask us. Your participation in this study is entirely voluntary.

What is the overall aim of the study?
The aim of this study is to find out whether standing regularly in an Oswestry Standing Frame at home helps improve people’s health and wellbeing. More specifically we will be looking at the impact of standing on muscle weakness, balance, spasms, joint stiffness, breathing difficulties and bladder and bowel control.
Why have I been chosen?
You have been chosen because you have progressive MS and are restricted in the length of time you can stand without support. In total 140 people with MS, from two different areas in England (the South West and East Anglia) will be participating in this study.

Do I have to take part?
No. It is up to you to decide whether or not you wish to join this study. Your participation is entirely voluntary and if you decide not to take part your usual medical and physiotherapy care will not be affected in any way. Even if you decide to take part in the study you can withdraw from it at any time and there will be no changes to the services you normally receive.

What will happen to me if I take part? What do I have to do?
If you choose to take part in this study your participation will be required for 36 weeks.

In the first instance we will ask you to complete a form to give us permission to contact your therapy team to check whether they feel you are fit and able to participate in a regular standing programme at home. If they agree, we will then telephone you to check whether you are eligible for this study. We will ask you a number of questions which will include your age, level of mobility, when/if you last had a relapse, the medications you are taking (or have recently taken), whether you are happy to have a standing frame in your house, and whether you have a medical condition (other than MS) which may affect your ability to stand. We will also check whether your carer / spouse is happy to help you get into and out of the standing frame, if you need assistance to do so. If you have relapsed or taken steroids within the last month then you will not be eligible to participate in this study at this stage. However, after one
month, if you are still interested in participating then you can contact us to ask to be re-screened again. Our contact details are at the end of this information sheet.

If you are eligible to participate we will then ask you to attend an assessment session. This will take place at a centre as close to where you live as possible. During this time you will have the opportunity to ask further questions. You will then be asked to complete a written consent form.

Following this, the research physiotherapist will undertake a number of assessments. In total these assessments will take approximately one hour. They will include measurements of how well you perform a number of different movements such as rolling to one side on a bed, how far you can reach forwards from a sitting position and the range of movement in your hips, knees and ankles. You will also be asked to complete a short questionnaire about the quality of your life. All of these assessments are commonly used by physiotherapists in their daily practice. You will be offered rests as you require throughout this session.

After completion of this assessment, you will be randomly allocated to one of two different interventions: either regular standing at home in an Oswestry Frame (Standing Frame Group) or to continue to receive your usual care from local services (Usual Care Group).

**For those allocated to the Standing Frame Group:**

If you have been allocated to the Standing Frame group, a wooden standing frame (about the size of an armchair; average height 86cm/34inches, width 74cm/29inches) will be delivered to your home. The frames are easy to move around on the carpet so can be pushed to one side of the room when not in use. You will be visited on two separate occasions by an NHS physiotherapist who will spend up to an hour providing advice and information about the standing programme and will instruct you on how to use the frame. You will probably require help to stand in the frame. This could be
done by a family member or carer. They will also receive instructions on how to use the frame. These instructions will be backed up with written instructions and a video showing you how to use the frame.

If you are using the frame at home, you will be asked to stand for **30 minutes, 3 times a week**. You are not expected to stand for this long in the first instance; the time you stand will be gradually progressed. You will be given a diary so that you can record the amount of standing you do as well as other information such as reasons for not standing. During the time you are using the frame a physiotherapist will contact you 6 times by phone to see how you are getting on. You will also be able to contact a named person during the study if you have any concerns regarding using the frame.

10 participants allocated to the Standing Group and 10 family members or carers will also be asked if they would complete an audio diary using an audio recorder during the study to record their experiences of using the frame in the home. If you agree to complete an audio diary, we will ask for your permission to publish anonymised extracts of the diary on to the study web-site and/or in articles written for both a lay and scientific audience so that we can share your experiences (both good and bad) with other people who may be interested in using a standing frame in their home. Before we do so we will first check with you that you are happy for the extract chosen to be shared.

**For those allocated to usual care**

If you have been allocated to the Usual Care group then you will continue with the usual care you receive from your local services.

For both groups at week 20 and again at week 36, the same measurements and assessments will be repeated by the same assessor at a centre near to you and at a time convenient to you. A flowchart on the following page summarises this process.
**Study Flow Chart**

Permission given by you for researcher to contact therapy team

Researcher telephones you to:
- Check entry criteria
- Arrange an appointment for assessment

**Week 1**
- Opportunity to ask questions
- Consent
- 60 minute baseline assessment by independent assessor at a local centre
- Allocation to intervention group

**Weeks 1 – 20**
**Standing Frame Group**
- Standing Frame delivered to your home
- Two physiotherapy sessions in your home to set up the standing programme
- Standing for 30 mins, 3x weekly
- 6 telephone calls by physiotherapist to check your progress

**Weeks 1 – 20**
**Usual Care Group**
- Continue with your usual physiotherapy and healthcare

**Week 20**
60 minute baseline assessment by independent assessor at a local centre
Continue with usual care / standing programme

**Week 36**
60 minute baseline assessment by independent assessor at a local centre
End of study

**Will the study involve taking any new medication?**
No. We will not change your existing medication during the time that you are involved in this study. You should continue to take all your usual medicines as prescribed and to participate in your usual activities and exercise programmes.
What if I’m already having physiotherapy or other therapy?
That’s fine. Any care you currently receive can carry on as normal even if you are in the study, regardless of which group you have been allocated to.

Will I have to make any extra visits to my neurologist or GP?
You will not have to make any extra visits to your GP or to your neurologist. The only extra appointments you will need to make are to the physiotherapist, as described below. If you decide to take part we will inform your GP by letter, with your permission.

Will any expenses be paid?
Your travel expenses will be paid for your return journey to attend the three assessment sessions at a local centre. Travel expenses will be reimbursed at a mileage rate of 40 pence per mile, to a maximum of £25. Alternatively, if you are unable to drive you will have a 20 mile round trip taxi fare reimbursed to attend the assessment sessions. The researchers will make and pay for the telephone calls to arrange your appointment.

Will my records be confidential?
All information collected about you during the project will be kept strictly confidential. You will be allocated a project number which we will use on all assessment records rather than your name or other identifying details. All information collected will be stored electronically on a computer which is password protected, in a document file that is also password protected. Your name and address will be stored separately from the other information so that you cannot be identified from your study records. If you choose to discontinue being involved in the study we will need to use the data you have provided so far so that we can analyse the results from the study accurately. All information will be handled in compliance with the Data Protection Act (1998).

What are the potential benefits of taking part in this study?
By participating in this study you will help to improve our understanding of the effectiveness of regular frame standing for people who are limited by MS in their ability to stand or walk. You may find it personally beneficial because you have increased
your activity. You should understand, however, that you may not gain benefits from undertaking this intervention.

**What are the potential risks of taking part in this study?**

For those allocated to the Standing Frame Group there are very few risks associated with using this frame as long as you follow the instructions given to you during the training session. The person helping you will be asked if they have had a back problem in the past as it may be unsafe for them to help you stand. As long as the straps are positioned and fastened correctly it should be impossible for you to fall out of the frame. You may experience some muscle stiffness, especially in your low back and thighs when you first start using the frame as you will be stretching muscles that may not have been stretched for a while. This usually wears off quickly. While it is not anticipated that you will experience fatigue, pain or increased spasms, nevertheless it is important that you are aware that it is possible that these may occur. You will be given contact details of the physiotherapist so that you can notify them if these types of issues occur, so that they can modify the standing regime accordingly, or if necessary that they can withdraw you from the study.

**Who is organising and funding the study?**

The project is being funded by the NHS on a Research for Patient Benefit grant. The Chief Investigator for this study is Dr Jenny Freeman (Reader in Physiotherapy) within the Faculty of Health at Plymouth University. The Principal Investigator in East Anglia is Dr Wendy Hendrie (MS Clinical Specialist Physiotherapist). The MS specialist Nurse on this team is Dr Louise Jarrett, Exeter.

**What happens when the research study stops?**

At the end of the study, if you feel the frame is of benefit to you and can demonstrate that you have been regularly using it (more than once per week), you will be allowed to keep the frame if you wish. The frames will continue to be the property of the NHS and
will be collected if no longer used. They will continue to be the responsibility of the NHS to maintain.

At the end of the study, we would like to briefly talk to you about your experience of participating in this study, for example to ask you whether there are certain aspects of the study that you feel we could have undertaken better. This will help to inform our conduct of future studies. This will be brief (approximately 5-10 minutes), informal and entirely optional. If you do not wish to pursue this then you are under no obligation to do so.

Who has reviewed this study?
This study has been reviewed and approved by the NRES Committee South West – Frenchay Research Ethics Committee (REC Ref: 15/SW/0088).

What if something goes wrong?
If you wish to complain, or have any concerns about this study then in the first instance please contact the researcher whose details are at the end of this Information Sheet. Should you have further complaints or questions then please contact Dr Jenny Freeman, Reader in Physiotherapy, at Plymouth University. If this does not resolve the issue, and you would like to formally complain you can do this through the normal National Health Service complaints mechanisms. These details can be obtained from the Patient Advice and Liaison Service in England.

This is an NHS-sponsored research study. If you suffer negligent harm as a result of participating in the study, NHS indemnity covers NHS staff and those people responsible for conducting the trial who have honorary contracts with the relevant NHS Trust. In the case of non-negligent harm, the NHS is unable to agree in advance to pay compensation, but an ex-gratia payment may be considered in the event of a claim.
**How will I hear about the results of the study?**

We anticipate that it will take approximately 36 months for the study to be completed. At the end of this period, if you wish, we will send you a summary of the results of this study. It is intended that the results of the study will be published. All data will be anonymised before this.

**Your rights**

Your participation in this study is entirely voluntary. If any new information becomes available during the course of this study, we will convey this information to you. You may withdraw at any time without it affecting your current or future medical treatment in any way. If you agree to take part in this study, you will need to sign a consent form.

**Contact for further information**

If you require any further information about this study, or have any questions please contact either:

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<thead>
<tr>
<th>Region</th>
<th>Contact Person</th>
<th>Contact Details</th>
</tr>
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<tbody>
<tr>
<td>South West</td>
<td>Dr Esther Fox or Dr Jenny Freeman</td>
<td>Tel: 01752 587599 <a href="mailto:SUMSstudy@plymouth.ac.uk">SUMSstudy@plymouth.ac.uk</a></td>
</tr>
<tr>
<td>East Anglia</td>
<td>Dr Wendy Hendrie</td>
<td>Tel: 01603 488561 <a href="mailto:SUMSstudy@plymouth.ac.uk">SUMSstudy@plymouth.ac.uk</a></td>
</tr>
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Alternatively you could complete the attached Reply Slip to provide us with your details so that we can get in contact with you.

Thank you for reading this Information Sheet and considering taking part in the study. If you decide to participate in this study you will be given a copy of this Information Sheet and a signed consent form to keep.