STANDING ASSISTANTS 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 this 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 read it carefully. If anything is unclear, or if you would like more information, please ask us. Your participation is entirely voluntary.

Why have I been invited?
Your family member/the person you care for has expressed an interest in participating in this study, which aims to find out whether regular standing in an Oswestry Standing Frame can help to improve their health and well being. In order for them to participate they require a “standing assistant” to help them to use the standing frame. They suggested you are the person most likely to be their “standing assistant”, and so we would like to tell you more about this study and invite you to participate in it.

What is the overall aim of the study?
This study aims to find out whether regular standing in an Oswestry Standing Frame at home helps improve the health of people with MS. More specifically we are looking at whether it impacts on muscle strength, balance, spasms, joint stiffness, bladder and bowel control and breathing difficulties.

Why have I been invited?
Your family member/the person you care for has been chosen
because they have progressive MS and are restricted in the length of time they can stand without support. In total 140 people with MS, from two different areas in England (the South West and East Anglia) will participate in this study.

Do I have to take part?
No. Your participation is entirely voluntary and if you decide not to take part, then your rights will not be affected in any way. Even if you decide to take part you can withdraw from it at any time without any impact.

Your family member/person you care for has been provided with a Participant Information Sheet (Version 2.0, 27.4.15) which provides a detailed explanation about what is involved in this study. Please read this “Standing Assistants Information Sheet” alongside this.

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.

As you have read, your family member/person you care for will have been asked to complete a form to give us permission to contact their therapy team to check whether the type of home-based standing programme is appropriate for them. If they agree, we will then telephone your family member/person you care for to check their eligibility for this study. At this time we will also speak to you to check whether you are happy to have the frame in your home, and to provide any assistance needed to help your family member/ person you care for to use the standing frame (if they have been allocated to the “Standing Frame group”).

If your family member/ person you care for is eligible to participate we will ask them to attend an assessment session. This will take place at a centre as close to where they live as possible. We would request that you also attend this session, although you are not required to do so. During this session there will be an opportunity for you both to ask further questions about this study, and to each complete a written consent form. After consent has been given, the research physiotherapist will undertake a number of assessments with your family member/person you care for, which will take about an hour, with rest breaks as needed. These have been described more fully in the “Participant information Sheet” - all of the assessments are commonly used by physiotherapists in their daily practice.
After completion of this assessment, your family member/person you care for 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 their usual care from local services (Usual Care Group).

**For those allocated to the Standing Frame Group:**
If your family member/person you care for has 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 their home. Close to this time an NHS physiotherapist will visit their home on two separate occasions. **It is essential that you attend both of these one hour sessions**, as this is when the physiotherapist will instruct you both on how to use the frame. This advice will be backed up with written instructions and a video showing you how to use the frame. In brief, it will be your role to move the frame into position in the room (the frames are easy to move around on the carpet so can be pushed to one side of the room when not in use), as well as to provide any assistance needed to help your family member/person you care for to stand in the frame.

Your family member/the person you care for will be asked to gradually increase their standing time so that they eventually stand for 30 minutes, 3 times a week. They will be given a diary so that they can record the amount of standing they undertake as well as other information such as reasons for not standing. You may need to help them complete this diary if they have difficulty writing; you are free to also make any comments you wish in this diary. A physiotherapist will also telephone your family member/person you care for 6 times over the course of the study to see how they are getting on. If you have any comments or questions, then you may also talk to them at the same time. Furthermore, you will both also be able to contact a named person during the study if either of you have any concerns regarding using the frame.

10 people with MS and 10 family members or carers (such as yourself) who have been allocated to the Standing Group will also be asked if they would complete an audio diary using an audio recorder during the study to record your experiences of using the frame in the home. **It is possible that you may be asked to do this – it is entirely up to you whether or not you wish to do so.** 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 your family member/person you care for has been allocated to the “Usual Care group” then they will continue with the usual care they receive from their 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 your family member/person you care for at a time convenient to them. You may also attend this assessment session if you wish. A flowchart on the following page summarises this process.

**Study Flow Chart**

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

2. **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

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

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

5. **Week 36**
   - 60 minute baseline assessment by independent assessor at a local centre
   - End of study
What information will be collected about me? And will this be confidential?
You will only have information collected about you if you are one of the 10 carers who has been asked to undertake the audio diaries. Should this be the case then we will ask some general information such as your age, gender, and your relationship to the person with MS. All information collected about you during the project will be kept strictly confidential. You will be allocated a project number; your name or other identifying details will not be used. This 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. 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 will also improve our understanding of the experience of people who assist others to implement a standing frame programme within their home. It is unlikely that you will personally benefit from participating in this study, other than gaining satisfaction from helping your family member/person you care for.

What are the potential risks of taking part in this study?
There are very few risks associated with using the standing frame, for either you or your family member/person you care for, as long as you follow the instructions given to you during the training session. If you have had a back problem in the past we may suggest that you do not participate as we would not wish to risk aggravating this problem. With regards to your family member/person you care for – as long as the straps are positioned and fastened correctly it should be impossible for them to fall out of the frame. They may experience some muscle stiffness when they first start using the frame as they are stretching muscles that may not have been stretched for a while. This usually wears off quickly. It is also possible that they may experience some fatigue, although this is not anticipated. You will both 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 your involvement in the study.
What happens when the research study stops?
At the end of the study, if your family member / person you care for feels the frame is of benefit to them, and they can show that they have been regularly using it (more than once per week), they will be allowed to keep the frame if they 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 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.

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>
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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.**