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INFORMATION SHEET

CARERS – SEMI STUCTURED INTERVIEWS

Title of study: A randomised controlled feasibility study investigating surface neuromuscular STIMulation as an exercise therapy versus usual care in people with multiple sclerosis (MS) to help improve lower limb strength, walking and fatigue (STIM-MS)

Invitation

- Thank you for considering taking part in this research study called "STIM MS".
- We are looking for people with all forms of Multiple Sclerosis (MS) and people who look after them to volunteer and help us in this study that people with MS helped to design.
- You are being invited to consider taking part.
- This information is available in Punjabi, Polish and Urdu.
- Please contact the team using the details on the last page if you would like this information in a different language or in a different format (such as audio recording).
- Please read these information sheets carefully. If you need more information or if anything is unclear, the research team at your local hospital will be happy to answer any questions. Their contact details are at the end of the information sheets.
- Before you decide whether to take part or not, it is important that you understand why this study is being done and what will it involve.
- University of Liverpool is the sponsor of this research. For the remainder of this document, any reference to 'we' means the sponsor and not the local site.

Why are we doing this study?

- We are carrying out this study to help us to plan a much larger study to find out if muscle stimulation for people with MS strengthens muscles, improves walking, helps with tiredness, and reduces muscle spasms.
- We want to find out whether people with MS want to take part, what outcomes matter the most to them and if people use the muscle stimulation equipment regularly.
- We also need to find out from people who help look after people with MS, who participated in our study, what their experiences were.
- This will help us decide if we can do the large future study and what needs to be changed.

Please be aware that **half of people with MS who volunteer for this study will not be given a muscle stimulator**, but their **involvement is vital** as **it helps us to make important comparisons** with the group who used the muscle stimulator.

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What is muscle stimulation?

- Muscle stimulation (like in the picture below) could be a way of helping people with MS to exercise more.
- It can be used at home and makes muscles contract, like when someone exercises with weights.
- It involves applying painless electrical signals using sticky pads on the skin and some braces for your joints.



Why am I being invited?

- We are inviting you to take part in this study as someone with MS who you help to look after is taking part in our study.

Do I have to take part?

- You don't have to take part. If you decide to take part, you will be asked to sign a consent form. You will be given a copy, and we will keep one for our records.
- If you decide not to take part or choose to stop being in the study at any stage, we may contact you to ask whether you are willing to share your reason.
- You don't have to tell us, but understanding why people decide not to take part or withdraw may help us plan our future study and better support participants and people who help look after them.

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If I would like to take part, what do I have to do?

- If you would like to take part, then please contact the person or hospital department who gave you this information sheet. Their contact details are at the end.
- A member of the study team will telephone you to discuss the study in more detail.
- If you would like an interpreter to help you with the discussion, please let the team know.
- They will wait at least 24 hours before speaking with you about the study, but you can take as much time as you need.
- We have made a key facts which outlines the main parts of the study if this is helpful.

What will I be asked to do if I take part?

- A diagram showing the different stages of the whole study is below.
- **For you, as a person who helps to look after someone with MS**, you may be asked to take part in a single interview lasting no more than 60 minutes.
- This will be after the 3-months point in the study.
- This can be done over the telephone or online at a time that suits you best.
- You **do not** need to attend the hospital for the interview.
- The conversations will be about your involvement in supporting someone with MS in the study, how you felt about them being put into one of two groups, what outcomes or measures were important and any feedback on the study information, processes, muscle stimulation programme and any improvements we could make to support people in a future study.
- Audio recordings of the interviews will be transcribed (written up) by a University approved transcription service who are required to comply with GDPR and the University's data protection regulations. They will be required to keep your information confidential.
- We will ensure that when written up, the transcripts do not contain any identifiable information about you, and you will be given a code number instead.
- Only anonymised data, that cannot be related to you personally, will be released or discussed publicly at scientific meetings or in research publications.

- A more detailed outline of what people with MS will be asked to do if they participate in our study has been provided in the information sheet for people with MS.

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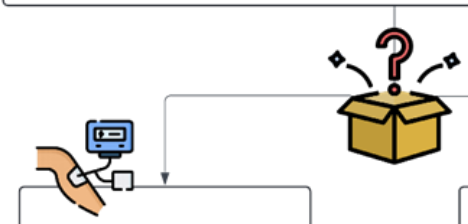
STUDY FLOW CHART

1ST HOSPITAL VISIT - BASELINE MEASURES
Information about your MS, leg strength, walking ability, & levels of tiredness collected in the clinic & with questionnaires

Which group you will be a part of will be decided using a process called randomisation



Muscle stimulator group
12 WEEKS

Usual care group
12 WEEKS

Each group will be asked to record information about what they are doing. They will complete the same measurements and questionnaires

Phone calls at **WEEK 1** & **WEEK 6** to see how you are getting on

2ND HOSPITAL VISIT - 3 MONTH FOLLOW UP
Repeat of the measurements & questionnaires taken at the start of the study

Some people & those who help look after them may be invited back for a telephone call or online interview to find out about their experiences of the study

3RD HOSPITAL VISIT - 6 MONTH FOLLOW UP
Final repeat of measurements & questionnaires taken previously

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What support will I receive for taking part in this study?

- If you take part in an interview (phone or online) about the study, we will be able to give you a £25 voucher in appreciation of your time.

For people with MS participating in our study and their carers

- We will reimburse them for their travel to the hospital for the visits identified above.
- If you need to post anything back to us, we will provide you with pre-paid envelopes.

What are the benefits of my taking part?

- We cannot guarantee any direct and immediate benefits to you or the person you help look after from this study.
- We hope that both yours and their participation will help us gather necessary information to plan a large study to see if muscle stimulation for people with MS strengthens muscles, improves walking, helps with tiredness, and reduces muscle spasms.
- This could improve treatment and rehabilitation approaches for people with MS in the future.

What are the risks and disadvantages of my taking part?

- We do not anticipate any risks to you individually when taking part in the interviews and discussing your experience of supporting someone in the study.
- Taking part in this study requires time to complete the questionnaires and attend the hospital for measurements.

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How will we use information about you?

- We will need to use information from you for this research project. This information will include your
  - name
  - date of birth
  - sex
  - ethnicity
  - post code
  - contact details

- University of Liverpool is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure by ensuring that:
- Relevant members of the research team will use this information to do the research or to check your records to make sure that the research is being done properly.
- People who do not need to know who you are will not be able to see your name or contact details.
- Your information will be linked to a code number instead.
- We will keep all information about you safe and secure.
- Once we have finished the study, we will keep some of the information so we can check the results.
- We will write our reports in such a way that no-one can work out that you took part in the study.
- We will keep your study data for a maximum of 10 years. The study data will then be fully anonymized and securely archived or destroyed.

What are your choices about how information is used?

- You can stop being part of this study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways so the research to be reliable. This means that we won't be able to let you see or change the information we hold about you.
- If you agree to take part in this study, you are agreeing to information collected about you being used anonymously in future projects including research and education.

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Where can you find out more about how your information is used?

- You can find out more about how we use your information
  - At www.hra.nhs.uk/information-about-patients/
  - by asking your local research team, or
  - by sending an email to rdm@liverpool.ac.uk

Safeguarding

- If during the study, or your visit, we become aware of anything that makes us concerned for your or the person you help look afters safety, we are required to report any safeguarding issues in accordance with the local hospitals safeguarding trust policies.
- Patient information for safeguarding at each of the two trusts can be found here
  - Walton centre - https://www.thewaltoncentre.nhs.uk/treatment-and-care/safeguarding.htm
  - Wolverhampton NHS trust - https://www.royalwolverhampton.nhs.uk/repo/about-us/documents/policies/15550_OP_05_PUBLIC_Policy_Printable_Version.pdf

How do I make a decision?

- Before you decided whether to take part we recommend that you speak to relatives, friends, acquaintances, and/or any health professional that you think would give good insights and advice.
- Also, if there is anything about this study that is unclear, please do not hesitate to contact the researcher, who would be more than happy to answer all of your questions.
- Please take the time you need before you make your decision.

What should I do next?

- ✗ If you are not interested in participating in this study, thank you for your time spent reading this document.
- ✓ If you wish to participate, the next step is to contact the researcher (see below) to arrange a suitable time for the interview.

Who is funding and organising the research?

- The National Institute of Health and Care Research (NIHR) has funded this study (Research for Patient Benefit (RfPB) Programme: NIHR207134)

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Who is running the study?

- The University of Liverpool is the sponsor for this study and is based in the United Kingdom.
- The Walton Centre is the host organisation for this study and the Royal Wolverhampton NHS trust is a participating site.
- The University of Liverpool is also the data controller for this study. This means that we are responsible for looking after your information and using it properly.

This is a research study being undertaken by

- Dr Fraser Philp (Physiotherapist), Dr Kerry Hanna (Orthoptist), Mrs Michaela Brown (Statistician) from University of Liverpool,
- Mrs Jenny Thain (Physiotherapist) from the Walton centre,
- Mrs Debbie Ainslie (public co-applicant),
- Dr Sarah Thomas (Psychologist and methodologist) and Prof. Anand Pandyan (Bioengineer) from Bournemouth University,
- Mr Dan Kucharczyk (MS Nurse) and Mr Mohan Mariappan (Consultant Neurologist) from the Royal Wolverhampton NHS Trust,
- Dr Neil Postans (Clinical scientist) from the Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust, and
- Prof Dyfrig Hughes (Health economist) from Bangor University.

Who has reviewed this study?

- All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee who are part of the Health Research Authority (HRA).
- The North West - Greater Manchester South Research Research Ethics Committee has reviewed and approved issued a favourable opinion in relation to this study (REC Number: 25/NW/0039).

How can I find out about the results of this study?

- If you agree to take part in this study, you can choose to be notified about the study findings and any research articles written about it.
- We will let you know about the results at the end of the study using an easily understandable summary.
- During the study we will also write a newsletter that includes updates about the study and share this using email, the study website and social media accounts listed below.

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What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researcher(s), using the details below, who will do their best to answer your questions**.**

Researcher(s)

Dr Fraser Philp	f.philp@liverpool.ac.uk	07436 052949

Alternatively, if you do not wish to contact the researcher you may contact other members of the research team.

The Walton Centre, Liverpool	**The Royal Wolverhampton NHS trust**
Principal investigator	**Principal investigator**
Mrs Jenny Thain	**Mr Dan Kucharczyk**
wcft.researchnurses2@nhs.net	rwh-tr.msnurses@nhs.net
0151 5563721	07990 777518

Research assistant (both sites)
Sugnia Rajkishor
[INSERT CONTACT EMAIL]
0151 5563721

Making a complaint

If you remain unhappy and wish to complain formally, you can do this by contacting the Clinical Research, Sponsorship and Governance Manager who is the University's contact for complaints regarding research. Details can be obtained below.

Clinical Research, Sponsorship and Governance Manager
Clinical Directorate
Miss Karen Wilding
4th Floor Thompson Yates Building, Faculty of Health and Life Sciences
University of Liverpool
Liverpool, L69 3GB
Tel: 07717 863747
Email: sponsor@liverpool.ac.uk

You could also contact Patient Advice and Liaison Service (PALS) at your hospital to assist you with any issue, concern, feedback and/or complaint related to this study:

Patient Experience Manager / PALS Lead

- The Walton Centre – https://www.nhs.uk/services/service-directory/the-walton-centre/N10866798
- The Royal Wolverhampton NHS trust - https://www.royalwolverhampton.nhs.uk/visiting-us/patient-experience-team/patient-experience-team.html

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What if something goes wrong?

The University of Liverpool holds Indemnity and insurance cover with Griffiths and Armour, which apply to this study.

Every care will be taken in the course of this clinical study. However, in the unlikely event that you are harmed by taking part in this research project of the study Sponsor (University of Liverpool), compensation may be available and you may have to pay your related legal costs. The team where you receive your treatment has a duty of care to you whether or not you agree to participate in the study and the study Sponsor accepts no liability for negligence on the part of your hospital's employees. However, if you are harmed and this is due to someone's negligence at the hospital, then you may have grounds for a legal action for compensation against the NHS Trust where you are being treated but you may have to pay for your legal costs. The normal National Health Service complaints procedures remain available to you.

More information about the STIM MS study

X: @STIM_MS

Website: confirm domain name

Scan the QR code below to go to the STIM MS website.

[insert holding code]

Thank you for taking the time to read this information sheet.

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