UNIVERSITY OF LIVERPOOL

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STIM MS v1.0

INFORMATION SHEET

HEALTHCARE PROFESSIONALS – 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 who helped in the running of the randomised controlled feasibility study investigating surface neuromuscular stimulation as an exercise therapy versus usual care in people with multiple sclerosis.
- If you would like this information in a different format such as an audio recording, please let us know.
- Please take some time to read this document carefully before you decide. If there is anything that is not very clear, or if you need more information, the research team at will be happy to answer any questions you may have. Their contact details are at the back of this leaflet.
- Before you make a decision about taking 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 trying to gather 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.
- Before we can do a large study to find out if muscle stimulation as an exercise therapy works, we need to
    - Find out from people who were involved in running and delivering the study how they found it e.g. practicalities of delivering the intervention, running the study and any recommendations for a future trial.
- This will help us decide if we can do the large future study and what needs to be changed.

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Why am I being invited?

- We are inviting you to take part in this study as someone who was involved in the running and delivery of the STIM MS 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 to keep, 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 people involved in similar research.

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

- A member of the research team will contact you by telephone 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 give you at least 24 hours before speaking with you about the study but you can take as much time as you need.

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

- You will be asked to take part in a single interview lasting no more than 60 minutes.
- This will be at the end of the STIM MS study.
- This can be done over the telephone or online at a time that suits you best.
- The conversations will be about your involvement in the study, how you found people responded to the group they were put into, what outcomes or measures you felt were important and any feedback on the study information, processes, muscle stimulation programme and how we can improve them to better support people in a future study.
- We will also ask you about the practicality of delivering the intervention across different settings and any recommendations for a future trial.
- 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.

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What are the benefits of my taking part?

- We cannot guarantee any direct and immediate benefits from this study.
- We hope that participation will help us gather 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 the study.
- Taking part in this study requires time to attend and be interviewed.

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
  - place of work
  - 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:
- People 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 data will have 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 data so we can check the results. We will write our reports in 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.

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What are your choices about how information is used?

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- You can stop being part of the 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 in order for the research to be reliable. This means that we won't be able to let you see or change the data 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.

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 interview, we become aware of anything that makes us concerned for you or the people you help look after, we are required to report any safeguarding issues in accordance with the local hospitals safeguarding trust policies.
- Patient information for safeguarding at the trust 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 to participate, or not, we recommend that you speak to relatives, friends, acquaintances, and/or any health professional that you might think would give good insight and advice. Also, if there is any unclear issue about this study, please do not hesitate to contact the researcher, who would be more than happy to answer all of your questions.
- Please allow yourself to take a considerable time to think before you make your decision.

What should I do next?

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

Who is funding and organising the research?

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

Who is running the study?

- 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.
- 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).

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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

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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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