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STIM -MS

EASY READ INFO & KEY FACTS SHEET

APPROX. READ TIME

12 MINS

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)

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RESEARCH TEAM

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HOSPITAL SITES (DOING THE RESEARCH)

The Walton Centre NHS Foundation Trust

NHS The Royal Wolverhampton NHS Trust

OTHER NHS PARTNERS (PROVIDING EXPERTISE)

NHS The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust

UNIVERSITIES

UNIVERSITY OF LIVERPOOL

Bournemouth University

PRIFYSGOL BANGOR UNIVERSITY

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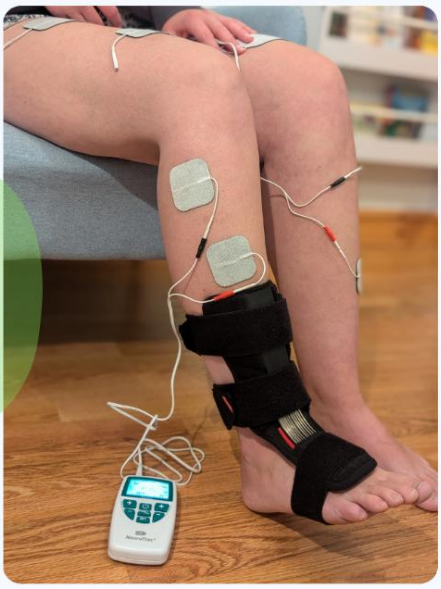
WHAT IS MUSCLE STIMULATION?

MUSCLE STIMULATION MAKES THE MUSCLES CONTRACT IN A SIMILAR WAY TO EXERCISING WITH WEIGHTS

IT USES PAINLESS ELECTRICAL SIGNALS & STICKY PADS ON THE SKIN



MUSCLE STIMULATORS ARE ALREADY USED IN SOME NEUROLOGICAL CONDITIONS

IT CAN BE USED AT HOME

PLEASE BE AWARE

NOT EVERYONE WILL BE GIVEN A MUSCLE STIMULATOR,

BUT YOUR INVOLVEMENT IS JUST AS IMPORTANT

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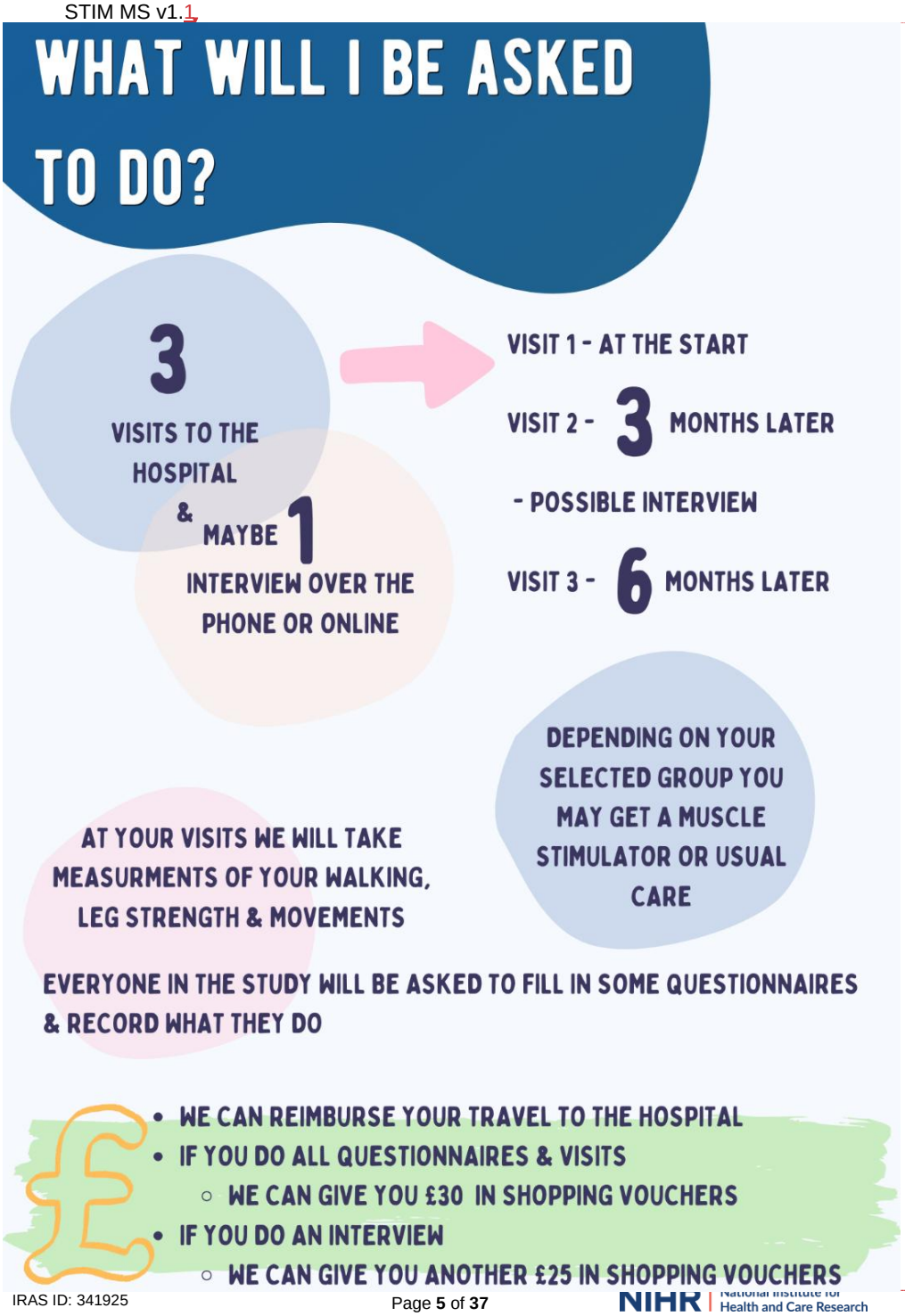

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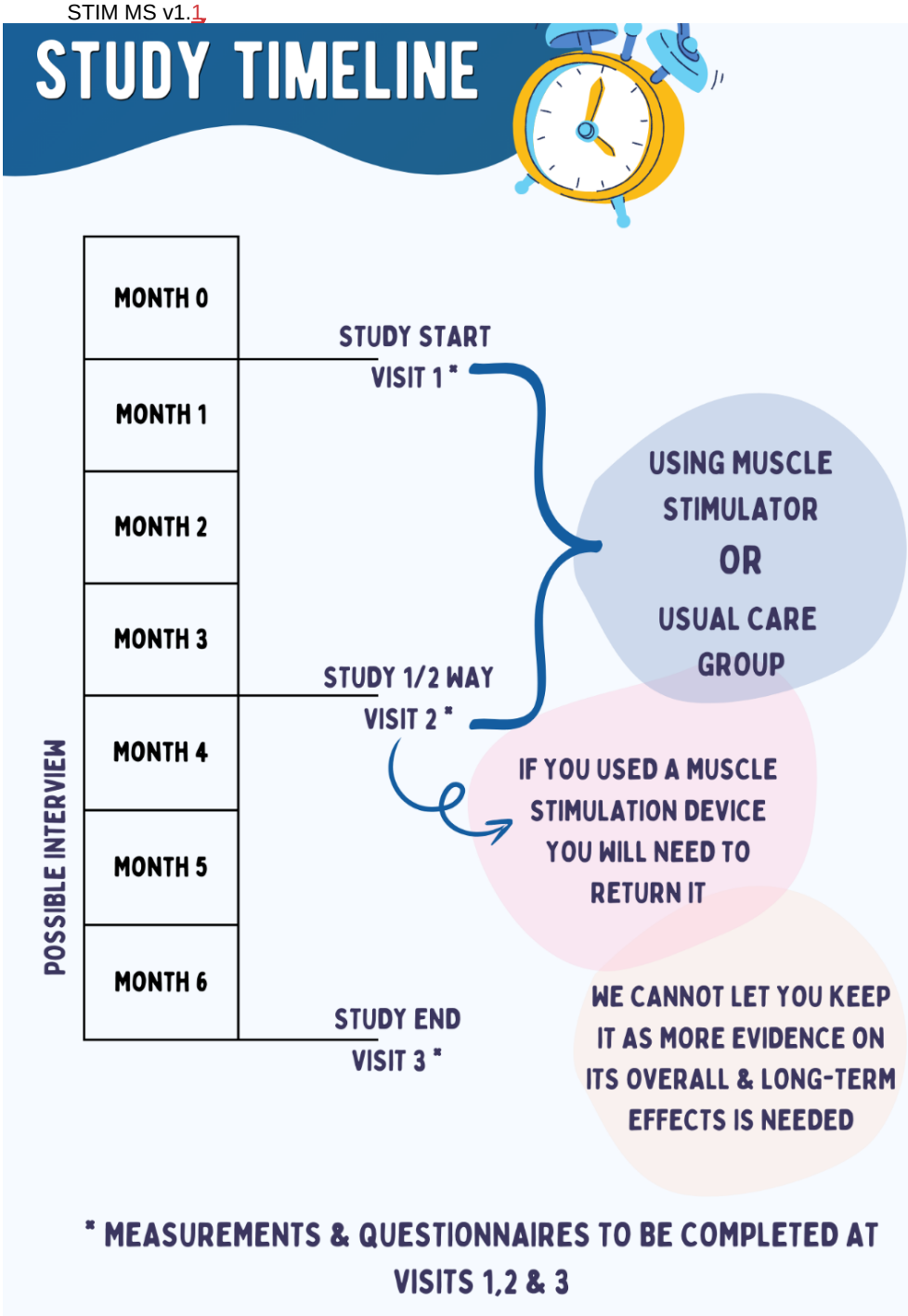

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DO I HAVE TO TAKE PART?

NO

- YOU DON'T HAVE TO TAKE PART
- YOU CAN STOP BEING IN THE STUDY AT ANY STAGE
- BUT WE WILL KEEP INFORMATION THAT HAS ALREADY BEEN COLLECTED

YOU DON'T HAVE TO TELL US WHY YOU DECIDE NOT TO TAKE PART OR WITHDRAW

WE MAY ASK YOU TO SHARE YOUR REASON. UNDERSTANDING THIS MAY HELP PLAN OUR FUTURE STUDY & BETTER SUPPORT PEOPLE

PEOPLE WITH MS HELPED DESIGN THIS STUDY

THEY ARE IN OUR RESEARCH TEAM
WE HAVE WORKED WITH THEM, MAKING SURE WE HELP PEOPLE STAY IN THE STUDY & COMPLETE THE QUESTIONNAIRES

AS MANY AS

1 IN 3 PEOPLE

STOP COMPLETING THE QUESTIONNAIRES OR WITHDRAW FROM MUSCLE STIMULATION STUDIES IN MS

IF NOT ENOUGH PEOPLE STAY IN THE STUDY OR COMPLETE THE QUESTIONNAURE, WE MAY NOT BE ABLE TO DO THE FUTURE STUDY

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WHO DECIDES WHICH GROUP I GO IN?

AT THE 1ST VISIT
WE USE A PROCESS CALLED
"RANDOMISATION"

THIS DECIDES WHETHER YOU WILL BE IN THE MUSCLE STIMULATION OR USUAL CARE GROUP

"RANDOMISATION" MEANS THAT EACH PERSON TAKING PART IN THE STUDY HAS AN EQUAL CHANCE OF BEING SELECTED FOR EITHER GROUP

THIS HELPS ENSURE THE STUDY IS A FAIR TEST

BOTH GROUPS WILL

- DO THE SAME MEASUREMENTS & QUESTIONNARES AT EACH VISIT
- RECORD SOME INFORMATION ABOUT
  - HOW MUCH PHYSICAL ACTIVITY THEY DO &
  - WHAT THEY GET AS A PART OF USUAL CARE

WE WILL ALSO PHONE YOU IN THE 1ST AND 6TH WEEK TO SEE HOW YOU ARE GETTING ON

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WHAT DOES MUSCLE STIMULATION INVOLVE?

MUSCLE STIMULATION

HALF OF THE PEOPLE WHO VOLUNTEER WILL BE PUT IN THIS GROUP

THE OTHER HALF WILL BE IN THE USUAL CARE GROUP

IF YOU ARE SELECTED FOR THE MUSLE STIMULATION GROUP

- YOU WILL GET YOUR USUAL CARE &
- WE WILL GIVE YOU THE EQUIPMENT
  - MUSCLE STIMULATOR, KNEE & ANKLE BRACES
- SHOW YOU HOW TO USE IT.
  - OR SOMEONE WHO LOOKS AFTER YOU
- GIVE YOU A BOOKLET TO HELP & SOMEONE YOU CAN CALL
  - WE WILL ASK YOU TO RECORD IN THE BOOKLET HOW OFTEN YOU USE THE MUSCLE STIMULATOR
- THE MUSCLE STIMULATOR WILL ALSO RECORD HOW OFTEN YOU USE IT

YOU START THE MUSCLE STIMULATION PROTOCOL AT A LEVEL YOU ARE COMFORTABLE WITH (FROM 15 MINS).

YOU WILL THEN WORK UP TO

- 3-4 SESSIONS/WEEK, ONCE A DAY
- MAXIMUM 30 MINS
- DOING THE FRONT & BACK THIGH & LOWER LEG MUSCLES

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WHAT DOES USUAL CARE INVOLVE?

USUAL CARE

BOTH GROUPS WILL RECIEVE THEIR USUAL CARE

HALF OF THE PEOPLE WHO VOLUNTEER WILL BE PUT IN THE USUAL CARE ONLY GROUP

- USUAL CARE IS USED TO DESCRIBE THE NORMAL, STANDARD OR ROUTINE CARE THAT YOU WOULD GET AS A PART OF HELPING TO MANAGE YOUR MS.
- WE WILL PROVIDE BOTH GROUPS WITH AN INFORMATION BOOKLET & DIARY THAT SIGNPOSTS ADVICE & INFORMATION ABOUT PHYSICAL ACTIVITY, EXERCISE &OTHER THINGS DELIVERED AS A PART OF USUAL CARE.
- THE INFORMATION BOOKLET & DIARY CAN BE USED TO KEEP TRACK OF
  - WHAT YOU GET AS A PART OF YOUR USUAL CARE &
  - ANY PHYSICAL ACTIVITY OR EXERCISES YOU USUALLY DO

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WHAT DO THE GROUPS HAVE TO DO?

MUSCLE STIMULATION

YOU WILL GET THE SAME AS THE USUAL CARE GROUP AND

WE WILL

- GIVE YOU THE EQUIPMENT
- SHOW YOU (OR SOMEONE WHO LOOKS AFTER YOU) HOW TO USE IT
- GIVE YOU A BOOKLET TO HELP & SOMEONE YOU CAN CALL

YOU START THE MUSCLE STIMULATION PROTOCOL AT A LEVEL YOU ARE COMFORTABLE WITH (FROM 15 MINS)

YOU WILL THEN WORK UP TO

- 3-4 SESSIONS/WEEK, ONCE A DAY
- MAXIMUM 30 MINS
- DOING THE FRONT & BACK THIGH & LOWER LEG MUSCLES

USUAL CARE

YOU WLL GET YOUR USUAL CARE

COMPLETE THE SAME MEASUREMENTS & QUESTIONNARES AT EACH VISIT

A PHONE CALL IN THE 1ST AND 6TH WEEK

RECORD INFORMATION ABOUT WHAT YOU GET AS A PART OF USUAL CARE E.G. HOSPITAL VISITS, REHABILITATION

RECORD HOW MUCH PHYSICAL ACTIVITY YOU DO

POSSIBLY BE INVOLVED IN AN INTERVIEW

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WHO CAN TAKE PART?

YOU CAN BE INVOLVED IN THIS STUDY IF

YOU HAVE

- ANY FORM OF MULTIPLE SCLEROSIS
- PROBLEMS WITH YOUR WALKING BUT CAN WALK AT LEAST 20 METERS WITHOUT RESTING (WITH OR WITHOUT WALKING AIDS)

YOU CANNOT BE INVOVLED IN THIS STUDY IF

- YOU HAVE CLINICALLY ISOLATED SYNDROME
- ARE IN RELAPSES OR HAVE HAD A RELAPSE IN THE LAST 8 WEEKS
- ARE PREGNANT
- HAVE UNCONTROLLED EPILEPSY
- ARE UNABLE TO USE THE EQUIPMENT
  - EITHER BY YOURSELF OR WITH SOMEONE ELSE TO HELP YOU
- OTHER MEDICAL CONDITIONS THAT AFFECT YOUR WALKING E.G. A STROKE
  - YOU HAVE ANY OF THE FOLLOWING IN YOUR LEGS:
  - NERVE INJURY
  - BROKEN BONE
  - CANCER
  - SKIN INFECTION OR POOR SKIN INTEGRITY WHERE THE ELECTRODES WILL BE PLACED

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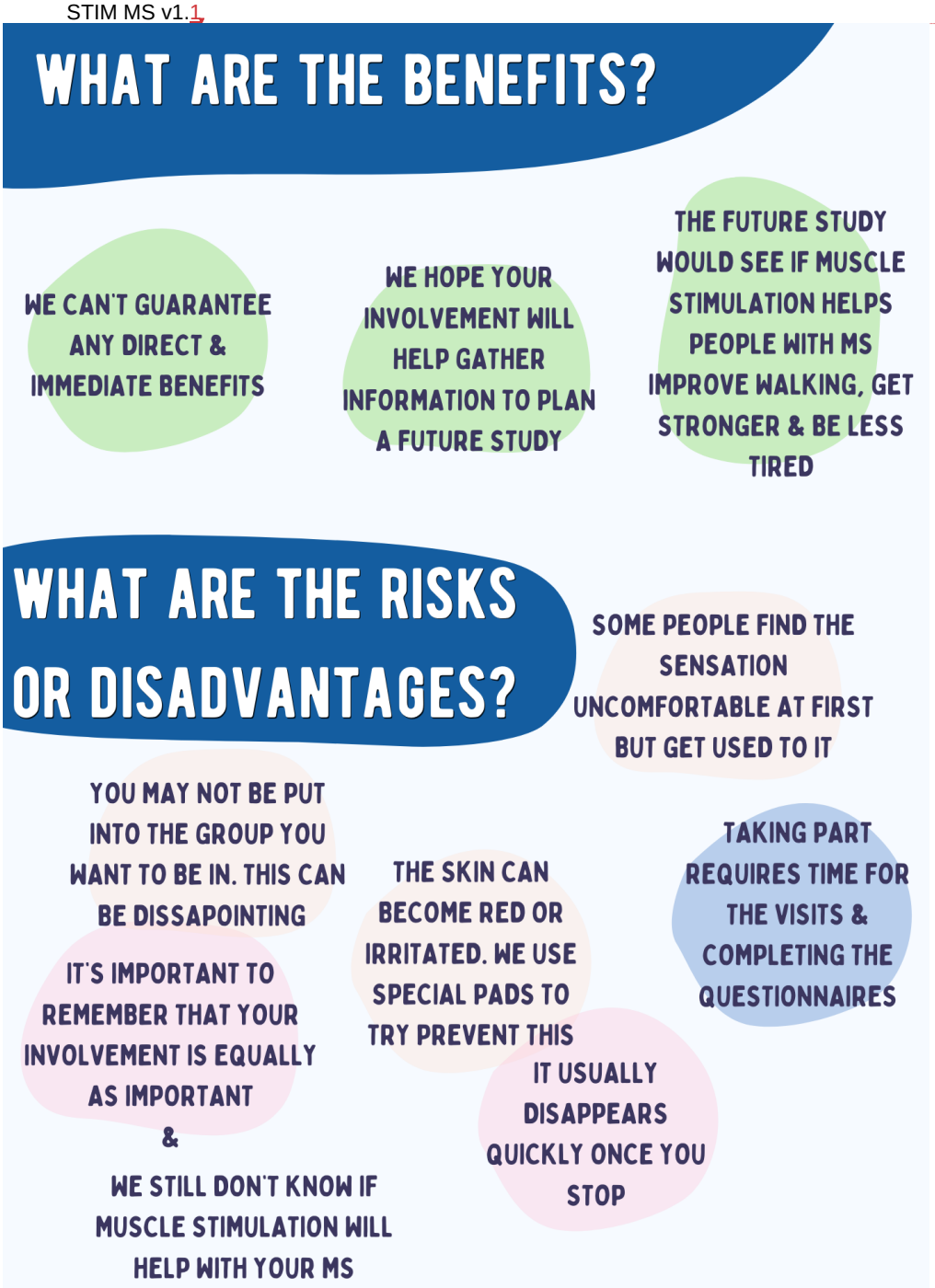

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HOW WILL MY INFORMATION BE USED?

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

PEOPLE MAY CHECK YOUR RECORDS TO MAKE SURE THAT THE RESEARCH IS BEING DONE PROPERLY

WE WILL WRITE OUR REPORTS IN A WAY THAT NO-ONE CAN WORK OUT THAT YOU TOOK PART IN THE STUDY

IF WE BECOME AWARE OF ANYTHING THAT MAKES US CONCERNED FOR YOUR SAFETY, WE ARE REQUIRED TO REPORT ANY SAFEGUARDING ISSUES IN ACCORDANCE WITH THE LOCAL HOSPITALS SAFEGUARDING TRUST POLICIES

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FREQUENTLY ASKED QUESTIONS

Q. CAN I CHANGE MY GROUP IN THE STUDY?

A. IT IS NOT POSSIBLE CHOOSE OR SWAP GROUPS IN THE STUDY. THIS IS TO MAKE SURE THE STUDY IS FAIR ONCE YOUR GROUP HAS BEEN SELECTED.

Q. HOW LONG WILL THE HOSPITAL VISITS TAKE?

A. WE DO NOT EXPECT THE VISITS TO LAST MORE THAN 2 TO 3 HOURS. THE VISITS MAY BE QUICKER, BUT WE WANT TO MAKE SURE YOU HAVE ENOUGH TIME TO DO ALL THE MEASUREMENTS & QUESTIONNAIRES WITHOUT GETTING TOO TIRED. WE WILL TRY AND MAKE THIS QUICKER AND EASIER FOR YOU BY SENDING THE QUESTIONNAIRES BEFORE YOUR VISITS.

Q. WHAT WILL THE QUESTIONNAIRES INVOLVE?

A. THEY WILL ASK QUESTIONS ABOUT YOUR MS, HOW TIRED YOU ARE, WHAT YOU CAN DO IN DAILY LIFE & ABOUT ANY MEDICAL APPOINTMENTS. WE CAN SEND PAPER OR ONLINE COPIES DEPENDING ON YOUR PREFERENCE.

Q. WHAT DOES THE INTERVIEW INVOVLE?

A. IT WILL BE A CONVERSATION OVER THE PHONE OR ONLINE. WE WANT TO HEAR ABOUT YOUR EXPERIENCES OF THE STUDY SUCH US DECISIONS TO TAKE PART, HOW YOU FOUND THE GROUP YOU WERE PUT INTO, WHAT WAS IMPORTANT TO YOU & ANY FEEDBACK TO HELP IMPROVE A FUTURE STUDY.

Q. WHY WON'T EVERYONE HAVE AN INTERVIEW?

A. WE NEED TO MAKE SURE WE GET A BROAD RANGE OF EXPERIENCES. THEREFORE WE WILL SELECT PEOPLE BASED ON THINGS SUCH AS WHICH HOSPITAL THEY WERE AT, THEIR WALKING ABILITY, DEMOGRAPHICS & WHICH STUDY GROUP THEY WERE IN.

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MORE INFORMATION

THANK YOU
FOR TAKING THE TIME TO READ
THIS INFORMATION SHEET

FURTHER INFORMATION IS PROVIDED
IN THE FULL READ INFORMATION
SHEET AFTER THIS LEAFLET

IF YOU HAVE ANY MORE QUESTIONS
PLEASE FEEL FREE TO CONTACT THE
RESEARCH TEAM USING THE DETAILS
PROVIDED AT THE END

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INFORMATION SHEET

(Approximate read time: 15 to 20 minutes)

PEOPLE WITH MULTIPLE SCLEROSIS

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) to volunteer and help us in this study. You are being invited to consider taking part.
- This information is available in Punjabi, Polish and Urdu.
- If you would like this information in a different language or in a different format (such as audio recordings), please contact the team using the details on the last page.
- 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 these information sheets.
- Before you decide whether to take part, 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.

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Why are we doing this study?

- We are carrying out this study to help us 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 they use the muscle stimulation equipment regularly.
- 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.



What does usual care involve?

- Usual care is used to describe the normal, standard or routine care that you would get as a part of helping to manage your MS.
- In this study you will continue to get your usual care, and we will provide you with an information booklet and diary that
    - signposts advice and information about physical activity, exercise and other things delivered as a part of usual care, and
    - can be used to keep track of what you get as a part of your usual care and any physical activity or exercises you usually do

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Why am I being invited?

- We are inviting you to take part in this study as you have MS and can walk at least 20 metres without resting (with walking aids if needed).

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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.
- If you decide to stop being involved in the study, we may ask if you are still happy for us to collect some information about you.
- We are making every effort to support people to stay in the study and complete all the questionnaires.
- As many as 1 in 3 people do not stay in MS research studies or complete all the measurements and questionnaires.
- Completing the measurements and questionnaires is important. If not enough people complete them we may not find out enough to be able to do the future study.

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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. We can then organise a date and time to see you at the hospital for your first visit.
- 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 appreciate that there is lots of information in these information sheets. We have made a key facts sheet 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 is below.
- If you take part, you will be in the study for **a total of 6 months** and you will **need to visit the hospital a total of 3 times:**
    - at the start and then
    - 3 months later and
    - 6 months later

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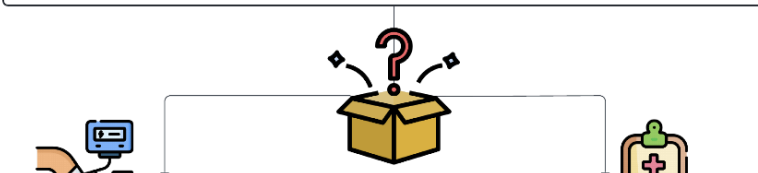
STUDY FLOW CHART

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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Visit 1 – Start of the study

- We will collect some information about how your MS affects you. This will include some questions about you and your MS and filling in questionnaires about mobility, pain spasm, fatigue and quality of life.
- We will also take some measurements of your walking ability, leg strength and joint movements.
- We will make sure you have enough time and can complete the measurements and questionnaires at a comfortable pace. Where possible will send you information beforehand.

- After the first measurements we will use a process called **"randomisation"** to decide whether you will be in the muscle stimulation or usual care group.
    - **"Randomisation"** means that **each person** taking part in the study **has an equal chance** of being selected for either group. This helps ensure the study is a fair test.
- If you are selected for the **usual care group,** you will continue to receive your usual care.
- If you are selected for the **muscle stimulation group**, you will also continue to receive your usual care, but we will also ask you to use a muscle stimulation machine for 12-weeks.
- Regardless of the group you are in, we will ask you to record some information about any exercise or physical activity you have been doing, and what you do or receive as a part of your usual care.
- We will also **phone you in the 1st and 6th week** to see how you are getting on.

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- If you are in the **muscle stimulation group**, we will give you the machine to use and all the necessary equipment.
- At the 1st visit we will show you (or the person who helps look after you) how to use it. Someone will also be available to provide advice and help, if needed, once you leave the hospital.
- We will provide you with an instruction booklet that will include a diary so you can fill in how often you use the muscle stimulation machine and any challenges or feedback about using it.
- The muscle stimulation machine will also record how often you use it and at the end of the study, data from the device will be downloaded and analysed.

- We will ask you to use the muscle stimulation machine once each day. You will be able to start at a level you feel comfortable with (from a minimum of 15 minutes per day) and we will ask you to gradually work up to completing:
    - 3-4 sessions per week, with each session lasting a maximum of **30 minutes.**
    - The stimulation will target the muscles on the front and back of your thighs (quadriceps and hamstrings) and lower legs (tibialis anterior and calf muscle group).

- We understand that use of the stimulation machine is likely to vary depending on what kind of a day someone is having, their MS symptoms, and how busy their life is. This is okay so long as you record this information, it could help us support people better in a future study.

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Visit 2 – The ½ way point of the study - 3 months

- After 12-weeks we will ask people from both groups to **come back to the hospital** and complete the same measurements and questionnaires as in the first visit plus a few new questions.

- We will collect the information you recorded about your usual care.
- People in the **muscle stimulation group will be asked to return the muscle stimulation machine**. It won't be possible to keep the machine as we still don't know enough about its' overall and long-term effects.
- This is what we want to test in a future bigger study.
- After this visit, we will ask you to continue collecting information on any medical appointments you have or if you experience any changes to your MS and symptoms.

Interview

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- After the 2nd visit, some people who took part in the study, and the people who look after them, may be invited for an interview (over the phone or online) to find out about their experiences of being in the study.
- We will ask them about deciding to take part in the study, how they felt about being put into one of two groups and what outcomes or measures were most important. We will also ask for feedback on the study information, processes, muscle stimulation programme and any improvements we could make to support people in a future study.

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- 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.

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- 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.

Visit 3 – End of the study – 6 months

- After 6 months, we will ask people from both groups to **return to the hospital** and redo the same measurements and questionnaires as in the previous visits.

What will the measurement tests at the hospital involve?

- At your visits, we will take some measurements of your walking ability, leg strength and joint movements.
- This will involve some walking tests that:
  - ask you to walk as far as you can in 2 minutes and
  - see how quickly you can stand up from a chair, walk and come back.
- All of these will be done at a pace you are happy and comfortable with.

- Because of this, we suggest that for all visits:
  - comfortable clothing is worn.
  - appropriate shoes for walking are worn,
  - you bring and use your usual walking aids during the test (cane, walker, etc.)
  - you continue your usual medical regimen,
  - a light meal is acceptable before early morning or early afternoon tests,
  - avoid any vigorous exercise within 2 hours of the visit.

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

- We will reimburse you for your study visit travel to the hospital.
- If you need to post anything back to us, we will provide you with pre-paid envelopes.
- We will also offer you a £15 shopping voucher (£30 in total) to thank you for your time when attending the hospital and completing the questionnaires for the 2nd and 3rd visits.
- If you take part in an interview (phone or online) about the study, we will give you a £25 voucher in appreciation of your time.
- You can choose to have the questionnaires emailed to you via an online link or by post. We will send these out before your appointments and make sure you have enough time to complete them and ask questions.
- If you need help completing the questionnaires over the phone, one of the research team will be available to help you.
- We may contact you to follow up and offer support if we have not received your questionnaires.
- We will let your care team know that you are taking part in this study, but this is for their information only.

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What are the benefits of my taking part?

- We cannot guarantee any direct and immediate benefits to you from this study.
- We hope that your 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.

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What are the risks and disadvantages of my taking part?

- Muscle stimulation is used commonly to assist with walking in people with MS, known as 'functional electrical stimulation' or FES. The stimulation device used is very similar, but we are just using it in a different way for our study.
- As a part of this study, we are investigating if there are any risks for people with MS who use muscle stimulation as an exercise therapy. We will monitor these closely during the study and ask you to let us know if you experience any problems.
- Some people can find the sensation uncomfortable at first. If you are put in the muscle stimulation group, you will have a chance to try out the equipment and make sure you are happy using it.
- Sometimes the pads placed on the skin can cause some irritation or redness. In most cases this disappears quite quickly once the pads have been removed, but if it becomes uncomfortable or stays irritated, we will ask you to let your local research team know and they can advise you on what to do.
- As we are using randomisation to put people into the two groups, there is an equal chance of you getting or not getting put into the muscle stimulator group. Sometimes people can feel disappointed by this, however, currently we still don't know if using the muscle stimulator will help with your MS.
- Even if you aren't put into to use the muscle stimulator group, your **involvement in the usual care group** and **completion of the measurements** and **questionnaires is equally as important**.
- It **helps us to make important comparisons** with the group who used the muscle stimulator.
- Taking part in this study requires time to complete the questionnaires and attend the hospital for measurements.

How will we use information about you?

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- We will need to use information from you and your medical records for this research project. This information will include your
  - name
  - date of birth
  - sex
  - ethnicity
  - post code
  - contact details
  - relevant medical notes regarding your MS and medical appointments

- 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 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.
- If you agree, we may notify any relevant health and care professionals involved in your care about your participation in this study.
- All information will be kept secure in lockable facilities or using password protected computers and online systems.
- 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.

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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.
- If during the study, you lose capacity (the ability to understand and retain information or weigh up the options and consequences of your decisions) you can no longer be a part of the study and will be withdrawn. We will still keep and use the information already collected with your consent, but no further information will be collected.
- We need to manage your records in specific ways, so the research is 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

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Safeguarding

- If during the study, or your visit, we become aware of anything that makes us concerned for your safety, we are required to report any safeguarding issues in accordance with the local hospital 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

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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.
- If there is anything about this study that is unclear, please do not hesitate to contact your local research team, who will be more than happy to answer all your questions.
- Please take all the time you need before making 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 the visit.

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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.

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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 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

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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

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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

What if something goes wrong?

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

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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

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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 QR code]

Thank you for taking the time to read this information sheet

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