

INTERACT-MS

Participant Information Sheet for Healthcare Professionals

We are inviting you to take part in our study:

Assessing NHS ImplemeNTation of an onlinE Resilience-training Acceptance and Commitment Therapy (ACT) programme to prevent job loss in MS (INTERACT-MS)

- Please take the time to read this information sheet carefully and discuss it with your family and friends
- If you are interested in taking part, you will be asked to complete a consent form and given a copy of the form and this sheet to keep

1. Why is the study being done?

Some people with multiple sclerosis (PwMS) find it difficult to stay in work. Psychological factors that affect PwMS may make it more difficult to manage staying in work. These can include psychological flexibility, which is the ability to effectively manage unwanted inner experiences (e.g., thoughts, memories, bodily sensations) in the present, as well as self-efficacy, which is the self-belief that an individual has in their ability to succeed.

There is a type of treatment which improves psychological flexibility and self-efficacy called “Acceptance and Commitment Therapy” (ACT). An online ACT-type programme called ‘READY’ (REsilience and Activities for every DaY) has recently been developed in the UK with the help of PwMS. This online programme may be helpful for PwMS who want to stay in work. READY can be used on a computer or mobile device and does not need time off work traveling to see a psychologist.

We want to test the READY programme in multiple NHS settings to see how it can be supported by healthcare professionals. It is important to assess that READY can be delivered and received as intended; this is known as ‘Intervention fidelity’. This is important for checking (validating) the use of READY in a real-world setting.

To do this, we will train MS healthcare professionals to support the delivery of READY and then check whether it has been delivered and received as intended. We will also check that READY continues to provide the intended benefits for PwMS who receive it. The READY programme is mostly self-guided with support from a facilitator. As such, it should not add significant burden to the healthcare professional workload.

We have already developed a questionnaire called the MS Work Instability Scale (MS-WIS) to help find out if PwMS are finding any parts of their job more difficult. This means we can use the questionnaire to target those who would be likely to get the most benefit from being in the trial.

2. Why am I being asked to take part?

You are being asked to take part as you are a registered or allied healthcare professional who is responsible for patients with multiple sclerosis (MS) as part of your job.

3. What will I need to do if I take part?

If you decide to take part, you will need to first sign a consent form. You will have the opportunity to ask any questions about the study and receive satisfactory answers before signing the consent form.

We plan to recruit 50 healthcare professionals and 250 people with MS to take part in the trial of the READY programme. The programme involves completing 7 online sessions delivered over 7 weeks and a further refresher session at 12 weeks. There is also a workbook to help with the online sessions. The whole-time commitment for all participation activities in this study is approximately 8 hours in total. This includes completing the READY programme modules and any questionnaires.

We will provide an introductory session to explain the programme to you and then you will be invited to complete the programme yourself. The programme content is not specific to MS and so you can use it to develop ACT-based skills or to focus on your own wellbeing.

A trained psychologist will contact you by telephone approximately halfway through the programme to see if there are any issues and provide additional support if needed. This support call will be audio-recorded, and the psychologist or researcher will make notes on any troubleshooting topics that arise from these support calls. Anonymised troubleshooting examples will be used to develop 'case examples' in a 'troubleshooting toolkit'. This troubleshooting toolkit will be shared with PwMS who use the programme and a copy given to you to aid support conversations you conduct later in the study.

Each module will be of approximately 30 minutes duration. The modules will consist of engaging animated presentations, guided experiential exercises, video clips, audio files and written exercises. The programme will be accompanied by a digital workbook which consists of two parts: written content for each module and your 'READY Personal Plan'.

The READY Personal Plan is an important resource as it contains reflection exercises and directed home practice tasks that are undertaken during and between modules. You can choose to print this workbook to complete at home or you can complete it on the computer. The workbook is personal to you and you will not be asked to share it with us.

You will be asked to complete questionnaires at the beginning of the study (baseline) and at 8 weeks and 6 months. The questionnaires will collect information about your work type, resilience,

psychological flexibility, and user experience. The questionnaire will take about half an hour to complete. The questionnaire can be completed and returned online.

Once you have completed the programme, you will be invited to a training workshop to help develop your ACT-based skills and prepare you for supporting patients with MS who will be completing the programme.

Following this training workshop, you will be asked to complete a knowledge questionnaire and have the opportunity to provide feedback on your experience of the training and any anticipated barriers to supporting others to complete the programme.

You will be asked to support a small number of patients with MS to complete the programme (approximately 5). This will involve contacting each patient approximately halfway through their completion of the programme (similar to how you were contacted by the psychologist) and make notes on any topics that arise. You will be provided with a 'troubleshooting toolkit' to aid these support conversations.

Once patients with MS begin to complete the programme, you will be sent optional pulse surveys at 2-weekly intervals. These brief surveys should take less than 5 minutes to complete and can be returned online. You will also be invited to take part in optional additional unstructured tele-interviews to discuss your responses further. These tele-interviews will be audio-recorded, with your verbal consent, and used to produce anonymised reports throughout the study.

Optional sub-study:

You may also be asked to have an interview with one of our researchers after you have completed the online sessions to understand your expectations around supporting patients with MS to complete the programme. The interview will last for 30 minutes.

The interview will be audio-recorded with your consent so that it can be transcribed and analysed. Interviews will be audio-recorded on an encrypted recording device and audio files and transcripts will be stored on a password protected secure drive with restricted access.

Audio files will be transcribed by an independent transcriptionist who will treat it as strictly confidential and delete audio-files and materials after providing us with the transcript. Transcripts will be anonymised.

4. What are the possible benefits of taking part?

The possible benefit of taking part is that the READY programme has been shown to lead to personal and professional benefits for health professionals. ACT interventions have also been shown to protect against burnout.

Training health professionals to support the UK digital READY programme may improve access to psychological interventions for PwMS who would benefit from them. MS nurses, occupational therapists, and physiotherapists may also be able to offer more personalised support as part of the digital READY programme.

There is an unmet need for timely interventions with a focus on keeping PwMS in work. Effective interventions need to be flexible and easily accessible for employed people. If this implementation trial is successful then the online READY may be made more widely available for PwMS to use.

All of the participants in the trial will receive a full report on the outcomes from the study.

5. What are the possible disadvantages and risks of taking part?

There are no blood tests or invasive tests and therefore we do not anticipate any physical distress. Some people can find completing questionnaires is stressful and can make them think about negative aspects of their psychological wellbeing.

The READY programme requires a commitment to completing an online session of 30 minutes every week for seven weeks and a refresher session at 12 weeks. There is also a workbook to use alongside these sessions. Some people may find it hard to keep up with doing the weekly sessions. We will send you reminders to help with this.

6. What if I do not want to take part, want to stop after I start the study, or lose capacity to continue taking part in the study?

Taking part in research is always voluntary. You will be free to withdraw from the study at any time by contacting the study team, even after you have signed the consent form, and you will not need to provide a reason.

If you lose capacity during the study, your participation and all identifiable data collected will be withdrawn from the study. Data which is not identifiable to the research team may be retained.

7. How will we use information about you?

We will need to use information from you for this research project.

This information will include your initials/ name/ contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

The Psychologist will be given your name and contact details to contact you for the support telephone call.

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.

What are your choices about how your information is used?

- 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 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.

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/
- our information on our website <https://www.leedsth.nhs.uk/patients-visitors/patient-and-visitor-information/how-we-use-your-data/>
- by asking one of the research team
- by sending an email to Leedsth-tr.informationgovernance@nhs.net
- by ringing us on 0113 2433144 and ask for the Data Protection Officer

8. Who is funding the study?

This study has been funded by a project grant from the UK MS Society.

9. Who is sponsoring the study?

This study is sponsored by Leeds Teaching Hospitals NHS Trust.

10. Who has reviewed the study?

The North of Scotland (2) Research Ethics Committee has reviewed the study.

11. Who should I contact for further information?

If you need any further information or have questions about the study please contact your local research team or the Project Lead below:

Project Lead: Charlotte Wicks
Leeds Teaching Hospitals NHS Trust
Tel: 0113 3925073
Email: charlotte.wicks1@nhs.net
Postal Address: Neurology Research Office, D Floor, Martin Wing, Great George Street, Leeds,
LS1 3EX

For questions related to research in general, or any concerns you have about the process of this research, you can contact the **Patient Advice Liaison Service** at Leeds by calling **0113 206 6261** or sending an email to patientexperience.leedsth@nhs.net

For general information about MS and Work, including legal advice, available support and information for employers, visit www.mssociety.org.uk/workandMS

Thank you for taking the time to consider this study
