

INTERACT-MS

Participant Information Sheet for People with Multiple Sclerosis

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
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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 aim to evaluate the READY programme in various NHS environments to determine how it can be effectively implemented by healthcare professionals. The goal is to ensure that the READY programme is delivering the outcomes it is supposed to be, a concept referred to as 'Intervention fidelity'. This is crucial for validating the application of READY in real-life settings.

To verify this, we intend to educate MS healthcare professionals on how to support delivery of the READY programme. We will then monitor how it is being delivered and received.

In addition, we will confirm that the programme continues to provide the expected benefits to PwMS who participate in it.

It is worth noting that the READY programme is primarily self-guided and supported by a facilitator, so it should not add significant pressure on the workload of healthcare professionals.

We have already developed a questionnaire called the MS Work Instability Scale (MS-WIS) to help find out if you are finding any parts of your 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 have multiple sclerosis (MS) and you are employed in a paid job. This includes working full-time or part-time or being self-employed.

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.

The first stage of the study will be completing the MS Work Instability Scale to see what you think about how you are coping with your job. This is a short questionnaire which takes about 15 minutes to complete.

The score on the questionnaire will show how well your job is going. If you have no problems at work then there will be no benefit for you in taking part in the study. If the questionnaire shows that you are having any problems or issues at work then we will ask you to take part in the trial.

We plan to recruit 250 people with MS to take part in the trial of the READY programme. All participants will receive 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.

Your MS healthcare provider will contact you by telephone approximately halfway through the programme to see if there are any issues and provide additional support if needed.

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 work, self-efficacy, mood, quality of life, fatigue and the impact of MS. The questionnaire will take about an hour to complete. The questionnaire can be completed and returned online.

Once you 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 before you start the study, after you have completed the online sessions and 6 months later.

Each interview will last for 30 minutes. These interviews will be used to understand the experience of using the digital READY programme and how it might be improved in the future.

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 help people with MS with 'bouncing back' (resilience) in the context of adversity. It aims to equip PwMS with skills to manage real world stressors.

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. All participants will continue to have access to the digital programme after the end of the trial.

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

Some people can find completing questionnaires is stressful and can make them think about problems related to their work or to living with MS.

Some people may feel distressed if the questionnaire highlights that they are having problems in their job. The MS nurses will be available to offer support and escalate any significant issues of psychological distress as necessary.

The READY programme may highlight thoughts and feelings that are uncomfortable or difficult to deal with. ACT-style therapy is designed to help you learn to cope with these difficult thoughts and feelings rather than avoid them. It is important to keep practicing the strategies and exercises in the READY programme for this to work.

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.

The MS nurses will be available to offer local support and advice.

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. Your medical care will not be affected by your decision to take part in this study or if you withdraw from the study.

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 your medical records for this research project.

This information will include your initials/ NHS number/ 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.

We will contact your GP to let them know you will be taking part in the study.

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 Manager below:

Project Manager:	Tel: 0113 3925073
Charlotte Wicks	Email: charlotte.wicks1@nhs.net
Department of Neurology	Postal Address: Neurology Research Office, D Floor,
Leeds Teaching Hospitals NHS Trust	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

Further support resources:

- **The Advisory, Conciliation and Arbitration Service (ACAS)**

ACAS provide free and impartial advice to employers, employees and their representatives on employment rights, best practice and policies, and resolving workplace conflict. Contact the ACAS helpline on **0300 123 1100** or visit <https://www.acas.org.uk/advice>

- **Equality Advisory Support Service (EASS)**

This Helpline advises and assists individuals on issues relating to equality and human rights, including disability employment rights. Call the EASS helpline on **0808 800 0082** or visit <https://www.gov.uk/equality-advisory-support-service>

- **Access to Work**

You may be able to claim a grant, based on your needs to cover:

- Special equipment, adaptations or a support worker to help you do things like answer the phone and go to meetings.
- Help getting to and from work and any travelling as part of your job.

Visit <https://www.gov.uk/access-to-work> for further information

- **Citizens' Advice Bureau**

Online, phone-based or face to face advice on a range of topics including:

- Your rights at work including pay, contracts, holiday and sick pay, agency workers' rights, flexible working and parental rights.
- Dealing with a problem at work.
- Discrimination at work

Visit <https://www.citizensadvice.org.uk/>

Thank you for taking the time to consider this study
