MS-PROACTIVE | Participant Information Sheet

We are inviting you to take part in our study:

Preventing job loss using Acceptance and Commitment Therapy in Vocational Rehabilitation (MS-PROACTIVE)

- 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) seem to cope better at work than others. Research suggests that this is not just due to the type of MS symptoms or degree of disability they have but that psychological factors may also be important. These might include things like mood (how anxious or depressed they might be), how much they feel in control of their lives and how much confidence they have in their own abilities to be able to negotiate their needs with their employer. Self-efficacy is something that PwMS describe as being difficult as they can lack confidence and self-belief in negotiating what they need from their employer and research has shown that this can lead to people losing their jobs.

There is a type of treatment which improves self-efficacy called “Acceptance and Commitment Therapy” (ACT). This can be used on the computer without having to go to hospital to see a psychologist. A type of ACT has been developed in Australia specifically for PwMS called ‘READY for MS’. We want to test whether this works in a trial with employed PwMS.

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 88 people with MS to take part in the trial of the READY for MS programme. The trial participants will be randomised to either receive 'the READY for MS programme and standard care' or 'standard care'. The active treatment group will complete 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. 'Standard care' includes the normal care from your MS team and a written information leaflet about employment and MS called 'Work and MS: An employee's guide' (produced by the MS Society).

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 digital program will be accompanied by a digital copy of the READY Participant Workbook which consists of two parts: written content for each module and the 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.

The MS nurses will contact the participants who are using the READY for MS online treatment at 2-3 weeks after randomisation to see if there are any issues or problems. The MS nurses will also be available to provide additional support if required to all participants in the trial.

All of the PwMS in the trial will be asked to complete questionnaires when they are first recruited (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.

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. The interview will last for 30 minutes. These interviews will be used to understand the experience of using the digital READY for MS 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 for MS 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 pilot trial is successful then the online READY for MS may be tested in a larger trial. In the longer term it 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 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 for MS 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, or want to stop after I start the study?

Taking part in research is always voluntary. You will be free to withdraw from the study at any time, 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.

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 should I contact for further information?

If you need any further information or have questions about the study please contact the Project Manager below:

Charlotte Wicks
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Great George Street,
Leeds, LS1 3EX

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Phone: 0113 3925073

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