

Pilot trial of an online Acceptance and Commitment Therapy course to help People with Multiple Sclerosis who want to stay in work

Submission date 09/12/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/12/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/09/2021	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

About 60-70% of people with multiple sclerosis (PwMS) lose employment within 10 years of the diagnosis. This can be due to complex personal and work-based factors including psychological factors. This study aims to test an online self-help therapy to support PwMS to stay in work called 'READY for MS'. This is a type of Acceptance and Commitment therapy. It is a way to provide treatment in a flexible way without people having to go to see a psychologist.

The aim of the treatment is to improve self-efficacy which has been shown to be a significant factor for helping PwMS who want to work to stay in work.

Who can participate?

Adults with a confirmed diagnosis of Multiple Sclerosis who are currently employed and are anticipated to remain so for the duration of the study.

What does the study involve?

The research team will initially develop an online version of READY for MS. Then 4 PwMS will be asked to test the online 'READY for MS' and provide feedback and advice on any necessary changes. The study team will then recruit a further 88 PwMS in Leeds and London who are at risk of job loss. Participants will be randomly allocated to either receive active treatment using the 'READY for MS' support in addition to their usual care or to receive usual care only.

The participants will complete questionnaires at the start of the study, at 8 weeks, and at 6 months measuring time off work and work instability (to measure the risk of job loss), self-efficacy, mood, quality of life, fatigue, and the impact of MS. The questionnaire data will be analysed to test the effectiveness of the treatment. The research team will also interview 4 PwMS at each site at the start of the study, at 8 weeks and 6 months to find out about their experience of using READY for MS in more detail. This will help to inform the use of READY for MS in a larger trial in the future.

What are the possible benefits and risks of participating?

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.

There are no blood tests or invasive tests and therefore physical distress is not anticipated. 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, so reminders will be sent to help with this.

Where is the study run from?

The Leeds Teaching Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?

From August 2020 to October 2022 (updated 13/09/2021, previously: June 2022)

Who is funding the study?

Multiple Sclerosis Society (UK) and the National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Dr Helen Ford

helen.ford17@nhs.net

Contact information

Type(s)

Public

Contact name

Ms Charlotte Wicks

ORCID ID

<http://orcid.org/0000-0002-4769-2249>

Contact details

Neurology Research Office

D Floor

Martin Wing

Leeds General Infirmary

Great George Street
Leeds
United Kingdom
LS1 3EX
+44 (0)113 3925073
charlotte.wicks1@nhs.net

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

279736

ClinicalTrials.gov number

NCT04515355

Secondary identifying numbers

CPMS 46161, IRAS 279736

Study information

Scientific Title

Preventing job loss using Acceptance and Commitment Therapy in Vocational Rehabilitation

Acronym

MS-PROACTIVE

Study objectives

Participants who complete the 'READY for MS' online ACT intervention will report a reduction in Work Instability level compared with the control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 13/08/2020, Yorkshire and the Humber - South Yorkshire REC (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; +44 (0)207 1048091; southyorks.rec@hra.nhs.uk), ref: 20/YH/0199

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Treatment

Participant information sheet

See additional file (ISRCTN14056874_PIS_v2.0_06July2020)

Health condition(s) or problem(s) studied

Multiple Sclerosis

Interventions

The adaptation of READY for MS and set up will last 6 months. The research team will work with a digital design company to develop the online version of READY for MS. Four PwMS will test the new online version completing seven, 30 min online sessions over seven weeks. The PwMS will feedback to the research team about their experience of completing the sessions and will advise on any changes needed. The research team will work with local clinical MS teams to prepare to set up the trial in Leeds and London.

There will be a 6 month period of recruitment. The MS clinical teams in Leeds and London will identify PwMS who are in paid employment in the MS outpatient services. The clinical teams will ask if they would like to receive further information about this study and if so whether their contact details can be given to the research team. The research team will then send a copy of the Participant Information Sheet to any PwMS who have expressed interest in the study.

The research team will then arrange a screening visit at the outpatient clinic for the potential participants to assess eligibility for the study and to complete the screening MS-WIS questionnaire to help find out who is at potential risk of losing their jobs. Those at risk will be invited to take part in the MS-PROACTIVE pilot trial. It is anticipated that there will be approximately 40% screen failures who are found to have no work instability. This is based on previous research using the MS-WIS questionnaire.

The MS-PROACTIVE feasibility trial and process evaluation will last 6 months. PwMS will 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. Randomisation will be carried out by an independent statistician based at the York Clinical Trials Unit. The statistician will use a standard randomisation algorithm to balance confounders (including age, gender and educational level). Allocation will be open and assessment will be blinded to allocation with outcomes collected via questionnaires.

Standard care includes the support of the clinical MS team and a written information leaflet about employment and MS using the 'Work and MS: An employee's guide' created by the MS Society.

The active treatment group will complete seven 30 min computer online sessions of the READY for MS programme, delivered over seven weeks, and a booster session at 12 weeks.

The MS Specialist nurses will contact the participants randomised to the on-line course at 2-3 weeks after randomisation. All of the PwMS in the trial will be asked to complete questionnaires when they are first recruited (baseline) and then at 8 weeks and 6 months. These questionnaires

will be self-completed at home by participants. The questionnaires will collect information about work, any time-off work, self-efficacy, mood, quality of life, fatigue, and the impact of MS. In order to work out how the online READY for MS programme works in practice, 4 PwMS from the Leeds and London sites will be interviewed at 3 points: before starting the programme, after finishing it, and 6 months later. These interviews will be conducted either in the outpatient department or via telephone. This will help the research team to understand their experience of completing the course.

Intervention Type

Behavioural

Primary outcome measure

1. Work instability measured using the MS Work Instability Scale (MS WIS) at screening, baseline, and 6 months

Secondary outcome measures

1. Health-related quality of life measured using the Euroqol 5 -dimension (EQ-5D) index and the 12-Item Short Form Survey (SF-12) at baseline and 6 months
2. Mood measured using the Hospital Anxiety and Depression Scale (HADS) at baseline and 6 months
3. Self-efficacy measured using the Uni-dimensional Self-efficacy Scale for Multiple Sclerosis (USE-MS) at baseline and 6 months
4. Impact of MS measured using the Multiple Sclerosis Impact Scale-29, (MSIS-29) at baseline and 6 months
5. Fatigue measured using the Neurological Fatigue Index for Multiple Sclerosis (NFI-MS) at baseline and 6 months
6. Psychological flexibility measured using the Comprehensive assessment of Acceptance and Commitment Therapy processes (CompPACT) at baseline and 6 months
7. Participant satisfaction with the technology post-intervention measured using the System Usability Scale (SUS) at baseline and 6 months

Overall study start date

26/06/2020

Completion date

31/10/2022

Eligibility

Key inclusion criteria

1. Confirmed diagnosis of multiple sclerosis
2. Paid employment including full-time or part-time work and self-employed
3. Aged ≥ 18 years
4. Access to a computer or tablet for the on-line sessions
5. Ability to complete questionnaires at three timepoints

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 92; UK Sample Size: 92

Key exclusion criteria

1. Unpaid employment such as voluntary work
2. Planning to retire or fully leave employment in the time period of the study
3. On sick leave or maternity leave at the time of recruitment
4. Significant cognitive impairment

Date of first enrolment

13/08/2020

Date of final enrolment

30/11/2021

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Leeds Teaching Hospitals NHS Trust

St. James's University Hospital

Beckett Street

Leeds

United Kingdom

LS9 7TF

Study participating centre

University College London Hospitals NHS Foundation Trust

250 Euston Road

London

United Kingdom

NW1 2PG

Sponsor information

Organisation

Leeds Teaching Hospitals NHS Trust

Sponsor details

St. James's University Hospital
Beckett Street
Leeds
England
United Kingdom
LS9 7TF
+44 (0)1132060469
anne.gowing@nhs.net

Sponsor type

Hospital/treatment centre

Website

<http://www.leedsth.nhs.uk/home/>

ROR

<https://ror.org/00v4dac24>

Funder(s)

Funder type

Charity

Funder Name

Multiple Sclerosis Society

Alternative Name(s)

Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society UK, Multiple Sclerosis Society UK, MS Society

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Funder Name

National Institute for Health Research (NIHR) (UK)

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

On completion of the study, the data will be analysed and a final study report will be prepared. The full study report will then be submitted for peer review publication in relevant journals. Shift.ms will support co-production of a plain English end of trial paper for trial participants, their families and the wider Multiple Sclerosis (MS) community especially People with MS and their employers.

Intention to publish date

30/06/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Charlotte Wicks at charlotte.wicks1@nhs.net

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2.0	06/07/2020	22/12/2020	No	Yes
Protocol file	version v2.0	06/07/2020	22/12/2020	No	No
HRA research summary			28/06/2023	No	No