ISRCTN14056874 https://doi.org/10.1186/ISRCTN14056874

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

Registration date
22/12/2020

Overall study status
Completed

Last Edited
13/09/2021

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
279736

ClinicalTrials.gov (NCT)
NCT04515355

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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
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NW1 2PG

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Charity

Funder Name
Multiple Sclerosis Society

Alternative Name(s)
mssocietyuk, MS Society UK, Multiple Sclerosis Society UK, Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, 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

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	version v2.0	06/07/2020	22/12/2020	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version v2.0	06/07/2020	22/12/2020	No	No