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Understanding how an online resilience-training programme can be utilised across NHS settings to support people with multiple sclerosis to stay in work

Submission date
17/06/2024

Recruitment status
No longer recruiting

Registration date
27/06/2024

Overall study status
Ongoing

Last Edited
31/01/2025

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
People with MS (PwMS) are disproportionately leaving work early. Previous research has shown that psychological factors, such as self-efficacy, play a key role in this. However, in the UK, psychological services are under significant strain with 1.6 million people reported to be on NHS waiting lists for specialised mental health support. A digital resilience-training programme called 'READY' has been co-developed in the UK and piloted with PwMS who report work instability. It is important to assess that the digital UK READY programme can be delivered and received as intended; this is known as intervention fidelity. Specifically, this study aims to monitor fidelity to function, i.e. measuring the core functions of the READY programme, through psychological self-report measures. This is important for checking (validating) the use of READY in a "real world" setting. To do this, the researchers will train MS healthcare professionals to support the delivery of READY and then check whether it has been delivered and received as intended. They will also check that READY leads to the intended long-term outcomes for PwMS who receive it.
This study aims to assess NHS implementation of an online type of Acceptance and Commitment Therapy (ACT) codeveloped with PwMS 'REsilience and Activities for every DaY for MS' (READY) resource to support resilience at work for PwMS. This will be delivered through five objectives:
1. The feasibility and effectiveness of training MS health practitioners in several NHS centres to support delivery of the digital READY programme to PwMS following an immersive training programme.
2. The effectiveness of delivering the READY programme in the NHS for PwMS when supported by trained MS practitioners and the long-term outcomes
3. Which/how contexts influence how MS practitioners support/engage with PwMS completing the READY programme?
4. Which/how contexts influence how PwMS engage with the READY programme and the long-term outcomes
5. To what extent intervention fidelity mediates these long-term outcomes

Who can participate?
Registered healthcare professionals or allied health professionals who work in direct contact with patients diagnosed with Multiple Sclerosis OR individuals aged 18 years or above with a clinical diagnosis of multiple sclerosis and an intention to remain in work for at least 6 months.

What does the study involve?
All participants will be invited to complete 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 about 8 hours in total. This includes completing the READY programme modules and any questionnaires. Participants will be asked to complete questionnaires at the beginning of the study (baseline) and at 8 weeks and 6 months. A small subset of participants will also be invited to take part in research interviews to understand their experiences with using the READY programme.

What are the possible benefits and risks of participating?
For health professionals, 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.
For people with MS, 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.
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 of the study.
In terms of risks, some people can find completing questionnaires stressful and can make them think about negative aspects of their psychological wellbeing. 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, therefore, it is important to keep practising the strategies and exercises in the READY programme for this to work.

Where is the study run from?
Leeds Teaching Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2022 to December 2026

Who is funding the study?
Multiple Sclerosis Society (UK)

Who is the main contact?
Dr Charli R Wicks, charlotte.wicks1@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
338801

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 61223, IRAS 338801

Study information

Scientific Title
Assessing NHS ImplemeNTation of an onlinE Resilience-training Acceptance and Commitment Therapy programme to prevent job loss in Multiple Sclerosis

Acronym
INTERACT-MS

Study objectives
The researchers expect that this Acceptance and Commitment Therapy (ACT)-based programme should lead to increased resilience, psychological flexibility, and self-efficacy. They theorise that increasing these psychological factors should lead to a reduction in work instability. This should mean there is a significant reduction in work instability in participants who complete the digital READY for MS programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/05/2024, North of Scotland Research Ethics Committee 2 (North of Scotland Research Ethics Service, Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0) 1224558458; gram.nosres@nhs.scot), ref: 24/NS/0041

Study design
Non-randomized; Both; Design type: Treatment, Prevention, Psychological & Behavioural, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
This is a multi-phase hybrid effectiveness-implementation study to test the effectiveness of the READY for MS intervention when NHS healthcare professionals are trained to support it for people with multiple sclerosis (PwMS).

The first phase will be to train the healthcare professionals (HCPs) in supporting the programme. This involves HCPs completing the READY for MS programme and then completing a training workshop to understand the core principles of Acceptance and Commitment Therapy. During programme completion, HCPs will receive support from a trained psychologist. The psychologist will audio-record these support calls to capture and assess troubleshooting topics that arise.

The researchers will invite HCPs to complete questionnaires at baseline (i.e. before doing the READY programme), week 8 (post-intervention) and month 6. Questionnaires will collect information on demographics and work details, a general health rating and include validated scales to measure resilience, psychological flexibility, and system usability.

Following the training workshop, HCPs will be asked to complete an ACT-competencies questionnaire and provide qualitative feedback on their experience of the training and any anticipated barriers to supporting others to complete the programme.

A small subset of HCPs will be invited to take part in semi-structured interviews which will be conducted after completing the programme to understand their experiences with the programme and expectations around supporting PwMS.

The second phase will recruit PwMS and invite them to complete the READY for MS programme supported by a HCP at their relevant NHS site.

PwMS will be invited to complete questionnaires at baseline, week 8 and month 6. Questionnaires will collect information on demographics and work details, a general health rating and include validated scales to measure work instability, resilience, psychological flexibility, self-efficacy, mood, impact of MS, and system usability.

A small subset of PwMS will be invited to take part in semi-structured interviews post-intervention and at 6-month follow-up.

All participants (HCPs and PwMS) from ≥2 weeks since baseline will be invited to complete an optional pulse free-text survey which will contribute to lightning reports. These surveys will take less than 10 minutes to complete. Participants will have the option to complete unstructured tele-interviews as part of these pulse surveys if they would like to discuss their feedback further.

Intervention Type
Behavioural

Primary outcome(s)
PwMS phase:
1. Work instability is measured using the Multiple Sclerosis work instability scale at baseline, week 8, and month 6
2. Resilience is measured using the Connor-Davidson Resilience Scale at baseline, week 8, and month 6
3. Psychological flexibility is measured using the Multi-dimensional psychological flexibility inventory at baseline, week 8, and month 6
4. Self-efficacy is measured using the unidimensional self-efficacy scale at baseline, week 8, and month 6

Key secondary outcome(s))
HCP phase:
1. Resilience is measured using the Connor-Davidson Resilience Scale at baseline, week 8, and month 6
2. Psychological flexibility is measured using the Multi-dimensional psychological flexibility inventory at baseline, week 8, and month 6
3. System useability is measured using the system useability scale at week 8 and month 6
4. ACT-based competencies are measured using the ACT knowledge questionnaire at week 8

PwMS phase:
1. Overall health is measured using a general health visual analogue scale at baseline, week 8, and month 6
2. Mood (anxiety, depression) is measured using the Hospital anxiety and depression scale at baseline, week 8, and month 6
3. Impact of MS is measured using the Multiple Sclerosis Impact scale at baseline, week 8, and month 6
4. System useability is measured using the system useability scale at week 8 and month 6

Completion date
31/12/2026

Eligibility

Key inclusion criteria

1. Participants capable of giving informed consent
2. Aged 18 years or above
3. Currently in paid employment with an intention to remain in employment for at least 6 months

Phase 2: A registered healthcare professional or allied health professional who works in direct contact with patients diagnosed with Multiple Sclerosis

Phase 3: An individual with a clinical diagnosis of Multiple Sclerosis and reporting a WI score >= 11/22 (on MS-WIS)

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Individuals lacking the capacity to give informed consent
2. Individuals intending to leave paid employment within the next 6 months
3. Individuals who will not have access to a device used to access the internet (e.g. laptop or smartphone) for the duration of study participation

Date of first enrolment
14/06/2024

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
University Hospital of Wales
Heath Park

Cardiff
United Kingdom
CF14 4XW

Study participating centre
Queen Square Multiple Sclerosis Centre
London
United Kingdom
WC1N 3BG

Study participating centre
Queen Mary University of London
327
Mile End Road
London
United Kingdom
E1 4NS

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
Seacroft Hospital
York Road
Leeds
United Kingdom
LS14 6UH

Study participating centre
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
South Tyneside NHS Foundation Trust
South Tyneside District Hospital
Harton Lane
South Shields
United Kingdom
NE34 0PL

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

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 Charli Wicks (charlotte.wicks1@nhs.net). The Trial Monitoring Group will review formal requests for access to the final dataset. Participant consent to share anonymised data for the purposes of future research will be obtained. The full dataset will be available on completion of the study and research data will be retained for 5 years.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Healthcare professionals version 1	18/04/2024	18/06/2024	No	Yes
Participant information sheet	People with MS version 1	18/04/2024	18/06/2024	No	Yes
Participant information sheet	Participant information sheet version 1	11/11/2025	11/11/2025	No	Yes
Protocol file		26/03/2024	18/06/2024	No	No