

A resilience group training program for people with multiple sclerosis: multi-centre trial (Multi_READY for MS)

Submission date 08/05/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/05/2022	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

Multiple sclerosis (MS) is a condition that can affect the brain and spinal cord, causing a wide range of potential symptoms, including problems with vision, arm or leg movement, sensation or balance.

It's a lifelong condition that can sometimes cause serious disability, although it can occasionally be mild. In many cases, it's possible to treat symptoms. Average life expectancy is slightly reduced for people with MS. It's most commonly diagnosed in people in their 20s and 30s, although it can develop at any age. It's about 2 to 3 times more common in women than men. MS is one of the most common causes of disability in younger adults.

Adjusting to MS can be highly demanding, and the disease can be a consistent source of stress. Resilience is an internal resource for alleviating the adverse effects of stress and sustaining good mental health through adversity.

In recent years, an Australian team developed and tested an Acceptance and Commitment Therapy (ACT)-based group resilience-training program: the REsilience and Activities for every DaY (READY). In view of the promising preliminary data on the READY for MS resilience training intervention, we decided to apply the READY for MS in Italy and to evaluate the efficacy of the program by following the Medical Research Council (MRC) framework for developing and evaluating complex interventions.

Aim: This study aims to evaluate the efficacy of the Italian READY for MS program in a multi-center cluster randomized trial.

Who can participate?

Adults over 18 years, diagnosed with MS.

What does the study involve?

Participants will be randomly allocated to receive the READY intervention consisting of seven weekly 2.5 hour sessions plus a 2.5 hour 'booster' session approximately five weeks after the seventh session, or a control program with the same number of sessions and schedules (but with different content).

What are the possible benefits and risks of participating?

This study will produce evidence on the efficacy of a brief, structured group intervention to promote resilience in people with MS by comparing it with an active group intervention. It is expected that, by empowering participant inner resources, Italian READY for MS can promote a personal growth that may help participants to prevent or overcome difficulties in adjustment to MS, and to live a full and rich life. The Italian READY for MS program is brief and highly structured, which ease its affordability.

We do not expect any negative effects due to the participation in this study.

Where is the study run from?

Fondazione IRCCS Istituto Neurologico Carlo Besta (Italy)

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

January 2020 to December 2022 (updated 09/04/2021, previously: December 2021; updated 20/10/2020, previously: September 2021)

Who is funding the study?

Fondazione Italiana Sclerosi Multipla – FISM (Italy)

Who is the main contact?

Ambra Mara Giovannetti, ambra.giovannetti@istituto-besta.it

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

A resilience group training program for people with multiple sclerosis: multi-centre randomized controlled trial

Acronym

Multi_READY for MS

Study objectives

Participants in the Italian READY for MS would show higher improvements on the primary outcome of resilience (CD-RISC 25) and on the secondary outcomes of mood (The Hospital Anxiety and Depression Scale, HADS; The Positive and Negative Affect Schedule, PANAS), health related quality of life (54-items MS Quality of Life inventory, MSQOL-54; the European Quality of life Five Dimensions, EQ-5D-3L), well-being (The short form of the Mental Health Continuum, MHC-SF) and psychological flexibility (The Comprehensive assessment Acceptance and Commitment Therapy processes, CompACT), compared to the control group (relaxation).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Current ethics approval as of 09/04/2021:

Approved 15/04/2020, amendment approved 18/11/2020, Ethics committees of the Fondazione IRCCS Istituto Neurologico Carlo Besta (Via Celoria 11, Milano, 20133, Italy; +39 (0)2 2394.2321; comitatoetico@istituto-besta.it), ref: 71, amendment ref: 78

Previous ethics approval:

Approved 15/04/2020, Ethics committees of the Fondazione IRCCS Istituto Neurologico Carlo Besta (Via Celoria 11, Milano, 20133, Italy; +39 (0)2 2394.2321; comitatoetico@istituto-besta.it), ref: 71

Study design

Multi-centre cluster randomised trial with an active control

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Multiple sclerosis

Interventions

READY for MS is an adult ACT (Acceptance and Commitment Therapy) informed group resilience training program which consists of seven weekly 2.5 hour sessions plus a 2.5 hour 'booster' session approximately five weeks after the seventh session. Content of the seven weekly sessions is as follows: an introductory module (Introduction to the READY Resilience Model), five modules focusing on each of the six ACT processes (Mindfulness, Acceptance, Cognitive Defusion, Self-as-Context, Values, Meaningful Action), and a review module (Review and Future Planning). The booster session provides a review of the program content.

The control program will match the study intervention in the number of sessions and schedules (but not in session content and length).

Patient-reported outcome measures (PROMs) will be assessed immediately before, after the booster session, at three and six-month follow-up. Additional process data will capture participants' attendance, homework completion, and facilitator perspectives on a weekly basis. Each session will be audio-recorded and self-rated by the facilitators. Two sessions for each Italian READY for MS group will be randomly selected and independently rated by two ACT experts to assess intervention fidelity. The control group session fidelity will be assessed following the same procedures except for the use of ACT-FM and audio recording assessment that will be done by one rate.

Randomization will be provided by an independent randomization unit, using computer-based cluster randomization with minimization (2 factors: Centre and CDRISC score < 50 and ≥ 50). Groups will be allocated to Italian READY for MS or control intervention in a 1:1 ratio. Confirmation e-mails will be sent to the study coordinator and centre PI. The interventions will start within two weeks of the baseline assessment.

Intervention Type

Behavioural

Primary outcome measure

Psychological resilience measured using the Connor-Davidson Resilience Scale 25 (CD-RISC 25) assessed immediately before (baseline visit, T0), after the booster session (T1, 12 weeks after baseline visit), at three (T2, 24 weeks after baseline visit), and six month follow-up (T2, 36 weeks after baseline visit)

Secondary outcome measures

Current secondary outcome measures as of 09/04/2021:

Assessed immediately before (baseline visit, T0), after the booster session (T1, 12 weeks after baseline visit), at three (T2, 24 weeks after baseline visit), and six month follow-up (T2, 36 weeks after baseline visit):

1. Mood (The Hospital Anxiety and Depression Scale, HADS; The Positive and Negative Affect

Schedule, PANAS)

2. Health related quality of life (54-items MS Quality of Life inventory, MSQOL-54; the European Quality of life Five Dimensions, EQ-5D-3L)
3. Well-being (The short form of the Mental Health Continuum, MHC-SF)
4. Psychological flexibility (the psychological flexibility subscale of The Multidimensional Psychological Flexibility Inventory, MPFI)

Previous secondary outcome measures:

Assessed immediately before (baseline visit, T0), after the booster session (T1, 12 weeks after baseline visit), at three (T2, 24 weeks after baseline visit), and six month follow-up (T2, 36 weeks after baseline visit):

1. Mood (The Hospital Anxiety and Depression Scale, HADS; The Positive and Negative Affect Schedule, PANAS)
2. Health related quality of life (54-items MS Quality of Life inventory, MSQOL-54; the European Quality of life Five Dimensions, EQ-5D-3L)
3. Well-being (The short form of the Mental Health Continuum, MHC-SF)
4. Psychological flexibility (The Comprehensive assessment Acceptance and Commitment Therapy processes, CompACT)

Overall study start date

01/01/2020

Completion date

31/12/2022

Eligibility

Key inclusion criteria

1. Diagnosis of MS
2. Age \geq 18 years
3. Written informed consent
4. Resilience score $<$ 83
5. Able to attend group sessions and fluent Italian speaker

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

A sample size of 12 clusters per treatment arm (total number of clusters=24) with 10 individuals per cluster (total sample size 240)

Key exclusion criteria

1. Severe cognitive compromise (Mini Mental State Examination <19)
2. Psychosis or other serious psychiatric conditions
3. Psychotherapy in the preceding six months
4. Prior formal training in mindfulness methods or current meditation practice
5. Severe suicidality, including ideation, plan and intent
6. One or more relapses in the previous month
7. Corticosteroid treatment during the previous month
8. Other serious medical disorders in addition to MS
9. Current pregnancy
10. MS diagnosis for less than three months

Date of first enrolment

01/09/2021

Date of final enrolment

31/03/2022

Locations**Countries of recruitment**

Italy

Study participating centre

Fondazione IRCCS Istituto Neurologico Carlo Besta

Servizio di Neuroepidemiologia

Centro Sclerosi Multipla

Via Celoria 11

Milan

Italy

20133

Study participating centre

Azienda Ospedaliera San Camillo - Forlanini

Centro Sclerosi Multipla

Circonvallazione Gianicolense, 87

Roma

Italy

00149

Study participating centre

Servizio di riabilitazione AISM

Via Operai 30

Genova
Italy
16149

Study participating centre

Azienda Ospedaliero-Universitaria "Policlinico-Vittorio Emanuele"

Centro sclerosi multipla

Via S. Sofia, 78

Catania

Italy

95123

Study participating centre

UOSD psicologia clinica e UOC neurologia, ASST Lariana

Laboratorio di neuropsicologia

Via Napoleona 60

Como

Italy

22100

Study participating centre

IRCCS Fondazione Istituto Neurologico Nazionale C. Mondino di Pavia

Centro Sclerosi Multipla

Divisione di Neurologia Generale

Via Mondino, 2

Pavia

Italy

27100

Study participating centre

Ospedale "San Giovanni Battista"

Dipartimento Riabilitazione ASLUMBRIA2

via Massimo Arcamone

Foligno

Italy

06034

Study participating centre

Università di Perugia

Centro Malattie Demyelinizzanti e Laboratori di Neurologia Sperimentale

Clinica Neurologica

Piazzale Giorgio Menghini, 1
Perugia
Italy
06129

Sponsor information

Organisation

Istituto Neurologico Carlo Besta

Sponsor details

Department of Research and Clinical Development
Scientific Directorate
Fondazione IRCCS Istituto Neurologico Carlo Besta
Milano
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+39 (0)2 2394 3568
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Sponsor type

Research organisation

Website

<http://www.istituto-besta.it>

ROR

<https://ror.org/05rbx8m02>

Funder(s)

Funder type

Charity

Funder Name

Fondazione Italiana Sclerosi Multipla

Alternative Name(s)

Italian Multiple Sclerosis Foundation, Italian MS Foundation, FISM

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Italy

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/03/2023

Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available upon request from Ambra Mara Giovannetti (ambra.giovannetti@istituto-besta.it). Data will be available after publication once the research team will end the dissemination process. People interested in receiving the data will need to ask and present a specific project on data use and ask the study SC for the approval.

The person interested in using data will be in charge for obtaining the consent from participants for that specific use of the data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		02/05/2022	03/05/2022	Yes	No