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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

Registration date
14/05/2020

Overall study status
Completed

Last Edited
03/05/2022

Condition category
Nervous System Diseases

[X] 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
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

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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 ≥ 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 Demielinizzanti e Laboratori di Neurologia Sperimentale
Clinica Neurologica

Piazzale Giorgio Menghini, 1
Perugia
Italy
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Sponsor information

Organisation
Istituto Neurologico Carlo Besta

Sponsor details
Department of Research and Clinical Development
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Fondazione IRCCS Istituto Neurologico Carlo Besta
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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