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READY for MS, a group intervention to promote resilience in people with multiple sclerosis in Italy

Submission date
28/03/2018

Recruitment status
No longer recruiting

Registration date
04/06/2018

Overall study status
Completed

Last Edited
14/07/2023

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims :
Living with multiple sclerosis (MS) can be a consistent source of stress. Targeted intervention aimed at promoting personal resilience (an individual's ability to adapt in the face of adverse conditions) can alleviate the adverse effects of stress and sustain good quality of life (QoL). The Acceptance and Commitment Therapy (ACT) is a third wave cognitive behavioural therapy, specifically aimed at promoting psychological flexibility, the key ingredient of resilience. Pakenham et al. created a highly structured group intervention based on ACT and called “The READY (REsilience and Activity for every DaY) program”. It has also been specifically adapted for people with MS (READY for MS). The aim of this study is to evaluate how well READY for MS program works, if compared to a relaxation intervention.

Who can participate?
People with a diagnosis of MS for more than three months, aged 18 and over, with a level of resilience that could still improve, and able to attend the program group sessions, will be invited to participate in the study.

What does the study involve?
Participants have the same chance of being placed in either group: READY for MS or relaxation. Both the treatments consist of 8 group sessions with 7 weekly sessions plus a booster session 5 weeks later and will be conducted by the same psychologist.
In the READY for MS each session will last 2.5 hours. All the sessions incorporates a blend of psychoeducation and experiential exercises, combined with readings and homework exercises that participants are encouraged to practice between sessions.
In the relaxation program each session will last 1 hour. The facilitator will guide the group through a series of relaxation exercises. Each session will finish with a debriefing about the experience. Participants are encouraged to practice between sessions.
At the end of follow-up, people that participate in the relaxation group will have the opportunity to participate in the READY for MS.

What are the possible benefits and risks of participating?
We do not expect any negative effects by participating in this study. In addition, we will carefully monitor participants' psychological condition and if necessary advise the participant about possible treatment options. Moreover, Pakenham and colleagues found that "READY for MS" improves quality of life and
resilience in people with multiple sclerosis. Those assigned to the relaxation group, will learn specific relaxation skills and techniques.

Where is the study run from?
Foundation IRCCS Neurological Institute C. Besta (Italy)

When is study starting and how long is it expected to run for?
February 2017 to July 2018

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Italian set up of the program "REsilience and Activity every DaY for MS", of outcomes, and pilot assessment of efficacy using a mixed methodology.

Acronym
READT-It-MS

Study objectives

To verify that participants assigned to the “READY for MS” group show higher improvements in QoL, measured with the MHC of the 54-items MS Quality of Life inventory (MSQOL-54) compared to the control group (relaxation).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study has been given ethical approval by the ethics committees of the Foundation IRCCS Neurological Institute C Besta, 08/02/2017, internal ref: 37; amendment approved 06/09/2017, internal ref: 43

Study design
Single-blind, single-centre RCT and nested qualitative study comparing READY for MS with relaxation. Each intervention consisted of 7 weekly group sessions, plus a booster session after 5 weeks. Data were collected at baseline, after 8, 12 and 24 weeks.

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Resilience in people with multiple sclerosis

Interventions
Interventions
Each group will be composed of 8-10 participants, a total of 4 groups will be performed (2 “READY for MS”, and 2 relaxation; within each arm, the two groups will be homogeneously assembled so that the participants will be as homogeneous as possible in terms of their EDSS score).

1. “READY for MS”: This is an adult resilience training program based on ACT (Acceptance Commitment Training) that comprises 7 modules of 2.5-hour weekly group sessions, with a 2.5-hour ‘booster’ session approximately 5 weeks after the final session of the intervention. The booster session starts with a mindfulness exercise, followed by a review of the contents covered across the READY program. Participants are encouraged to share their progress and experience of applying the strategies and techniques learned through attending the READY program. All the sessions are guided by a facilitator (Ambra Mara Giovannetti, a trained psychotherapist). It incorporates a blend of psychoeducation and experiential exercises, combined with readings and homework exercises that participants are encouraged to practice between sessions.
2. Control treatment: This consists of a group relaxation program (7 1-hour weekly group sessions, followed by a ‘booster’ session approximately after 5 weeks). This control program matches the study intervention in duration and schedule (but not in content), in order to control for the non-specific effect of the intervention. We decided to limit the duration to 1 hour, as 2.5 hours was judged too much for group relaxation.
Relaxation is based on the principles of the autogenic training (desensitization-relaxation technique).

Trial Procedures
Potential participants will be provide with a general overview of the study. Subsequently, one trained clinical psychologist (not involved with the treatment and blind to group allocation) will make an appointment with those patients who met the inclusion criteria and agreed to participate in the study. The psychologist will check all the eligibility criteria and perform the baseline evaluation (T0). Information on all screened PwMS and reasons for exclusion will be recorded. After that the participant is assigned to “READY for MS” vs. “control” (see randomization below).
The interventions start within 2 weeks from the baseline assessment.

Withdraw
Participants will be free to withdraw from the study at any time, without giving reasons and with no risk of prejudicing future care. Study personnel will make every effort to obtain, and record, information about the drop out reasons.

Pre-study interview and informed consent (visit 0)
During the pre-study evaluation each potential participant receives full and adequate verbal and written information about the nature and purpose of the study. A written, signed informed consent is obtained, according to the Declaration of Helsinki and to the GCP Guidelines of the EU. The informed consent form will be kept on file by the study personnel and will be available for inspection by regulatory authorities or authorized persons.

Assessments
At baseline (T0), 8 weeks (T1), 12 weeks (T2) and 24 weeks after treatment beginning (T3) the participant completes the following PROMs (cited in order of administration): MSQOL-54, CDRISC-25, HADS, PSS, CompACT, MAAS, VLQ, AAQII, DDS. Further to questionnaire completion the examiner administers the SEIQoL-DW at T0, T2 and T3. The total assessment will last about 40 minutes in T1 and about one hour in all the other timepoints.

Randomization
Randomization will be provided by an independent randomization service at the Besta Neuroepidemiology Unit and accessed via a web-based system, using computer-based block randomization (2 factors: resilience score: CDRISC-25; Expanded Disability Status Scale (EDSS) score < 3.0 and >= 3.0). Patient will be allocated to two arms: “READY for MS” vs. relaxation program in a 1:1 ratio.
Confirmation e-mails will be sent to the principal investigator.

Intervention Type
Behavioural

Primary outcome(s)
The MSQOL-54 is a health-related quality of life (QoL) measure that comprises the generic Short-Form 36-item (SF-36), plus 18 MS-specific items. The 54 items are organized into 12 multi-item and two single item subscales. As for SF-36, two composite scores (Physical Health Composite [PHC] and Mental Health Composite [MHC]) are derived by combining scores of the relevant subscales. The MSQOL-54 has well documented validity in terms of content, constructs, reliability, discrimination, and responsiveness. To limit multiple comparisons, we will primarily assess changes in PHC and MHC.

Key secondary outcome(s))

1. Mood assessed using the Hospital Anxiety and Depression Scale (HADS), a well-validated measure that consists of two seven-item subscales to assess anxiety and depressive levels. Higher scores indicate higher level of depressive or anxiety symptoms. Unlike a number of other measures, the HADS excludes somatic symptoms of anxiety and depression, which may overlap with physical illness .
2. Stress assessed using the 10-item version of the Perceived Stress Scale (PSS) will be used to assess the extent to which life situations are appraised as stressful. Higher score indicates higher level of stress perceived.
3. Psychological resilience assessed using the Connor-Davidson Resilience Scale (CDRISC-25). It is composed of 25 items, each rated on a 5-point scale (0-4), with higher scores reflecting greater resilience. The scale demonstrated good psychometric properties.
4. Psychological flexibility assessed using the CompACT scale consisting of 23 items, each rated on a 0-6 Likert scale and grouped in three scales (openness to experience, behavioral awareness, and valued action). A total score is calculated as the sum of the three subscale scores (range 0-138, higher values indicating greater psychological flexibility). The CompACT demonstrated good internal consistency, and converged and diverged in theory-consistent ways with other measured variables: higher levels of psychological inflexibility were associated with higher levels of distress and lower levels of health and wellbeing.
5. Mindfulness assessed using the Mindful Attention Awareness Scale (MAAS), a 15-item scale aimed to assess a core characteristic of dispositional mindfulness across interpersonal cognitive, physical, emotional, and general domains. Items are rated on a 6-point Likert scale, and responses are then summed with higher scores indicating a greater presence of mindfulness. The MAAS has validity, internal reliability and sensitivity to change.
6. Values and meaningful action assessed using the 20-item Valued Living Questionnaire (VLQ), which measures the relative importance of certain life domains and the consistency of behaviours with the identified personal values. Respondents are asked to rate the 10 life domains on a 1–10 scale on level of importance (importance subscale) and how consistently they have lived in accord with those values in the past week (consistency subscale). Higher scores indicate greater importance and consistence. The VLQ displays good inter-item consistency, test-retest reliability, and construct validity.
7. Acceptance assessed using the Acceptance and Action Questionnaire II (AAQ-II), a 10-item self-report measure of acceptance and experiential avoidance. Items are rated using a 7-point Likert scale. High scores on the AAQ-II are reflective of greater experiential avoidance and immobility, while low scores reflect greater acceptance and action. It has been shown to have good internal reliability and convergent validity.
8. Defusion assessed using the Drexel Defusion Scale (DDS). The DDS measures psychological distance from a broad range of internal experiences incorporating both thoughts and feelings (it is a person’s ability to see thoughts as they are, not as what they say they are). Subjects are asked to read a definition of defusion prior to indicating the extent to which they would normally be in a state of defusion across ten different scenarios, using a 6-point Likert scale (higher scores indicating greater ability to defuse from distressing thoughts and feelings).
9. Individualized QoL assessed using the SEIQoL-DW, an interview-based instrument to assess the level of functioning in, and relative importance of, areas of life individually identified by the respondent. The evaluation is based on three steps: (a) to name the subject 5 most important QoL areas; (b), to rate the relative importance of each identified area, using a disk that can be rotated around a central point to form a type of pie chart (it displays a 0–100 scale); (c), to assign a satisfaction score to each of the five areas. The SEIQoL-DW index is obtained from the satisfaction and the weight of each elicited area, and can range from 0 (worst possible) to 100 (best possible).
10. Clinical information and measures. The following information will be also provided by the PwMS neurologist at T0:
10.1. EDSS score

10.2. MS course (relapsing remitting, primary progressive, secondary progressive)
10.3. Presence/type of co-pathologies, and ongoing treatment.
At T1 and T2, the neurologist will update the EDSS score, treatment, and occurrence of new relapses.
11. Satisfaction with the READY program. An ad hoc questionnaire has been built-up to explore the satisfaction with the READY program. It is composed of three sections:
11.1. Usefulness of the READY program in promoting the 6 protective factors of resilience (6 items).
11.2. Overall evaluation of the READY program (5 items, plus 8 open questions on their experience).
11.3. Satisfaction with the READY Personal Plan (5 items, plus we ask the participants to rate the level of commitment with the READY Personal Plan, after each session).

At baseline (T0), 8 weeks (T1), 12 weeks (T2) and 24 weeks after treatment beginning (T3) the participant completes the following PROMs (cited in order of administration): MSQOL-54, CDRISC-25, HADS, PSS, CompACT, MAAS, VLQ, AAQII, DDS. The SEIQoL-DW will be administered at T0, T2 and T3.

Completion date
31/07/2018

Eligibility

Key inclusion criteria
1. Diagnosis of MS
2. Aged >=18 years
3. Signed informed consent
4. The Connor-Davidson Resilience Scale (CDRISC-25) score <83, which indicates that the person could still improve his/her level of resilience)
5. Able to attend the program group sessions (8 sessions, each lasting 2.5 hours)
6. Fluent Italian speaker

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
39

Key exclusion criteria
1. Severe cognitive compromise (MMSE <19)
2. Psychotherapy ongoing or in the preceding 6 months
3. Previous experience in meditation or other mind-body therapies
4. Major psychiatric disorders (including psychotic disorders or active substance abuse problems)
5. Pregnancy
6. MS diagnosis for less than 3 months
7. One or more relapses of MS in the last month.

Date of first enrolment
16/03/2017

Date of final enrolment
23/10/2017

Locations

Countries of recruitment
Italy

Study participating centre
Foundation IRCCS Neurological Institute C. Besta
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Sponsor information

Organisation
Fondazione IRCCS Istituto Neurologico C. Besta

ROR
https://ror.org/05rbx8m02

Funder(s)

Funder type
Not defined

Funder Name
Fondazione Italiana Sclerosi Multipla (FISM, www. aism.it, grant number 2016/B/3)

Results and Publications

Individual participant data (IPD) sharing plan

Ambra Mara Giovannetti (ambra.giovannetti@istituto-besta.it) can share the quantitative dataset and the Italian transcript of the nested qualitative study. The audio file will be deleted once verbatim transcription has been completed. The data will be available upon request after publication of the results, with no time limit on availability.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/04/2020	15/04/2020	Yes	No
Participant information sheet		17/08/2017	05/06/2018	No	Yes
Protocol (other)			14/07/2023	No	No