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Effectiveness of an emotion-focused behavioral treatment program for adults with multiple sclerosis

Submission date
15/09/2019

Recruitment status
No longer recruiting

Registration date
26/09/2019

Overall study status
Completed

Last Edited
05/10/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is a potentially disabling disease of the brain and spinal cord. In MS, the immune system attacks the protective myelin sheath that covers nerve fibers. This results in communication problems between the brain and the rest of the body. Eventually, the disease can cause permanent damage or deterioration of the nerves. Signs and symptoms of MS vary widely and depend on the amount of nerve damage and which nerves are affected. Some people with severe MS may lose the ability to walk independently or at all, while others may experience long periods without any new symptoms.
In addition to physical problems, a broad range of mental and emotional problems can occur in this condition. Some patients focus only on physical symptoms, and do not pay attention to psychological consequences. Emotional problems are more widespread in people with MS.
The Unified Protocol is a new psychological transdiagnostic intervention based on cognitive behavioural therapy (CBT) that helps people learn how to face inappropriate emotions and respond to their emotions in a more adaptive way. This method tries to reduce the intensity and frequency of emotional habits by adjusting the person's emotional ordering habits, increasing their emotional functioning.

Who can participate?
Adults who have had MS for at least 3 years and who have anxiety and depression.

What does the study involve?
Participants will be randomly allocated to one of two groups. One group will receive treatment as usual from their hospital and doctor. This involves no behavioural therapy. The other group will receive treatment as usual as well as the Unified Protocol behavioural therapy. This will involve 12-14 weekly sessions with a therapist that will aim to increase participants' awareness of their emotions and ability to manage emotions.

What are the possible benefits and risks of participating?
There are no risks associated with participating. At each visit, the mental health of the participant is assessed. There is also a 24-hour helpline available to participants. Those in the Unified Protocol group might benefit from learning to cope better with their illness.

Where is the study run from?
Islamic Azad University (Iran)

When is the study starting and how long is it expected to run for?
March 2019 to October 2019

Who is funding the study?
Islamic Azad University (Iran)

Who is the main contact?
Dr Nabi Nazari, nnpilotiriaf@gmail.com

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
1265491

Study information

Scientific Title
Efficacy of the Unified Protocol on difficulties with emotional regulation in people with multiple sclerosis and associated depression or anxiety disorder: a randomized controlled trial

Acronym
EUPDERPMSDAIRCT

Study objectives
Transdiagnostic Group Therapy improves emotion regulation and reduces difficulties in emotion regulation in adults with MS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/02/2019, WIRBRMC (PO Box 6545676545, Vali-Asr Ave, Tehran, Iran; +98 021 883232333; info@wirbrmc.com); ref: wirb IR 20192297 LO

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Emotional regulation difficulties in people with multiple sclerosis and associated depression or anxiety disorder

Interventions
Immediately after randomization using a random digits table, participants in the experimental group will receive the Unified Protocol for Adolescents (UP-A) for 12-14 weeks. The control group will receive treatment as usual, which involves no behavioural treatment.
The UP-A sessions are delivered in a flexible manner. Several of the UPs treatment elements are fixed and received by all participants (psychoeducation about emotions and emotional behavior, awareness and mindfulness skills, antecedent cognitive reappraisal/problem-solving skills, emotion exposure strategies, and relapse prevention skills), although applied for varying

numbers of sessions depending on clinical need. Other strategies (motivational enhancement, parenting strategies and crisis management strategies) are applied on an as-needed basis based on client needs.

Intervention Type
Behavioural

Primary outcome measure
1. Depression assessed using the Hospital Anxiety and Depression Scale (HADS) at baseline, after the end of the intervention and 3 months after the end of the intervention
2. Anxiety assessed using the Hospital Anxiety and Depression Scale (HADS) at baseline, after the end of the intervention and 3 months after the end of the intervention
3. Emotion regulation difficulties assessed using the Difficulties in Emotion Regulation Scale (DERS) at at baseline, after the end of the intervention and 3 months after the end of the intervention

Secondary outcome measures
1. Extent of emotion regulation difficulty assessed using the Difficulties in Emotion Regulation Scale (DERS) at baseline, after the end of the intervention and 3 months after the end of the intervention
2. Positive and negative affect assessed using the Positive and Negative Affect Schedule (PANAS) at baseline, after the end of the intervention and 3 months after the end of the intervention
3. Mindful awareness of distressing thoughts and images assessed using the Southampton Mindfulness Questionnaire (SMQ) at baseline, after the end of the intervention and 3 months after the end of the intervention
4. Use of emotional regulation strategies assessed using the Emotion Regulation Questionnaire (ERQ-R) at baseline, after the end of the intervention and 3 months after the end of the intervention

Overall study start date
01/03/2019

Completion date
21/10/2019

Eligibility

Key inclusion criteria
1. Diagnosis of MS for 3 years or more
2. Fluent in Persian
3. Aged at least 18 years
4. Received at least one current diagnostic of a valid depression disorder and an anxiety disorder on Structural Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, fourth edition Axis I Disorders.
4. Received at least one self-report score outside the cut-off range specified for screening measures for anxiety (using the HADS-A scale) and depression (using the HADS-S scale
5. Willing to participate in the research
6. Completed and signed consent form
7. Medical MS agreement for participation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
98

Total final enrolment
64

Key exclusion criteria
1. Co-occurring conditions, including positive diagnosis of schizophrenia, bipolar I or II disorder, pervasive developmental disorder, organic brain syndrome, mental retardation , or current suicidal/homicidal ideation
2. A prior course of cognitive behavioral treatment during the previous year
3. Other chronic physical illnesses (such as insulin-dependent diabetes and chemotherapy for cancer)
4. Pregnancy or lactation
5. Evidence of current or past schizophrenia, psychosis, or organic mental disorder, bipolar disorder, or organic mental disorder
6. Drug abuse history or drug dependence, except for nicotine
7. Absenteeism for more than three sessions

Date of first enrolment
01/05/2019

Date of final enrolment
01/06/2019

Locations

Countries of recruitment
Iran

Study participating centre
Iranian MS Association
PO Box 63654852001
Tehran
Iran
-

Study participating centre
Sina Hospital
Imam Square
Tehran
Iran
-

Sponsor information

Organisation
Islamic Azad University

Sponsor details
Hesaarak Square
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-
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Sponsor type
University/education

ROR
https://ror.org/01kzn7k21

Funder(s)

Funder type
University/education

Funder Name
Islamic Azad University

Alternative Name(s)
IAU

Funding Body Type
Private sector organisation

Funding Body Subtype

Universities (academic only)

Location
Iran

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication and are available on request from the investigators.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			27/09/2019	No	Yes
Basic results		21/12/2019	06/01/2020	No	No
Results article	results	31/10/2020	03/11/2020	Yes	No
Protocol file			05/10/2022	No	No