ISRCTN16135866 https://doi.org/10.1186/ISRCTN16135866

Emotion-focused cost-effective cognitive behavioral intervention for multiple sclerosis

Submission date
04/08/2019

Recruitment status
No longer recruiting

Registration date
07/11/2019

Overall study status
Completed

Last Edited
20/02/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] 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 potentially disabling disease of the brain and spinal cord (central nervous system). In MS, the immune system attacks the protective sheath (myelin) that covers nerve fibers and causes communication problems between your brain and the rest of your 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 of remission without any new symptoms.
In addition to physical impairment, a broad range of mental and emotional problems are typical in this condition. Unfortunately, some patients focus only on physical symptoms, and they do not pay attention to psychological consequences. We call it MS focus. Emotional problems are more widespread in people with MS.
This study aims to investigate the effect of psychological therapy on mental health problems related to MS.

Who can participate?
All MS patients over 18 years old

What does the study involve?
All participants will first take part in an interview with the psychologist to learn about their current mental health and coping strategies. Participants will then be randomly assigned to receive either a psychological group intervention for coping with MS, or will receive treatment as usual. The therapy consists of 14 weekly 2-hour sessions with a 15-min break after 60 min. After 14-weeks, and again three months later, all participants will have another interview with the psychologist.

What are the possible benefits and risks of participating?
Benefits: The therapy may contribute to an improvement in mental health.
Risks: None

Where is the study run from?
Farshchian Hospital, Hamedan, Iran

When is the study starting and how long is it expected to run for?
November 2019 to January 2020 (updated 08/11/2019, previously: August 2019 to September 2019)

Who is funding the study?
National Institute for Medical Research Development, Iran (updated 08/11/2019, previously: Islamic Azad University of Hamedan, Iran)

Who is the main contact?
Mr Nabi Nazari
naviddrphd@gmail.com

Study website
http://wirbrmc.com

Contact information

Type(s)
Scientific

Contact name
Mr Nabi Nazari

ORCID ID
http://orcid.org/0000-0003-3771-3699

Contact details
Islamic Azad University of Hamedan
Professor Mussivand Blvd
Hamedan
Iran
6558225885
00989179188209
naviddrphd@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Efficacy of unified protocol on difficulties with emotional regulation in people with multiple sclerosis and depression or anxiety disorder

Study objectives
Current hypothesis as of 08/11/2019:
1. The group format of the UP can improve emotion regulation
2. The web-based format of the UP can reduce emotion regulation

Previous hypothesis:
1. Unified Protocol (UP) is effective in emotion regulation in females with MS with comorbid anxiety and depressive disorders
2. UP for anxiety disorders can improve the symptom of depression symptoms in the participants
3. The group format of the UP can reduce depression and anxiety symptoms
4. The web-based format of the UP can reduce depression and anxiety symptoms

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/10/2019, National Institute for Medical Research Development (Hamedan, Iran), ref: IR.NIMAD.REC.1398.259

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Anxiety and depression in patients with multiple sclerosis

Interventions
The study comparing a psychological group intervention, based on transdiagnostic therapy principles developed by Barlow et al. (the Unified Protocol), with a control group. Group therapy consists of 14 weekly 2-h sessions with a 15-min break after 60 min.

Participants were randomly assigned to the treatment or control groups using a computerised method (www.randomizer.org).

The intervention comprised the following modules:
1. Module 1 (session 1): Unified model of psychopathology, motivation enhancement strategies, treatment goal setting, decisional balance exercise, changing versus staying
2. Module 2 (session 2): Psychoeducation on the adaptive function of emotions, three-component model of emotional experiences, describing the sequence of events around emotions, anchoring in the present
3. Module 3 (sessions 3 and 4): Reviewing primary emotions, natural course of emotions and role of avoidance, present-focused, non-judgmental emotion awareness, recognising the interaction between thoughts, feelings and behaviours during an emotional experience
4. Module 4 (sessions 5 and 6): Flexible thinking, automatic appraisals , thinking traps, distress tolerance skills, familiarizing with various emotional avoidance strategies and their impact on emotional experience, knowledge of the contradictory effects of avoiding emotions
5. Module 5 (session 7): Examining emotion-driven behaviours (EDBs), knowledge and identification of their effects on emotional experiences, identifying maladaptive EDBs, and creating alternatives for acting through behaviours
6. Module 6 (session 8): Increasing patients' awareness and tolerance of somatic sensations, knowledge and tolerance of physical senses, increasing awareness of the role of emotional feelings in emotional experiences, practicing exercises or visceral confrontation in order to be aware of physical sensations and increase tolerance of these symptoms
7. Module 7 (sessions 9-13): Emphasising the practice of treatment concepts through in-session and out-of-session exposures to emotional experiences, focusing on provoking the emotion, replacing interpretations about the dangerousness of situations with more adaptive appraisals, extinguishing anxious reactions to intense emotional experiences, modifying EDBs, visceral confrontation, providing the opportunity for skills rehearsal and consolidation in the context of a strong emotion
8. Module 8 (session 14): Overview of significant treatment concepts and the patient's progress is reviewed. Specific strategies for preserving and extending treatment gains are discussed. Prevention of recurrence, an overview of treatment concepts and discussion about patient's healing and progress and plans for future practices.

The control group followed an online version of the therapy for 14-weeks (updated 08/11/2019, previously: The control group remained on the waiting list for treatment)

Intervention Type
Behavioural

Primary outcome measure
At baseline, post-treatment (14-weeks), and three months:
1. Psychological or psychiatric diagnosis assessed using SCID-DSM-IV: The Structured Clinical Interview for DSM-IV (SCID)
2. Tendency, intensity and excessiveness of worry assessed using the Penn State Worry Questionnaire (PSWQ)
3. Anxiety symptoms assessed using the Hospital Anxiety and Depression Scale (HADS) anxiety subscale
4. Depression symptoms assessed using the Hospital Anxiety and Depression Scale (HADS) depression subscale

Secondary outcome measures

Current secondary outcome measures as of 08/11/2019:
1. Mindfulness (mindful observation, non-aversion, non-judgment, and letting go) assessed using the Southampton Mindfulness Questionnaire (SMQ)
2. Emotionality assessed using the Emotional style Questionnaire (2019) ESQ
3. Depression symptoms assessed using the Beck Depression Inventory
4. Emotional dysregulation assessed using the Difficulties in Emotion Regulation Scale (DERS)
5. Tendency, intensity and excessiveness of worry assessed using the Penn State Worry Questionnaire (PSWQ)

Previous secondary outcome measures:
At baseline, post-treatment (14-weeks), and three months:
1. Psychological or psychiatric diagnosis assessed using SCID-DSM-IV: The Structured Clinical Interview for DSM-IV (SCID)
2. Anxiety-related symptom severity and impairment assessed using the Overall Anxiety Severity and Impairment Scale (OASIS)
3. Tendency, intensity and excessiveness of worry assessed using the Penn State Worry Questionnaire (PSWQ)
5. Emotional regulation assessed using the Emotion Regulation Questionnaire (ERQ-R)
6. Positive and negative affect assessed using the Positive and Negative Affect Schedule (PANAS)
7. Mindfulness (mindful observation, non-aversion, non-judgment, and letting go) assessed using the Southampton Mindfulness Questionnaire (SMQ)
8. Emotional dysregulation assessed using the Difficulties in Emotion Regulation Scale (DERS)
9. Anxiety symptoms assessed using the Hospital Anxiety and Depression Scale (HADS) anxiety subscale
10. Depression symptoms assessed using the Hospital Anxiety and Depression Scale (HADS) depression

Overall study start date
01/01/2018

Completion date
08/01/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 08/11/2019:
1. Valid MS diagnosis
2. No suicidal Ideation or threatening behaviors, no history span attempted suicide
3. Valid diagnosis of depression or anxiety disorder
4. Internet availability

Previous inclusion criteria:
1. Diagnosis of MS for 3 years or more
2. Fluent in Persian
3. At least 18 years of age
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
5. Received at least one self-report score, without the cut-off range, specified for each of

screening domains:
5.1 Anxiety screening measures included the Penn State Worry Questionnaire (PSWQ), Anxiety Severity and Impairment Scale (OASIS). HADS-A
5.2 Depression screening measures include Anxiety Severity and Impairment Scale ODSIS HADS-D.
5.3 Emotional screening measures include Difficulties in Emotion Regulation Scale (DERS), the Positive and Negative Affect Schedule (PANAS), the Southampton Mindfulness Questionnaire (SMQ), and Emotion Regulation Questionnaire (ERQ-R).
6. Willing to participate in the research
7. Fill and sign consent
8. Medical agreement for participation.

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
130

Total final enrolment
70

Key exclusion criteria
1. Initial diagnosis of current or past schizophrenia, psychosis, or organic mental disorder, bipolar disorder, or organic mental disorder
2. Other Chronic physical illnesses (such as insulin-dependent diabetes and chemotherapy for cancer)
3. Pregnancy or lactation
4. Drug abuse history or drug dependence except for nicotine
5. Absenteeism for more than three sessions
6. Receiving psychological interventions during previous year
7. Presence of another comorbid neurological disorder such as Alzheimer's disease, Parkinson's disease or dementia

Date of first enrolment
08/11/2019

Date of final enrolment
08/01/2020

Locations

Countries of recruitment
Iran

Study participating centre
Farshchian Hospital
Mirzade Eshqi Street
Hamedan
Iran
6517839131

Sponsor information

Organisation
Islamic Azad University of Hamedan

Sponsor details
Professor Mussivand Blvd
Imam Khomeini Blvd
Hamedan
Iran
6558225885
+98 81 34481000
info@iauh.ac.ir

Sponsor type
University/education

Website
https://www.iauh.ac.ir/en/

ROR
https://ror.org/007zpd132

Funder(s)

Funder type
Government

Funder Name
National Institute for Medical Research Development

Alternative Name(s)

NIMAD

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Iran

Results and Publications

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

Intention to publish date
01/11/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request