Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Efficacy of the Unified Protocol on Emotion Regulation and mindfulness in People with Multiple Sclerosis

Protocol summary

Study aim
Efficacy of Transdiagnostic Group Therapy on Difficulties Emotion Regulation and emotion regulation

Design
We designed a diagnostic process based on co-morbidity between anxiety disorder and depression symptoms. Also, we served various materials to identify the appropriate subjects. A combination of Clinical diagnostic and self-report assessments more limited the eligibility of participation. Patients who met The Structured Clinical Interview for DSM-IV SCID-I criteria, for anxiety disorders, were evaluated in terms of the scales of emotion regulation, the scales of depression, and the scales of anxiety disorders. At last, only people who exclusively received at least one self-report score in each of the three domains were selected to randomization. Also, we investigate a web based intervention condition simoultanously.

Settings and conduct
Lorestan University

Participants/Inclusion and exclusion criteria
Eligibility criteria included: (a) Diagnosis of MS for three years or more, (b) Fluent in Persian, at least 18 years of age, (c) 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.,provide consent, exclusion criteria: suicidal

Intervention groups
The sessions were structured based on the Transdiagnostic Therapy basics developed by Barlow et al. Group therapy consisted of 12 weekly sixty-minute sessions.. The subjects who were randomly assigned to two groups of Transdiagnostic Increasing motivation: Motivational interviewing for participation and involvement of patients during therapy.

Main outcome variables
EMOTION REGULATION

General information

Reason for update
I have not starting rthe enrollment process. The mentioned date is an expected day. We are going to in start recruitement in the next week.

Acronym
EUPERMPWMS

IRCT registration information
IRCT registration number: **IRCT20190711044173N1**
Registration date: **2019-10-31, 1398/08/09**
Registration timing: **prospective**

Last update: **2019-11-10, 1398/08/19**
Update count: **1**

Registration date
2019-10-31, 1398/08/09

Registrant information

Name
Nabi Nazari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 81 3448 1000
Email address
nnpilotiriaf@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-02, 1398/08/11

Expected recruitment end date
2019-12-02, 1398/09/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of the Unified Protocol on Emotion Regulation and mindfulness in People with Multiple Sclerosis

Public title
Effectiveness of a cost effective cognitive behavioural program on improvement mentall health in MS

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of MS for three years or more Fluent in Persian Internet availibility

Exclusion criteria:
Other Chronic physical illnesses (such as insulin-dependent diabetes and chemotherapy for cancer) Pregnancy or lactation, Evidence of current or past schizophrenia, psychosis, or organic mental disorder, bipolar disorder, or organic mental disorder Drug abuse history or drug dependence except for nicotine Absenteeism for more than three sessions Presence of comorbid neurological disorders such as Alzheimer, Parkinson's disease, Dementia

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
All patients, met all inclusion criteria, were assigned to treatment and control groups using computer-generated random numbers.

Blinding (investigator's opinion)
Single blinded

Blinding description
The blinded researchers did randomization. This study was a clinical elevator-blinded, data-collector Blinded, analyst-blinded, and statistician blinded study.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

1

Registry name
Who International Clinical Trials

Secondary trial Id
U1111-1238-0965

Registration date
2019-08-05, 1398/05/14

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Commitee of NATIONAL INSTITUTE FOR MEDICAL RESEARCH DEVELOPMENT

Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
۱۴۱۹۶۹۳۱۱۱

Approval date
2019-10-28, 1398/08/06

Ethics committee reference number
IR.NIMAD.REC.1398.259

Health conditions studied

1

Description of health condition studied
Multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
depression

Timepoint
before allocation

Method of measurement
The hospital anxiety and depression scale (HADS): , Structured Clinical Interview for DSM-IV (SCID)

2

Description
anxiety

Timepoint
before allocation , post intervention, three month follow up

Method of measurement
The hospital anxiety and depression scale (HADS): , Structured Clinical Interview for DSM-IV (SCID)

Secondary outcomes

1

Description
depression
Timepoint
, post intervention, three month follow up
Method of measurement
The hospital anxiety and depression scale (HADS): , Structured Clinical Interview for DSM-IV (SCID)

Intervention groups

1

Description
The sessions were structured based on the Transdiagnostic Therapy basics developed by Barlow et al. Group(2018 edition) therapy consisted of 12 weekly sixty-minute sessions.. The subjects who were randomly assigned to two groups . Transdiagnostic intervention based on group intervention and consist of 12 session and 8 modules: 1) Increasing motivation: Motivational interviewing for participation and involvement of patients during therapy, providing treatment logic and setting treatment goals. 2)Providing psychological education, recognition of emotions, tracking emotional experiences, and training . 3)Training emotional awareness, learning to see emotional experiences (emotions and response to emotions) especially using mindfulness techniques. 4)IAssessment and cognitive reassessment, awareness of the impact and interaction between thoughts and emotions, identification of maladaptive automated evaluations and common 5)Examining EDBs, knowledge and identification of their effects on emotional experiences, identifying maldaptive EDBs, and creating alternatives for acting through behaviors. 6)Knowledge and tolerance of physical senses, increase awareness of the role of emotional feelings in emotional experiences, practice exercises or visceral confrontation in order to be aware of physical sensations and increase tolerance of these symptoms7)Visceral confrontation and confrontation with situational emotions, awareness of the logic of emotional confrontation, training how to prepare the fear hierarchy, avoidance and design of repeated and effective emotional exposure exercises, visual, objective and avoidance.8)Prevention of recurrence, overview of treatment concepts and discussion about patient's healing and progress
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian hospital
Full name of responsible person
Nabi Nazari
Street address
NO1 STREET, MIRZADE ESHQI STREET
City
HAMEDAN
Province
Hamadan
Postal code
6517839131
Phone
+98 81 3838 1749
Email
nazariirani@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
ISLAMIC AZAD UNIVERSITY
Full name of responsible person
MANSOR ESMAEEL POR
Street address
MOSIVAND PROF. STREET
City
HAMEDAN
Province
Hamadan
Postal code
65181-5743
Phone
+98 81 3449 4000
Email
info@iauh.ac.ir
Web page address
https://www.iauh.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
ISLAMIC AZAD UNIVERSITY
Proportion provided by this source
1
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
islamic azad university hamedan branch
Full name of responsible person
Nabi Nazari
Position
resercher
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
koosha apatement parvaz street,etemadie
City
hamedan
Province
Hamadan
Postal code
63952555711
Phone
+98 81 3555 2719
Email
nazariirani@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Nabi Nazari
Position
Ma
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Mosivand boulvared
City
Hamadan
Province
Hamadan
Postal code
651811574
Phone
+98 81 3448 1000
Fax
Email
nazariirani@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Nabi Nazari
Position
Ma
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Mosivand boulvared
City
Hamadan
Province
Hamadan
Postal code
6514873136
Phone
+98 81 3448 1000
Fax
Email
nazariirani@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Results will send to a peer reviewed international journal without selectivity.
When the data will become available and for how long
After trearment without delay
To whom data/document is available
All reserchers who confirm an existing study in line with this research must be provided an academic email.
Under which criteria data/document could be used
Represnt an Academic Email and IRB code
From where data/document is obtainable
Prencipal Invistigator
What processes are involved for a request to access data/document
Send an email, Provided by an Academic Email and IRB code
Comments