Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The study of the efficacy of the Transdiagnostic Treatment of the Unified for the Improvement of Comorbid Psychological Disorders (Depression, Anxiety and Health Anxiety), Fatigue and Quality of Life in Patients with Multiple Sclerosis (Ms)

Protocol summary

Study aim
Determining efficacy of the transdiagnostic treatment Unified Protocol on improving comorbid psychological disorders (Depression, Anxiety and Health Anxiety), fatigue and quality of life in patients with Multiple sclerosis (Ms)

Design
Clinical trial with control group, Not blinded, Randomized

Settings and conduct
This study is conducted at the counseling Center of Kermanshah University of Medical Sciences. Patients receive 12 sessions of acceptance and commitment therapy individually and weekly. The duration of each session is 90 minutes. To evaluate the follow up period again three months after the end of the intervention the subjects are evaluated. In order to evaluate the effects of treatment subjects will be evaluated one week before, one week after and three months after the end of the intervention respectively. The intervention is done by an experienced psychologist and based on barlow unified protocol for transdiagnostic treatmenl.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Ms disease diagnosed with a neurologist as the primary diagnosis. Exit criteria: Current diagnosis of any common mental disorder in Diagrams 1 and 2 based on a psychiatrist's diagnostic interview, with the exception of emotional disorders including depression, anxiety and health anxiety

Intervention groups
Intervention group: 15 people suffering from Ms disease, and psychiatric disorders receive 12 sessions the transdiagnostic treatment Unified. Control group: 30 people and do not receive any special treatment.

Main outcome variables
Depression; anxiety; health anxiety; fatigue; quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180421039369N2**
Registration date: **2019-05-10, 1398/02/20**
Registration timing: **prospective**

Last update: **2019-05-10, 1398/02/20**
Update count: **0**

Registration date
2019-05-10, 1398/02/20

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-19, 1398/02/29

Expected recruitment end date
2019-06-19, 1398/03/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The study of the efficacy of the Transdiagnostic Treatment of the Unified for the Improvement of Comorbid Psychological Disorders (Depression, Anxiety and Health Anxiety), Fatigue and Quality of Life in Patients with Multiple Sclerosis (Ms)

Public title
The study of the efficacy of the Transdiagnostic Treatment of the Unified for the Improvement of Comorbid Psychological Disorders in Ms Patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Suffering Ms disease with diagnosis of the neurological department Having a score of less than 5 in the (EDSS) Disability Indicator based on a neurologist's assessment to determine the individual's ability to attend a therapeutic session The age range is between 50 to 18 years old Affliction of emotional coexistence disorders including depression, anxiety and health anxiety based on diagnostic interview by psychologist Motivation and satisfaction for participation during treatment and research implementation Failure to receive psychological treatment in the past year Have at least a cycle of educationNot having other chronic diseases such as severe liver disorder The lack of current diagnosis of any mental disorder is consistent in Diagram 1 and 2 based on a psychologist's diagnostic interview, with the exception of emotional disorders including depression, anxiety and health anxiety No obvious risk of suicide now There is no history of drug abuse or dependence at the current time and within one year before the start of treatment

Exclusion criteria:
Unwillingness to attend research meetings Not attending at least 50% of the sessions Creating severe physical problems so that it can not be present at meetings

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**
More than 1 sample in each individual
Number of samples in each individual: **5**
Using Beck Depression Inventory (BDI-II), Beck Anxiety Inventory, Short form Health Anxiety Scale (SHIA), Fatigue Exercise Scale (FSS), and Quality of Life Scale (MSQOL-54) questionnaire for assessing the level of participants' problems.

Randomization (investigator's opinion)
Randomized

Randomization description
For randomizing assignment, the Simple Random method is used. 45 cards with the same appearance are provided. On 15 of cards the number 1 and on 30 of them the number 2 is written which represent the intervention group and the control group respectively. Then, one card is given to each qualified individual randomly and his assignment to the group is recorded. This process is continues until all individuals are assigned. It should be noted that participants are unaware of the nature of the numbers and type of intervention.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sciences

Street address
Central Building of Kermanshah University of Medical Sciences, Shahid Beheshti Blvd, Kermanshah

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Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2019-04-24, 1398/02/04

Ethics committee reference number
IR.KUMS.REC.1398.093

Health conditions studied

1

Description of health condition studied
comorbidity of Psychological disorders in Patient with MS

ICD-10 code
F06.8

ICD-10 code description
Other specified mental disorders due to brain damage and dysfunction and to physical disease

Primary outcomes

1

Description

Comorbidity of psychological disorders of patients with MS

Timepoint

A week before the intervention, one week after the intervention, Three months after the intervention

Method of measurement

Beck Depression Inventory (BDI-II), Beck Anxiety Inventory, Short form Health Anxiety Scale (SHIA), Fatigue Exercise Scale (FSS), and Quality of Life Scale (MSQOL-54) questionnaire

Secondary outcomes

1

Description

Depression

Timepoint

A week before the intervention, one week after the intervention, three months after the intervention

Method of measurement

Beck Depression Inventory (BDI-II)

2

Description

Anxiety

Timepoint

A week before the intervention, one week after the intervention, three months after the intervention

Method of measurement

Beck Anxiety Inventory

3

Description

Health Anxiety

Timepoint

A week before the intervention, one week after the intervention, three months after the intervention

Method of measurement

Short Form Health Anxiety Scale (SHIA)

4

Description

Fatigue Severity

Timepoint

A week before the intervention, one week after the intervention, three months after the intervention

Method of measurement

Fatigue Severity Scale (FSS)

5

Description

Quality of Life

Timepoint

A week before the intervention, one week after the intervention, three months after the intervention

Method of measurement

Multiple Sclerosis Quality of Life-54 (MSQOL-54)

Intervention groups

1

Description

Intervention group:In this study, the Barlow unified protocol for transdiagnostic treatment method will be used.The sample size in this study is 45. They are randomly divided into two experimental and control groups, in which 15 subjects in the experimental group and 30 in the control group are placed and the program The treatment, along with the workbook, will be provided to an individual group for 12 consecutive sessions. The treatment sessions are divided into eight sections: Section 1: Increased motivation for participation in treatment, Section 2: Psychological training and tracking emotional experiences, Section 3: Exercise Excitement Education Section, 4) Assess and modify cognitive assessment, Section 5) Avoid Excitement and Excitement, Section 6) Awareness of physical feelings and tolerance with them, Section 7) Exposure to internal and external triggers of excitement, Section 8) Prevention of recurrence

Category

Behavior

2

Description

Control group: Control group: consists of 30 people who are waiting in the waiting list and do not receive treatment during the time of intervention. but after treatment, they will receive Transdiagnostic Treatment of the Unified Protocol for maintaining the ethics of the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah University of Medical Sciences

Full name of responsible person

sasan amiri

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Sponsors / Funding sources

1

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Grant name
Kermanshah University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
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
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Position
MSc
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available