Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Compare the effectiveness of ACT (Acceptance and Commitment Therapy) and Mindfulness Based Cognitive - Behavioral Stress Management on the coping with stress, physical symptoms and psychological well being in patients with multiple sclerosis

Protocol summary

Study aim
The goal is to educate patients so that they can use the best possibe ways to deal with life problems, also to improve the individual satisfaction of life quality and ultimately reduces stress and improves physical symptoms in MS patients.

Design
The clinical trial has two intervention groups and a control group based on society and pragmatic with parallel, non blinded, randomized groups, each group consists of 20 people.

Settings and conduct
Scouting and treatment will take place in the Mehregan clinic and MS society during a weekly course that will include 8 sessions, each sessions lasts 120 minutes .

Participants/Inclusion and exclusion criteria
Age range 20 to 40 years ؛ Not having motion impairment ؛ Not having chronic disease ؛ Not having mental illness ؛ Having a high school diploma ؛

Intervention groups
ACT intervention group (Acceptance and commitment Therapy) Mindfulness Based Cognitive - Behavioral Stress therapy intervention group Control group

Main outcome variables
How to deal correctly with problems Change the styles of coping with stress Improving the judgment of the person from the degree of quality of the whole life Reducing stress Improve physical symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180206038644N1**
Registration date: **2018-06-14, 1397/03/24**
Registration timing: **retrospective**

Last update: **2018-06-14, 1397/03/24**
Update count: **0**

Registration date
2018-06-14, 1397/03/24

Registrant information

Name
Sahar Montazeri

Name of organization / entity
Khorasgan azad islamic unervisity

Country
Iran (Islamic Republic of)

Phone
+98 11 3575 0320

Email address
psychologist_68@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-09, 1397/02/19

Expected recruitment end date
2018-05-12, 1397/02/22

Actual recruitment start date
2018-05-10, 1397/02/20

Actual recruitment end date
2018-05-15, 1397/02/25

Trial completion date
empty

Scientific title
Compare the effectiveness of ACT (Acceptance and Commitment Therapy) and Mindfulness Based Cognitive - Behavioral Stress Management on the coping with stress,

physical symptoms and psychological well being in patients with multiple sclerosis

Public title
Compare the effectiveness of two psychological treatment methods on the symptoms of MS patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Not having motion impairment Not having chronic disease Not having mental illness Having a high school diploma Age range 20 to 40 years
Exclusion criteria:
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Purposeful random sampling method Individual random unit Randomization tool:random numbers
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
Reasearch Ethics Committe of Chalus
Street address
Islamic Azad University of Chalus ,17th Shahrivar Blvd
City
Chalus
Province
Mazandaran
Postal code
46615397
Approval date
2018-05-08, 1397/02/18
Ethics committee reference number
IR.IAU.CHALUS.REC.1397.5

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis (MS)
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Coping styles with stress score in Andler & Parker questionnaire,Physical symptoms score in Thirty-Six questionnaire Quality of Life, Psychological well being score in Ryff questionnaaire
Timepoint
Measurment of coping styles with stress, Physical symptoms and Psychological well being at the begining of the study (before the intervention begins) and two months after intervention and follow up 3 moths after the end of the intervention
Method of measurement
Andler & Parker coping styles with stress questionnaire, Thirty-Six question Quality of Life questionnaire, Ryff psychological well being questionnaaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first intervention is Mindfulness based cognitive- Behavioral stress management, The statistical population of the study consisted of all women with MS in Mazandaran and the sample group included 60 people who were randomly divided into three groups (Mindfulness based cognitive-Behavioral intervention group, Acceptance and Commitment therapy and control group), each one with 20 patients .The patients of experimental group were under Mindfulness Based cognitive - Behavioral Stress therapy.They recieved 8 sessions of therapy every week and each session lasted120 minutes .The purpose of this treatment is to help the authorities to achieve a more valuable life through increased psychological flexibility.
Category
Treatment - Other

2

Description
Intervention group: The second intervention is ACT Therapy (Acceptance and Commitment therapy), The

statistical population of the study consisted of all women with MS in Mazandaran and the sample group included 60 people who were randomly divided into three groups (Mindfulness Integrated Behavior-Cognitive therapy groups, Acceptance and Commitment therapy and control group), each one with 20 patients .The patients of experimental group were under Acceptance and Commitment Therapy .They recieved 8 sessions of therapy every week and each session lasted120 minutes .In this type of treatment instead of changing cognitive, it attemps to increase the psychological relationship of an individual with his thoughts and feelings.

Category

Treatment - Other

3

Description

Control group: There are no intervention such as (Acceptance and Commitment Therapy and Mindfulness Based Cognitive - Behavioral stress Management)during the study.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehregan clinic

Full name of responsible person

Sahar Montazeri

Street address

Mehregan Clinic., Gol Building., Sharifi Blvd.,Shahrbani Square

City

Babolsar

Province

Mazandaran

Postal code

4741741961

Phone

+98 11 3575 0320

Email

psychologist_68@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University Of Khorasgan

Full name of responsible person

Asghar Aghayi Jashoughani

Street address

University Blvd., Arghavanieh., East Gey Street

City

Khorasgan

Province

Isfehan

Postal code

8155139998

Phone

+98 31 3535 4001

Email

aghaeipsy@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University Of Khorasgan

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

Islamic Azad University of Khorasgan

Full name of responsible person

Sahar Montazeri

Position

University lecturer

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Termeh Buigding., Valiasr 1 Ave., Amirmazandarani Blvd

City

Babolsar

Province

Mazandaran

Postal code

4741637095

Phone

+98 11 3525 9911

Email

psychologist_68@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University of Khorasgan

Full name of responsible person

Sahar Montazeri

Position

University lecturer

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
Termeh Building., Valiasr 1 ave., Amirmazandarani Blvd

City
Babolsar

Province
Mazandaran

Postal code
4741637095

Phone
+98 11 3525 9911

Email
psychologist_68@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University of Khorasgan

Full name of responsible person
Sahar Montazeri

Position
University lecturer

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
Termeh building .,Valiasr Ave., Amirmazandarani Blvd

City
Babolsar

Province
Mazandaran

Postal code
4741637095

Phone
+98 11 3525 9911

Email
psychologist_68@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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