

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effectiveness of acceptance and commitment-based therapy and compassion-focused therapy on death anxiety, fear of falling, life expectancy and demoralization symptoms in patients with multiple sclerosis

Protocol summary

Study aim

Determining the comparative effectiveness of acceptance and commitment-based therapy and compassion-focused therapy on death anxiety, fear of falling, life expectancy and demoralization symptoms in patients with multiple sclerosis.

Design

The clinical trial will include two intervention groups, ACT, CFT, and a control group, which will be purposefully sampled and assigned to the groups using a random number table.

Settings and conduct

After sampling and performing the pre-test, each group will be individually subjected to CFT and ACT intervention, and then the post-test will be performed in that case, and these measures will be performed by obtaining the necessary permits in Imam Reza Hospital, Tabriz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Criteria for the diagnosis of MS by a neurologist Being 20 to 50 years old At least two years have passed since the illness Consent to participate in the research and not having other acute and chronic physical and psychological diseases based on the patient's medical record Exit criteria Absence in two training sessions Non-cooperation and not doing the tasks specified in the training course

Intervention groups

In this research, there will be three groups including two intervention groups with ACT and CFT treatment on MS patients and one group as a control group.

Main outcome variables

death anxiety ; fear of falling (falling); life expectancy; Depression syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231112060034N1**

Registration date: **2024-01-04, 1402/10/14**

Registration timing: **prospective**

Last update: **2024-01-08, 1402/10/18**

Update count: **1**

Registration date

2024-01-04, 1402/10/14

Registrant information

Name

AmirAbolfazl Azizpour

Name of organization / entity

Tabriz Azad University

Country

Iran (Islamic Republic of)

Phone

+98 41 4423 9382

Email address

stu.a.azizpour@iaut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-05, 1402/10/15

Expected recruitment end date

2024-02-04, 1402/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of acceptance and commitment-based therapy and compassion-focused therapy on death anxiety, fear of falling, life expectancy and demoralization symptoms in patients with multiple sclerosis

Public title

Investigating the effect of acceptance and commitment-based therapy and compassion-focused therapy on multiple sclerosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of MS disease by brain and nerve specialist and referral of medical case to MS Society Being 20 to 50 years old At least two years have passed since the illness Consent to participate in the research Not having other acute and chronic physical and psychological diseases based on the patient's medical record

Exclusion criteria:

Absence in two training sessions and non-cooperation Not doing the tasks specified in the training course

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Research Ethics Committees of Islamic Azad university-Tabriz Branch

Street address

Nagin Building, Golestan Street, Amir Kabir Street, Baghmisheh Town

City

Tabriz

Province

East Azarbaijan

Postal code

5155994599

Approval date

2023-08-08, 1402/05/17

Ethics committee reference number

IR.IAU.TABRIZ.REC.1402.201

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

The score that subjects will get from answering the questions of the death anxiety scale (Templer, 1970).

Timepoint

Pre-test and post-test before and after ACT, CFT intervention and after the follow-up period

Method of measurement

Templer Death Anxiety Scale

2

Description

The score that the subjects will get from the answers to the questions of the short scale of efficiency in falling the international form (Kampen et al., 2008).

Timepoint

Pre-test and post-test before and after ACT, CFT intervention and after the follow-up period

Method of measurement

Short scale of efficiency in falling - international form

3

Description

The score that the subjects will get from the answers to the questions of the depression syndrome questionnaire (Kisan et al., 2004).

Timepoint

Pre-test and post-test before and after ACT, CFT intervention and after the follow-up period

Method of measurement

Questionnaire of Kisan's low morale syndrome

4

Description

The score that subjects will get from answering the questions of Omid Snyder's questionnaire (Snyder, 1991).

Timepoint

Pre-test and post-test before and after ACT, CFT intervention and after the follow-up period

Method of measurement

Hope Snyder questionnaire

5

Description

In the current research, acceptance and commitment based therapy is the training of skills based on the acceptance and commitment therapy protocol (Hayes and Stroschall, 2005), and it will be carried out during 8 sessions of 60 minutes.

Timepoint

Pre-test and post-test before and after ACT, CFT intervention and after the follow-up period

Method of measurement

Treatment protocol based on acceptance and commitment

6

Description

In the present research, the treatment focused on compassion is the training of skills based on the program of Gilbert (2010) and will be carried out during 8 sessions of 60 minutes.

Timepoint

Pre-test and post-test before and after ACT, CFT intervention and after the follow-up period

Method of measurement

Compassion-focused therapy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the first experimental group, commitment-based acceptance therapy will be performed in 8 sessions of 60 minutes. The commitment-based acceptance therapy used in this research will be based on the therapeutic protocol of Hayes and Stroschall (2005).

Category

Treatment - Other

2

Description

Intervention group: For the second experimental group, treatment focused on compassion will be done in 8

sessions of 60 minutes. The therapy focused on compassion used in this study was determined based on the program of Gilbert (2010).

Category

Treatment - Other

3

Description

Control Group: Includes 20 samples who will not get any therapeutic intervention

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Tabriz Hospital

Full name of responsible person

Mojtaba Mohammadzadeh

Street address

Golgasht St., in front of the central organization of the University-Imam Reza Educational and Medical Center

City

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imamreza@tbzmed.ac.ir

Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Rahim Vakilzadeh

Street address

astern side of Pasdaran highway, Tabriz Islamic Azad University educational complex

City

Tabriz

Province

East Azarbaijan

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Fax

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Email

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Web page address

https://tabriz.iau.ir/

Grant name

Grant code / Reference number

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

No

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

Full name of responsible person

AmirAbolfazl Azizpour

Position

Psychologist

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Person responsible for updating data

Contact

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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

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

There is no further information

When the data will become available and for how long

There is no further information

To whom data/document is available

There is no further information

Under which criteria data/document could be used

There is no further information

From where data/document is obtainable

There is no further information

What processes are involved for a request to access data/document

There is no further information

Comments