

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The Effectiveness of Group Metacognitive Therapy on Defense Mechanisms, Resiliency and Self Efficacy of Females with Multiple Sclerosis

Protocol summary

Summary

Objective: This study aims to investigate the effectiveness of cognitive group therapy in cognitive components, resilience, self-efficacy and defensive styles of females with multiple sclerosis. **Design:** This research is a quasi-experimental study with a pretest-posttest control group design accompanied by a two-step follow-up procedure. Of all the patients with multiple sclerosis referring to the MS Society of Khorasan-e- Razavi in 2014, 30 individuals were selected through available sampling method and were randomly assigned to two experimental and control groups. **Implementation:** The experimental group underwent metacognitive therapy during 8 weeks while the control group followed the ordinary course of the sessions provided by the MS Society. Metacognition questionnaire-30 (MCQ-30), Connor and Davidson Resilience Scale (CD-RISC), Sherer General Self-Efficacy Scale and Defense Style Questionnaire (DSQ) were used in the pretest, posttest and follow-ups. **Inclusion criteria** consisted of the following: The final diagnosis of developing MS by the neurologist, signing a written consent form to participate in the study, having at least a diploma and achieving scores 1 to 4 in EDSS diagnosed by the neurologist. **Exclusion criteria** were as follows: Receiving psychological treatments at least one month prior to entering the study, a history of metabolic diseases like thyroid and absence of more than two sessions. **Interventions:** The experimental group underwent metacognitive therapy during 8 weeks while the control group followed the ordinary course of the MS Society sessions. Metacognition questionnaire-30 (MCQ-30), Connor and Davidson Resilience Scale (CD-RISC), Sherer General Self-efficacy Scale and Defense Style Questionnaire (DSQ) were applied in the pretest, posttest and follow-ups. The main outcome variables: Cognitive components, resilience, self-efficacy, defensive styles

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091624054N1**
Registration date: **2015-12-11, 1394/09/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-11, 1394/09/20

Registrant information

Name

Elahe Asgharkhah

Name of organization / entity

Islamic Azad University of Neyshabur

Country

Iran (Islamic Republic of)

Phone

+98 51 3759 3284

Email address

elaheasgharkhah@gmail.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Group Metacognitive Therapy on Defense Mechanisms, Resiliency and Self Efficacy of Females with Multiple Sclerosis

Public title

The Effect Metacognitive Therapy on patient with Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Main inclusion and exclusion criteria: Inclusion criteria: The final diagnosis of developing MS by the neurologist, signing a written consent form to participate in the study, having at least a diploma and achieving scores 1 to 4 in EDSS diagnosed by the neurologist. Exclusion criteria: Receiving psychological treatments at least six month prior to entering the study, a history of metabolic diseases like thyroid and absence of more than two sessions.

Age

From **30 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Of all the patients with multiple sclerosis referring to the MS Society of Khorasan-e- Razavi in 2014, 30 individuals were selected through available sampling method and were randomly(Using a table of random numbers) assigned to two experimental and control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Azad University of Neyshabur

Street address

Complex of Islamic Azad University of Neyshabur,

Pazhouhesh Street, Neyshabur Branch, Khorasan e Razavi, Iran

City

Neyshabur

Postal code

Approval date

2014-08-16, 1393/05/25

Ethics committee reference number

23420701922036

Health conditions studied

1

Description of health condition studied

Multiple SCLEROSIS

ICD-10 code

G35-G37

ICD-10 code description

Demyelinating diseases of the central nervous system

Primary outcomes

1

Description

Metacognitive Components

Timepoint

pre test, Post test, two-step follow-up

Method of measurement

Metacognition Questionnaire -30 (MCQ-30)

2

Description

Resiliency

Timepoint

pre test, Post test, two-step follow-up

Method of measurement

Connor and Davidson Resilience Scale (CD-RISC)

3

Description

Self-Efficacy

Timepoint

pre test, Post test, two-step follow-up

Method of measurement

General Self-Efficacy Questionnaire

4

Description

Defense Mechanisms

Timepoint

pre test, Post test, two-step follow-up

Method of measurement

Defense Styles Questionnaire (DSQ)

Secondary outcomes

empty

Intervention groups

1

Description

The experimental group received metacognitive therapy for eight weeks

Category

Behavior

2

Description

the control group spent the routine process of the sessions held by the MS Society.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

MS Society in Khorasan-e- Razavi

Full name of responsible person

Docter Hossein Shareh

Street address

Unit 3, Negin building, Aref Avenue, Ahmadabad Street, Mashhad Khorasan-e- Razavi, Islamic Republic Of Iran

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

elahe asgharkhah

Street address

Khorasan-e- Razavi

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Investigator

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hakim Sabzevari University

Full name of responsible person

Dr Hossein Shareh

Position

PhD

Other areas of specialty/work

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Fax**Email**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty