

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of Cognitive rehabilitation on cognitive status (attention, memory, executive function) and quality of life in patients with multiple sclerosis: A randomized control clinical trial.

Protocol summary

Summary

Objectives: This study has been designed to evaluate the effect of cognitive rehabilitation on memory, attention, executive function and quality of life in patients with multiple sclerosis. **Design:** The present study is a randomized clinical trial with control group, a cross sectional study. **Setting and conduct:** The patients who live in Shiraz, suffering from multiple sclerosis and are referred to Imam Reza medical clinic and some private clinics will be selected. They will be evaluated and then divided into two groups, randomly. **Participants including major eligibility criteria:** 30 patients who meet the inclusion criteria; age between 18 to 45 years, relapsing-remitting MS and be educated more than 6 grades will be selected and the ones with other psychiatric or medical disorders, major motor deficit, pregnant and those who had any attack during the previous 6 months will be excluded from the study. **Intervention:** All the patients will take pre-test exams then they are divided into two groups (control and intervention). the intervention group will participate 8 sessions of cognitive rehabilitation in 2 weeks. Both groups will be tested the same exams again (just after group therapy is finished and then 3 months later). **Data collecting methods are:** Demographic Questionnaire, Right/Left Dominance Questionnaire, ACE-R Questionnaire, CPT/WSCT Tests, Psychiatric interview, CFQ executive function test, DASS test. **Main outcome variables:** The cognitive status (attention, memory, executive function) of the patients and their quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090929714N1**
Registration date: **2016-12-18, 1395/09/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-18, 1395/09/28

Registrant information

Name

Elnaz Chohedri

Name of organization / entity

Shiraz University of Medical Sciences

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echohedri@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Cognitive rehabilitation on cognitive status (attention, memory, executive function) and quality of life in patients with multiple sclerosis: A

randomized control clinical trial.

Public title

Effectiveness of Cognitive Rehabilitation in Multiple Sclerosis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- At least 6 grade of school education; 2- Age between 18 to 45 years old; 3- Relapsing-Remitting multiple sclerosis; 4- Right dominance
Exclusion criteria: 1- Multiple sclerosis attack in the recent 6 months; 2- Left dominance or ambidexterity; 3- Patients unwilling to participate in the survey; 4- Psychiatric debilitating illness; 5- Chronic psychiatric disease; 6- No motor deficit; 7- Pregnancy

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Shiraz University of Medical Sciences

Street address

Ethic Committee, 7th floor, Medical School, Zand St.

City

Shiraz

Postal code

Approval date

2016-01-21, 1394/11/01

Ethics committee reference number

ir.sums.med.rec.1394.74

Health conditions studied

1

Description of health condition studied

Dementia in other specified diseases classified elsewhere

ICD-10 code

F02.8

ICD-10 code description

Dementia (in): cerebral lipidosis, epilepsy, hepatolenticular degeneration, hypercalcaemia, hypothyroidism, acquired, intoxications, multiple sclerosis, neurosyphilis, niacin deficiency, polyarteritis nodosa, systemic lupus erythematosus, trypanosomiasis

Primary outcomes

1

Description

memory

Timepoint

before intervention- immediately after intervention- 3 months after intervention

Method of measurement

ACE-R test

2

Description

Executive function

Timepoint

before intervention- immediately after intervention- 3 months after intervention

Method of measurement

CFQ Quastinaire, WSCT test

3

Description

attention

Timepoint

before intervention- immediately after intervention- 3 months after intervention

Method of measurement

Reactio time, CPT test

Secondary outcomes

1

Description

quality of life

Timepoint

before intervention- immediately after intervention- 3 months after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: 8 sessions of cognitive rehabilitation group therapy with focus on attention, memory and executive function, for a duration of 4 weeks, 2 sessions in each week, lasts 45 to 60 mins

Category

Rehabilitation

2

Description

Control group: no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Medical Clinic

Full name of responsible person

Mani Arash M.D.

Street address

Psychiatry department, 4th floor, Imam Reza Medical Clinic, Nemazee SQ, Shiraz, Iran

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Hashemi Seyed Basir

Street address

Vice chancellor for research, 6th floor, Shiraz University of Medical Sciences, Zand St.A

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

Mani Arash

Position

Assistant Professor and Member of Shiraz Psychiatric Group

Other areas of specialty/work

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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