Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Country

Iran (Islamic Republic of)

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+98 71 3627 9319

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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 comittee of Shiraz University of Medical Sciences
Street address
Ethic Comittee, 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 elsewher
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
questionaire

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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Resident of Psychiatry

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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