Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of cognitive rehabilitation based on information processing speed on occupational performance in people with Multiple Sclerosis (MS)

Protocol summary

Study aim
The effect of cognitive rehabilitation based on information processing speed on balance and mobility in people with Multiple Sclerosis (MS)

Design
Clinical trial with control group, randomized, single blinded, with 70 patients

Settings and conduct
The intervention group will receive a cognitive rehabilitation program in Rofeideh Hospital. They will also receive common therapies of occupational therapy that include flexibility and balance exercises. The control group will receive common therapies of occupational therapy that include flexibility and balance exercises in Sina Hospital. Also, the intervention will be explained to all patients, but will not be mentioned the impact of intervention on evaluation tests and mobility and balance.

Participants/Inclusion and exclusion criteria
The person would be willing to participate in the research؛ The person has a definite diagnosis of MS by a specialist؛ The person has an EDSS score of 5 down؛ The person has a FSS score of 9-35؛ The person can work with the camputer؛ The person has no other neurological diseases؛ The person has not taken corticosteroids 28 days before the intervention؛ The person has no psychological disorders.

Intervention groups
The intervention group will receive a cognitive rehabilitation program based on the information processing speed through the Can Tab system for 12 sessions. They will also receive common therapies of occupational therapy that include flexibility and balance exercises. The control group will receive common therapies of occupational therapy that include include flexibility and balance exercises for 12 sessions.

Main outcome variables
Balance score in the Balance Evaluation System Test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180517039699N1**
Registration date: **2018-07-08, 1397/04/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-08, 1397/04/17**
Update count: **0**

Registration date
2018-07-08, 1397/04/17

Registrant information
Name
Zahra Yaghoobi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2244 1197
Email address
z.yaghoobi1993@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-07, 1397/04/16

Expected recruitment end date
2018-11-07, 1397/08/16

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of cognitive rehabilitation based on information processing speed on occupational performance in people with Multiple Sclerosis (MS)

Public title

The effect of cognitive rehabilitation based on information processing speed on occupational performance in people with Multiple Sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The person would be willing to participate in the research. The person has a definite diagnosis of MS by a specialist. The person has an EDSS score of 5 down. The person has a FSS score of 9-35. The person can work with the camputer. The person has no other neurological diseases. The person has not taken corticosteroids 28 days before the intervention. The person has no psychological disorders. The age of the person is 20 to 60 years. Gender of patients has no limit.

Exclusion criteria:

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients in two Rofaydeh and Sina centers are randomly divided into control and intervention groups (refer odd days to Sina hospital for control group and refer even days to Rofaydeh hospital for intervention group). This division was done by draw with cup.

Blinding (investigator's opinion)

Single blinded

Blinding description

After receiving consent from patients, the way of intervention will be explained to them. But the impact of intervention on evaluation tests and mobility and balance will not be mentioned.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Social Welfare and Rehabilitation Sciences

Street address

Koudakyar dead end, Daneshjou blvd, Evin, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۷۱

Approval date

2018-02-26, 1396/12/07

Ethics committee reference number

IR.USWR.REC.1396.328

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

Balance score in the Balance Evaluation System Test

Timepoint

The balance will be evaluated before the beginning intervention, after the end of intervention and two months after the end of intervention.

Method of measurement

The Balance Evaluation System Test

Secondary outcomes

1

Description

The information processing speed score in Paced Auditory Serial Addition Test (PASAT)

Timepoint

The information processing speed will be evaluated before the beginning intervention, after the end of intervention and two months after the end of intervention.

Method of measurement

The Paced Auditory Serial Addition Test

2

Description

The information processing speed score in the Symbol Digit Modalities Test (SDMT)

Timepoint

The information processing speed will be evaluated before the beginning intervention, after the end of intervention and two months after the end of intervention.

Method of measurement

The Symbol Digit Modalities Test (SDMT)

Intervention groups

1

Description

Intervention group: The intervention group will receive a cognitive rehabilitation program based on the information processing speed through the Can Tab system for 12 sessions. They will also receive common therapies of occupational therapy that include flexibility and balance exercises.

Category

Rehabilitation

2

Description

Control group: The control group will receive common therapies of occupational therapy that include include flexibility and balance exercises for 12 sessions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofeideh hospital

Full name of responsible person

Fereydoon Layeghi

Street address

Nemati Alley, Soleimani St, Qeytariye

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1935973476

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Email

rofeideh.hospital@uswr.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Amir Massoud Arab Loodaricheh

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Koudakyar dead end, Daneshjou blvd, Evin, Tehran

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rd@uswr.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of social welfare and rehabilitation sciences

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

University of social welfare and rehabilitation sciences

Full name of responsible person

Zahra Yaghoobi

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

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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
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