

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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 computer! 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 computer. 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 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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1935973476

##### **Phone**

+98 21 2220 5326

##### **Fax**

+98 21 2223 2741

##### **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

##### **Street address**

Koudakyar dead end, Daneshjou blvd, Evin, Tehran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1985713834

##### **Phone**

+98 21 2218 0039

##### **Email**

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

##### **Street address**

No. 55 , Sadaf Town., NakhI Ave., Artesh Hwy

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##### **Email**

Z.yaghoobi1993@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Zahra Yaghoobi

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## Person responsible for updating data

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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