

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effectiveness of Cognitive Rehabilitation and Life Style Modification on Executive Function of Patients with Non Amnestic Mild Cognitive Impairment

#### Protocol summary

2016-01-15, 1394/10/25

#### Summary

Today elderly population is growing. Cognitive disorders are the major health issues associated with this age group. These cognitive problems impose large economical and social costs on the society due to their impact on individual functioning. Mild Cognitive Impairment (MCI) is considered as a transient phase between normal aging and dementia. Nowadays, there is no effective treatment for MCI, so alternative therapies are under investigation. One of these methods is cognitive interventions. In this study we are going to assess the effect of cognitive rehabilitation on executive functioning in patients older than 60 years old with non-amnestic MCI, without any diagnostic criteria of dementia or any other major psychiatric problems. Patients were randomly divided into three groups of fifteen. The first group was assigned to life style interventions treatment, the second group was assigned to executive function rehabilitation, and finally the control group received educational pamphlets of other groups after six months of interventions. For all the patients we will assess neuropsychological tests before, just after and six months after interventions, and analyze the test scores differences. Note that double-blinding has been conducted throughout this experiment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201203029188N1**

Registration date: **2016-01-15, 1394/10/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Majid Barekatin

##### Name of organization / entity

Isfahan university of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1222 2475

##### Email address

barekatin@med.mui.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Isfahan University of Medical Science

#### Expected recruitment start date

2014-09-20, 1393/06/29

#### 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

Effectiveness of Cognitive Rehabilitation and Life Style Modification on Executive Function of Patients with Non Amnestic Mild Cognitive Impairment

#### Public title

effect of cognitive rehabilitation and life style modification on patients with mild cognitive intervention

#### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria :Age above 60 years; minimum 9 years of school education;NeuroCognitive Unite assesment (noucog) test score 75to 85 with executive function subscale score under 12 and memory subscale score above 15; /general Health Questioner(GHQ )test score under 22 ; physical ability to participate in training classes . Exclusion criteria : complaint of disability in daily activities, ; major psychiatric or neurological diagnosis ; diagnosis of dementia; substance abuse with effect on cognitive abilities ; use of psychotropic drug with effect on cognitive abilities

### Age

From **60 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **45**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Isfahanl University of Medical Siences

##### Street address

Ethics Committee, Isfahan University of Medical Scienses, Hezarjerib Street, Isfahan, Iran

##### City

Isfahan

##### Postal code

#### Approval date

2014-08-27, 1393/06/05

#### Ethics committee reference number

393560

## Health conditions studied

### 1

#### Description of health condition studied

mild cognitive impairment

#### ICD-10 code

786.5

#### ICD-10 code description

Personal history of other mental and behavioural disorders

## Primary outcomes

### 1

#### Description

changes of cognitive test's scores

#### Timepoint

Befor interventin-immediately after interventions-6months after intervention

#### Method of measurement

Go no go test

### 2

#### Description

changes of cognitive test's scores

#### Timepoint

Before intervention-immediately after intervention-6months after intervention

#### Method of measurement

Design fluency test

### 3

#### Description

changes of cognitive test's scores

#### Timepoint

Before intervention-immediately after intervention-6 months after intervention

#### Method of measurement

Five points test

### 4

#### Description

changes of cognitive test's scores

#### Timepoint

Before intervention-immediately after intervention-6 months after intervention

#### Method of measurement

Category fluency test

### 5

#### Description

changes of cognitive test's scores

#### Timepoint

Before intervention-immediately after intervention-6 months after intervention

#### Method of measurement

Tower of london test

**6**

**Description**

changes of cognitive test's scores

**Timepoint**

Before intervention-immediately after intervention-6 months after intervention

**Method of measurement**

BRIEF-A

**7**

**Description**

changes of cognitive test's scores

**Timepoint**

Before intervention-immediately after intervention-6 months after intervention

**Method of measurement**

Color trail making test

**Secondary outcomes**

**1**

**Description**

changes in scores of qialoty of life test

**Timepoint**

Before intervention-immediately after intervention-6months after intervention

**Method of measurement**

health promoting lifestyle test

**Intervention groups**

**1**

**Description**

"Intervention group:" nine sessions of executive functions rehabilitation

**Category**

Rehabilitation

**2**

**Description**

" Control group" will receive educational pamphlet of the other groups( after 6months)at the end of the assessments.

**Category**

Other

**3**

**Description**

" Intervention group": Nine sessions of life style educations in the same time with the other intervention group

**Category**

Lifestyle

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Isfahan Retired Educators Associaciation

**Full name of responsible person**

**Street address**

**City**

Isfahan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Isfahan University of Medical Sciences

**Full name of responsible person**

Mehdi Nematbakhssh

**Street address**

Vice chancellor for research, Isfahan University of Medical Sciences,Hezarjerib street,Isfahan,Iran

**City**

Isfahan

**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, Isfahan 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**

Isfahan University of Medical Sciences

**Full name of responsible person**

Maryam Alavirad

**Position**

Phsychiatric resident

**Other areas of specialty/work**

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**Position**

Psychiatrist

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**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*