Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of Cognitive-Based Occupational Therapy Interventions on The Level of Cognitive Performance of Elderly Women with Mild Cognitive Impairment (MCI) In Shiraz City: A Randomized Controlled Trial

Protocol summary

Study aim
Determining the effect of cognitive-based occupational therapy interventions on cognitive function of elderly women with mild cognitive impairment (MCI) in Shiraz city

Design
A randomized clinical trial using the Ephron equal block randomization method, in a single-blind manner, the sample size was obtained using NCSS-PASS version 15 software, 62 people, who were equally allocated into 2 groups (intervention and control).

Settings and conduct
Intervention classes and questionnaire completion are conducted in the Farzanegan Foundation of Shiraz in the presence of the facilitator and the clinic manager. Blinding occurs in the participants in such a way that they are unaware of the study group allocation and all participants involved in the study assume that all participants have received the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Elderly women with mild cognitive impairment evaluated with the Mocha test with a score of less than 26, Elderly women with memory complaints, Willingness to participate in the study Exclusion criteria: Having more than one absent session or more in treatment programs, Elderly women who attended the pre-test but did not attend the post-test, Incomplete completion of questionnaires, Transfer of residence or long-term illness or refusal of treatment and death.

Intervention groups
The elderly will be divided into two groups: intervention and control, and the intervention group will receive a class to increase cognitive skills. The control group will receive yoga classes from Soroush Center.

Main outcome variables
Mild cognitive impairment, executive functions, cognitive flexibility, memory, cognitive-based occupational therapy interventions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180514039648N9**
Registration date: **2024-12-25, 1403/10/05**
Registration timing: **prospective**

Last update: **2024-12-25, 1403/10/05**
Update count: **0**

Registration date
2024-12-25, 1403/10/05

Registrant information

Name
Abdolrahim Asadollahi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-08, 1403/10/19

Expected recruitment end date
2025-04-08, 1404/01/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of Cognitive-Based Occupational Therapy Interventions on The Level of Cognitive Performance of Elderly Women with Mild Cognitive Impairment (MCI) In Shiraz City: A Randomized Controlled Trial

Public title
Effectiveness of Cognitive-Based Occupational Therapy Interventions on The Level of Cognitive Performance of Elderly Women with Mild Cognitive Impairment (MCI)

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Elderly women with mild cognitive impairment evaluated with the Mocha test with a score less than 26 Elderly women with memory complaints Willingness to participate in the study

Exclusion criteria:
Having more than one absent session or more in treatment programs Elderly women who attended the pre-test but did not attend the post-test. Incomplete completion of questionnaires Transfer of residence or long-term illness or refusal of treatment and death.

Age
From **60 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
In the intervention phase in random trials, for sampling the study samples into different groups of control and control groups, randomly divided in this type of trials, a group of people who are members of Farzangan Shiraz Foundation and meet the entry criteria will be selected (Random Allocation) In each care center for the elderly, there is a list of the names of the members in the center with the national code, and each number will be defined as a variable ID number in the software. We will select about 200 members of Farzangan Shiraz Foundation and measure them using the Montreal Cognitive Status Questionnaire (MOCA) and 62 people who meet all the conditions for entering the study will be selected and using the technique Random sampling in such a way that these 31 people will be classified into 2 equal blocks in each block of 31 people between the groups and the final sample will be set. Random allocation of elderly people referring to the day care center for the elderly with the help of statistical software in intervention and control groups with Efron's randomization algorithm with blocks equal to Efron's P = 0.75 and 500 rotations (chance in the control and intervention groups is done using blinding In this Procedures DOE► Randomization Lists version 15.0.1 with the command CSS-PASS, the study was a blind study so that the elderly are unaware of their group title.

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinding occurs in participants in such a way that they are unaware of the study group allocation and all participants involved in the study assume that all participants have received the intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
School of Health, Razi Ave.

City
Shiraz

Province
Fars

Postal code
7153675541

Approval date
2024-12-11, 1403/09/21

Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1403.084

Health conditions studied

1

Description of health condition studied
Mild cognitive impairment

ICD-10 code
G31. 84

ICD-10 code description
Mild cognitive impairment of uncertain or unknown etiology

Primary outcomes

1

Description
Executive Functions

Timepoint

Before the intervention, immediately after the end of the intervention, and two months after the intervention

Method of measurement

Tower of London test

2

Description

Cognitive flexibility

Timepoint

Before the intervention, immediately after the end of the intervention, and two months after the intervention

Method of measurement

Wisconsin Card Sorting Inspired Task (WCST)

3

Description

memory

Timepoint

Before the intervention, immediately after the end of the intervention, and two months after the intervention

Method of measurement

Wechsler Memory Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: 12 one-hour intervention sessions will be held for the intervention group (31 people) with the aim of increasing the cognitive skills of elderly women. In the intervention group, the Wechsler Memory Inventory and the Wisconsin Card Test along with the Tower of London Test will be administered before the start of the intervention, immediately after the intervention, and 2 months after the end of the intervention.

Category

Prevention

2

Description

Control group: Control group: 12 one-hour yoga and exercise class intervention sessions will be conducted for the control group at the Soroush older adults Center. In the control group, the Wechsler Memory Inventory and the Wisconsin Card Test along with the Tower of London Test will be administered before the start of the intervention, immediately after the intervention, and 2 months after the end of the intervention. After completing the intervention package provided to the experimental group, it will also be provided to the control group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

FDCF of Shiraz

Full name of responsible person

Dr.Abdolrahim Asadollahi

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No . 30, Dinakan5 , Mirzaye Shirazi Blvd, Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical 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
Shiraz University of Medical Sciences

Full name of responsible person
Mahdis Ferasat

Position
Trial Project Associate and Student

Latest degree
Master

Other areas of specialty/work
Geriatrics

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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
The datasets generated and/or analysed during the current study are available from the authors upon reasonable request and with the permission of SUMS.

When the data will become available and for how long
Immediately at the time of printing the results

To whom data/document is available
Data will be made available to academic researchers upon request.

Under which criteria data/document could be used
Allowed with source reference.

From where data/document is obtainable
Scientific supervisor of the study: Dr. Abdolrahim Asadollahi by sending him an official email.

What processes are involved for a request to access data/document
Upon receiving an email from the applicant and reviewing his/her academic qualifications, data will be shared immediately to the same email.

Comments