

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effectiveness of a Multi-Component Lifestyle Intervention on Cognitive Function and Instrumental Activities of Daily Living in Adults at Risk of Dementia

Protocol summary

Study aim

To determine the effectiveness of a multi-component lifestyle intervention on instrumental activities of daily living and cognitive function in adults at risk of developing dementia.

Design

This is a randomized controlled trial with a parallel design and double-blind protocol, conducted to evaluate the effectiveness of a multi-component lifestyle intervention compared to routine care. Participants will be allocated using stratified randomization based on the type of cognitive impairment, and the sample size is calculated with 90% power and a significance level of 0.01.

Settings and conduct

This study will be conducted in elderly care centers in Tehran on adults over 55 diagnosed with MCI or SCD, who will be stratified-randomized into intervention and control groups; the trial is double-blind, and allocation is concealed using sealed envelopes.

Participants/Inclusion and exclusion criteria

Adults aged 55 and above who are independent in self-care, have difficulty with at least one IADL, no severe psychiatric or neurological disorders, and meet MCI or SCD criteria will be included; those with physical disabilities, a history of severe mental illness, or unwillingness to participate will be excluded.

Intervention groups

The control group will receive routine care provided by elderly care centers. The intervention group, in addition to routine care, will participate in a 6-week multi-component lifestyle program including cognitive training, physical activity, and social engagement. The aim of the intervention is to improve cognitive function and daily activities in older adults at risk of dementia.

Main outcome variables

Overall cognitive performance score based on MoCA;

Instrumental activities of daily living (IADLs) score based on Bayer-ADL questionnaire;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250326065160N1**

Registration date: **2026-08-13, 1405/05/22**

Registration timing: **registered_while_recruiting**

Last update: **2026-08-13, 1405/05/22**

Update count: **0**

Registration date

2026-08-13, 1405/05/22

Registrant information

Name

Fereshteh Torki

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 24 3525 1316

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-04-21, 1405/02/01

Expected recruitment end date

2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effectiveness of a Multi-Component Lifestyle Intervention on Cognitive Function and Instrumental Activities of Daily Living in Adults at Risk of Dementia

Public title
Effect of a Lifestyle Program on Cognition and Daily Activities in People at Risk of Cognitive Decline

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Aged 55 years and older Able to perform self-care activities independently The individual must have difficulty performing at least one Instrumental Activity of Daily Living (IADL) MoCA score between 19 and 24 MoCA score above 24 accompanied by the following two criteria: Persistent self-experienced cognitive decline compared to the individual's previous normal state, not attributable to an acute event, as measured by the Jessen criteria A score of 0.5 on the Clinical Dementia Rating (CDR) scale
Exclusion criteria:
History of severe psychiatric disorders or neurological conditions Physical disability or any condition that limits physical activity Participation in a similar intervention program Unwillingness to participate in the study

Age
From **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be allocated to the intervention and control groups in a 1:1 ratio using stratified block randomization. Stratification will be based on cognitive impairment type (MCI or SCD), with blocks of four used to maintain balance between the groups. Separate computer-generated randomization sequences will be prepared for each stratum by an independent individual. Allocation codes will be placed in sequentially numbered, opaque, sealed envelopes. Following enrollment and baseline assessment, the randomization officer will open the next envelope corresponding to the participant's stratum and inform the principal investigator of the group assignment.

Blinding (investigator's opinion)
Single blinded

Blinding description

Due to the nature of the intervention, blinding of participants and the interventionist will not be feasible, as they will be aware of the intervention being received or delivered. However, the assessor of participants' cognitive and daily functioning will remain blinded to group allocation and will not have access to the randomization records. Participants will also be instructed not to disclose their group assignment or details of the intervention during the assessments. The assessor is an occupational therapist with two years of experience in clinical cognitive assessment and certification in administering the MoCA. The intervention will be delivered by an occupational therapist with two years of experience in geriatric care. Any accidental unblinding of the assessor will be documented. In addition, the statistical analyst will receive coded group data and remain blinded to group allocation until the primary analyses have been completed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
No 1470, North Kargar St, Tehran
City
Tehran
Province
Tehran
Postal code
1439955975
Approval date
2025-03-22, 1404/01/02
Ethics committee reference number
IR.TUMS.FNM.REC.1404.009

Health conditions studied

1

Description of health condition studied
dementia
ICD-10 code
F00
ICD-10 code description
Alzheimer disease is a primary degenerative cerebral disease of unknown etiology with characteristic neuropathological and neurochemical features. The disorder is usually insidious in onset and develops slowly

but steadily over a period of several years.

2

Description of health condition studied

mild cognitive disorder

ICD-10 code

F06.7

ICD-10 code description

A disorder characterized by impairment of memory, learning difficulties, and reduced ability to concentrate on a task for more than brief periods. There is often a marked feeling of mental fatigue when mental tasks are attempted, and new learning is found

Primary outcomes

1

Description

global cognitive

Timepoint

pre and post intervention

Method of measurement

MoCA test

2

Description

Instrumental Activities of Daily Living

Timepoint

pre and post intervention

Method of measurement

Bayer-ADL

3

Description

executive functions

Timepoint

pre and post intervention

Method of measurement

BRIEF-A

4

Description

attention

Timepoint

pre and post intervention

Method of measurement

Stroop Color and Word Test

5

Description

working memory

Timepoint

pre and post intervention

Method of measurement

Digit Span Test

6

Description

processing speed

Timepoint

pre and post intervention

Method of measurement

Stroop Color and Word Test

7

Description

cognitive flexibility

Timepoint

pre and post intervention

Method of measurement

Stroop Color and Word Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to usual services provided by participating older-adult day centers, participants will receive a structured multicomponent lifestyle intervention over a 7-week study period. The program includes 12 active 90-minute intervention sessions delivered twice weekly, in addition to pre- and post-intervention assessments. The intervention comprises: (1) computerized and non-computerized cognitive training targeting memory, attention, working memory, problem solving, cognitive flexibility, and executive functions; (2) individually adapted low- to moderate-intensity aerobic, stretching, and resistance exercise; (3) healthy lifestyle education addressing diet, sleep, stress management, cardiovascular health, and physical activity with weekly behavioral goal setting; and (4) structured social engagement through group discussion, games, team problem solving, reminiscence, and social activities. Home assignments and adherence to the intervention components will be regularly monitored.

Category

Prevention

2

Description

Control group: participants allocated to the control arm will continue to receive the usual services routinely provided by the participating older-adult day centers during the study period. They will not receive any of the study-specific structured multicomponent lifestyle sessions, including the study cognitive training program, structured physical activity program, healthy lifestyle education program, or structured social engagement intervention during the active trial period. Participants in the control group will undergo the same pre- and post-intervention assessments as the intervention group.

After completion of the post-intervention assessments, the multicomponent lifestyle program may be offered to control participants who wish to receive it.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas Rehabilitation Centre

Full name of responsible person

Fereshteh Torki

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Yas Rehabilitation Centre, Alestom St, Satar-Khan N, Tehran

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ramin Kordi

Street address

6th Floor, Deputy of Research and Technology, Central Administration Building, University Headquarters, at the corner of Ghods Street and Keshavarz Boulevard

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Web page address

<https://vcr.tums.ac.i>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Fereshteh Torki

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

De-identified individual participant data (IPD), including key outcomes, demographic variables, and cognitive and functional assessment results, will be made available upon request. Additionally, supporting documentation such as the statistical analysis plan, analysis code (upon request), and clinical outcome reports will be shared.

Data will be accessible for up to 3 years post-publication via formal request and with approval from the ethics committee. Access will be granted to qualified researchers for legitimate academic purposes.

When the data will become available and for how long

Access to de-identified participant data, statistical analysis outputs, and related documents will begin 6 months after publication of the final results and will remain available for a period of 3 years. Access will be granted upon formal request and subject to ethical approval.

To whom data/document is available

Data and related documentation will be made available only to researchers affiliated with recognized academic, medical, or research institutions. Industry-based researchers may also apply, provided they submit a well-defined research proposal, obtain ethics approval, and collaborate with an academic or scientific entity. All data must be used strictly for non-commercial, scientific purposes only.

Under which criteria data/document could be used

The shared data may only be used for non-commercial, scientific, and research purposes. Analyses must be limited to secondary research aligned with the original study's aims or closely related research questions. Meta-analyses, academic training, and systematic reviews are permitted with proper citation. Any use that violates participant privacy, research ethics, or informed consent agreements is strictly prohibited. Data may not be re-shared with third parties without prior written approval. Requirements for data access request: Submission of a formal request with an institutional affiliation letter A detailed research proposal outlining objectives, methodology, and type of intended analyses A valid ethical approval from a recognized ethics committee A signed data use and confidentiality agreement Acceptance of review and possible rejection by the principal research team based on ethical/scientific grounds

From where data/document is obtainable

Contact Information for Data Access Requests:

Applicants interested in accessing participant data or related study documents may proceed through the following channels (in order of priority): Official email request:

What processes are involved for a request to access data/document

Process for Requesting and Receiving Data/Documents:

To access de-identified data or study documentation, applicants must complete the following steps: Submit a formal request via email or post, including: A full research proposal (objectives, methodology, intended analyses) Institutional affiliation letter Ethics committee approval Confidentiality agreement (a template will be provided, if needed) Initial review by the research team within 7 working days, to assess ethical and scientific compatibility Feedback and (if approved) provision of the confidentiality agreement for applicant signature Delivery of data/documents within 10-14 working days of receiving complete documentation and signed agreement □ If all documents are submitted properly, the

total turnaround time for access is estimated at 2 to 3 working weeks.

Comments