Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 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)

Phone

+98 24 3525 1316

Email address

fereshteh914turki@gmail.com

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 committe 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

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

City
Tehran

Province
Tehran

Postal code
۱۴۴۴۶۱۵۷۱۱

Phone
+98 21 6650 0140

Email
fereshteh914turki@gmail.com

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

City
Tehran

Province
Tehran

Postal code
141765383761

Phone
+98 21 8163 3698

Fax
+98 21 8898 9664

Email
fereshteh914turki@gmail.com

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

Street address
Student dormitory, Tehran University of Medical Sciences Residential Complex, Jalal Al-e-Ahmad Expressway, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1419733171

Phone
+98 24 3525 1316

Email
fereshteh914turki@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Fereshteh Torki

Position
Master student

Latest degree
Master

Other areas of specialty/work
Occupational Therapy

Street address
Tehran university of medical sciences dormitory, North Kargar St., Tehran

City
Tehran

Province
Tehran
Postal code
1419733171
Phone
+98 24 3525 1316
Fax
Email
fereshteh914turki@gmail.com

Person responsible for updating data

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
Street address
Tehran University of Medical Sciences Residential Complex, Jalal Al-e-Ahmad Expressway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 24 3525 1316
Email
fereshteh914turki@gmail.com

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