Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of Efficacy of multidomain interventions of diet, exercise, managing of vascular risk factors and cognitive training to prevent cognitive decline in Iranian older adults

Protocol summary

Study aim

The effect and feasibility of multi-domain intervention of diet, exercise, cardiovascular risk factors management and cognitive training on prevention of cognitive decline in Iranian elderly

Design

This study is an outcome assessor-blinded, randomized controlled trial with a two parallel groups design on 196 healthy adults aged 55 to 74 years old. one is the intervention group and the other is control group as a comparator. The multidomain intervention period is 6 months.

Settings and conduct

People aged 55 to 74years who was visited in the west public health center in Tehran in the first 6month of the year 1401, will be called by the researcher, invited to come to the Brain-cognitive clinic. At base time everyone who enter to the study according to inclusion criteria will be assessed cognitively, nutritionally, physically, psychiatry and medically. then, they divided in to two groups of intervention and the control using the permuted block randomization.

Participants/Inclusion and exclusion criteria

healthy adults Aged 55 to 74 years having at least one modifiable dementia risk factor

Intervention groups

Participants in the intervention group will receive all components of the intervention, such as diet, exercise, cardiovascular risk management, and cognitive training. Participants in the control group basically will be visited by a study physician and will receive medical advice and, if necessary, will be referred to a specialist. At the same time, they will receive a pamphlet on lifestyle guidelines to prevent dementia.

Main outcome variables

The primary outcome are adherence and retention rates and the change in the total scale index of the addenbrooke's cognitive examination and the reaction time, paired associate learning, delayed match to sample and spatial working memory modules of Cambridge neuropsychological test automated battery (cantab) from baseline to the end of the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151122025191N3**
Registration date: **2022-05-07, 1401/02/17**
Registration timing: **prospective**

Last update: **2022-05-07, 1401/02/17**
Update count: **0**

Registration date

2022-05-07, 1401/02/17

Registrant information

Name

Behnam Shariati

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

shariati.b@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Efficacy of multidomain interventions of diet, exercise, managing of vascular risk factors and cognitive training to prevent cognitive decline in Iranian older adults

Public title
Evaluation of Efficacy of multidomain interventions of diet, exercise, managing of vascular risk factors and cognitive training to prevent cognitive decline in Iranian older adults
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Aged 55 to 74 years. Having at least one modifiable dementia risk factor from among hypertension, diabetes mellitus, dyslipidemia, obesity, abdominal obesity, abdominal obesity, metabolic syndrome, smoking, educational level less than 9 years, physical inactivity, and social inactivity. No neurocognitive disorder detected by the psychiatrist with the use of DSM5 criteria at the base time. The score 85 or more in the Addenbrooke cognitive test at the base time. Able to independently perform the activities of daily living. Can read and write in Farsi. Able to participate in the exercise program safely. Having a reliable informant who can provide investigators with requested information. Providing written informed consent.
Exclusion criteria:
Existence of major psychiatric illness such as major depressive disorder. Existence of other neurodegeneration disease such as Parkinson's disease. The history of malignancy within the previous 5 years. The history of cardiac stent or revascularization within the previous 1 year. Existence of serious or unstable medical disease such as acute or sever asthma, active gastric ulcer, sever liver disease, or sever renal disease. Existence of sever loss of vision or hearing, or communication disability. Existence of any conditions preventing cooperation as judged by the study physician. Existence of significant laboratory abnormality that may result in cognitive impairment. The simultaneous participation in any other intervention trial.
Age
From **55 years** old to **74 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **196**
Randomization (investigator's opinion)
Randomized
Randomization description
Restricted randomization with the permuted block method was used to create the random sequence and balance the number of allocated samples in each group (control and intervention). The Excel was used for a random sequence in blocks of 2, 4, and 6. Each block has an equal number of control and HemoHIM groups. It is written on the cards and placed respectively for hiding in locked opaque packets. A packet was selected for each patient according to the study recruitment, which determines the related study group.In this way, we will have two groups of 98 that are assigned completely randomly.
Blinding (investigator's opinion)
Single blinded
Blinding description
To do study with concealment, table of block will be used by one of researchers, other than interviewer and who assess patients in follow-up visits. Therefore, interviewer and who evaluates patients in follow-up visits will be unaware if each number belongs to which groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of Iran University of Medical Sciences
Street address
No. 28, 28th street, Arashmehr Ave., Jalal e Al e Ahmad Highway.,
City
Tehran
Province
Tehran
Postal code
1445713363
Approval date
2021-07-27, 1400/05/05
Ethics committee reference number
IR.IUMS.REC.1400.402

Health conditions studied

1

Description of health condition studied
Major neurocognitive disorder
ICD-10 code
F02
ICD-10 code description
Dementia in other diseases classified elsewhere

Primary outcomes

1

Description
Addenbrooke's Cognitive Examination Score
Timepoint
at the baseline, and the third and the sixth month after intervention.
Method of measurement
Addenbrooke's Cognitive Examination-II Score.

2

Description
Cambridge Neuropsychological Test Automated Battery
Timepoint
At the baseline, the third and the sixth month after intervention.
Method of measurement
CANTAB Cognitive Software

Secondary outcomes

1

Description
Barthel Index of Activities of Daily Living Score
Timepoint
At the baseline time, and the third and the sixth month after the start of intervention.
Method of measurement
Barthel Index of Activities of Daily Living Questionnaire

2

Description
Lawton instrumental activity of daily living diary Score
Timepoint
At the baseline time, and the third and the sixth month after the start of intervention.
Method of measurement
Lawton instrumental activity of daily living diary Questionnaire

3

Description
Short Physical Performance Battery Scale Score
Timepoint
At the baseline time, and the third and the sixth month after the start of intervention.
Method of measurement
Short Physical Performance Battery Scale Questionnaire

4

Description
Food Frequency Questionnaire Score
Timepoint
At the baseline time, and the third and the sixth month after the start of intervention.
Method of measurement
Food Frequency Questionnaire

5

Description
A Three Day Food Record Score
Timepoint
At the baseline time, and the third and the sixth month after the start of intervention.
Method of measurement
A Three Day Food Record Questionnaire

Intervention groups

1

Description
Intervention group: In the intervention group of vascular risk factors management intervention, those who need medication for physical problems will be treated with medication. For those who suffer from mild to moderate psychiatric disorder, medication will prescribe by the study psychiatrist. In exercise intervention, after physical evaluation, the exercise program is given to participants in individual sessions by use of clips. these sessions will be held every two weeks in the first month and then monthly. In nutritional intervention, after nutritional evaluation, if there is a nutritional deficiency, multivitamins will be prescribed. Nutritional sessions based on MIND diet will be held every two weeks in the first two months and then monthly. In cognitive training intervention, cognitive rehabilitation program will performed by the use from Rehocom cognitive rehabilitation software and the pencil and paper workbook. the individualized session will be held every week as well as group sessions at the beginning and month 3. Cognitive assessment will be performed by Addenbrooke’s cognitive examination and The Cambridge Neuropsychological Test Automated Battery, physical activity assessment will be performed by Barthel Index of Activities of Daily Living and Lawton instrumental activity of daily living and short physical performance battery scale, nutritional assessment will be performed by A Three-day food record form and Food frequency questionnaire. In addition to the baseline the evaluation will be repeated in the third and sixth months.
Category
Prevention

2

Description
Control group: After initial assessments in the baseline, including physical, psychiatric, nutritional, exercise, and cognitive status assessments in all participants,

individuals who are placed in the control group according to randomization will receive routine health advice. They are given a training pamphlet on risk factors for cognitive decline. If treatment is needed, they are advised to visit a relevant specialist.Then they will be re-evaluated at the third and sixth months.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrate Rasoule Akram Hospital

Full name of responsible person
Behnam Shariati

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Hazrate Rasoole Akram Hospital., Niayesh St., Satarkhan Av., Tehran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Department of health and ageing - Department of population, family and school health

Full name of responsible person
Seyed Hamed Barekati

Street address
Ministry of health and medical education,. Eyvanak Blvd,. Farahzadi Blvd,. District 2,. Tehran,. Iran.

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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
Department of health and ageing - Department of population, family and school health

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
Iran University of Medical Sciences

Full name of responsible person
Behnam Shariati

Position
associate professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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School of Behavioral Sciences and Mental Health., Shahid Mansouri Street., Niyayesh Street., Satarkhan Avenue., Tehran., Iran

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Person responsible for scientific inquiries

Contact

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Position
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Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after being unidentified.

When the data will become available and for how long

Access will be allowed 3 month after publication.

To whom data/document is available

Researchers

Under which criteria data/document could be used

For use in meta-analysis studies with a written request stating the reason for the request and documentation

From where data/document is obtainable

Dr Behnam Shariati

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

By Sending an email to the corresponding person along with mentioning the documents and the reason for the request.

Comments