Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Investigating the effect of a “My Plate” nutrition training program on anthropometric indices, muscular strength and function, and quality of life among older adults with overweight and/or obesity; application of Health Belief Model

Protocol summary

Study aim

Preparation and compilation of protocol and educational content for empowering the elderly with obesity and overweight as a suitable solution for weight control and prevention of loss of muscle mass and strength and increasing the quality of life

Design

The samples are selected from 4 comprehensive urban health centers located in Jahrom city, completely randomly and in a cluster, 2 centers and two bases from each center are selected randomly, and two bases are randomly selected as the control group and Two bases will be selected as the intervention group. the names of the eligible people were prepared from the Sib system, and then 25 elderly people were selected from each center by regular random method.

Settings and conduct

Training sessions will be held twice a week. After the end of the training sessions, the members of the intervention group and one of their family members will become members of a virtual group. Three months after the initial measurements, the measurements will be repeated in both groups.

Participants/Inclusion and exclusion criteria

Body mass index of 25 and above - They have not used any type of protein supplement in the past 6 months. - Be able to walk - At least have reading and writing literacy (completion of the third grade). - Do not suffer from chronic diseases such as kidney disease and diabetes.

Intervention groups

an educational program including nutrition and exercise training according to the My Plate method and the 2020-2025 USDA guidelines will be implemented for the intervention group. The elderly who are in the comparison group (control) will receive a healthy nutrition brochure during the implementation of the project and a program They will experience the routines of health centers

Main outcome variables

Muscle strength,function, anthropometric indices, quality of life,physical activity, health belief mode

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110423006261N21**
Registration date: **2024-04-26, 1403/02/07**
Registration timing: **prospective**

Last update: **2024-04-26, 1403/02/07**
Update count: **0**

Registration date

2024-04-26, 1403/02/07

Registrant information

Name

Mohammad Hussein Kaveh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

Email address

kaveh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-03, 1403/02/14

Expected recruitment end date

2024-05-08, 1403/02/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of a “My Plate” nutrition training program on anthropometric indices, muscular strength and function, and quality of life among older adults with overweight and/or obesity; application of Health Belief Model

Public title

Investigating the effect of a “My Plate” nutrition training program on anthropometric indices, muscular strength and function, and quality of life among older adults with overweight and/or obesity; application of Health Belief Model

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Body mass index of 25 and above. They have not used any type of protein supplement in the past 6 months Be able to walk and be able to go to the health center without the help of others. At least have reading and writing literacy (completion of the third grade). Do not suffer from chronic diseases such as kidney disease and diabetes that require special diet and care.

Exclusion criteria:

Have an injury or an acute illness that requires special care. To withdraw from continuing to participate in the study for any reason (disability, personal preference, illness). Absent more than two sessions from training sessions Their questionnaires are very distorted and incompletely completed (they have not answered more than 30% of the questions).

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to be able to generalize the results of the study and to reduce the socio-economic differences as much as possible, the samples of the two control and experimental groups from 4 comprehensive urban health centers located in Jahrom city, completely randomly and in a cluster, 2 centers and two bases from each center are selected and randomly two bases will be selected as the control group and two bases as the intervention group. In the selected centers, the names of eligible people include the elderly in both sexes, according to the different proportion of women and men in terms of obesity, which according to statistics, about 60% of women and about 40% of men have a body mass index above 25. 60% of the samples are women. And 40% are men Therefore, separate lists of men and women were prepared from the Sib system, and then 25 elderly people who met the study entry criteria were selected from each center by regular random method.

Blinding (investigator's opinion)

Single blinded

Blinding description

None of the participants will be given an explanation about which group, intervention or control group they are in, while the control group will also receive a healthy eating brochure.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shiraz University of Medical Sciences

Street address

Zand Street

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2024-03-13, 1402/12/23

Ethics committee reference number

IR.SUMS.REC.1402.607

Health conditions studied

1

Description of health condition studied

Overweight and/or obesity in the elderly

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description
Weight is measured using a scale.
Timepoint
At the beginning of the study (before the start of the intervention) and 3 months after the initial measurements
Method of measurement
The weight of the elderly is measured with a Seka scale, with an accuracy of 0.1 kg, and with minimal clothes and no shoes in the morning.

2

Description
Muscle strength
Timepoint
At the beginning of the study (before the start of the intervention) and 3 months after the initial measurements
Method of measurement
We will use Sammons Preston Hand Dynamometer, JAMAR Plus) hydraulic hand dynamometer.

3

Description
Quality of Life
Timepoint
At the beginning of the study (before the start of the intervention) and 3 months after the initial measurements
Method of measurement
Quality of Life Questionnaire for the Elderly (World Health Organization)

4

Description
Muscle function
Timepoint
At the beginning of the study (before the start of the intervention) and 3 months after the initial measurements
Method of measurement
Balance test with balance test TUG

5

Description
Around the waist around the hips WHR
Timepoint
At the beginning of the study (before the start of the intervention) and 3 months after the initial measurements
Method of measurement
It is measured with an inflexible tape measure with an accuracy of 0.1 cm

6

Description
physical activity
Timepoint
At the beginning of the study (before the start of the intervention) and 3 months after the initial measurements
Method of measurement
Physical activity measurement questionnaire IPAQ-SF

Secondary outcomes

1

Description
Constructs of health belief model
Timepoint
Three months after the initial measurements, the measurements will be repeated in both groups
Method of measurement
A researcher-made questionnaire to measure the constructs of the health belief model

2

Description
24-hour food reminder
Timepoint
First, before the start of the study, it is measured on two different days and three months later, it is measured again on two different days.
Method of measurement
Questionnaire learned 24 hours of food

Intervention groups

1

Description
Intervention group: Two groups of 25 people from two different comprehensive health centers, that is, a total of 50 people, who will receive training on the My Plate method and the necessary exercise as an intervention.
Category
Lifestyle

2

Description
Control group: two groups of 25 people from two sub-bases of the same comprehensive health center as the intervention group were sampled. This group will only receive healthy eating brochures.
Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Jahrom University of Medical Sciences
Full name of responsible person
Elham Foroodi Jahromy
Street address
Jimhoorie Aslamie Street
City
Jahrom
Province
Fars
Postal code
7417753161
Phone
+98 71 5423 4611
Email
elhamforoodi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hashem Hashempour
Street address
Zand street
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3212 2430
Email
vcrdep@sums.ac.ir
Web page address
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
Mohammad Hossein Kaveh
Position
Professor of all academic staff
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
Razi Blvd., in front of the Electrical Club of the Faculty of Health
City
Shiraz
Province
Fars
Postal code
7153675541
Phone
+98 71 3725 1001
Email
Mhkaveh255@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hossein Kaveh
Position
full Profesor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
Razi Street, Faculty of Health
City
Shiraz
Province
Fars
Postal code
7153675541
Phone
+98 71 3725 1001
Email
Mhkaveh255@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hossein Kaveh
Position
full Profesor
Latest degree
Ph.D.
Other areas of specialty/work

Health Promotion

Street address

Razi Street, Faculty of Health

City

Shiraz

Province

Fars

Postal code

7153675541

Phone

+98 71 3725 1001

Email

Mhkaveh255@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

Yes - There is 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

Participants' data, including height and weight, anthropometric measurements, and muscle strength and function, will be shared after de-identification and after the end of the study.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions and the Ministry of Health and Industry can apply for them.

Under which criteria data/document could be used

People who deal with the elderly or the elderly themselves

From where data/document is obtainable

Mr. Dr. Mohammad Hossein Kaveh: Mhkaveh255@gmail.com Elham Foroodi: elhamforoodi@yahoo.com

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

First, write the reason for the need for the data in a word, and then send an email, and the data will be sent after 30 days.

Comments