Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Effect of isowhey supplementation alone, or in combination with omega-3 fatty acids, on mobility, muscle strength and cognitive state in prefrail older adults

Protocol summary

Study aim

Investigating the effect of the supplementation isowhey alone, or in combination with omega-3 fatty acids on mobility, muscle strength and cognitive status in prefrail older adult

Design

A randomized, double-blind, parallel design clinical trial, with two intervention groups (isowhey alone and isowhey plus omega-3 fatty acids) and a control group

Settings and conduct

In this clinical trial, older adult who referred to health centers of Iran University will be included if they met the inclusion criteria.After obtaining a written consent, patients will be randomly divided to three groups to receive isowhey alone (20 g daily), isowhey plus omega-3 fatty acids (20 g daily plus two capsules omega-3 fatty acids) and control (placebo with similar characteristics) .In each group, 30 patients will receive the supplements for 12 weeks.The placebo and supplements are similar in appearance and coded by an individual other than the researcher.The participants and main investigators will not be aware of the contents of the supplement and placebo. Cognitive and nutritional status participants will be evaluated at the beginning and end of the intervention. At the beginning, and at the end of weeks 6 and 12 Gait Speed, TUG test and hand grip strength will also be implemented to assess elderly mobility and muscle strength.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Community dwelling older adults Man or woman aged 60 years or older Meet one or two CHS frailty criteria Exclusion criteria: Taking any steroids Taking anticoagulant drugs

Intervention groups

A.Daily supplementation Isowhey and the omega-3 fatty acids for 12 weeks. B.Daily supplementation Isowhey and omega-3 fatty acids placebo for 12 weeks. C.Daily supplementation Isowhey placebo and omega-3 fatty acids placebo for 12 weeks.

Main outcome variables

Muscle strength

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090901002394N43**
Registration date: **2019-06-13, 1398/03/23**
Registration timing: **prospective**

Last update: **2019-06-13, 1398/03/23**
Update count: **0**

Registration date

2019-06-13, 1398/03/23

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-05-04, 1399/02/15

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

Scientific title
Effect of isowhey supplementation alone, or in combination with omega-3 fatty acids, on mobility, muscle strength and cognitive state in prefrail older adults

Public title
Effect of isowhey and omega-3 fatty acids on mobility, muscle strength in prefrail older adult
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Community dwelling older adults Man or woman aged 60 years or older Meet one or two CHS frailty criteria: 1 - Weight loss 2 - Weakness 3 - Exhaustion 4 - Slowness of movement 5 - Low physical activity
Exclusion criteria:
Taking any steroids Taking anticoagulant drugs Regular consumption of omega-3 fatty acid supplements over the 3 months prior to study (more than twice a week) Critical illnesses including kidney failure, liver, heart disease, or chronic pulmonary failure, diabetes, malignancy (over the past 5 years) A history of exercises during the past two years (more than twice a week) Regular use of food supplements (more than twice a week) other than calcium and vitamin B12 Smoking and alcohol consumption Use of mobility devices (wheelchairs, cane ...) severe cognitive problems
Age
From **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
For random allocation of individuals to the three groups, the permuted block randomization method will be applied, using a computer program, and the length of blocks will be considered randomly as 3, 6 or 9.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding: Placebo and supplements are similar in appearance and coded by someone other than the researcher. All investigators, study staff, and participants will be unaware of the allocations. When the statistical model of the primary and secondary results is not complete, the randomization code will not be broken.
Placebo
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
Iran University of Medical Sciences, Besides Milad Tower, Hemmat, Tehran
City
Tehran
Province
Tehran
Postal code
14665-354
Approval date
2017-10-14, 1396/07/22
Ethics committee reference number
IR.IUMS.FMD.REC.1396.9321324004

Health conditions studied

1

Description of health condition studied
Frailty syndrome
ICD-10 code
R54
ICD-10 code description
Age-related physical debility

Primary outcomes

1

Description
Muscle strength (Handgrip Strength):Muscle strength will assess by handgrip Strength,The difference in the rate of these outcomes changes between the intervention and placebo groups will be determined.
Timepoint
At the beginning, and at the end of weeks 6 and 12 hand grip strength will be implemented.
Method of measurement
Muscle strength will assess by hand grip Strength. Measured using a dynamometer device.

Secondary outcomes

1

Description
Mini Nutritional Assessment (MNA): assessment of the nutritional status is conducted with a brief nutritional assessment. The difference in the rate of change between the intervention and placebo groups will be determined.
Timepoint
Participants in the study will be evaluated at the beginning and end of the intervention(at the end of 12 week intervention)
Method of measurement
Nutritional status will assess with MNA(mini nutritional assessment) questionnaire

2

Description
Physical performance: The difference in the rate of change between the intervention and placebo groups will be determined
Timepoint
At the beginning, and at the end of weeks 6 and 12 hand grip strength will be implemented.
Method of measurement
It will be run using a clinical test (TUG; Time Up and GO) and will be performed by evaluator.

3

Description
Gait Speed: The difference in the rate of change between interventional and placebo groups will be determined.
Timepoint
At the beginning, and at the end of weeks 6 and 12 hand grip strength will be implemented.
Method of measurement
It will be run using a clinical test and will be performed by evaluator.

4

Description
Cognitive status : In order to assess the cognitive status of elderly people participating in the intervention, they will be evaluated. The difference in the rate of these outcomes changes between the intervention and placebo groups will be determined.
Timepoint
Participants in the study will be evaluated at the beginning and end of the intervention(at the end of 12 week intervention)
Method of measurement
Cognitive function will assess by cognitive examination. Stroop وDSB(Digit Span Backward)

5

Description
CRP(C-Reactive Protein)
Timepoint
Participants in the study will be evaluated at the beginning and end of the intervention(at the end of 12 week intervention)
Method of measurement
Turbidimetric test

6

Description
BDNF(Brain-derived neurotrophic factor)
Timepoint
Participants in the study will be evaluated at the beginning and end of the intervention(at the end of 12 week intervention)
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group 1: Daily intake of 20 gr isowhey and omega-3 placebo for 12 weeks
Category
Prevention

2

Description
Intervention group 2: Daily intake of 20 gr isowhey and two omega-3 fatty acids capsules for 12 weeks
Category
Prevention

3

Description
Control group: Placebos with same characteristics for 4 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers of Iran University
Full name of responsible person
Dr Shima Jazayeri
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Sponsors / Funding sources

1

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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
Iran University of Medical Sciences
Proportion provided by this source
77
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

2

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
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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
University of social welfare and rehabilitation sciences
Proportion provided by this source
23
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
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Dr Shima Jazayeri
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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