

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Effect of Educational Intervention based on Self-care model on malnutrition in older people

Protocol summary

Study aim

The effect of educational intervention based on self-care model on malnutrition in the older people

Design

Randomized, educational, trial with control group

Settings and conduct

Location: Shahid Motahary hospital, Isfahan Instrument: MNA (Mini Nutritional Assessment) Entrance: Score below 17 Allocation: Simple randomized

Participants/Inclusion and exclusion criteria

People more than 60 years old who referred to nutrition clinic of Shahid Motahari hospital and willing to participate in the study and in the initial sampling the score were lower than 17 will enter in the study. People who miss more than one session of training sessions or suffering from cardiovascular and respiratory and another debilitating diseases which make trouble walking and attending in classes alone, are excluded from the study

Intervention groups

The intervention group will receive four training sessions and to the control group will be given the usual recommendations include diet and required nutrition plan

Main outcome variables

Awareness of severity of malnutrition in the study population

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200119046186N1**

Registration date: **2020-03-10, 1398/12/20**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-10, 1398/12/20**

Update count: **0**

Registration date

2020-03-10, 1398/12/20

Registrant information

Name

Majid Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 9821

Email address

rahimi@hlth.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Educational Intervention based on Self-care model on malnutrition in older people

Public title

Effect of Educational Intervention on malnutrition in older people

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

people older than 60 years old Willingness to participate

in the study

Exclusion criteria:

Suffering from diseases which Which make them unable to attend classes

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomizing using random number table

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

The intervention group received four training sessions and the control group is given regular recommendations including the diet and diet plan needed

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

No. 47 Hajian Lane Simin Ave.

City

Isfahan

Province

Isfahan

Postal code

81769-35747

Approval date

2019-12-25, 1398/10/04

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.592

Health conditions studied

1

Description of health condition studied

Malnutrition

ICD-10 code

E46

ICD-10 code description

Unspecified protein-calorie malnutrition

Primary outcomes

1

Description

Malnutrition Score in Mini Nutrition Assessment Questionnaire

Timepoint

Before and two weeks after the 4th educational session

Method of measurement

Mini Nutrition Assessment Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to the usual recommendations in the nutrition clinic including obtaining a nutrition history and prescribing a proper diet ,there are four training sessions based on the self-care model about the following topics: 1- Impact of lifestyle on health and its components, 2- Healthy nutrition and malnutrition and how to cook, 3- Depression and its effect on nutrition and 4- Drug usage and its effect on nutrition

Category

Lifestyle

2

Description

Control group: The usual recommendations including obtaining a nutrition history and prescribing a proper diet are made.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shdhid Motahary Hospital at Isfahan

Full name of responsible person

Majid Rahimi

Street address

Next to Zobeahan Highway

City

Foolad Shahr

Province

Isfahan

Postal code
84918-13113
Phone
+98 31 5262 4141
Fax
+98 31 5262 3142
Email
mail@motaharyhospital.com
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjooye Javanmard
Street address
Hezarjerib Ave., Isfahan University Of Medical Sciences
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3668 8138
Email
research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Majid Rahimi
Position
Assistant Professor
Latest degree
Ph.D.

Other areas of specialty/work
Geriatrics
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In the results section according to the variables table, things like age, gender, body mass will be shared

When the data will become available and for how long

Documentation will be published shortly after the results are completed and the paper is prepared

To whom data/document is available

Data access will have no modifications except personal information of study participants

Under which criteria data/document could be used

In cases where further research is needed

From where data/document is obtainable

Refer to the project manager and it's possible to request data access via email: majidnh79@gmail.com

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

It must be requested via email with valid documentation provided about the research related to the subject of the present research, Submit written commitment to use the documentation with citing to original reference and Submit results of next research to project manager

Comments