

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effectiveness of healthy lifestyle-based interventions on intrinsic capacity in older women adults

Protocol summary

Study aim

The Effectiveness of healthy lifestyle-based interventions on intrinsic capacity in older women adults.

Design

Randomized clinical trial with control

Settings and conduct

This study will be conducted as a cluster randomized clinical trial in the elderly center of Babol. After selecting 10 qualified elderly women, we will determine the type of intervention based on randomization list. The primary outcomes will be assessed at the beginning and the end of the trial.

Participants/Inclusion and exclusion criteria

Women aged 60-80 years Healthy women who do not have any diagnosed neurological, physical or mental disorders Unwillingness to participate in the study Hormone therapy in the last two months History of substance abuse, addiction, smoking or alcohol History of eating disorders. Having a severe physical activity Participate in another study at the same time Having a special diet, such as being vegetarian or eating raw foods.

Intervention groups

Interventions will be conducted in 24 focused groups of 10 people during 8 sessions with a time of 30 to 45 minutes. According to the selected topics and the objectives of study, there will be a discussion and consultation for each cluster. Also, educational pamphlets will be provided to the intervention group according to the predetermined topics and objectives. In the control group, there is no special intervention, and at the end of the course, the educational content will be provided to the control group.

Main outcome variables

Intrinsic capacity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230328057780N1**

Registration date: **2023-06-26, 1402/04/05**

Registration timing: **prospective**

Last update: **2023-06-26, 1402/04/05**

Update count: **0**

Registration date

2023-06-26, 1402/04/05

Registrant information

Name

mahsa rouhani otaghsara

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3245 4043

Email address

m.rohani@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2024-02-09, 1402/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of healthy lifestyle-based interventions on intrinsic capacity in older women adults

Public title
Healthy lifestyle-based interventions on intrinsic capacity

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Women aged 60-80 years Healthy women who do not have any diagnosed neurological, physical or mental disorders
Exclusion criteria:
 Unwillingness to participate in the study Hormone therapy in the last two months History of substance abuse, addiction, smoking or alcohol History of eating disorders. Having severe physical activity Participate in another study at the same time Having a special diet, such as being vegetarian or eating raw foods.

Age
From **60 years** old to **80 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **240**

Randomization (investigator's opinion)
Randomized

Randomization description
 A computer-generated balanced block randomization (Sealedenvelope.com) in a 1:1 ratio will be conducted. The sample size of the study will be 240 women, which will be arranged in 24 clusters of 10. For the allocation of the participants, an investigator with no clinical involvement in the trial generated the randomization sequence with 1:1 allocation ratio using random block sizes of 6. Allocation concealment will be performed by preparing 24 sealed and unnumbered envelopes containing a piece of paper printed with the word 'Intervention' or 'Control'.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Ganj Afrooz Ave., Babol, Iran.

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2023-06-13, 1402/03/23

Ethics committee reference number

1401.242

Health conditions studied

1

Description of health condition studied

Elderly women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Inherent capacity

Timepoint

The inherent capacity will be assessed at the beginning and the end of trial.

Method of measurement

The primary outcome of the present study is intrinsic capacity. The five main areas of intrinsic capacity include mobility, vitality, cognitive, psychological and sensory. 1. Mobility: SPPB (Short Physical Performance Battery) and TUG (Timed Up and Go Vitality: Mini-Nutrition assessment questionnaire. Cognitive: Mini-Cog questionnaire. Psychological: Geriatric Depression Scale (GDS) questionnaire. Sensory: hearing from Whisper self test, vision from WHO simple eye chart.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the healthy-life program in the elderly people affiliated to Department of Elderly Health of the Ministry of Health will be used. This program has different parts, which include: a- nutrition, b- physical exercises, c- happy life, d- depression, e- balance. The interventions included eight sessions, with a time of 30 to 45 minutes. In each session, discussion and consultation will be done according to the selected topics and the objectives of the trial. The predetermined questions will be asked from participants. Intervention in the control group: No specific intervention is performed in the control group. And at the end of the course, after

the completion of the intervention in the test group, the educational content will be provided to the control group.

Category

Lifestyle

2

Description

Intervention in the control group: No specific intervention is performed in the control group. And at the end of the course, after the completion of the intervention in the test group, the educational content will be provided to the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Day care center for the elderly

Full name of responsible person

Mahsa rouhani

Street address

No 102, 26th Baharan, Janbazan Street

City

Babol

Province

Mazandaran

Postal code

4718658135

Phone

+98 911 661 6410

Email

mahsarouhani1374@gmail.com

2

Recruitment center

Name of recruitment center

Shafa Clinic

Full name of responsible person

Mahsa Rohani

Street address

No 8, Tohid 39, Janbazan Street

City

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Province

Mazandaran

Postal code

4714863843

Phone

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Email

mahsarouhani1374@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mehdi Rajabnia

Street address

Babol University of Medical Sciences, Ganj Afrooz Ave., Babol, 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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

shabnam omidvar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Babol University of Medical Sciences, Ganj Afrooz Ave., Babol, Iran

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Phone

011 32199592-1

Email
shomidvar@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
shabnam omidvar

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Nursing and Midwifery faculty, Babol University of Medical Sciences

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shomidvar@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
mahsa rouhani

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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mahsarouhani1374@gmail.com

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

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

There are no plans to release it

When the data will become available and for how long

There are no plans to release it

To whom data/document is available

There are no plans to release it

Under which criteria data/document could be used

There are no plans to release it

From where data/document is obtainable

There are no plans to release it

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

There are no plans to release it

Comments