Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2026

Comparison the effectiveness of lifestyle modification interventions (nutrition and physical activity) in comparison with lifestyle education on nutritional behaviors, physical activity, anthropometric measurements, fasting blood sugar and serum lipid profile in the adults aged 40-60 years

Protocol summary

Summary

The aim of this study is to evaluate the effectiveness of nutrition and physical activity interventions in comparison with education in the population of 40- 60 years old of Amirkola; which will be conducted with random sampling of participants referring to the health center of Amirkola. Enrolled participants will be allocated randomly in the three groups: highly-intensive intervention group, low- intensive intervention group and education group. The sample size is 300. Highly-intensive intervention includes weekly group-training about nutrition and physical activity, individualized nutrition counseling, providing educational materials and weekly free aerobic exercises. Low- intensive intervention includes weekly group-training about nutrition, individualized nutrition counseling and providing educational materials. The third group (control group) will not participate in weekly group-training classes and will receive only educational packages related to the study. Lifestyle status (based on Health-Promoting Life Style Profile questionnaire), nutritional and physical activity behaviors (based on Food Recall questionnaire and the Iranian version of International Physical Activity Questionnaire), besides body mass index, waist, neck, buttock and arm circumferences, body fat, blood pressure, fasting blood glucose and serum lipids will be examined before and after the intervention.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015070423055N1**
Registration date: **2016-02-05, 1394/11/16**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-02-05, 1394/11/16

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effectiveness of lifestyle modification

interventions (nutrition and physical activity) in comparison with lifestyle education on nutritional behaviors, physical activity, anthropometric measurements, fasting blood sugar and serum lipid profile in the adults aged 40-60 years

Public title
Comparison the effectiveness of lifestyle modification interventions
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion Criteria: Age 40-60 years; Living in Amirkola Babol; Desire to participate in the study, fill out and sign the informed consent form of the research Exclusion Criteria: Unable to read and write; Pregnancy or child breast feeding; Severe physical or mental disease which make them disable; Probable migration from Amirkola in 10 months
Age
From **40 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **300**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization in study population will be performed with random allocation of subjects in the age group of 40- 60 years old in the three groups by random numbers table.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical Sciences
Street address
Ganjafrooz Avenue, Babol
City
Babol
Postal code
4136747176
Approval date
2015-06-02, 1394/03/12
Ethics committee reference number
mubabol.rec.1394.45

Health conditions studied

1

Description of health condition studied
Life-style (Factors influencing health status and contact with health services)
ICD-10 code
Z40,Z41,Z4
ICD-10 code description
Persons encountering health services for specific procedures and health care

Primary outcomes

1

Description
Life style status
Timepoint
Before (0 week) and after the intervention (16th week)
Method of measurement
HPLP-II questionnaire (Health-Promoting Life Style Profile-II)

2

Description
Main dietary pattern
Timepoint
Before (0 week) and after the intervention (16th week)
Method of measurement
Food Recall Questionnaire

3

Description
Physical activity status
Timepoint
Before (0 week) and after the intervention (16th week)
Method of measurement
IPAQ:International Physical Activity Questionnaire

Secondary outcomes

1

Description
Anthropometric measures
Timepoint
Before (0 week) and after the intervention (16 th week)
Method of measurement
Physical examination

2

Description
Blood pressure
Timepoint
Before (0 week) and after the intervention (16 th week)
Method of measurement
Physical examination

3

Description
Fasting blood glucose
Timepoint
Before (0 week) and after the intervention (16 th week)
Method of measurement
Blood sample

4

Description
Serum lipid profile
Timepoint
Before (0 week) and after the intervention (16 th week)
Method of measurement
Blood sample

Intervention groups

1

Description
Intervention group 1: For 4 months (16 weeks), weekly group training about nutrition and physical activity, individualized nutrition counseling, providing educational materials and weekly free aerobic exercises. The content of nutrition classes is adapted from nutritional principles which Ministry of Health and Medical Education of Iran has released. The trainer is an expert nutritionist. The duration of each class is 45 minutes, classes will be taken as group discussion and approximate number of participants is 25-30 persons.
Category
Lifestyle

2

Description
Intervention group 2: For 16 weeks, weekly group training about nutrition and physical activity, individualized nutrition counseling and providing educational materials.
Category
Lifestyle

3

Description
Control group: Only educational package included booklet, CD, pamphlet and papers about lifestyle especially improving nutrition and physical activity.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
population lab of Amirkola
Full name of responsible person
Seyed Reza Hosseini
Street address
Research center, Amirkola
City
Amirkola

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Babol University of Medical Sciences
Full name of responsible person
Ali Akbar Moghadamnia
Street address
Ganjafrooz Avenue, Babol
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Grant name
دانشگاه علوم پزشکی و خدمات بهداشتی درمانی بابل
Grant code / Reference number
2786 research code
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Specialist in Social Medicine, Associate Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty