

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Investigation of the effect of lifestyle modification based on Health Belief Training Model on bone density in middle-aged women with osteopenia

Protocol summary

Study aim

Determination of effect of lifestyle modification based on Health Belief Model on bone density in middle-aged women with osteopenia

Design

Clinical trial with two intervention groups, in parallel groups, single blind, randomized with simple method, with sample size 64

Settings and conduct

This study is a randomized controlled clinical trial that the population of this study is middle-aged women referred to Isfahan Oil Company clinic. After estimating the sample size, 4 training sessions of 40-60 minutes for 4 consecutive weeks will be conducted with the aim of adjusting the lifestyle based on Health Belief Model on bone density in middle-aged women with osteopenia for the intervention group. Before the intervention, both control and intervention groups will complete the questionnaire. These questionnaires will also be completed by the same participants six months after the first training session.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Middle-aged women (40-55 years); According to the BMD in the case file, they have osteopenia; Not postmenopausal; Do not use corticosteroids or chemotherapy drugs for up to a year before taking the study; Do not use anti-osteoporotic drugs; Do not suffer from any rheumatic diseases, types of cancer and bone metastasis, thyroid and parathyroid problems, and bone fractures, which will be done by referring to patients' electronic records; Tend to be involved in research; Exclusion criteria: Not to be a client of Isfahan Oil Company clinic; Do not reside in Isfahan.

Intervention groups

The intervention group attends training sessions and the control group will receive only pamphlets.

Main outcome variables

Knowledge; Attitude; Perceived sensitivity; Perceived severity; Perceived benefits; Perceived barriers;

Guidelines for action; Urinary telopeptide; Physical activity; Calcium intake; Vitamin D intake

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N39**

Registration date: **2020-06-05, 1399/03/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-05, 1399/03/16**

Update count: **0**

Registration date

2020-06-05, 1399/03/16

Registrant information

Name

Sadra Ansari pour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 3487

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st_ansari.s@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2020-10-11, 1399/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation of the effect of lifestyle modification based on Health Belief Training Model on bone density in middle-aged women with osteopenia

Public title
The effect of lifestyle modification on bone density in middle-aged women with osteopenia

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Middle-aged women (40-55 years) According to the Bone Mineral Density (BMD) in the case file, they have osteopenia. Not postmenopausal. Do not use corticosteroids or chemotherapy drugs for up to a year before taking the study. Do not use anti-osteoporotic drugs. Do not suffer from any rheumatic diseases, types of cancer and bone metastasis, thyroid and parathyroid problems, and bone fractures, which will be done by referring to patients' electronic records. Tend to be involved in research.
Exclusion criteria:
Not to be a client of Isfahan Oil Company clinic. Do not reside in Isfahan.

Age
From **40 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
The study sample was simple randomly divided into two groups of 32 people, each by selective envelopes. Thus, each envelope containing one of the two A and B labels represented one of the groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Isfahn University of Medical Sciences, Hezar Jarib st, Isfahan
City
Isfahan
Province
Isfahan
Postal code
7346181746
Approval date
2019-03-12, 1397/12/21
Ethics committee reference number
IR.MUI.MED.REC.1397.338

Health conditions studied

1

Description of health condition studied
Osteoporosis
ICD-10 code
M81
ICD-10 code description
Osteoporosis without current pathological fracture

Primary outcomes

1

Description
Knowledge
Timepoint
Before and after the study
Method of measurement
Questionnaire

2

Description
Attitude
Timepoint
Before and after the study
Method of measurement
Questionnaire

3

Description
Perceived sensitivity
Timepoint
Before and after the study
Method of measurement
Questionnaire

4

Description

Perceived severity
Timepoint
Before and after the study
Method of measurement
Questionnaire

5

Description
Perceived benefits
Timepoint
Before and after the study
Method of measurement
Questionnaire

6

Description
Perceived barriers
Timepoint
Before and after the study
Method of measurement
Questionnaire

7

Description
Guidelines for action
Timepoint
Before and after the study
Method of measurement
Questionnaire

8

Description
Urinary telopeptide
Timepoint
Before and after the study
Method of measurement
Questionnaire

9

Description
Physical activity
Timepoint
Before and after the study
Method of measurement
Questionnaire

10

Description
Calcium intake
Timepoint
Before and after the study
Method of measurement
Questionnaire

11

Description
Vitamin D intake

Timepoint
Before and after the study
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: four 40-60 minute training sessions for consecutive weeks, aimed at modifying lifestyle based on health belief model on bone density in middle-aged women with osteopenia. Meetings will be as group meetings and question and answer session on osteoporosis complications, the ways to reduce it, the importance of vitamin D and calcium absorption, and daily activity.

Category
Lifestyle

2

Description
Control group: This group received only pamphlets containing amounts of calcium and vitamin D in food and no training session.

Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Oil Company Clinic
Full name of responsible person
Ziba Farajzadegan
Street address
Isfahan University of Medical Sciences, Hezar Jarib Avne
City
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Isfahan
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7346181746
Phone
+98 31 3668 0048
Email
farajzadegan@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

Street address

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Phone

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Email

sh_haghjoo@med.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

Ziba Farajzadegan

Position

Professor of Community Medicine

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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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