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 Ansaripour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 3650 3487

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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

Ethics committees

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

Isfehan

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
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Isfehan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjooy Javanmard
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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
Street address
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Person responsible for updating data

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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