

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Effect of an empowerment program on prevention of osteoporosis in female students of Shiraz university of medical sciences

Protocol summary

Summary

The present study was an educational randomized control trial investigated the effect of an empowerment program based on Transtheoretical model to obtain osteoporosis preventive lifestyle on female students of Shiraz University of Medical Sciences. 152 female students who are in second year of Shiraz University of Medical Sciences were participated in two groups: experimental (n=76) and control groups (n=76). In this investigation which lasted 6 weeks, was surveyed the effect of Independent variable (empowerment program) on dependent variables (structures of TTM model and lifestyle factors). Pre and post intervention data (1 and 6 weeks after intervention) were collected by using: the SECQ, the process of change, the self-efficacy and the decisional balance questionnaires both in calcium intake and physical activity behaviors. It should be noted that the Students who had one absence session in training period and those who participated in the pre-test and post-test but did not participate were excluded.

General information

Acronym

empowerment

IRCT registration information

IRCT registration number: **IRCT201212016261N2**

Registration date: **2014-01-21, 1392/11/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-21, 1392/11/01

Registrant information

Name

Mohammad Hussein Kaveh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

Email address

kaveh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences- Ali Poost Froush

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of an empowerment program on prevention of osteoporosis in female students of Shiraz university of medical sciences

Public title

Effect of an empowerment program on prevention of osteoporosis

Purpose

Prevention

Inclusion/Exclusion criteria

Entrance requirements: The students of Shiraz University of Medical Sciences; University student studying in the second year; People are willing to cooperate; the continuous and sequential training program participants. Exclusion criteria: Students in training sessions have been held for more than one session may be absent; Students who have participated in the pre-test and post-

test, but do not attend; Exclusion reason of such transfer, cancel or migrate from Shiraz.

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **152**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Shiraz University of Medical Sciences

Street address

Fars

City

Shiraz

Postal code

0098

Approval date

2012-11-26, 1391/09/06

Ethics committee reference number

CT-91-6345

Health conditions studied

1

Description of health condition studied

Osteoporosis

ICD-10 code

M81

ICD-10 code description

Osteoporosis without pathological fracture

Primary outcomes

1

Description

TTM structures

Timepoint

1 week after educational intervention

Method of measurement

Self-reported questionnaire based on Marcus's stages of change; process of change, self-efficacy and decisional balance

Secondary outcomes

1

Description

Lifestyle factors

Timepoint

6 weeks after educational intervention

Method of measurement

self-reported questionnaire

Intervention groups

1

Description

perform educational intervention in experimental group through 4 sessions (8 hours) with interactive methods

Category

Lifestyle

2

Description

Distribute educational booklets and Cd among students in the control group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hussein Kave

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Ali Poost Froosh

Street address

Shiraz, Fars , Shiraz University of Medical Sciences,
School of Public Health and nutrition,department of
health education and promotion

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Kaveh

Position

PHD of health education and promotion

Other areas of specialty/work**Street address**

Shiraz University of Medical Sciences, school of public
health and nutrition, Department of health education
and promotion

City

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Postal code**Phone**

+98 71 1725 1001

Fax**Email**

kave@sums.ac.ir

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

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Web page address**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