

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 2026

Design and evaluation of an educational intervention on the empowerment of female students for preventive selfcare for osteoporosis

Protocol summary

Summary

The aim of this study, is to design and evaluate an educational intervention to empower female students in preventive selfcare for osteoporosis. Study population includes female students of Islamic Azad University Shahrekord Branch. This is a controlled before-and-after study with two experimental and control groups. There will be no intervention in the control group. The sample size has been calculated in this study 150 people, including 75 people in the intervention group and 75 people in the control group. Sampling method in this study is a multi-stage stratified random sampling. The intervention group and the control group will be randomly selected between two distinct colleges. The intervention group, will receive training program. There will be no intervention in the control group. This study consists of five stages: designing questionnaires and assessing its validity and reliability; completing Demographic Information, Empowerment and Self-care Questionnaires by students; educational intervention; The students will complete the Empowerment for the Prevention of Osteoporosis Questionnaire three months after the completion of intervention; The students will complete the Self Care for the Prevention of Osteoporosis based on Orem Self Care Model Questionnaire six months after the completion of intervention. Primary outcomes include Empowerment and Self-care structures and lifestyle modification is a secondary consequence. Inclusion criteria: students aged 18 to 30 years; at least 5 semesters left to finish their education. Exclusion criteria: the lack of consent to participate in the study; people with osteoporosis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510028742N8**

Registration date: **2015-12-15, 1394/09/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-15, 1394/09/24

Registrant information

Name

Fereshteh Majlessi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8898 9134

Email address

majlesif@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-10-24, 1394/08/02

Expected recruitment end date

2015-10-29, 1394/08/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design and evaluation of an educational intervention on the empowerment of female students for preventive selfcare for osteoporosis

Public title

empowerment of females for selfcare of osteoporosis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: students aged from 18 to 30 years; at least five semesters left to finish their education

Exclusion criteria: the lack of consent to participate in the study; those who intend to transfer to other universities or are likely to dropout of school; students with osteoporosis

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: **150**

Randomization (investigator's opinion)

Not 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

Ethics Committee of Tehran University of Medical Sciences

Street address

Ethics Committee of Tehran University of Medical Sciences, Research and Technology Management, Tehran University of Medical Sciences, Qouds Ave, Keshavarz Boulvar, Tehran

City

Tehran

Postal code

Approval date

2015-09-05, 1394/06/14

Ethics committee reference number

IR.TUMS.REC.1394.691

Health conditions studied

1

Description of health condition studied

Osteoporosis

ICD-10 code

M80, M81,

ICD-10 code description

Disorders of bone density and structure

Primary outcomes

1

Description

Empowerment

Timepoint

Before the intervention, three months after the completion of intervention

Method of measurement

Empowerment For The Prevention of Osteoporosis Questionnaire

2

Description

Selfefficacy

Timepoint

Before the intervention, three months after the completion of intervention

Method of measurement

Empowerment For The Prevention of Osteoporosis Questionnaire

3

Description

Knowledge

Timepoint

Before the intervention, three months after the completion of intervention

Method of measurement

Empowerment For The Prevention of Osteoporosis Questionnaire

4

Description

Attitude

Timepoint

Before the intervention, three months after the completion of intervention

Method of measurement

Empowerment For The Prevention of Osteoporosis Questionnaire

5

Description

life skills

Timepoint

Before the intervention, three months after the completion of intervention

Method of measurement

Empowerment For The Prevention of Osteoporosis
Questionnaire

6

Description

Self care

Timepoint

Before the intervention, six months after the completion of intervention

Method of measurement

Self Care for The Prevention Of Osteoporosis Based On Orem Self Care Model Questionnaire

7

Description

Self-care demand

Timepoint

Before the intervention, six months after the completion of intervention

Method of measurement

Self Care for The Prevention Of Osteoporosis Based On Orem Self Care Model Questionnaire

8

Description

Self-care agency

Timepoint

Before the intervention, six months after the completion of intervention

Method of measurement

Self Care for The Prevention Of Osteoporosis Based On Orem Self Care Model Questionnaire

9

Description

Self-care operation

Timepoint

Before the intervention, six months after the completion of intervention

Method of measurement

Self Care for The Prevention Of Osteoporosis Based On Orem Self Care Model Questionnaire

Secondary outcomes

1

Description

Lifestyle modification

Timepoint

Before the intervention, six months after the completion of intervention

Method of measurement

Self Care for The Prevention Of Osteoporosis Based On Orem Self Care Model Questionnaire

Intervention groups

1

Description

Intervention group: Educational intervention in the intervention group includes lectures, brainstorming, modeling and distribution package. Intervention for two months during eight sessions on a weekly basis.

Category

Prevention

2

Description

Control group: there is no intervention in control group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University Shahrekord Branch

Full name of responsible person

Nader Sharifi

Street address

Islamic Azad University Shahrekord Branch,
Rahmatieh, Shahrekord

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of
Medical Sciences

Full name of responsible person

Professor Masud Yunesian

Street address

Tehran University of Medical Sciences ,Qouds Ave,
Keshavarz Boulvar, Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Fereshteh Majlessi

Position

Professor

Other areas of specialty/work

Street address

Department of Health Education and Promotion,
School of Public Health, Tehran University of Medical
Sciences, Poursina

City

Tehran

Postal code

Phone

+98 21 8898 9134

Fax

Email

dr_f_majlessi@yahoo.com

Web page address

Phone

+98 21 8898 9134

Fax

Email

dr_f_majlessi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Dr. Fereshteh Majlessi

Position

MD

Other areas of specialty/work

Street address

Department of Health Education and Promotion,
School of Public Health, Tehran University of Medical
Sciences, Poursina

City

Tehran

Postal code

Phone

+98 21 8898 9134

Fax

Email

dr_f_majlessi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Dr Fereshteh Majlessi

Position

MD

Other areas of specialty/work

Street address

Department of Health Education and Promotion,
School of Public Health, Tehran University of Medical
Sciences, Poursina

City

Tehran

Postal code

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