

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Educational intervention program based on BASNEF Model on preventing Osteoporosis among women referred to health center affiliated to TUMS

#### Protocol summary

##### Study aim

Determination of the effect of BASNEF model educational intervention on health promotion behaviors for prevention of osteoporosis in women member of health centers of Tehran University of Medical Sciences

##### Design

In this research, 162 eligible women aged 30 to 49 years old referring to the health centers of the Tehran University of Medical Sciences were chosen purposefully and a code was allocated to each one of them Then, women were randomly divided into two control and intervention groups.

##### Settings and conduct

Study population includes women aged 30 to 49 years old attending the health centers in south of Tehran. sample size is 162(81 participants intervention group and 81 participants in control group). In this study there has been employed BASNEF questionnaire including demographic information, the structures of BASNEF model, HPLPII question. Pre-test is taken from both groups. Intervention program will take place over a month of training sessions (four weeks with one session weekly) in form of blended education training (lecture ,question and answer). Every session will take 30 to 45 minutes. In these sessions, the attempt is sharing necessary information to Prevent osteoporosis preventive behaviors . Six months later, in order to assess the interventional program effects, the questionnaire will be completed again for both groups. The study not blinded

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study: Women aged 30 to 49 years old who go to the health centers of southern Tehran and who have not been postmenopausal and have the consent to participate in the study. Non-inclusion criteria: Specific disease, menopause, unwillingness to participate in the study.

##### Intervention groups

The study consists of 162 women aged 30 to 49 who are

not specific illnesses and are not suffering from postmenopausal women.The 162 patients included 81 in the intervention group and 81 in the control group.The tool of this study is a questionnaire based on the BASNEF model. we are taken pre-test from each of them.then For the intervention group, one-month training sessions (4weeks and each week one session) are conducted as a combined intervention (lecture, question and answer) intervention.Each training session is 30 to 45 minutes. During these sessions, provide information on the prevention of osteoporosis and preventive measures.

##### Main outcome variables

The training with the BASNEF model, according to the structures that this model has, can enhance the preventive behaviors of osteoporosis.

#### General information

##### Reason for update

##### Acronym

ندارد

##### IRCT registration information

IRCT registration number: **IRCT20130213012460N15**

Registration date: **2018-03-07, 1396/12/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-03-07, 1396/12/16**

Update count: **0**

##### Registration date

2018-03-07, 1396/12/16

##### Registrant information

##### Name

Roya Sadedgi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 327 5692

**Email address**  
sadeghir@tums.ac.ir

**Recruitment status**  
**Recruitment complete**  
**Funding source**

**Expected recruitment start date**  
2018-01-21, 1396/11/01

**Expected recruitment end date**  
2018-08-23, 1397/06/01

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Educational intervention program based on BASNEF Model on preventing Osteoporosis among women referred to health center affiliated to TUMS

**Public title**  
Educational intervention program for preventing Osteoporosis among women

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Criteria for entering the study : women aged 30 to 49 years old who go to the health centers of southern Tehran. Women who have not been postmenopausal. Women who are willing to participate in the study.  
**Exclusion criteria:**  
Specific illness during the study start menopause during the study unwillingness to continue cooperation Absence of more than two out of five sessions of educational classes

**Age**  
From **30 years** old to **49 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **162**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Sampling method will be done by simple random method. In this way, after the list of health centers in south Tehran, randomly selected four centers, then the two groups will be placed in the group and two centers will be placed in the comparison group. Finally, by referring to each center and coordinating with the responsible, the samples will be selected by simple random sampling with a coupled number to reach the desired sample size. These samples come together on special days at the health center, and they are invited to

participate in the study by familiarizing them with the subjects and expressing the research goals.

**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, School of Public Health, Tehran University of Medical Sciences  
**Street address**  
Keshavarz Blvd, Poursina St., School of Public Health, Tehran University of Medical Sciences  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
14155-6446

**Approval date**  
2017-08-09, 1396/05/18

**Ethics committee reference number**  
IR.TUMS.SPH.REC.1396.3.137

**Health conditions studied**

**1**

**Description of health condition studied**  
Preventive behaviors of osteoporosis .

**ICD-10 code**  
M81.8

**ICD-10 code description**  
Other osteoporosis without current pathological fracture

**Primary outcomes**

**1**

**Description**  
Preventive behaviors of osteoporosis.

**Timepoint**  
Before and six months after the intervention.

**Method of measurement**  
Questionnaire

**Secondary outcomes**

## 1

### Description

Health promotion behaviors

### Timepoint

Before and six months after intervention

### Method of measurement

Questionnaire

## 2

### Description

BASNEF theory constructs

### Timepoint

Before and six months after intervention

### Method of measurement

Questionnaire

## Intervention groups

## 1

### Description

Intervention group:Using lectures, pamphlets, booklets, posters, educational videos and questions and answers discussions (30-45 minutes)

### Category

Behavior

## 2

### Description

Control group: For this group, a preliminary test will be performed at the beginning.no intervention was done

### Category

Behavior

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

South health centers of Tehran University of Medical Sciences

#### Full name of responsible person

Mrs.Akram-o-Sadat Mohseni Tekye

#### Street address

No. , Shafiee Alley , Ghods St.

#### City

Tehran

#### Province

Tehran

#### Postal code

1417863181

#### Phone

+98 21 6697 8200

#### Email

sthn@tums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Mohammad Ali Sahraian

#### Street address

Keshavarz Blvd, Poursinia Street ,vice chancellor for research of Tehran University of Medical Sciences

#### City

Tehran

#### Province

Tehran

#### Postal code

1417653761

#### Phone

+98 21 8898 7381

#### Email

Msahrai@sina.tums.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Tehran 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

Tehran University of Medical Sciences

#### Full name of responsible person

Dr. Roya Sadeghi

#### Position

Associate Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Health Promotion

#### Street address

Keshavarz Blvd, Poursinia St., School of Public Health, Tehran University of Medical Sciences

#### City

Tehran

#### Province

Tehran

#### Postal code

141556446

**Phone**

+98 21 4293 3210

**Email**

sadeghir@tums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Roya Sadeghi

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

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Tehran University of Medical Sciences

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## Person responsible for updating data

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**Name of organization / entity**

Tehran University of Medical Sciences

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Dr. Roya Sadeghi

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Associate Professor

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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