

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Comparison of the effect of resistance training on women's bone parameters, before and after menopause

#### Protocol summary

##### Study aim

Comparison of the effect of resistance training on bone mineral density and bone mineral content and bone youth index and bone age and bone area adaptation of postmenopausal and non-menopausal women with osteopenia

##### Design

A clinical trial with a control group with parallel blind groups is randomly assigned to 40 people with osteopenia. A lottery was used for randomization.

##### Settings and conduct

Subjects were selected from the Endocrine and Metabolism Research Center of the Red Crescent Subspecialty and Physical Rehabilitation Center And after examination by an endocrinologist and referral to the researcher has completed the consent and personal information And they start training at the Red Crescent Rehabilitation Center.

##### Participants/Inclusion and exclusion criteria

Age range 40 to 60 years Menopausal and non-menopausal women with osteopenia with body mass index between 18 to 25 No history of hormone therapy No use of any hormonal drugs during treatment No history of joint disease No history of any fractures or surgery

##### Intervention groups

In the experimental groups (menopause and non-menopause), resistance training due to individual differences, the intensity of training was 70 to 85% 1RM. The number of repetitions also changed from 8 repetitions to 12 repetitions from the first to the fourth month. It is 60 minutes, the researcher monitored the exercises throughout the duration, the control group did not intervene during these 4 months and continued their daily life.

##### Main outcome variables

Independent variable: resistance training Dependent variables: bone mineral density, bone mineral content, T score, Z score, Bone area

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211017052792N1**

Registration date: **2021-11-13, 1400/08/22**

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

Last update: **2021-11-13, 1400/08/22**

Update count: **0**

##### Registration date

2021-11-13, 1400/08/22

##### Registrant information

##### Name

Fatemeh Ghorbani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3340 5980

##### Email address

lotfi@bondagroup.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2021-10-23, 1400/08/01

##### Expected recruitment end date

2022-01-21, 1400/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of resistance training on women's bone parameters, before and after menopause

### Public title

The effect of resistance training on improving bone mineral density

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Postmenopausal and non-menopausal women in the age range of 40 to 60 years with osteopenia approved by an endocrinologist weight in the normal range and with a body mass index between 18 and 25 according to the criteria of the World Health Organization

#### Exclusion criteria:

Any fractures or surgery on the lower limbs and spine hormone intake that affects bone tissue metabolism pre-hormone therapy and exercise in the past 6 months and during the study period people with joint diseases such as osteoarthritis and osteoarthritis In the lower limbs

### Age

From **40 years** old to **60 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

- Participant

### Sample size

Target sample size: **40**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The present study consists of 4 postmenopausal groups (intervention and control) and non-menopausal group (intervention and control). We use the classification randomization method to randomize the sample selection. In this method, participants are placed in two classes A and B based on menopausal status factor (menopause and non-menopause) and then in each class, simple randomization (lottery) is used to select samples for the intervention and control groups.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

In the present study, blindness is one-sided and due to the fact that the researcher interviews individuals personally and after the study description and obtaining written consent, puts them under medical intervention or control group, the researcher assigns individuals and groups. It is aware and only patients do not know which group they belong to.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shahid Beheshti University of Tehran

##### Street address

Daneshjoo Blvd, Shahid Shahriari Square, Yemen St., Chamran Highway, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1983969411

#### Approval date

2021-04-26, 1400/02/06

#### Ethics committee reference number

IR.SBU.REC.1400.009

## Health conditions studied

### 1

#### Description of health condition studied

Decreased bone density in postmenopausal and non-menopausal women

#### ICD-10 code

M81.0

#### ICD-10 code description

Age-related osteoporosis without current pathological fracture

## Primary outcomes

### 1

#### Description

The effect of exercise on bone mineral density

#### Timepoint

Measurement of bone mineral density at the beginning of the study (before the intervention) and 4 months after the intervention.

#### Method of measurement

Bone Density Tester

### 2

#### Description

The effect of exercise on bone mineral content

#### Timepoint

Measurement of bone mineral density at the beginning of the study (before the intervention) and 4 months after the intervention.

#### Method of measurement

Bone Density Tester

### 3

#### **Description**

The effect of exercise on bone Z- score

#### **Timepoint**

Measurement of bone mineral density at the beginning of the study (before the intervention) and 4 months after the intervention.

#### **Method of measurement**

Bone Density Tester

### 4

#### **Description**

The effect of exercise on bone T-score

#### **Timepoint**

Measurement of bone mineral density at the beginning of the study (before the intervention) and 4 months after the intervention.

#### **Method of measurement**

Bone Density Tester

### 5

#### **Description**

The effect of exercise on bone area

#### **Timepoint**

Measurement of bone mineral density at the beginning of the study (before the intervention) and 4 months after the intervention.

#### **Method of measurement**

Bone Density Tester

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Due to individual differences and a maximum repetition, ie the maximum weight that a person can move for one time, resistance exercises with dumbbells with an intensity of 70 to 85% of a maximum repetition and 8 to 12 repetitions on the extensor muscles of the trunk and front muscles. And the back of the foot is done for 4 months. It should be noted that the duration of the exercises, taking into account warm-up and cooling, is 60 minutes.

#### **Category**

Treatment - Other

### 2

#### **Description**

Intervention group 2 (non-menopausal group): Non-menopausal group such as menopausal group due to individual differences and a maximum repetition means the maximum weight that a person can move for one time. And 8 to 12 repetitions are done on the extensor muscles of the trunk and the muscles of the front and

back of the leg for 4 months. It should be noted that the duration of the exercises is 60 minutes, taking into account warm-up and cooling.

#### **Category**

Treatment - Other

### 3

#### **Description**

Control group: The postmenopausal control group and the non-menopausal control group resume their normal daily activities for 4 months and avoid taking bone density medication.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Red Crescent Rehabilitation Center

##### **Full name of responsible person**

Fatemeh Ghorbani

##### **Street address**

Red Crescent Comprehensive Rehabilitation Center, next to Khatam Al-Anbia Hospital, Rashid Yasemi St., above Mirdamad, Valiasr St., Tehran,

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University

##### **Full name of responsible person**

Babak shokri

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Blvd. Student, Shahid Shahriari Square, Yemen St., Shahid Chamran Highway

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**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
Shahid Beheshti University  
**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**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Fateme Ghorbani  
**Position**  
Masters student  
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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