

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The effect of activity and spiritual health based self-care program on hypertension among the Kahrizak elderly people in the Alborz province.

#### Protocol summary

##### Study aim

1-Determining the Effectiveness of Self-Care-Based Activity Program - Spiritual Health on Hypertension in Kahrizak Alborz Elderly

##### Design

This study is a clinical trial with three groups: control group, self-care program group and activity group, purposeful and pragmatic, single blind and non-randomized.

##### Settings and conduct

Study place: Alborz Provincial Kahrizak Care Center, Mohammad Shahr, Karaj, Iran

##### Participants/Inclusion and exclusion criteria

1-Elderly diagnosed by a specialist physician residing in a hypertensive center 2-The patient's age is 65 to 90 years. Because they have at least one chronic disease, according to the sources of people over the age of 60 years Non-arrival conditions like: 1. During the study of elderly death or leaving the sanatorium for any reason. 2. During the study, you are suffering from diseases caused by hypertension or heart attacks.

##### Intervention groups

For the 30 elderly in the control group, the activity and self-care program of the consent form of the company were completed in the research, and the demographic information, daily life and spiritual well-being questionnaires were completed. Systolic and diastolic blood pressure was measured with a barometric device at two times in the morning and evening for three consecutive days and recorded in the blood pressure check list. For the elderly, the intervention group was first trained in two sessions of 30-45 minutes about the purpose of the study, its elderly age and its accompanying problems, the role of exercise and physical activity in controlling hypertension. For the self-care program group, the spiritual health program was presented about value-holds. In the implementation section, the activities were carried out according to what was taught.

#### Main outcome variables

The rate of hypertension, self-care and activity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180527039870N1**

Registration date: **2018-07-04, 1397/04/13**

Registration timing: **retrospective**

Last update: **2018-07-04, 1397/04/13**

Update count: **0**

##### Registration date

2018-07-04, 1397/04/13

##### Registrant information

##### Name

Saeedeh Khalili

##### Name of organization / entity

The University of Tarbiyat modares

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3730 4592

##### Email address

saeedehkhalili@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-03-05, 1395/12/15

##### Expected recruitment end date

2017-07-21, 1396/04/30

##### Actual recruitment start date

2017-03-19, 1395/12/29

##### Actual recruitment end date

2017-09-06, 1396/06/15  
**Trial completion date**  
empty

**Scientific title**  
The effect of activity and spiritual health based self-care program on hypertension among the Kahrizak elderly people in the Alborz province.

**Public title**  
The effect of self-care program on hypertension

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Elderly diagnosed as hypertensive disease by a specialist physician residing in center. The age of the patient is 65 to 90 years old. Older people have read and write literacy or ability to interview. Have a tendency to participate and collaborate in research.  
**Exclusion criteria:**  
Illnesses caused by complications of hypertension or myocardial infarction during the study. Elderly death or leaving the sanatorium for any reason during the study

**Age**  
From **65 years** old to **90 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **90**  
Actual sample size reached: **89**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Participants in the study were placed in separate groups so that they did not deal with each other

**Placebo**  
Not used

**Assignment**  
Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tarbiat Modarres University

##### Street address

Tehran Jalal Al Ahmad Nasr Bridge

#### City

Tehran

#### Province

Tehran

#### Postal code

14115-111

#### Approval date

2016-12-11, 1395/09/21

#### Ethics committee reference number

IR.TMU.REC.1395.431

## Health conditions studied

### 1

#### Description of health condition studied

hypertension in the elderly

#### ICD-10 code

110

#### ICD-10 code description

Essential (primary) hypertension

## Primary outcomes

### 1

#### Description

Percentage of people with hypertension above 140/90

#### Timepoint

Measuring hypertension at the beginning of the study three consecutive days at two times in the morning and at night, and then at the end of the study three consecutive days at two times in the morning and evening after the presentation of the training program

#### Method of measurement

Yamasu counter barometer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: For 30 elderly people in the control group consent to participate in research and demographic, complete with Shd.fsharkhvn systolic and diastolic pressure gauge Japanese Yamasv in the morning and afternoon on three consecutive days to measure and record blood pressure at the Czech medical records and in the last 1.5 months without intervention seniors again in the morning and evening blood pressure measurements were recorded in the Czech list.

#### Category

Rehabilitation

### 2

#### Description

Intervention group: For the 30 aged people in the activity group, at first, the satisfaction of the company in the research and the demographic information questionnaire, the daily routine life questionnaire was completed for elderly in terms of physical activity and resting time during physical or physical activity. Then, elderly blood pressure at two times in the morning The age of measurement was recorded in the blood pressure check list. In the implementation section, the items of the daily life activity questionnaire were explained to the elderly in 5 dimensions and they were asked to perform their duties and duties according to the items of the daily life activities questionnaire. And register in the self-report checklist. In the follow up section, the researcher's presence was followed up within 3 weeks of the elderly's performance. At the end of the first 1.5 months, the questionnaire was completed daily living and elderly blood pressure was measured at two times in the morning and in the evening and recorded in the checklist.

#### **Category**

Rehabilitation

### **3**

#### **Description**

Intervention group: For the 30 elderly in the self-care program group (spiritual activity), the consent of the company in the research and the demographic information questionnaire, the daily living practice questionnaire for assessing the elderly in terms of physical activities and resting time during physical or physical activity, as well as the questionnaire Spiritual health was completed. In the implementation section, the activities were followed in the same way as the second intervention group, and the spiritual health program was presented in different fields such as values (encouragement to help others), connecting point (listening to the verses of the verse, 3 times a week). 1.5 months later. The intervention was again completed and scaled.

#### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

Kahrizak Center for Alborz Province

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

Saeedeh Khalili

##### **Street address**

Mohammad Shahr, at the end of Golestan St.,  
Beginning of Isfahan Street

##### **City**

Karaj

##### **Province**

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##### **Postal code**

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##### **Phone**

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##### **Email**

sos.khalili@gmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

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

The University of Tarbiat modares

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

Yaghoub Fathollahi

##### **Street address**

Nasr briddge, Jalal All Ahmad, Tehran

##### **City**

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##### **Province**

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##### **Postal code**

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##### **Email**

saeedehkhalili@modares.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

The University of Tarbiat modares

##### **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**

Tarbiat Modares University

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

Saeedeh Khalili

##### **Position**

MSc student of nursing

##### **Latest degree**

Master

##### **Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

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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