

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

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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

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Mohammad Shahr, at the end of Golestan St.,
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

The University of Tarbiat modares

Full name of responsible person

Yaghoob Fathollahi

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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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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