

# Effectiveness of gentle exercise in lowering blood pressure for inactive elderly Saudis with high blood pressure in social home care

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<b>Registration date</b> 31/05/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/06/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The impact of aerobic exercise on the blood pressure of sedentary older individuals receiving social home care in Saudi Arabia has yet to be investigated. This study aimed to investigate the effects of non-pharmacological aerobic exercise training on resting blood pressure, heart rate, body fat, cholesterol, and functional status in sedentary older hypertensive Saudis living in social home care settings.

### Who can participate?

Sedentary individuals aged 60-85 years with hypertension (high blood pressure) living in social home care in Makkah, Saudi Arabia, were eligible to participate.

### What does the study involve?

All participants were asked to fill out questionnaires about their age, gender, socioeconomic status, sedentary lifestyle, and physical abilities. A blood sample was taken to measure their total cholesterol, LDL (bad cholesterol), and HDL (good cholesterol) levels. The participants were then randomly assigned to one of two groups.

The experimental group engaged in mild to moderate-intensity aerobic exercise, specifically stationary cycling, for a total of 24 sessions lasting 45 minutes each. These sessions took place three times per week over an eight-week period and were supervised by a physiotherapist. The exercise program started with 20-minute sessions at 30% of the participants' heart rate during the first week. The intensity and duration gradually increased, reaching 45-minute sessions at 50% of their heart rate.

The control group received standard care, but for ethical reasons, participants in this group were given the option to join the aerobic exercise program after completing the eight-week intervention period. All participants were expected to attend more than 90% of the training sessions at the Medical Department of Social Home Care physiotherapy gym. The researchers recorded the participants' adherence to the exercise sessions. If participants no longer wished to continue, they had the option to withdraw from the study without providing a reason.

What are the possible benefits and risks of participating?

There were no immediate direct benefits or risks for those taking part. Risks could be associated with an elevated heart rate during exercise. Each session included a 10-minute warm-up and cool-down period supervised by a physiotherapist to mitigate risks.

Where is the study run from?

Medical Department of Social Home Care for Older Adults in Makkah, Saudi Arabia

When is the study starting and how long is it expected to run for?

January 2021 to March 2021

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

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## Contact information

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **ClinicalTrials.gov (NCT)**

Nil known

### **Protocol serial number**

Nil known

## **Study information**

### **Scientific Title**

Efficacy of low-to-moderate-intensity aerobic exercise training in reducing resting blood pressure in sedentary older Saudis with hypertension living in social home care: a pilot randomized clinical trial

### **Study objectives**

Inactive elderly hypertensive Saudis receiving social home care would benefit from non-pharmacological aerobic exercise regarding resting blood pressure, heart rate, body fat, cholesterol, and functional status.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 14/01/2021, Institutional Review Board of King Saud University (P.O. Box 7805, Riyadh 11472, Kingdom of Saudi Arabia; +966114670011; aalsultan1@ksu.edu.sa), ref: E-20-5451

### **Study design**

Single-center interventional nonblinded randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Efficacy

### **Health condition(s) or problem(s) studied**

Hypertension

### **Interventions**

By computerized random sequence allocation, we split sedentary men or women between the ages of 60 and 85 who were living in social home care and had hypertension into experimental and control groups. We gave the experimental group participants instructions to engage in mild-to moderate-intensity aerobic exercise involving 24 sessions lasting 45 minutes each, three times a week for eight weeks, in accordance with the American College of Sports Medicine guidelines, under the guidance of a physiotherapist. In the medical department of Social Home Care's physiotherapy gym, participants are required to attend at least 90% of all training sessions. Every adult should engage in at least 30 minutes of moderate physical activity on the majority of days of the week, according to the program's eight-week prescription. Participants steadily increased from 20 minutes at 30% of their heart rate in the first week to 45 minutes at 50%. A 10-minute warm-up and cool-down were included in each session's total running time. Under the guidance of a physiotherapist, we employed a heart rate monitor to keep aerobic exercise intensity high during training and avoid exceeding a maximum heart rate of 160 beats per minute (bpm).

The normal treatment was given to participants in the control group. After the eight-week intervention period, participants in the control group were given the option to continue with the aerobic exercise program for moral grounds. Participants' adherence to the exercise sessions was documented. Both groups used antihypertensive drugs.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Resting blood pressure is measured by a systolic and diastolic pressures with a traditional mercury sphygmomanometer (Rossmax Swiss GmbH, Heerbrugg, Switzerland) at the initial stage of the exercise program and eight weeks afterwards.

## **Key secondary outcome(s))**

At baseline and after 8 weeks:

1. Heart rate measured using heart rate monitor
2. body fat determined using body mass index
3. Total cholesterol, low-density lipoprotein (LDL), and high-density lipoprotein (HDL) levels by analyzing the blood sample in the laboratory.
4. Functional status measured using the Katz index scale

## **Completion date**

30/03/2021

## **Eligibility**

### **Key inclusion criteria**

1. Sedentary men or women aged 60 to 85 years with hypertension
2. Living in social home care

Hypertension was defined as systolic blood pressure  $\geq 130$  mmHg and diastolic blood pressure  $\geq 80$  mmHg. A sedentary lifestyle is not engaging in sports or regular exercise during the previous three months. Sedentary behavior was assessed using the Saltin–Grimby Physical Activity Level Scale (SGPALS).

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Lower age limit**

60 years

**Upper age limit**

85 years

**Sex**

All

**Total final enrolment**

27

**Key exclusion criteria**

Participants were excluded if they had heart failure, a history of unstable angina or myocardial infarction, chronic pulmonary disease, or major musculoskeletal disorders.

**Date of first enrolment**

15/01/2021

**Date of final enrolment**

30/03/2021

**Locations****Countries of recruitment**

Saudi Arabia

**Study participating centre**

Social Home Care for Elderly

Makkah

Saudi Arabia

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**Sponsor information****Organisation**

King Saud University

ROR

<https://ror.org/02f81g417>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### Individual participant data (IPD) sharing plan

To obtain the datasets generated in this study, researchers can make a request to any of the study investigators.

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Written consent in the Arabic language was obtained from all participants in the study.

After enrollment, each patient was assigned a unique identification number, which was used to record all data. Personal identifying information of participants was removed and modified in the dataset. As a result, outcome assessors and data analysts were kept blinded throughout and after data collection, ensuring they had no access to information that could identify specific individuals.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	18/06/2023	28/06/2023	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes