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

Submission date
26/05/2023

Recruitment status
No longer recruiting

Registration date
31/05/2023

Overall study status
Completed

Last Edited
29/06/2023

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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2. Abdulrahman A. Alzahrani, a.rahman85@hotmail.com

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Care home, Medical and other records

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet.

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 measure
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.

Secondary outcome measures
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

Overall study start date
09/01/2021

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 ≥130 mmHg and diastolic blood pressure ≥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

Age group
Senior

Lower age limit
60 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
65

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
1111

Sponsor information

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King Saud University

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Sponsor type
University/education

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ROR
https://ror.org/02f81g417

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/05/2023

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.
1. Prof. Saad M. Bindawas, sbindawas@ksu.edu.sa
2. Abdulrahman A. Alzahrani, a.rahman85@hotmail.com

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?
Results article	results	18/06/2023	28/06/2023	Yes	No