Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Aerobic, Resistance, and Combined Training on Hypertension Patients: A randomized Controlled Trial

Protocol summary

Study aim

The aim of this study was comparing the effects of aerobic, resistance, and a combination of aerobic plus resistance training on blood pressure (BP), cardiorespiratory fitness (CRF) and body composition.

Design

The research design of this study was reflective of a “classic design for exploring cause-and-effect relationships”, the pretest-posttest parallel group experimental design

Settings and conduct

This study was conducted in Finoteselam hospital in Jabi Tehinan wereda, West Gojjam Zone, Amhara Regional State, Ethiopia

Participants/Inclusion and exclusion criteria

Criteria for inclusion: 1) All consenting patients with hypertension between the ages of 18 and 65. 2) Individuals with hypertension who have been treated for at least three months. 3) Stage 1 and 2 hypertension patients who are willing to participate in the study (systolic blood pressure < 180 mmHg and diastolic blood pressure < 100 mmHg) (41), 4) reside in the town of Finoteselam, and 5) do not have any injuries.6) For at least the last three months, patients were sedentary. Criteria for rejection:1) People who are unfit for exercise and have hypertension-related complications, such as coronary heart disease, congestive heart failure, and cerebrovascular disease; 2) people who have other co-morbidities, such as diabetes mellitus, chronic kidney disease, and musculoskeletal injuries, that prevent them from exercising.

Intervention groups

The intervention groups in this trial: Aerobic exercise intervention group, strength exercise intervention group and combined aerobic plus strength exercise intervention group.

Main outcome variables

Blood pressure, body composition and cardiorespiratory fitness.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220615055181N1**
Registration date: **2023-02-15, 1401/11/26**
Registration timing: **retrospective**

Last update: **2023-02-15, 1401/11/26**
Update count: **0**

Registration date

2023-02-15, 1401/11/26

Registrant information

Name

Getu Teferi

Name of organization / entity

Debremarkos University

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Ethiopia

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-01, 1400/09/10

Expected recruitment end date

2022-02-01, 1400/11/12

Actual recruitment start date

2021-12-08, 1400/09/17

Actual recruitment end date

2022-02-08, 1400/11/19

Trial completion date

2022-02-08, 1400/11/19

Scientific title
Effectiveness of Aerobic, Resistance, and Combined Training on Hypertension Patients: A randomized Controlled Trial

Public title
Effect of exercises on hypertension

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Criteria for inclusion: 1) All consenting patients with hypertension between the ages of 18 and 65. 2) Individuals with hypertension who have been treated for at least three months. 3) Stage 1 and 2 hypertension patients who are willing to participate in the study (systolic blood pressure < 180 mmHg and diastolic blood pressure < 100 mmHg) (41), 4) reside in the town of Finoteselam, 5) do not have any injuries. 6) For at least the last three months, patients were sedentary.

Exclusion criteria:
Criteria for rejection:1) People who are unfit for exercise and have hypertension-related complications, such as coronary heart disease, congestive heart failure, and cerebrovascular disease. 2) people who have other co-morbidities, such as diabetes mellitus, chronic kidney disease, and musculoskeletal injuries, that prevent them from exercising.

Age
From **35 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**
More than 1 sample in each individual
Number of samples in each individual: **12**
12 participants in each four groups (aerobic intervention group =12, strength intervention group = 12, combined intervention group = 12 and control group = 12).
Actual sample size reached: **48**
More than 1 sample in each individual
Actual sample size in each individual: **48**
12 participants in each four groups (aerobic intervention group =12, strength intervention group = 12, combined intervention group = 12 and control group = 12).

Randomization (investigator's opinion)
Randomized

Randomization description
The subjects were 48 adults with T2DM who were attending the diabetes clinic of the Finoteselam referral hospital were randomly assigned to one of four groups using a random numbered table: the aerobic intervention group (aerobic IG), the strength intervention group (strength IG), the combined both aerobic and strength intervention group (combined IG) or control group (CG). We used a simple randomization method for individual patients. Mechanism used to implement the random allocation sequence was a random numbered table by staffs who were not assessors of the outcome.

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants were assigned randomly to three intervention groups and a control group. In our study the following groups are involved blindly: fitness professionals who provide exercise interventions, data collectors, outcome assessors, lab technicians and investigator-initiated trials.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research ethics committee

Street address
Kebel 08, Debremarkos

City
Debremarkos

Postal code
269

Approval date
2021-12-08, 1400/09/17

Ethics committee reference number
SPSC04/21

Health conditions studied

1

Description of health condition studied
Comparing the effects of aerobic, resistance, and a combination of aerobic plus resistance training on blood pressure (BP), cardiorespiratory fitness (CRF) and body composition.

ICD-10 code

ICD-10 code description
Our study focuses on the effect of different exercise modalities on blood pressure (BP), cardiorespiratory fitness (CRF) and body composition. That means we were studying on the effect of exercise on hypertension patients.

Primary outcomes

1

Description

The primary outcome variable of this trial is blood pressure (systolic and diastolic blood pressure).

Timepoint

The baseline (pre-test) data were gathered; at week 1, prior to the intervention (also known as the baseline or pre-intervention), and at week 13, after the 12-week intervention (also known as the post-intervention).

Method of measurement

The automated Sphygmacor XCEL (AtCor Medical, Itasca, IL, USA) was used to measure blood pressure and resting heart rate. The participant was seated with their legs straight and a brachial pressure cuff placed over the brachial artery on their left arm. The device measured the brachial systolic and diastolic blood pressure three times, with a two-minute rest in between each measurement. For all measurements, the SphygmaCor XCEL reported the average of the last two readings instead of the initial reading.

2

Description

The second outcome variable of this trial is body composition (body fat percentage and body mass index).

Timepoint

The baseline (pre-test) data were gathered; at week 1, prior to the intervention (also known as the baseline or pre-intervention), and at week 13, after the 12-week intervention (also known as the post-intervention).

Method of measurement

The body mass index was calculated by dividing the height in meters squared by the body weight in kilograms using a standard stadiometer. The body fat percentage was measured using a skinfold caliper. With the help of a skinfold caliper and a properly trained technician, the skinfold percentage of body fat can be determined with great precision. Gender and age are thought to have an impact on the ratio of subcutaneous fat to total fat (Medicine, 2013). Based on the specific recommendations of (Medicine, 2013), we used the Jackson-Pollock 3-Site Skinfold Formula for Body Density J-P 3-Site (Jackson & Pollock, 1985) for this study. As a result, the three site: triceps, suprailiac, and abdominal sites were used to measure women's body fat using the three-site formula: Body Density = 1.089733 - 0.0009245 (sum of three skinfolds) + 0.0000025 (sum of three skinfolds)2 - 0.0000979 (age), whereas for men, the three-site formula for the chest, triceps, and subscapular is as follows: Body Density is equal to 1.1125025 minus 0.0013125 (sum of three skinfolds) plus 0.0000055 (sum of three skinfolds)2 minus 0.000244. Body Density (BD) can be used to determine the percentage of body fat, according to the Siri Equation(Jackson & Pollock, 1985) :The percentage of body fat calculated using the Siri Equation is: % BF = 495/BD – 450.

3

Description

The third outcome variable of this trial is cardiorespiratory fitness.

Timepoint

The baseline (pre-test) data were gathered; at week 1, prior to the intervention (also known as the baseline or pre-intervention), and at week 13, after the 12-week intervention (also known as the post-intervention).

Method of measurement

Queens College Step Test was employed to measure cardiovascular endurance. The subjects will be started by steps up and down on the platform at a given rate for three minutes. For three minutes, the subjects would begin by moving up and down on the platform at a predetermined rate. This action will be repeated, and the test will continue until the allotted amount of time has passed. Stepping time and/or heart rate after exercise are used to calculate the results. After completing the test, participants use their index finger to locate the radial or carotid arteries. Subjects will be counted for the number of heartbeats (pulses) that occur over a 15-second period following the discovery of radial or carotid pulse. By multiplying the number of heartbeats counted in 15 seconds by 4, heart rates for one minute can be calculated. The recovery HR is then used to calculate the subject's Vo2max in mL'kg-I'min-1 using the following formula: Men:Vo2max = mL kg-1min-1) = 111.33 - (0.42.HR) (Davis, 2008).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: aerobic exercise intervention: During the 12-week training period, all study participants, with the exception of the non-exercise control group, exercised for 60 minutes, which included 5 minutes of warming up and 5 minutes of cooling down. All training sessions were overseen by health fitness professionals and exercise physiologists. The exercise regimens developed by the American College of Sports Medicine (Garber, Blissmer, Deschenes, Franklin, Lamonte, Lee, Nieman, & Swain, 2011; Pescatello, Franclin, Fagard, & Faqquhar, 2004) served as the foundation. The aerobic exercise-only group performed floor aerobics or aerobic dance at an initial heart rate of 40% and gradually increased to approximately 70% as the intervention progressed. The heart rate monitor that was worn by the participants throughout each exercise session recorded their maximum heart rate, which could be exercised at an intensity that did not exceed 80% of their maximum heart rate.

Category

Other

2

Description

Intervention group: strength exercise intervention group:

The only resistance group that includes standing plantar flexion, triceps pulley, neutral rowing, squatting, dumbbell supine, knee extension with ankle weights, dumbbell development, dumbbell curl and trunk flexion and vertical bench press (Carvalho et al., 2019). The circuit type of resistance training (RT) was used with intervals of 15–20 s between exercises, with 3 sets of 10 repetitions with a rest of 1–2 minutes between sets. Due to the patients' lack of physical fitness and motor coordination, the loads were determined by their perceived exertion using the scale of 6 to 20 proposed by Borg in 1982 (Borg, 1982). The values used were 11 to 13, which represented a moderate effort. The load was then increased with the goal of maintaining constant value of perceived exertion.

Category
Other

3

Description
Intervention group: Combined aerobic plus strength intervention group. The combined group participated in 30 minutes of resistance training and 30 minutes of aerobic exercise at the same intensity, progression, and method in each session. The only difference for aerobic exercise was that it was cut down to 30 minutes rather than 60. With the exception of the neutral rowing, dumbbell supine, dumbbell development and standing plantar flexion, these participants performed their resistance training with the same intensity and protocol as the afore-mentioned individual groups, reducing it to six exercises instead of ten and two sets instead of three.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Finoteselam Fitness center
Full name of responsible person
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Sponsors / Funding sources

1

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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
Self funded
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
Getu Teferi
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Deidentified individual participant data (IPD) collected in this study will be available to other researchers (typically after publication of this study). The measured data on blood pressure (BP), cardiorespiratory fitness (CRF) and body composition will be share to other researchers. The data sharing plan of this trial includes study protocol, statistical analysis plan, informed consent form and summary reports of the trial.

When the data will become available and for how long
The data files will become available when summary data are published.

To whom data/document is available
Scholars: this is only available for people working in academic institutions.

Under which criteria data/document could be used
Accessing criteria for this deidentified IPD and any additional supporting information/documents will be for research purpose, to design strategies for prevention and management of blood pressure, weight management and cardiovascular diseases. Scholars can request who are from academic institutions (students, teachers and researchers).

From where data/document is obtainable
This trial data is available from corresponding author (Getu Teferi).

What processes are involved for a request to access data/document
To scholars from academic institution can access the data from corresponding author through email (teferigetu36@gmail.com).

Comments