

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Metabolic Impact of Exercise Modalities in Inactive Overweight and Obese Adults: A Randomized Controlled Trial

Protocol summary

Study aim

the objective of this study was to assess and compare the efficacy of various exercise modes (aerobic, resistance training, and combined exercise) and changes over time in enhancing lipid profile changes and glucose tolerance among adults who are obese.

Design

Randomized, three arm parallel group trial with blinded outcome assessment. Participants were randomly assigned to groups using a computerized system that generated a sequence of random numbers at an external site.

Settings and conduct

Our study recruited physically inactive volunteers (45-60 years, BMI > 30 kg/m²) from Debre Markos, Ethiopia (radio & notice boards). To minimize bias, data collectors were blinded to participant group assignments (single-blind design).

Participants/Inclusion and exclusion criteria

Eligible participants were those aged 45-60 with a BMI above 24.9, physically inactive, willing, and able to exercise. Exclusions included significant health conditions like cardiovascular, respiratory, or musculoskeletal disorders, uncontrolled diabetes, hypertension, infections, or recent severe medical events.

Intervention groups

Intervention group 1 (The resistance training group): performed standing plantar flexion, squatting, machine leg press, neutral rowing, bicep curl, triceps pulley, dumbbell curl, and vertical bench press. The exercise routine involved three sets per session, with 8 to 12 repetitions at an intensity of 50% to 75% of their one-repetition maximum (1RM). Intervention group 2 (Aerobic exercise training group): They involved using a treadmill at an intensity level ranging from 50% to 75% of HR max, for 25-40 minutes. The control group (CG) engaged in a training regimen that combined the total volume of the RT and the endurance group AT. In each session,

participants performed AT exercises before moving on to RT.

Main outcome variables

Glucose tolerance; lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240430061607N1**

Registration date: **2024-06-06, 1403/03/17**

Registration timing: **retrospective**

Last update: **2024-06-06, 1403/03/17**

Update count: **0**

Registration date

2024-06-06, 1403/03/17

Registrant information

Name

Friew Amare

Name of organization / entity

Debre Markos University

Country

Ethiopia

Phone

+251 58 771 6070

Email address

firewa6070@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-20, 1400/12/29

Expected recruitment end date

2022-04-15, 1401/01/26

Actual recruitment start date

2022-04-01, 1401/01/12
Actual recruitment end date
 2022-04-10, 1401/01/21
Trial completion date
 2022-06-20, 1401/03/30

Scientific title
 Metabolic Impact of Exercise Modalities in Inactive Overweight and Obese Adults: A Randomized Controlled Trial

Public title
 Impact of Exercise on Metabolism in Overweight/Obese Adults

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Had a BMI > 24.9 kg/m² Were aged between 45 and 60 years Volunteered to participate Were physically inactive (not achieving 30–60 min per day or 150 min per week of moderate intensity exercise or 20–60 min per day (75 min per week) of vigorous intensity and cleared a medical history form the physical activity readiness questionnaire) Were able to perform the necessary exercises
Exclusion criteria:
 Any cardiovascular, respiratory, or muscle-skeletal disorders precluding physical exercise Uncontrolled hyperglycemia (≥ 126 mg/d) Uncontrolled hypertension (a resting blood pressure $\geq 140/100$ mm hg) Active infection Acute myocardial infarction, stroke, trauma, surgery or severe liver dysfunction

Age
 From **45 years** old to **60 years** old

Gender
 Male

Phase
 2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
 Target sample size: **24**
 Actual sample size reached: **20**

Randomization (investigator's opinion)
 Randomized

Randomization description
 In our clinical trial, randomization was achieved through simple random sampling, with individuals as the unit of randomization. A computerized random number generator created a sequence to allocate participants to their respective groups, ensuring each had an equal chance of assignment. Allocation concealment was implemented using sealed opaque envelopes, which were opened only after baseline assessments, to prevent selection bias and uphold the study's integrity.

Blinding (investigator's opinion)
 Single blinded

Blinding description
 The outcome assessors and data analysts were masked

to the group assignments of participants. This was achieved by assigning codes to participant groups that were only known to researchers. The assessors and analysts worked with these codes, devoid of any knowledge regarding which group each code represented. This method effectively prevented potential bias in the assessment of outcomes and the analysis of data, thereby upholding the integrity of the research findings.

Placebo
 Not used
Assignment
 Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Debre Markos University Sport Science Academy
 Ethics committee
Street address
 Abima, Debre Markos
City
 Debre Markos
Postal code
 no
Approval date
 2022-01-15, 1400/10/25
Ethics committee reference number
 SPSC05/22

Health conditions studied

1

Description of health condition studied
 glucose intolerance
ICD-10 code
ICD-10 code description

2

Description of health condition studied
 dyslipidemia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
 glucose tolerance
Timepoint
 before intervention and at the end of eighth week

Method of measurement

GOTT tests were analyzed by the hexokinase method (COBAS, Roche), and its intracoefficient of variation ranged between 1.58% ($\mu=64.7$ mg/dl) and 1.38% ($\mu=369$ mg/dl).

2

Description

Lipid profile

Timepoint

before intervention and at the end of eighth week

Method of measurement

An enzymatic method utilizing an Alpha X autoanalyzer with E2HL-100 kits and a sensitivity of 0.1 mmol/dL (Hitachi, Tokyo, Japan) was employed for lipid measurement.

3

Description

Body composition

Timepoint

before intervention and at the end of eighth week

Method of measurement

body fat percentage were determine by abdominal, thigh, suprailiac and triceps skinfolds measurements on the right side of the body to the nearest 0.5 mm with a Lange caliper (Cambridge Scientific Instruments, Cambridge, MD, USA). and determined by sari equation.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Aerobic exercise training group. Participants in the AT group engaged in treadmill exercise at 50-75% of their maximum heart rate for 25-40 minutes, 3 times per week.

Category

Treatment - Other

2

Description

Intervention group 2: resistance Exercise training group. The RT group performed 6 major muscle exercises targeting major muscle groups at 50-75% of their 1-RM, 3 times per week.

Category

Treatment - Other

3

Description

Control group: concurrent training group. The CT group combined the total volume of both the RT and AT groups, performing endurance exercises followed by strength

exercises in each session.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Debre Markos City

Full name of responsible person

Dr. Ashenafi Kefyalew

Street address

Abima, Debre Markos

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no

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Debre Markos University

Full name of responsible person

Ashagrie Sharew

Street address

Abima, Debre Markos

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Grant name

Debere Markos University annual research grant

Grant code / Reference number

DMU/1412/2022

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

Yes

Title of funding source

Debre Markos University

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

Debre Markos University

Full name of responsible person

Friew Amare

Position

Lecturer and Researcher

Latest degree

Master

Other areas of specialty/work

Sport Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The datasets generated and/or analyzed during the current study are not publicly available due to data security before publication but are available from the corresponding author on reasonable request.

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Anonymized participant data and statistical code will be made available upon reasonable request to researchers for purposes of replicating procedures and results.

When the data will become available and for how long

the data will be available after publication for 3 years

To whom data/document is available

for the corresponding author on reasonable request.(firewa6070@gmail.com)

Under which criteria data/document could be used

The data should be used solely for scientific research and educational purposes..

From where data/document is obtainable

direct contact with corresponding author
(firewa6070@gmail.com)

What processes are involved for a request to access data/document

The entire process can take several weeks to a few months, depending on the complexity of the request, the volume of data, and the responsiveness of the applicant to any follow-up queries or requirements. Applicants are

encouraged to plan accordingly and allow sufficient time for each step of the process.

Comments