Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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
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Ethiopia
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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 ≥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% (μ=64.7 mg/dl) and 1.38% (μ=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
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Sponsors / Funding sources

1

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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
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Position
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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