Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of aerobic dance exercise intensity on body composition, cholesterol, glucose, and cardiovascular fitness in sedentary rural obese black African women

Protocol summary

Study aim

The aim of this study was to assess the impact of aerobic dance exercise intensity in modulating body composition, blood cholesterol and glucose, and cardiorespiratory fitness in Black African sedentary rural obese adults.

Design

Pragmatic, community based, parallel group, participant single-blind, randomised controlled trial

Settings and conduct

This randomised controlled study, was conducted in in the rural Kwadlangezwa settlement, located in the district of uThungulu about 88 miles or 142 kilometres (km) north of Durban in the province of KwaZulu-Natal, South Africa.,participants randomly divided into 3 The HIG programmes group ,The MIG programme group and control group.

Participants/Inclusion and exclusion criteria

To be included in the study, participants had to Black African, female, live in a rural community, have a BF% of more than 32%, be between the ages of 18 and 25 years, self-report as being sedentary and weight stable for at least six months before the beginning of the intervention, and were not taking any medication or supplements that could enhance their metabolism or alter their fat metabolism. Participants were excluded from participation in this study if they had any relative or absolute contraindication to exercise and/or testing, or any systemic condition or disease, physical disability and/or psychosocial distress precluding them from exercise testing and training.

Intervention groups

The HIG programmes group The MIG programme group

Main outcome variables

body composition, cholesterol, glucose, and cardiovascular fitness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190908044722N6**
Registration date: **2024-07-17, 1403/04/27**
Registration timing: **retrospective**

Last update: **2024-07-17, 1403/04/27**
Update count: **0**

Registration date

2024-07-17, 1403/04/27

Registrant information

Name

Razieh Khanmohamadi

Name of organization / entity

The university of Urmia

Country

Iran (Islamic Republic of)

Phone

+98 86 3221 4311

Email address

r.khanmohamadi@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-01, 1397/11/12

Expected recruitment end date

2019-07-10, 1398/04/19

Actual recruitment start date

2019-02-10, 1397/11/21

Actual recruitment end date

2019-09-01, 1398/06/10

Trial completion date

empty

Scientific title
Effects of aerobic dance exercise intensity on body composition, cholesterol, glucose, and cardiovascular fitness in sedentary rural obese black African women

Public title
Effects of aerobic dance exercise intensity on body composition, cholesterol, glucose, and cardiovascular fitness in sedentary rural obese black African women

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Black African female live in a rural community, have a BF% of more than 32%, be between the ages of 18 and 25 years self-report as being sedentary and weight stable for at least six months before the beginning of the intervention, and were not taking any medication or supplements that could enhance their metabolism or alter their fat metabolism

Exclusion criteria:
Participants were excluded from participation in this study if they had any relative or absolute contraindication to exercise and/or testing any systemic condition or disease, physical disability and/or psychosocial distress precluding them from exercise testing and training

Age
From **18 years** old to **25 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **90**
Actual sample size reached: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were randomised using Random Allocation Software (version 1.0.0) by entering participant details, specifying the randomisation parameters (matching by age and body fat percentage, and assignment to one of 3 groups namely; high-intensity group, moderate-intensity group, and non-exercising control group), and then clicking the "Generate Random Allocation" button to assign participants to different groups randomly.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study was a blind single in that the evaluators did not know which patient was in the intervention group and which was in the control group..

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
University of Zululand Research Ethics Committee

Street address
Department of Human Movement Science, University of Zululand, Kwadlangezwa, KwaZulu-Natal, South Africa, 3886

City
Kwadlangezwa

Postal code
3886

Approval date
2019-09-26, 1398/07/04

Ethics committee reference number
UZREC 171110-030 PGM 2019/33

Health conditions studied

1

Description of health condition studied
obesity

ICD-10 code
E66.9

ICD-10 code description
Obesity, unspecified

Primary outcomes

1

Description
body composition

Timepoint
before intervention and at 8 weeks after start of intervention

Method of measurement
Participants were evaluated for body composition as per the International Society for the Advancement of Kinanthropometry (ISAK) guidelines [20]. Body weight was measured and recorded (to the nearest 0.1 kilogramme (kg)) using a digital scale (Jawon, Model IOI-353, Kyungsun City, Korea), while body height was measured (to the nearest 0.5 cm) using a stadiometer (Marsden HM-250P Portable Height Measure, London, UK). Body mass index (BMI) was calculated by dividing the participant’s body mass (kg) by stature squared (m^2) and expressed as kilogrammes per square meter (kg.m-2). Waist circumference was measured at the mid-point between the iliac crest and bottom of the ribcage while hip circumference measurement was taken at the widest circumference of buttocks and these two values

were used to calculate the waist-to-hip ratio (WHR). Skinfolds of the triceps, subscapular, chest, mid-axillary, suprailiac, abdominal, and thigh were measured to the nearest 0.2 millimetres with a Holtain skinfold calliper (Holtain Ltd Crymych, UK). Body fat percentage (BF%) was calculated using the equation of Jackson and Pollock.

2

Description
Blood total cholesterol,
Timepoint
before intervention and at 8 weeks after start of intervention
Method of measurement
Following a nine to 12-hour overnight period of fasting and 48-hour period of no exercise, blood glucose and total cholesterol (TC) were assessed from capillary blood samples collected through transcutaneous puncture on the medial side of the tip of the middle finger using a disposable hypodermic lancet. Prior to puncture, 70% alcohol was used to promote antisepsis. The first drop of blood was discarded, and the following were used in random order for the analyses using a validated and reliable point-of-care (POC) monitoring device (Accutrend Plus system, Roche Diagnostics, USA). The Accutrend Plus system has previously demonstrated good reproducibility (Lin's coefficient: glucose = 0.958, and TC = 0.940) and high concordance with the laboratory method (Lin's coefficient: glucose = 0.952, and TC = 0.944) and high sensitivity (glucose = 80.0%, and total cholesterol = 84.4%) and specificity (glucose = 100.0%, and total cholesterol = 95.2%).

3

Description
Blood glucose,
Timepoint
before intervention and at 8 weeks after start of intervention
Method of measurement
Following a nine to 12-hour overnight period of fasting and 48-hour period of no exercise, blood glucose and total cholesterol (TC) were assessed from capillary blood samples collected through transcutaneous puncture on the medial side of the tip of the middle finger using a disposable hypodermic lancet. Prior to puncture, 70% alcohol was used to promote antisepsis. The first drop of blood was discarded, and the following were used in random order for the analyses using a validated and reliable point-of-care (POC) monitoring device (Accutrend Plus system, Roche Diagnostics, USA). The Accutrend Plus system has previously demonstrated good reproducibility (Lin's coefficient: glucose = 0.958, and TC = 0.940) and high concordance with the laboratory method (Lin's coefficient: glucose = 0.952, and TC = 0.944) and high sensitivity (glucose = 80.0%, and total cholesterol = 84.4%) and specificity (glucose = 100.0%, and total cholesterol = 95.2%).

4

Description
cardiovascular fitness
Timepoint
before intervention and at 8 weeks after start of intervention
Method of measurement
Cardiorespiratory fitness (VO2max) was evaluated using the 20-metre shuttle run test [22]. For this test, participants were instructed to run back and forth shuttles between two cones placed 20 metres apart from each other. The pace of participants was controlled by an audible beep on a pre-recorded tape that sounded each time the participant was expected to reach the cone for the completion of a shuttle. The test was automatically cancelled if a participant failed to complete two successive shuttles. VO2max was estimated by retroextrapolating the oxygen recovery curve at time zero of recovery [22].

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Non-exercising control group advised to continue their usual daily routines.
Category
Other

2

Description
Intervention group:The HIG programmes consisted of supervised aerobic dance sessions performed in the afternoon, three times weekly for eight weeks [23]. All sessions were preceded by a standardised five minute warm-up and concluded with a standardised five minute cooldown [23]. Exercise intensity was monitored continuously as heart rate (HR) using telemetry (Polar Accurex Plus Monitor, Polar Electro Oy, FIN-90440 Kempele, Finland) to ensure workload and the achievement of target heart rate. The HIG performed theirs at 76-95% HRmax for 30 minutes. An experienced Black African dance instructor led each dance session to local and international Black African music. Non-exercising control group participants were instructed to maintain their normal daily activities and dietary practices throughout the experimental period and were phoned three times weekly to ensure compliance.
Category
Rehabilitation

3

Description
Intervention group: The MIG programme consisted of supervised aerobic dance sessions performed in the

afternoon, three times weekly for eight weeks. All sessions were preceded by a standardised five minute warm-up and concluded with a standardised five minute cooldown. Exercise intensity was monitored continuously as heart rate (HR) using telemetry (Polar Accurex Plus Monitor, Polar Electro Oy, FIN-90440 Kempele, Finland) to ensure workload and the achievement of target heart rate. The MIG participants performed their programme at 60-75% of heart rate maximum (HRmax) for 60 minutes. An experienced Black African dance instructor led each dance session to local and international Black African music. Non-exercising control group participants were instructed to maintain their normal daily activities and dietary practices throughout the experimental period and were phoned three times weekly to ensure compliance

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Tribal leader, Kwadlangezwa Village, KwaZulu-Natal Province, South Africa

Full name of responsible person
Musa Lewis Mathunjwa

Street address
1 Main Road Vulindlela, kwadlangezwa, Empangeni, South Africa

City
Kwadlangezwa

Postal code
3886

Phone
+27 73 895 5897

Email
MathunjwaM@unizulu.ac.za

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Zululand,

Full name of responsible person
Musa Lewis Mathunjwaa

Street address
1 Main Road Vulindlela, kwadlangezwa, Empangeni, South Africa

City
Kwadlangezwa

Postal code
3886

Phone
+27 73 895 5897

Email
MathunjwaM@unizulu.ac.za

Grant name

Grant code / Reference number

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

Title of funding source
University of Zululand,

Proportion provided by this source
10

Public or private sector
Public

Domestic or foreign origin
Foreign

Category of foreign source of funding
UN agencies and international organizations

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
University of Zululand,

Full name of responsible person
Musa Lewis Mathunjwaa

Position
Senior lecturer

Latest degree
Ph.D.

Other areas of specialty/work
Biochemistry

Street address
1 Main Road Vulindlela, kwadlangezwa, Empangeni, South Africa

City
Kwadlangezwa

Province
KwaZulu-Natal Province

Postal code
3886

Phone
+27 73 895 5897

Email
MathunjwaM@unizulu.ac.za

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Zululand

Full name of responsible person
Musa Lewis Mathunjwaa

Position
Senior Lecturer

Latest degree
Ph.D.

Other areas of specialty/work
Biochemistry

Street address
Main Road Vulindlela, kwadlangezwa, Empangeni, South Africa

City

Kwadlangezwa

Province
KwaZulu-Natal Province

Postal code
3886

Phone
+27 73 895 5897

Email
MathunjwaM@unizulu.ac.za

Web page address
https://www.unizulu.ac.za/

Person responsible for updating data

Contact

Name of organization / entity
Urmia University

Full name of responsible person
Razieh Khanmohammadi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
motor behavior

Street address
Urmia University, Kilometer 11 of Cypress Road, Urmia, West Azarbaijan Province

City
Urmia

Province
West Azarbaijan

Postal code
5756151818

Phone
43-32752741-044

Email
r.khanmohamdi@urmia.ac.ir

Sharing plan

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

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not 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
The analysis of information obtained from the results of the interventions onPrimary outcomes can be published

When the data will become available and for how long
From the time the article was published until a year later

To whom data/document is available
All researchers

Under which criteria data/document could be used
Provided Someone wants to do a similar research project

From where data/document is obtainable
r.khanmohamadi65@yahoo.com

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

Comments