Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Regional adipose tissue changes after upper- vs lower-body combined resistance-aerobic training in men with overweight/obesity

Protocol summary

Study aim

Investigating the effects of upper body (UB) and lower body (LB) combined resistance aerobic training (CRAT) on regional body composition (BC) in healthy, overweight, and obese men.

Design

A single-blind randomized clinical trial with UB and LB intervention groups conducted on 32 participants. Randomization will perform by an expert blinded to the study using randomizer.org.

Settings and conduct

study will conducted at Kowsar Hospital, Sanandaj, Iran. BC assessed by DEXA under supervision of physician and technician. Participants randomly will divided into UB and LB groups by an expert randomizer. Pre-test and post-test assessments will conducted 48 to 72 hours before and after the training session. The physician, technician, and randomizer will blinded to the study.

Participants/Inclusion and exclusion criteria

Males aged 20 to 45; 2. BMI over 25 kg/m²; 3. Inactive for at least six months; 4. No history of metabolic, cardiac, or musculoskeletal diseases; 5. No use of medications, supplements, or anabolic steroids; 6. No smoking or regular alcohol consumption.

Intervention groups

study will include two CRAT program for 10 weeks (30 sessions, three times per week). Resistance training will include chest press, row, biceps, triceps, shoulder press, and abdominal for UB and leg press, leg extension, leg curl, leg abduction, leg adduction, and calf raises for the LB, performed in 3 to 4 sets of 8 to 12 repetitions to muscle failure. The UB group perform three consecutive UB training sessions followed by one LB training session and the LB group performed the opposite pattern. After resistance training, participants perform 20 to 29 minutes of aerobic training using a arm ergometer on the UB training day and a stationary bicycle on the LB training day at an intensity of 57 to 66 percent of maximum heart rate.

Main outcome variables

Body weight, BMI, fat and lean mass of UB, LB and total body

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251103067863N1**
Registration date: **2025-12-02, 1404/09/11**
Registration timing: **retrospective**

Last update: **2025-12-02, 1404/09/11**
Update count: **0**

Registration date

2025-12-02, 1404/09/11

Registrant information

Name
Saeed Khani
Name of organization / entity
University of Tehran
Country
Iran (Islamic Republic of)
Phone
+98 31 3367 0470
Email address
saeed.khani@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-10, 1403/04/20

Expected recruitment end date

2024-08-10, 1403/05/20

Actual recruitment start date

2024-07-10, 1403/04/20

Actual recruitment end date
2024-08-10, 1403/05/20
Trial completion date
2024-10-22, 1403/08/01

Scientific title
Regional adipose tissue changes after upper- vs lower-body combined resistance-aerobic training in men with overweight/obesity

Public title
Can we have regional fat reduction?
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
male individuals aged 20 to 45 years a body mass index (BMI) exceeding 25 kg/m² individuals who are inactive or have not engaged in regular physical exercise for a minimum of six months
Exclusion criteria:
history of metabolic, cardiac, or musculoskeletal diseases use of medical medications, sports supplements, or anabolic steroids Being a smoker regular alcohol consumption
Age
From **20 years** old to **45 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**
Actual sample size reached: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
The individuals randomly assigned using www.randomizer.org by an expert individual external to the study who is blinded to the participants, the training protocol, and the training group to either the upper body training group or the lower body training group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Both the hospital nuclear medicine specialist and the device technician will be unaware of the study group assignment at both the pre-test and post-test. The nuclear medicine specialist and the device technician will be unaware of the intervention and the details of the research work and will only be asked to perform the analyses according to the researchers' criteria. The nuclear medicine specialist will have no contact with the participants in either session, and the device technician will have only one pre-test check-up with the participants, which will be done in the presence of the researchers to ensure that no verbal communication about the study will take place.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of the University of Tehran, Faculty of Sport Sciences and Health
Street address
Tehran - North Kargar Street - Above Jalal Al-Ahmad Intersection - Between 15th and 16th Streets - Opposite Tehran University Alley
City
Tehran
Province
Tehran
Postal code
۱۴۱۷۹۳۵۸۳۷
Approval date
2024-05-11, 1403/02/22
Ethics committee reference number
IR.UT.SPORT.REC.1403.024

Health conditions studied

1

Description of health condition studied
over weight and obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
body weight
Timepoint
48 to 72 hours before the first training session and 48 to 72 hours after the last training session
Method of measurement
Participants will be admitted to Kowsar Hospital in Sanandaj, Iran, between 7:00 and 9:00 a.m. They will be instructed to refrain from any physical activity for a duration of 24 to 48 hours prior to the pre-test and to undergo an overnight fasting period of at least 12 hours. Their weight will be measured using a digital scale with an accuracy of 0.01 kg, and participants will be requested to void their bladders prior to measurement.

2

Description

body mass index

Timepoint

48 to 72 hours before the first training session and 48 to 72 hours after the last training session

Method of measurement

Participants will be admitted to Kowsar Hospital in Sanandaj, Iran, between 7:00 and 9:00 a.m. They will be instructed to refrain from any physical activity for a duration of 24 to 48 hours prior to the pre-test and to undergo an overnight fasting period of at least 12 hours. Height will be measured using a wall-mounted height gauge with an accuracy of 0.01 cm. The measurement conditions will be standardized: subjects will be attired in medical gowns, with bare feet, standing on a completely flat surface. Participants will be instructed to position the backs of their heels, buttocks, and the area between their shoulder blades against the wall while maintaining a forward gaze. Researchers will verify the alignment of these three anatomical points along with the positioning of the head before recording height measurements from the scalp. Body mass index will be calculated using the formula: Body mass index = body weight (kg) / height squared (m^2).

3

Description

Upper body fat mass

Timepoint

48 to 72 hours before the first training session and 48 to 72 hours after the last training session

Method of measurement

Participants will be admitted to Kowsar Hospital in Sanandaj, Iran, between 7:00 and 9:00 a.m. They will be instructed to refrain from any physical activity for a duration of 24 to 48 hours prior to the pre-test and to undergo an overnight fasting period of at least 12 hours. They will also be asked to wear a hospital gown and empty their bladder before the analysis. Subjects will be asked to lie on the DEXA machine, and their body position will be checked by the DEXA technician. The researchers will be present to ensure that the DEXA technician is blinded and to prevent any exchange of information between the subjects and the technician. After the subjects' body position has been checked, the DEXA analysis will begin. The area between a horizontal line traversing the superior aspect of the acromion and a horizontal line passing through the apex of the iliac crest will be considered the upper body. A vertical line will also be drawn from the outermost point of the pelvic bone to the apex of the axilla on both sides, with all areas outside this line classified as hands and their data calculated as upper body. All scans will be performed by STRATOS DR (v4.0.13.1 19-06-2020).

4

Description

Lower body fat mass

Timepoint

48 to 72 hours before the first training session and 48 to 72 hours after the last training session

Method of measurement

Participants will be admitted to Kowsar Hospital in Sanandaj, Iran, between 7:00 and 9:00 a.m. They will be instructed to refrain from any physical activity for a duration of 24 to 48 hours prior to the pre-test and to undergo an overnight fasting period of at least 12 hours. They will also be asked to wear a hospital gown and empty their bladder before the analysis. Subjects will be asked to lie on the DEXA machine, and their body position will be checked by the DEXA technician. The researchers will be present to ensure that the DEXA technician is blinded and to prevent any exchange of information between the subjects and the technician. After the subjects' body position has been checked, the DEXA analysis will begin. The area between the horizontal line passing through the apex of iliac crest to the sole of the foot will considered as the lower body. All scans will be performed by STRATOS DR (v4.0.13.1 19-06-2020).

5

Description

Whole body fat mass

Timepoint

48 to 72 hours before the first training session and 48 to 72 hours after the last training session

Method of measurement

Participants will be admitted to Kowsar Hospital in Sanandaj, Iran, between 7:00 and 9:00 a.m. They will be instructed to refrain from any physical activity for a duration of 24 to 48 hours prior to the pre-test and to undergo an overnight fasting period of at least 12 hours. They will also be asked to wear a hospital gown and empty their bladder before the analysis. Subjects will be asked to lie on the DEXA machine, and their body position will be checked by the DEXA technician. The researchers will be present to ensure that the DEXA technician is blinded and to prevent any exchange of information between the subjects and the technician. After the subjects' body position has been checked, the DEXA analysis will begin. The whole body fat mass will defined as the sum of the upper and lower body fat masses. All scans will be performed by STRATOS DR (v4.0.13.1 19-06-2020).

6

Description

upper body lean mass

Timepoint

48 to 72 hours before the first training session and 48 to 72 hours after the last training session

Method of measurement

Participants will be admitted to Kowsar Hospital in Sanandaj, Iran, between 7:00 and 9:00 a.m. They will be instructed to refrain from any physical activity for a duration of 24 to 48 hours prior to the pre-test and to undergo an overnight fasting period of at least 12 hours. They will also be asked to wear a hospital gown and empty their bladder before the analysis. Subjects will be

asked to lie on the DEXA machine, and their body position will be checked by the DEXA technician. The researchers will be present to ensure that the DEXA technician is blinded and to prevent any exchange of information between the subjects and the technician. After the subjects' body position has been checked, the DEXA analysis will begin. The area between a horizontal line traversing the superior aspect of the acromion and a horizontal line passing through the apex of the iliac crest will be considered the upper body. A vertical line will also be drawn from the outermost point of the pelvic bone to the apex of the axilla on both sides, with all areas outside this line classified as hands and their data calculated as upper body. All scans will be performed by STRATOS DR (v4.0.13.1 19-06-2020).

7

Description

lower body lean mass

Timepoint

48 to 72 hours before the first training session and 48 to 72 hours after the last training session

Method of measurement

Participants will be admitted to Kowsar Hospital in Sanandaj, Iran, between 7:00 and 9:00 a.m. They will be instructed to refrain from any physical activity for a duration of 24 to 48 hours prior to the pre-test and to undergo an overnight fasting period of at least 12 hours. They will also be asked to wear a hospital gown and empty their bladder before the analysis. Subjects will be asked to lie on the DEXA machine, and their body position will be checked by the DEXA technician. The researchers will be present to ensure that the DEXA technician is blinded and to prevent any exchange of information between the subjects and the technician. After the subjects' body position has been checked, the DEXA analysis will begin. The area between the horizontal line passing through the apex of iliac crest to the sole of the foot will considered as the lower body. All scans will be performed by STRATOS DR (v4.0.13.1 19-06-2020).

8

Description

Whole body lean mass

Timepoint

48 to 72 hours before the first training session and 48 to 72 hours after the last training session

Method of measurement

Participants will be admitted to Kowsar Hospital in Sanandaj, Iran, between 7:00 and 9:00 a.m. They will be instructed to refrain from any physical activity for a duration of 24 to 48 hours prior to the pre-test and to undergo an overnight fasting period of at least 12 hours. They will also be asked to wear a hospital gown and empty their bladder before the analysis. Subjects will be asked to lie on the DEXA machine, and their body position will be checked by the DEXA technician. The researchers will be present to ensure that the DEXA technician is blinded and to prevent any exchange of information between the subjects and the technician. After the subjects' body position has been checked, the DEXA analysis will begin. The whole body lean mass will defined as the sum of the upper and lower body lean masses. All scans will be performed by STRATOS DR (v4.0.13.1 19-06-2020).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The study duration will be 10 weeks, with 3 sessions per week, for a total of 30 training sessions. The upper body group is a group whose training will be based on the upper body limbs. They will perform three consecutive sessions of upper body training, and after these three consecutive sessions, one session of lower body training, and maintain this pattern until the end, so that after completing their training, they will perform 23 sessions of upper body training and 7 sessions of lower body training. The upper body training program will include chest press, shoulder press, biceps curl, rowing, and abdominal press, which will be immediately followed by an aerobic exercise with an arm ergometer. The lower body training program will include leg press, leg extension, leg curl, leg abduction, leg adduction, and calf raise, which will be immediately followed by an aerobic exercise with a leg cycle ergometer. All resistance training will be performed in 3 sets until week 5 and in 4 sets from week 6 to the end. The repetition range in each set will be maintained between 8 and 12 repetitions, and the repetitions will continue until muscle failure. Rest between each set will be 1 to 1.5 minutes. Both aerobic exercises will be performed at an intensity of 61 to 66 percent of maximum heart rate (220-age) for those with a body fat percentage below 35 percent and at an intensity of 57 to 64 percent of maximum heart rate (220-age) for those with a body fat percentage above 35 percent. The duration of both aerobic exercises will be 20 minutes in the first week, with 1 minute added each week, so that the duration will be 29 minutes in the last week. The subjects' heart rates will be monitored during the aerobic exercise using a Polar H-10. All exercise sessions will be conducted under the supervision of the researchers.

Category

Treatment - Other

2

Description

Intervention group: The study duration will be 10 weeks, with 3 sessions per week, for a total of 30 training sessions. The lower body group is a group whose training will be based on the lower body limbs. They will perform three consecutive sessions of lower body training, and after these three consecutive sessions, one session of upper body training, and maintain this pattern until the end, so that after completing their training, they will

perform 23 sessions of lower body training and 7 sessions of upper body training. The lower body training program will include leg press, leg extension, leg curl, leg abduction, leg adduction, and calf raise, which will be immediately followed by an aerobic exercise with a leg cycle ergometer. The upper body training program will include chest press, shoulder press, biceps curl, rowing, and abdominal press, which will be immediately followed by an aerobic exercise with an arm ergometer. All resistance training will be performed in 3 sets until week 5 and in 4 sets from week 6 to the end. The repetition range in each set will be maintained between 8 and 12 repetitions, and the repetitions will continue until muscle failure. Rest between each set will be 1 to 1.5 minutes. Both aerobic exercises will be performed at an intensity of 61 to 66 percent of maximum heart rate (220-age) for those with a body fat percentage below 35 percent and at an intensity of 57 to 64 percent of maximum heart rate (220-age) for those with a body fat percentage above 35 percent. The duration of both aerobic exercises will be 20 minutes in the first week, with 1 minute added each week, so that the duration will be 29 minutes in the last week. The subjects' heart rates will be monitored during the aerobic exercise using a Polar H-10. All exercise sessions will be conducted under the supervision of the researchers.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Kowsar Hospital
Full name of responsible person
Saman Negahdar
Street address
Sanandaj, Khanqa, Allameh Hamdi Boulevard between Pasdaran Bypass and Nahid Fatehi Square
City
Sanandaj
Province
Kurdistan
Postal code
۶۶۱۷۹۸۳۴۷۶
Phone
+98 87 3361 1232
Email
kowsar@muk.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of Tehran
Full name of responsible person
Rahman Soori
Street address
pposite Tehran University Alley, between 15th and 16th Streets, above Jalal Al Ahmad Intersection, North Kargar Street, Amir Abad, Tehran
City
Tehran
Province
Tehran
Postal code
1417935840
Phone
+98 21 8835 1730
Email
infosport@ut.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The University of Tehran
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
The University of Tehran
Full name of responsible person
Saman Negahdar
Position
Graduate student
Latest degree
Master
Other areas of specialty/work
Physiology
Street address
Morvarid Alley 6, Lazur St., Baharan Town 2/19, Sanandaj
City
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Province
Kurdistan
Postal code
6617874784
Phone
+98 87 3371 0120
Email
samanneghdar@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
The University of Tehran

Full name of responsible person
Saman Negahdar

Position
Graduate student

Latest degree
Master

Other areas of specialty/work
Physiology

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City
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Province
Kurdistan

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6617874784

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Email
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Person responsible for updating data

Contact

Name of organization / entity
The University of Tehran

Full name of responsible person
Rahman Soori

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
exercise physiology

Street address
opposite Tehran University Alley, between 15th and 16th Streets, above Jalal Al Ahmad Intersection, North Kargar Street, Amir Abad, Tehran

City
Tehran

Province
Tehran

Postal code
1417935840

Phone
+98 21 8835 1730

Email
soorirahman@yahoo.com

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
anonymized individual participant data (IPD) will be shared upon reasonable request. Anonymized datasets including demographic information, primary and secondary outcomes, and variables used in statistical analyses will be shared

When the data will become available and for how long
Data will be available approximately 6 months after completion of the main analyses and publication of the results, and will remain available for 5 years thereafter.

To whom data/document is available
Data will be shared with academic researchers, research institutions, or other individuals with valid scientific purposes.

Under which criteria data/document could be used
Data may be used for secondary analyses, meta-analyses, or related research within the same scientific field.

From where data/document is obtainable
To receive the data, contact the researcher responsible, Saman Negahdar, via email at samanneghdar@gmai.com.

What processes are involved for a request to access data/document
Interested researchers should submit a formal request to the corresponding investigator. After receiving the request, the research committee will review it, and if approved, a Data Use Agreement will be sent to the applicant. Upon signing this agreement by both parties, anonymized data will be shared in Excel or SPSS format via email or secure cloud storage.

Comments