

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of 4 weeks of continuous training with abdominal massage on the levels of lipolytic enzymes and VEGF in the subcutaneous fat tissue of the abdominal region of obese men.

Protocol summary

Study aim

1) Determining the activity levels of HSL and ATGL enzymes before and after 4 weeks of endurance training with and without massage in the subcutaneous fat tissue of the abdominal area in obese men. 2) Determining the levels of angiogenic proteins VEGF and VEGF-R2 before and after 4 weeks of endurance training with and without massage in the subcutaneous fat tissue of the abdominal area in obese men. 3) Determination of anthropometric changes, subcutaneous fat, and fat percentage after 4 weeks of endurance training with and without massage in obese men. 4) Investigating changes in fat oxidation through respiratory gases before and after endurance training with and without massage in obese men.

Design

According to the number and type of groups, this project will be done in parallel.

Settings and conduct

Shahid Beheshti University, Faculty of Sports Sciences and Health, Tehran Faculty of Medicine, Shahid Beheshti University, Tehran

Participants/Inclusion and exclusion criteria

The statistical sample of this research will be 45 obese men (BMI<29.9) with a range of the age 20-30 years who have no history of metabolic diseases, surgery, drug use, etc. Subjects will be randomly selected based on the conditions of the research and completion of the satisfaction questionnaire and will be divided into three groups: endurance training (N=15), endurance training + massage (N=15), and massage (N=15).

Intervention groups

control group (without any intervention) Endurance training group (4 weeks of endurance training) Exercise group and massage before sports activity

Main outcome variables

Recommending a non-invasive method to increase general and local fat burning in the abdominal area for

obese people

General information

Reason for update

Acronym

CTML

IRCT registration information

IRCT registration number: **IRCT20231122060134N1**

Registration date: **2023-11-25, 1402/09/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-25, 1402/09/04**

Update count: **0**

Registration date

2023-11-25, 1402/09/04

Registrant information

Name

MOEIN FASIHIYAN

Name of organization / entity

Shahid Beheshti University

Country

Iran (Islamic Republic of)

Phone

+98 71 3624 8291

Email address

m_fasihian@sbu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-23, 1402/09/02

Expected recruitment end date

2023-12-06, 1402/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 4 weeks of continuous training with abdominal massage on the levels of lipolytic enzymes and VEGF in the subcutaneous fat tissue of the abdominal region of obese men.

Public title

The effect of continuous training with abdominal massage on the subcutaneous fat tissue of obese men.

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Absence of metabolic diseases such as: blood pressure, diabetes, metabolic syndrome, etc. No orthopedic problems Body mass index higher than 29.9 No smoking or stimulant drugs Not taking sports supplements Sign the health consent form Age range 20 to 30 years

Exclusion criteria:

Having metabolic diseases Age less than 20 years or more than 30 years Having a body mass index less than 30 Smoking and stimulants Having joint and bone injuries Taking sports supplements Having eating disorders

Age

From **20 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **36**

More than 1 sample in each individual

Number of samples in each individual: **4**

Sampling of the participants will be before and after the first session as well as before and after the last session after 4 weeks of research interventions.

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize the groups, a systematic random method will be used, in which the researcher will not have any role in assigning people to specific groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

After the initial evaluation, the subjects will be randomly placed in one of the 3 control groups, exercise training, and exercise-massage, and the training and intervention sessions will be in such a way that the participants will not be informed about the other groups, and also for sample analysis. laboratory tests, an expert who does

not know about the type of intervention and groups will be helped, so it is necessary to mention that all the samples will be coded with an abbreviation to ensure that the person who evaluates the samples is not informed.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

research ethics committee of shahid beheshti university

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Shahriari Square, Evin, Tehran, Iran Postal Code: 1983969411

City

Tehran

Province

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Postal code

کدپستی: 1983969411

Approval date

2023-09-30, 1402/07/08

Ethics committee reference number

IR.SBU.REC.1402.131

Health conditions studied**1****Description of health condition studied**

obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes**1****Description**

Body fat percentage values

Timepoint

Before and after the first session, before and after the last session

Method of measurement

Using ultrasound machine

2

Description

Proteins associated with angiogenesis in adipose tissue

Timepoint

Before and after the first session, before and after the last session

Method of measurement

Immunoblotting test

3

Description

Enzymes related to fat burning

Timepoint

Before and after the first session, before and after the last session

Method of measurement

Immunoblotting test

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: Endurance Training

Category

Other

2

Description

Second Intervention group: Endurance exercises + abdominal fat tissue massage

Category

Other

3

Description

Control group: No exercise or massage

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti University

Full name of responsible person

Moein Fasihiyan

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Shahriari Square, Evin, Tehran, Iran Postal Code: 1983969411

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

5th floor, Building No 2, Shahid Arabi St, Yamen St, Shahid Cahmran Highway, Tehran

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pr-office@sbu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti University

Full name of responsible person

Moein Fasihiyan

Position

Ph.D. Student

Latest degree

Master

Other areas of specialty/work

Physiology

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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

Confidentiality of personal information

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not 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

Due to the confidentiality without some information such as personal and private details of the participants, this information will not be published in any way and instead all the information obtained from the research will be shared in some way that will contribute to the future research.

When the data will become available and for how long

The access period starts immediately after the results are printed

To whom data/document is available

All researchers and students in scientific centers

Under which criteria data/document could be used

Students and active people in prestigious institutions to conduct research projects and in medical centers to use the executive protocol

From where data/document is obtainable

To the main researcher (Moin Fasihian) Email: moein.fasihyan@gmail.com Contact number: 00989178933109

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

At first, the applicant must send the basic information such as first and last name along with the name of the field and level of education in the form of a message, and then give a complete explanation regarding the purpose of the request, and finally, after a day The data file will be sent to that person by email.

Comments