Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of cavitation and energy therapy on localized obesity

Protocol summary

Study aim
Determining the effect of cavitation and energy therapy on localized obesity

Design
Controlled clinical trial, with parallel groups, no blinding, non-randomized, on 110 patients

Settings and conduct
110 candidate patients who refer to Bu Ali Hospital in Tehran during the study will be included in the study on a case-by-case basis if they are eligible and will be divided into two intervention and control groups. A similar diet and 30 minutes of daily walking are recommended in both groups. Weight, waist circumference, and BMI will be measured and compared before and after the intervention. This study is a non-randomized, unblinded clinical trial.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Body mass index greater than 30 kg/m2; Exclusion criteria: Abdominal hernia, Severe diabetes

Intervention groups
The first group will undergo ultrasound cavitation treatment.This treatment will be performed using a PromoItalia device(made in Italy)that transmits low-frequency ultrasound pulse waves to the abdominal area through a 45mm diameter transducer with a power of 3 W/m^2. The patient will lie on their back and the abdominal area will be covered with conductive gel, then the transducer will be gently moved over it.Each treatment session will last 30min and will be repeated every 2 weeks for 2 months.The second group will undergo energy therapy.In this group,a trained therapist will perform the intervention using mental induction methods and focusing energy on the abdominal area,non-contact or with limited contact, in 30min sessions,every 2weeks for 2months.

Main outcome variables
Waist circumference

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250826067003N1**
Registration date: **2025-10-20, 1404/07/28**
Registration timing: **prospective**

Last update: **2025-10-20, 1404/07/28**
Update count: **0**

Registration date
2025-10-20, 1404/07/28

Registrant information

Name
Mohammadjavad Heidari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2293 4596

Email address
mojavad2030@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-25, 1404/08/03

Expected recruitment end date
2026-02-20, 1404/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effect of cavitation and energy therapy on localized obesity

Public title
Evaluation of the effect of cavitation and energy therapy on localized obesity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Body mass index greater than 30 kg/m2
Exclusion criteria:
Severe diabetes Abdominal hernia
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Faculty of Medicine, Islamic Azad University of Medical Sciences, Tehran
Street address
Headquarters Building of Tehran Islamic Azad University of Medical Sciences, Corner of Gol Yakh St, Ayane Blvd, Amir Pabarja St, Golhak Road, Dr. Shariati St, Tehran
City
Tehran
Province
Tehran
Postal code
1949635881
Approval date
2025-08-27, 1404/06/05
Ethics committee reference number
IR.IAU.TMU.REC.1404.276

Health conditions studied

1

Description of health condition studied
Local obesity
ICD-10 code
E66.9
ICD-10 code description
Obesity, unspecified

Primary outcomes

1

Description
Waist circumference
Timepoint
Before the intervention and 2 weeks after the intervention
Method of measurement
Non-stretchable measuring tape

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group will undergo ultrasound cavitation treatment for 10 sessions, each session lasting 15 minutes(interval of 1 week/intervention period 10 weeks). This treatment will be performed using the RF Slimming Device – Model 3Max, made in South Korea. The treatment area (with localized fat) is determined and a conductive gel is applied. Cavitation is applied to the target area at an intensity of 8 degrees for about 10 minutes. Then, thermal RF is applied for 5 minutes to increase blood flow and facilitate the excretion of metabolites. Patients are required to follow a controlled diet and walk for 30 minutes daily to increase the excretion of fat metabolites. After each session, the patient is monitored and possible side effects (redness, skin warmth) are checked. RF creates radiofrequency heat waves in the subcutaneous layers, leading to increased metabolism of adipose tissue and stimulation of collagen synthesis. Cavitation (low-intensity ultrasound) causes microscopic bubbles to form in adipose tissue, which destroy fat cells (adipocytes) through mechanical destruction. Finally, the released fatty acids enter the bloodstream and are excreted through natural metabolism or physical activity.
Category
Treatment - Devices

2

Description
Control group: In this group, the participants will be

subjected to Energy Therapy intervention. This method is of the Therapeutic Touch type, which is based on the mental focus of the therapist on the vital energy flow of the body. Performance environment: a quiet room with soft light and constant temperature (24-25°C). Therapist: a person trained in the field of energy therapy (with a valid certificate in Therapeutic Method Touch). Implementation method: The therapist is placed at a distance of about 5 to 10 cm from the patient's body and performs hand movements slowly and intermittently in the abdomen, with the aim of adjusting and harmonizing the body's energy field. Physical contact: minimal and non-invasive (short-term surface contact in necessary cases). Duration of each session: 30 minutes. The intervention is purely mental-energetic. The goal of the intervention: to create an energy balance in the abdominal area in order to investigate possible effects on fat metabolism.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Bu Ali Hospital, Tehran

Full name of responsible person
Mohammad Javad Heidari

Street address
at the beginning of Damavand St, Imam Hossein Square, Tehran

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https://tms.iau.ir/bouali/fa

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Masoud Parsania

Street address
Headquarters Building of Tehran Islamic Azad University of Medical Sciences, Corner of Gol Yakh St, Ayane Blvd, Amir Pabarja St, Golhak Road, Dr. Shariati St, Tehran

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Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad 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
Islamic Azad University

Full name of responsible person
Mohammad Javad Heidari

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Person responsible for updating data

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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
No more information available.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available