Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessment of standard diet and Embedding Therapy on Anthropometric Indices, Ghrelin Levels , and Bioelectrical Impedance Analysis parameters in overweight and simple obesity individuals.

Protocol summary

Study aim

Investigation of the effect of embedding on weight reduction, anthropometric indices, ghrelin levels, and selected bioimpedance parameters in patients with overweight and non-morbid obesity undergoing standard dietary treatment compared with a control group

Design

The study includes two groups: a control group (diet only) and an embedding group (diet plus thread embedding). It is a single-blind (assessors and analysts) parallel-group clinical trial. The sample size is 30 participants in each group; considering possible attrition, 33 participants will be recruited for each group. Randomization will be performed using pre-prepared envelopes.

Settings and conduct

The study will be conducted at the Acupuncture Clinic of Imam Reza Hospital in Mashhad. To prevent selection bias, the standard technique of opaque, sealed envelopes will be used. Patients will be randomly assigned to either the intervention group (embedding plus diet) or the control group (diet only). Both groups will receive dietary intervention, and the embedding group will undergo one session of thread embedding.

Participants/Inclusion and exclusion criteria

Male or female patients aged 18–60 years Body mass index (BMI) between 28 and 40 Waist circumference greater than 90 cm in men and greater than 80 cm in women More than 6 months postpartum Blood pressure less than 140/90 mmHg No specific conditions that contraindicate acupuncture or embedding No use of weight-loss medications No history of kidney and/or liver disease

Intervention groups

Control group: Nutritional intervention (diet therapy) Embedding group: Nutritional intervention combined with thread embedding

Main outcome variables

Weight, body mass index , waist circumference, muscle mass, fat mass, phase angle, and serum ghrelin levels.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121228011912N9**
Registration date: **2026-08-07, 1405/05/16**
Registration timing: **prospective**

Last update: **2026-08-07, 1405/05/16**
Update count: **0**

Registration date

2026-08-07, 1405/05/16

Registrant information

Name

Hamidreza Bahrami Taghanaki

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1841 5666

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bahramihr@mums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2027-09-23, 1406/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of standard diet and Embedding Therapy on Anthropometric Indices, Ghrelin Levels , and Bioelectrical Impedance Analysis parameters in overweight and simple obesity individuals.

Public title

Investigation of the effect of diet and embedding on serum ghrelin levels and body measurements in individuals with overweight and simple obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

BMI between 28-40 Waist circumference greater than 90 cm in men and 80 cm in women. More than 6 months postpartum. blood pressure less than 140/90 no contraindication for embedding No consumption of weight-reducing medications. No hepatic/renal disease

Exclusion criteria:

history of acupuncture/embedding for weight loss in the past months diabetes presence of febrile disease pregnancy

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with block sizes of 4 and 6 will be used. The random allocation sequence will be generated using a valid online tool (Randomization.com). To ensure allocation concealment, sequentially numbered, sealed envelopes will be employed. To prevent selection bias, the standard technique of opaque, sealed, and sequentially numbered envelopes will be applied. The allocation codes generated in the previous step will be written on cards by an individual independent of the research team and outcome assessors. These cards will then be placed inside opaque envelopes. The envelopes will be sealed and numbered sequentially from 1 to 64 according to the order of participant enrollment. After confirming eligibility criteria, finalizing participant enrollment, and obtaining informed consent, the next envelope in the sequence will be opened. Participants will then be assigned to either the intervention group (embedding plus diet) or the control group (diet only).

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, blinding was performed as single-blinding, meaning that the participants were unaware of their allocation to the study groups, while the assessors and data analysts were aware of the study conditions. Due to the nature of the intervention, complete blinding of all parties involved was not feasible.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Daneshgah st , acupuncture clinic , Imam Reza hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9177764668

Approval date

2026-06-17, 1405/03/27

Ethics committee reference number

IR.MUMS.IRH.REC.1405.051

Health conditions studied

1

Description of health condition studied

Over weight & Simple obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Body weight

Timepoint

Before intervention , 4 weeks and 16 weeks after intervention.

Method of measurement

Using a weighing scale and a bioimpedance analyzer.

2

Description
Body Mass Index.
Timepoint
Before intervention , 4 weeks and 16 weeks after intervention.
Method of measurement
Using a bioimpedance analyzer.

3

Description
Weight circumference
Timepoint
Before intervention , 4 weeks and 16 weeks after intervention.
Method of measurement
Using a bioimpedance analyzer.

4

Description
Body fat mass
Timepoint
Before intervention , 4 weeks and 16 weeks after intervention.
Method of measurement
Using a bioimpedance analyzer.

5

Description
Body muscle mass
Timepoint
Before intervention , 4 weeks and 16 weeks after intervention.
Method of measurement
Using a bioimpedance analyzer.

6

Description
Phase angle .
Timepoint
Before intervention , 4 weeks and 16 weeks after intervention.
Method of measurement
Using a bioimpedance analyzer.

Secondary outcomes

1

Description
Serum Ghrelin level.
Timepoint
before intervention , 4 weeks and 16 weeks after intervention
Method of measurement
Using Plasma sample and Ghrelin kit

2

Description
Quality of life
Timepoint
before intervention , 4 weeks and 16 weeks after intervention.
Method of measurement
World Health Organization (WHO) questionnaire

Intervention groups

1

Description
Control group: Under standard dietary treatment .Participants in the control group will receive a standard nutritional regimen prescribed by a specialized nutritionist. Based on the participants' Body Mass Index (BMI), daily caloric intake will be gradually reduced as follows: a 500 kcal reduction for individuals with a BMI between 28 and 29.9, and a 700 kcal reduction for those with a BMI between 30 and 40. Before the intervention, as well as 4 and 16 weeks post-intervention, serum ghrelin levels, waist circumference, body fat and muscle mass, and phase angle will be assessed using Bioelectrical Impedance Analysis (BIA)
Category
Treatment - Other

2

Description
Intervention group: Under standard dietary & embedding treatment .In this group, participants will be provided with a customized diet plan under the supervision of a nutritionist. Daily caloric intake will be gradually reduced as follows: a 500 kcal deficit for individuals with a Body Mass Index (BMI) of 28–30, and a 700 kcal deficit for those with a BMI of 30–40. Concurrently with the initiation of the diet, each participant will undergo a single session of PDO thread embedding at twenty specific anatomical points. Serum ghrelin levels, waist circumference, body fat and muscle mass, and phase angle will be measured using Bioelectrical Impedance Analysis (BIA) at three time points: at baseline (pre-intervention), and at 4 and 16 weeks post-intervention.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Acupuncture clinic , Imam Reza hospital , Mashhad
Full name of responsible person
Dr.Sara Mousavinik
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Sara Mousavinik
Position
Student
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Title and more details about the data/document
The statistical details of the data will be mentioned in the published article.
When the data will become available and for how long
After finishing the research
To whom data/document is available
All individuals who have access to the published article or those who obtain permission from the Research Vice-Chancellor of Mashhad University of Medical Sciences.
Under which criteria data/document could be used
With the permission of the principal investigator and the approval of the University Research Council, and solely for informational purposes without any possibility of using or exploiting the data content.
From where data/document is obtainable
After publication of the article, the data will be available to the corresponding author; before publication, if necessary, they may be provided to the principal investigator upon request by the relevant authorities.
What processes are involved for a request to access data/document
By means of Vice research of Mashhad University of Medical Science
Comments