Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of integrative medicine (acupuncture, Hypericum perforatum and life style modification) with life style modification in appetite and weight control

Protocol summary

Study aim
To determine and compare the effect of adding acupuncture and / or Hypericum perforatum to life style modification in appetite and weight control

Design
A randomized, sham controlled, parallel group, phase III clinical trial with blinded patients, nutritionist, outcome assessor and statistician

Settings and conduct
Eighty-eight overweight or obese patients with appetite score ≤ 5 out of 10 will be randomly assigned to one of four groups to be treated for 6 weeks in the acupuncture and nutrition clinics affiliated to Mashhad University of Medical Sciences. Patients, nutritionist, outcome assessor and statistician will be blinded to study groups. acupuncturist could not be blinded in this study.

Participants/Inclusion and exclusion criteria
Main inclusion criteria: People with BMI 24.9 to 39.9; women 18 years to premenopausal and men 18 to 60 years. Main exclusion criteria: 1- diseases affecting metabolism such as hypothyroidism 2- drugs affecting weight and metabolism or interfering with Hypericum perforatum 3- allergy to hypericum perforatum or metal

Intervention groups
1. Acupuncture + Hypericum perforatum + life style modification; 2. acupuncture + placebo + life style modification; 3. Sham acupuncture + Hypericum perforatum + life style modification; 4. sham acupuncture + placebo + life style modification

Main outcome variables
BMI; the appetite score; Nesfatin 1 level; waist circumference; hip circumference; body composition

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201706107265N9**
Registration date: **2017-06-24, 1396/04/03**
Registration timing: **prospective**

Last update: **2019-09-17, 1398/06/26**
Update count: **2**

Registration date
2017-06-24, 1396/04/03

Registrant information
Name
Hoda Azizi
Name of organization / entity
Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 51 1855 2188
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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date
2017-10-23, 1396/08/01

Expected recruitment end date
2019-11-01, 1398/08/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of integrative medicine (acupuncture, Hypericum perforatum and life style modification) with life style modification in appetite and weight control

Public title
The effect of acupuncture, hypericum perforatum and diet in appetite and weight control

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Appetite score more than 5 according to visual analogue scale Body mass index between 24.9 to 39.9 Women 18 years old to pre-menopause; men 18 to 60 years old Failure to life style modification alone "Liver qi stagnation" syndrome according to Chinese Medicine syndrome differentiation

Exclusion criteria:
Hypothyroidism, Cushing's syndrome, cancer, liver or kidney failure Using drugs effective on appetite, weight and metabolism in the previous month Using drugs that interfere with Hypericum perforatum such as protease inhibitors, amiodarone, anticoagulants, cyclophosphamide, cyclosporine, monoamine oxidase inhibitors, phenytoin, tacrolimus, tamoxifen and trazodone drug Drug abuse or alcoholism Breast-feeding, pregnancy or planning a pregnancy during the next two months Having pacemaker or any other metal device inside the body due to the use of electroacupuncture and Bioelectrical Impedance Analyzer disability to do recommended physical activity Allergy to Hypericum perforatum or metal Coagulation disorders History of receiving acupuncture

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization will be done using SPSS version 16 by selecting quadrants blocks.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants, the nutritionist, the outcome assessor, and the statistician will be blinded from the identity of the study groups. The acupuncturist will not be blinded. The participant blindness will be performed using sham acupuncture and placebo.

Placebo
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
Qorashi building, Daneshgah Street

City
Mashhad

Province
Razavi Khorasan

Postal code
91357345

Approval date
2017-06-06, 1396/03/16

Ethics committee reference number
IR.MUMS.REC.1396.43

Health conditions studied

1

Description of health condition studied
obesity

ICD-10 code
E66.0

ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Plasma nesfatin-1

Timepoint
Before intervention, Sixth week

Method of measurement
Laboratory: ELISA

2

Description
Appetite score

Timepoint
Before intervention, weeks 2, 4, 6, 24

Method of measurement
Visual Analogue Scale

3

Description
Body Mass Index
Timepoint
Before intervention, weeks 2, 6, 24
Method of measurement
Using the bioelectrical impedance analyzer; kg/m2

Secondary outcomes

1

Description
Waist circumference
Timepoint
Before intervention, weeks 2, 6, 24
Method of measurement
Using a tape measure; centimeters

2

Description
Hip circumference
Timepoint
Before intervention, weeks 2, 6, 24
Method of measurement
Using a tape measure; centimeters

3

Description
Body composition
Timepoint
Before intervention, weeks 2, 6
Method of measurement
Using the bioelectrical impedance analyzer

4

Description
Lipid profile
Timepoint
Before intervention, week 6
Method of measurement
Laboratory

5

Description
Liver enzymes
Timepoint
Before intervention, week 6
Method of measurement
Laboratory

6

Description
Blood glucose level
Timepoint
Before intervention, week 6
Method of measurement
Laboratory

7

Description
Adverse events
Timepoint
During the study period within 48 to 72 hours of incidence; week 6
Method of measurement
Study checklist

Intervention groups

1

Description
Intervention group 1: acupuncture, 3 times per week + 4 tablets of 160 mg Perforan (Goldaru company) + life style modification for 6 weeks
Category
Other

2

Description
Intervention group 2: acupuncture 3 times/week + placebo tablets+ life style modification for 6 weeks
Category
Other

3

Description
Intervention group 3: sham acupuncture, 3 times/week+ 4 tablets of 160 mg Perforan (Goldaru company) + life style modification for 6 weeks
Category
Other

4

Description
Control group: sham acupuncture, 3 times/week + placebo + life style modification for 6 weeks
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Acupuncture clinic, Imam Reza Hospital
Full name of responsible person
Dr. Hoda Azizi
Street address
Daneshgah Street
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2

Recruitment center

Name of recruitment center
Nutrition clinic, Qaem Hospital

Full name of responsible person
Dr. Mohammad Safarian

Street address
Ahmadabad Street, Mashhad, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi

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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
Vice chancellor for research, 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
School of Traditional and Complementary Medicine

Full name of responsible person
Dr. Monirsadat Sahebkar Khorasani

Position
PhD candidate

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Assistant Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available