

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Survey the effect of standard diet, acupuncture and chi-gong on the weight loss of overweight and Non-morbid obese patient

Protocol summary

Study aim

The effects of a standard diet, acupuncture, and Qigong exercise on weight control of overweight and obese individuals (with a BMI less than 35) Specific objectives: The effects of acupuncture on weight control/BMI change/reducing waist circumference/weight control/reducing BMI/waist reduction/weight control/weight change/reducing waist circumference

Design

Randomized clinical trial double blind.Final sample size is 195 patients

Settings and conduct

Through general and intra-university calls, overweight and non-morbidly obese people are registered in the clinic office of the Chinese Medicine Department. Then, all the anthropometric measurements calculated in the plan, including weight, height and waist circumference, are measured by a partner expert, and then the BMI of the individuals is calculated. Based on entry and exit criteria, the equivalent of the sample size of individuals are counted. Then, based on the standard extended random distribution model mentioned below, they are divided into 3 groups: The first group to a nutritionist to receive a standard diet/ The second group is in accordance with the adaptation plan to acupuncturists, male and female/ The third group is trained to teach Chi-gong sports movement to an expert

Participants/Inclusion and exclusion criteria

Study group: Overweight and non-morbidly obese (BMI under 35) over 18 years and under 65 years of age/ Inclusion criteria/ Age over 18 and under 65 years/ BMI above 25 and below 35/ Living in Mashhad/ Fluency in Persian/ Being literate

Intervention groups

Three interventions in three different groups, in one group the intervention is receiving a standard diet, in the second group the intervention is acupuncture, and in the third group the intervention is the Qigong exercise.

Main outcome variables

Weight, BMI, waist circumference in 3 times: prior to the intervention/ immediately after the intervention/ one month after the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200919048763N1**

Registration date: **2021-02-11, 1399/11/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-11, 1399/11/23**

Update count: **0**

Registration date

2021-02-11, 1399/11/23

Registrant information

Name

ghazaleh donyadideh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3880 0330

Email address

donyadidehg931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Survey the effect of standard diet, acupuncture and chi-gong on the weight loss of overweight and Non-morbid obese patient

Public title
The Effect of Standard Acupuncture and Qigong Diet on Weight Loss

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 and under 65 BMI over 25 and under 35
Living in Mashhad Fluency in Persian Being literate
Exclusion criteria:
Age under 18 and over 65 BMI under 25 and over 35 Not living in Mashhad Lack of fluency in Persian Being illiterate

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **195**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation will be in the form of triple blocks which is done by SPSS software. The method is as follows: The letters A, B, C can be put together in six ways. ABC, ACB, BAC, CAB, CBA are selected by a number of numbers, random numbers. We keep the numbers from zero to 5, then if the random number was zero, the expression ABC, if it was 1, the expression ACB, if it was 2, the expression BAC, if it was 3, the expression CAB, and if it was 5, the expression CBA. Put together. Individuals are referred to one of groups A, B, and C, respectively.

Blinding (investigator's opinion)
Double blinded

Blinding description
Double blind (Assessor blind, Analyzer blind)

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

17 unit, No. 92, between 27 & 29 St., Saremi Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9178657877

Approval date

2019-12-22, 1398/10/01

Ethics committee reference number

ir.MUMS.MEDical.REC.1398.819

Health conditions studied

1

Description of health condition studied

Overweight patients and Non-morbid obesity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of individuals with BMI above 25 and below 35, Weight, body mass index, and waist circumference

Timepoint

1- Prior to the intervention 2- Immediately after the intervention 3- One month after the intervention

Method of measurement

Use of body mass index (the variable resulting from dividing patient's weight in kilograms by patient's height squared in meters, which is more than 25); Patient waist size in centimeters, which can be measured from the perimeter of the highest part of the pelvic wall; patient weight in kilograms

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: are referred to a nutritionist to receive a standard diet.

Category

Lifestyle

2

Description

Second intervention group (in control group): Acupuncture is given in the form of a standard 12-session course of treatment (every other day) for one month. Each session of acupuncture lasts 30 minutes, using JUK needles from South Korea with a size of 40 by 0.25 mm.

Category

Treatment - Devices

3

Description

Control group: In addition to acupuncture, they use the Qigong exercise, on which are fully instructed by a trained expert. The exercises will be twice a day (during a month of acupuncture).

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Acupuncture Clinic of Imam Reza Hospital

Full name of responsible person

Hamidreza Bahrami Taghanaki

Street address

Unit 17, No 92, before Honarestan Sq., between 27 and 29 St., Saremi Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9178657877

Phone

+98 51 3880 0330

Email

donyadidehg931@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research, Mashhad University of Medical Sciences

Street address

Unit 17, No 92, before Honarestan Sq., between 27 and 29 St., Saremi Ave, Mashhad

City

Mashad

Province

Razavi Khorasan

Postal code

9178657877

Phone

+98 51 3880 0330

Email

donyadidehg931@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

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

Hamidreza Bahrami Taghanaki

Position

Associate professor of Chinese medicine

Latest degree

Ph.D.

Other areas of specialty/work

Chinese and complementary medicine

Street address

Unit 17, No. 92, between 27 and 29 St., Saermi Ave., Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9178657877

Phone

+98 51 3880 0330

Email

BahramiHR@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamidreza Bahrami Taghanaki

Position

Associate professor of Chinese medicine

Latest degree

Ph.D.

Other areas of specialty/work

Chinese and complementary Medicine

Street address

Unit 17, No. 92, between 27 and 29 St., Saermi Ave.,
Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9178657877

Phone

+98 51 3880 0330

Email

BahramiHR@mums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Hamidreza Bahrami Taghanaki

Position

Associate professor of Chinese medicine

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Unit 17, No. 92, between 27 and 29 St., Saermi Ave.,
Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9178657877

Phone

+98 51 3880 0330

Email

BahramiHR@mums.ac.ir

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

Yes - There is 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

The data accessible by the researcher, student, analyst, project supervisor, and the Vice Chancellor for Research.

The data is only available to the public through academic publication in the form of an article. Access to the data and the sampling process is possible through a written request approved by the Vice Chancellor for Research.

The data is only available to the public through academic publication in the form of an article.

When the data will become available and for how long

Access time is from the end of sampling until the results are presented.

To whom data/document is available

The data accessible by the researcher, student, analyst, project supervisor, and the Vice Chancellor for Research.

Under which criteria data/document could be used

The data and the sampling process are accessible through a written request approved by the Vice Chancellor for Research. The data is available to the public only through academic publication in the form of an article.

From where data/document is obtainable

Data are accessible through a written request approved by the Vice Chancellor for Research

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

Data are accessible through a written request approved by the Vice Chancellor for Research

Comments