

# 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

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#### 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

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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

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

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#### Province

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#### Phone

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#### 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

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**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

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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**

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.

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**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**