

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the effect of schema therapy interventions, Iranian medicine and combined intervention on body mass index in overweight women

Protocol summary

Study aim

Investigating the effect of Iranian medicine measures and group schema therapy on body mass index in overweight women

Design

Clinical trials without blindness in the face of a parallel group with a sample size of 60 people are randomly divided between groups.

Settings and conduct

Women are selected from among those who go to the Imam Reza Hospital Clinic in Mashhad and, after evaluating the entry criteria, are randomly assigned to groups. Training in Iranian medicine and schema therapy in eight weeks and two sessions per week is two hours. All questionnaires and indicators are determined before and after the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women between 19 and 40 years old, body mass index between 25 and 30, consent to study
Exclusion: having a malignant disease and liver failure, addiction, alcohol, pregnancy and lactation, drug consumption affecting weight gain and appetite

Intervention groups

Four groups: the first group receives the intervention of Iranian medicine, the second group receives the intervention of schema therapy, the third group receives the combination of these two interventions. The fourth group does not receive any intervention.

Main outcome variables

BMI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131125015533N3**

Registration date: **2020-06-05, 1399/03/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-05, 1399/03/16**

Update count: **0**

Registration date

2020-06-05, 1399/03/16

Registrant information

Name

Mohammadreza Noras

Name of organization / entity

Faculty of Traditional Medicine

Country

Iran (Islamic Republic of)

Phone

+98 51 3855 2189

Email address

norasmr901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of schema therapy interventions, Iranian medicine and combined intervention on body mass index in overweight women

Public title

Schema therapy, Iranian Medicine BMI in overweight women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Body mass index between 25 to 30 kg / m² Women Age between 19 and 40 Satisfaction with participating in the study

Exclusion criteria:

Having malignant disease, liver failure Addiction Pregnancy breastfeeding alcohol consumption Medication is effective in increasing weight and appetite

Age

From **19 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with a table of random numbers : To select sample people from the table, the researcher randomly starts from one point in the table in the direction of the row or column. Individuals fall into two random groups

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Integrated approach: psychosomatic medicine and traditional medicine

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mashhad University of Medical Sciences

Street address

Mashhad, Daneshgah Street- 18

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2020-04-16, 1399/01/28

Ethics committee reference number

IR.MUMS.REC.1399.121

Health conditions studied**1****Description of health condition studied**

Women who are overweight

ICD-10 code

E66.09

ICD-10 code description

Other obesity due to excess calories

Primary outcomes**1****Description**

Body Mass Index

Timepoint

Start of study (before of the intervention) and 4 and 8 weeks after the of the study

Method of measurement

Scales and meters

Secondary outcomes

empty

Intervention groups**1****Description**

The first intervention group: Lifestyle training and modification of nutrition habits based on Iranian medicine are taught for 8 weeks and two sessions per week.

Category

Lifestyle

2**Description**

Second Intervention Group: Teaching and modifying maladaptive patterns (schema therapy) inconsistently during two weeks and two sessions per week.

Category

Treatment - Other

3**Description**

Third intervention group: A combination of lifestyle modification training and nutritional habits of Iranian medicine and training and modification of maladaptive schema patterns (schema therapy) during two weeks and two sessions per week.

Category

Treatment - Other

4

Description

Control group: They do not receive any intervention during the study.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital Clinic in Mashhad

Full name of responsible person

Mohammad Reza Noras

Street address

Khorasan Razavi, Mashhad, Imam Reza Hospital Square, Imam Reza Research and Medical Training Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghdi

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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 Vice Chancellor for Research

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

Mohammad Reza Nors

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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82/5000 Vakilabad Blvd., Azadi Square, Ferdowsi University, Faculty of Medicine, Faculty of Traditional and Complementary Medicine

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Person responsible for scientific inquiries

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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

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

Statistical results of demographic and treatment data

When the data will become available and for how long

After reading and printing the results

To whom data/document is available

public

Under which criteria data/document could be used

Research and training

From where data/document is obtainable

Email to the person in charge of the project:

norasmr@mums.ac.ir

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

The request will be reviewed and sent to the university's
ethics committee

Comments