Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
City
Mashhad
Province
Razavi Khorasan
Postal code
۹۱۳۷۹۱۳۳۱۶
Phone
+98 51 3854 3031
Fax
+98 51 3854 3031
Email
norasmr@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghdi
Street address
Mashhad, Daneshgah Street -18
City
Mohsen Tafaghdi
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Fax
+98 51 3841 1538
Email
vcresraech@mums.ac.ir
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
Street address
82/5000 Vakilabad Blvd., Azadi Square, Ferdowsi University, Faculty of Medicine, Faculty of Traditional and Complementary Medicine
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3884 8930
Fax
+98 51 3884 8930
Email
norasmr@mums.ac.ir

Person responsible for scientific 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
Street address

Vakilabad Blvd., Azadi Square, Ferdowsi University, Faculty of Medicine, Faculty of Iranian Medicine and Supplement

City
Mashhad

Province
Razavi Khorasan

Postal code
9177899191

Phone
+98 51 3884 8930

Fax
+98 51 3884 8930

Email
norasmr@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohammad Reza Nors

Position
Associate professor

Latest degree
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Vakilabad Blvd., Azadi Square, Ferdowsi University, Faculty of Medicine, Faculty of Traditional and Complementary Medicine

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Province
Razavi Khorasan

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9177899191

Phone
+98 51 3884 8930

Fax
+98 51 3884 8930

Email
norasmr@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
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