

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Assessment and compression of the influence of traditional medicine based food regime and behavior on anthropometric indexes, blood tests, and mental health in adult fasting Muslims in Shiraz

Protocol summary

Summary

The purpose of this study is a comparison between traditional medicine based food regime and behavior and a regular one in adult fasting Muslims at Ramadan in a selected population of Shiraz city. Finally, if traditional medicine based diet regime and behavior are more effective than a regular one on the mental and physical health of adult Muslims, we can recommend it to them and thus improve the quality of fasting and promote the spiritual and psychological well-being of the community. The main inclusion criteria are age and having physically affordable, and the main exclusion criteria are having critical underlying diseases, Pregnant and lactating mothers and having very low or high BMI. The study population included all fasting people in Shiraz during Ramadan. In this double-blind study, the participants will be randomly assigned into two groups of 100 people with computer software. Traditional medicine tips training will be done in Intervention group. So a booklet which published by Office of Traditional Medicine of the Ministry of Health of Iran will be given to this group. For the control group, Traditional medicine tips training and consultation will not be done.(No action) then two groups in three-time sections including before Ramadan, after Ramadan and three months after Ramadan will be assessed through anthropometric indexes, blood tests, and mental health.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070434897N1**
Registration date: **2017-10-15, 1396/07/23**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-15, 1396/07/23

Registrant information

Name

Seyed Hossein Owji

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3624 7985

Email address

owji_h@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-05-23, 1396/03/02

Expected recruitment end date

2017-05-26, 1396/03/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment and compression of the influence of traditional medicine based food regime and behavior on anthropometric indexes, blood tests, and mental health in adult fasting Muslims in Shiraz

Public title

effect of the traditional medicine on health during fasting

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Ages between 18 to 60 years which can afford fasting; People who tend to fast during Ramadan and this Ramadan is not their first fasting time. Exclusion criteria: having uncontrolled hypertension or malignant hypertension; having severe neurological disease (depression, schizophrenia, and addiction); having severe medical disease (diabetes, hyperlipidemia, cancer and rheumatologic disorder); Pregnant and lactating mothers; having swallowing problem, under therapeutic regime or having body mass index under 20 or above 40 kilograms per square meters; having history of at least 15 days fasting during 2 months before Ramadan; having at least 5 days not fasting during Ramadan

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of medical sciences

Street address

Shiraz University of medical sciences, Zand street,
Shiraz

City

Shiraz

Postal code

Approval date

2017-05-20, 1396/02/30

Ethics committee reference number

IR.SUMS.REC.1396.34

Health conditions studied

1

Description of health condition studied

traditional medicine based food regime and behavior

ICD-10 code

Y98

ICD-10 code description

Lifestyle-related condition

Primary outcomes

1

Description

Blood urea nitrogen(BUN)

Timepoint

before Intervention, after Intervention

Method of measurement

by standard device- in mg/dl

2

Description

Height

Timepoint

before Intervention, after Intervention, three months
after Intervention

Method of measurement

By meter, in cm

3

Description

weight

Timepoint

before Intervention, after Intervention, three months
after Intervention

Method of measurement

By balance, in kg

4

Description

blood Pressure

Timepoint

before Intervention, after Intervention, three months
after Intervention

Method of measurement

by Mercury barometric- in mm Hg

5

Description

Round the abdomen

Timepoint

before Intervention, after Intervention, three months
after Intervention

Method of measurement

By meter, in cm

6

Description

Hip circumference

Timepoint

before Intervention, after Intervention, three months
after Intervention

Method of measurement

By meter, in cm

7

Description

Mental Health Indicators

Timepoint

before Intervention, after Intervention, three months
after Intervention

Method of measurement

By questionnaires: WQ5, HAD5, IPAQ, HQ28

8

Description

fasting blood sugar

Timepoint

before Intervention, after Intervention

Method of measurement

by standard device- in mg/dl

9

Description

cholesterol

Timepoint

before Intervention, after Intervention

Method of measurement

by standard device- in mg/dl

10

Description

triglyceride

Timepoint

before Intervention, after Intervention

Method of measurement

by standard device- in mg/dl

11

Description

LDL cholesterol

Timepoint

before Intervention, after Intervention

Method of measurement

by standard device- in mg/dl

12

Description

HDL cholesterol

Timepoint

before Intervention, after Intervention

Method of measurement

by standard device- in mg/dl

13

Description

AST

Timepoint

before Intervention, after Intervention

Method of measurement

by standard device- in u/L

14

Description

ALT

Timepoint

before Intervention, after Intervention

Method of measurement

by standard device- in u/L

15

Description

creatinine

Timepoint

before Intervention, after Intervention

Method of measurement

by standard device- in mg/dl

Secondary outcomes

empty

Intervention groups

1

Description

Type of intervention in Intervention group: Traditional medicine tips training will be done through a booklet which published by Office of Traditional Medicine of the Ministry of Health of Iran in person within half an hour in Intervention group. In this booklet there are many tips about Less consuming sweets and industrial foods, consumption of warm liquid in breakfast time, avoiding Eating different foods at the same time, Full food chewing on meals, avoiding consumption of water and food Simultaneously.

Category

Lifestyle

2

Description

Type of intervention in control group: For the control group, Traditional medicine tips training and consultation will not be done. (No action)

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

8 large mosques of Shiraz from different regions - including the holy Mosque of Fatemeh Zahra

Full name of responsible person

Seyed Hossein Owji

Street address

8 different addresses from different parts of the city - including the Fatemeh Zahra Mosque in the Zand street

City

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mehdi Pasalar

Street address

Medical School, Imam Hossein Square, Shiraz

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Hossein Owji

Position

Medical Student

Other areas of specialty/work**Street address**

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owji_h@sums.ac.ir.s.h.owji.j.e@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mehdi Pasalar

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Assistant Professor

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Shiraz University of Medical Sciences

Full name of responsible person

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Position

Medical Student

Other areas of specialty/work**Street address**

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Postal code**Phone**

00

Fax**Email**

owji_h@sums.ac.ir

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary
empty