

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of time restricted eating on cognitive function in men with metabolic syndrome: a randomized controlled trial

Protocol summary

Study aim

Investigating the effect of time restriction of eating for ten hours on the cognitive performance of men with metabolic syndrome

Design

Clinical trial with control group, with parallel groups, without blinding, simple randomization, using sealed envelopes and random numbers using sealed envelopes, on 40 patients.

Settings and conduct

Study subjects will be randomly selected from participants in the Mashhad-Persian Cohort who have metabolic syndrome. People will start doing cognitive tests with a single computer system in a special room . The Wisconsin test and go/nogo will be taught to people first, then in turn. The tests mentioned at the end of the study (week 6) will also be repeated. After completing the tests , depending on whether the person was placed in the intervention or control group, they will be given explanations about the diet. In the intervention group, people will receive food in a 10-hour period between 6 am and 8 pm.

Participants/Inclusion and exclusion criteria

Inclusion criteria: men between the ages of 18 and 65 years specific work and sleep schedule daily food intake more than 14 hours diagnosis of metabolic syndrome
Exclusion criteria: diabetes thyroid disorders cancer diagnosed sleep disorder diagnosed cognitive disorders

Intervention groups

People in the intervention group will be selected from patients with metabolic syndrome. They will receive in a period of 10 hours. The control group has a diet with no time limit.

Main outcome variables

changes in eating inhibition behavior resulting from the

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230820059191N1**
Registration date: **2023-08-22, 1402/05/31**
Registration timing: **prospective**

Last update: **2023-08-22, 1402/05/31**

Update count: **0**

Registration date

2023-08-22, 1402/05/31

Registrant information

Name

Mohammad Masoumvand

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of time restricted eating on cognitive function in men with metabolic syndrome: a randomized controlled trial

Public title

The effect of time restricted eating on cognitive function in men with metabolic syndrome

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Men aged between 18 and 65 years, defined work and sleep schedule more than 14 hours of daily intake diagnosis of metabolic syndrome according to the International Diabetes Federation (IDF) definition mild to moderate activity level according to the IPAQ questionnaire

Exclusion criteria:

Diabetes thyroid disorders based on thyroid tests or thyroxine intake eating disorders serious diseases that affect food intake such as cancer inability to follow a time-limited meal plan sleep disorder diagnosed by a psychiatrist or psychologist known disorders Psychology or psychiatry that affect the quality of sleep (anxiety, depression, stress) use of drugs that change the quality or pattern of sleep (sedative and sleep-inducing drugs, stimulant drugs). Drugs that take dopamine agonist drugs, procyclidine, primidone, valproic acid, olanzapine, topiramate, gabapentin, fluoxetine, sertraline, quetiapine, and trazodone.

Age

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

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: using sealed envelopes in a container that according to the sample size, 20 with control text and 20 with intervention text, which the participant will randomly choose.

Blinding (investigator's opinion)

Not blinded

Blinding description**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

Azadi Square, East Gate of Ferdowsi University of Mashhad Campus, Mashhad University of Medical Sciences, Faculty of Medicine

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2023-06-13, 1402/03/23

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1402.242

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

Metabolic syndrome

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

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

Changes in eating inhibition behavior resulting from go/no go test scores

Timepoint

The beginning of the study and the end of the sixth week

Method of measurement

go/nogo cognitive test

Secondary outcomes**1****Description**

Changes in cognitive flexibility

Timepoint

The beginning of the study and the end of the sixth week

Method of measurement

Wisconsin cognitive Test

2**Description**

Active memory changes

Timepoint

The beginning of the study and the end of the sixth week

Method of measurement

Wisconsin cognitive Test

Intervention groups

1

Description

Intervention group: In the intervention group, people will receive food in a period of 10 hours. It is recommended that this period be between 6 am and 8 pm. All foods and drinks except water, tea and coffee without added sweeteners should be consumed during this period. Due to not affecting the quality of sleep, tea and coffee consumption is allowed before 8 pm. With the help of researchers, participants will choose the best time frame that fits their life schedule. The patients' diet is according to their taste and freely, and there are no food restrictions. Participants will be explained about a healthy diet based on national dietary recommendations.

Category

Lifestyle

2

Description

Control group: The control group will have a diet without time limit and will receive the necessary recommendations about a healthy diet based on national dietary guidelines. In this group, the diet of the patients is according to their taste and freely, and there are no food restrictions.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Cohort Center

Full name of responsible person

Mohsen Nematy

Street address

Imam Reza Square, Imam Reza Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayor Mobarhan

Street address

University St., facing 18 University, Qorshi Building,
Research Vice-Chancellor of Mashhad University of
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GhayourM@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

Mohammad Masoum Vand

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Azadi Square, East Gate of Ferdowsi University of
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Person responsible for scientific inquiries

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Professor

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Only part of the data, such as information related to the main outcome or similar, can be shared.

When the data will become available and for how long

Data access will start 6 months after the results are published.

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions and people working in industry if action is taken.

Under which criteria data/document could be used

The conditions of using non-identifiable data or other research achievements will be reviewed on a case-by-case basis after sending an official request by the Faculty of Medical Sciences.

From where data/document is obtainable

Dr. Mohsen Nematy Address: Mashhad, Azadi Square, East Gate of Ferdowsi University Campus, Mashhad University of Medical Sciences, Faculty of Medicine, Department of Nutrition Postal Code: 9177948564 Email: NematyM@mums.ac.ir Phone: 0098 51 38827034

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

The applicant must send the data request with details via e-mail, and the request will be provided to the applicant after it is reviewed by the researchers and Mashhad University of Medical Sciences and if approved.

Comments