Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of jujube consumption on anthropometric indices, lipid parameters, blood pressure, glycemic status, and mood in military personnel with metabolic syndrome referred to Shahid Sadoughi Hospital in Isfahan

Protocol summary

Study aim
The effect of jujube consumption on anthropometric indices, lipid parameters, blood pressure, glycemic status, and mood in military personnel with metabolic syndrome referred to Shahid Sadoughi Hospital in Isfahan

Design
A parallel, double-blind, randomized controlled trial. Randomization was done using the random table of numbers.

Settings and conduct
The study will be performed on 60 patients with metabolic syndrome referred to Shahid Sadoughi Hospital in Isfahan who will be randomly assigned to two groups of intervention and control. Patients in the intervention and placebo groups will receive 30 grams of jujube powder or 30 grams of wheat flour daily after meals for 8 weeks. The researcher and participants will be blind to randomization and assignments until the end of the study.

Participants/Inclusion and exclusion criteria
Using the military personnel referred to Shahid Sadoughi Hospital in Isfahan and according to international standards, patients with metabolic syndrome will be diagnosed by an expert cardiologist. Among subjects with metabolic syndrome, those who agree to participate in the trial (age 30-50) will be included. People who follow special diets or have kidney, liver, thyroid, and parathyroid, lung, cancer and heart diseases will not be included in the study.

Intervention groups
Intervention: Patients in the intervention group will receive 30 grams of jujube powder daily after meals for 8 weeks. Placebo: Patients in the control group will receive 30 grams of wheat flour daily as a placebo after meals for 8 weeks.

Main outcome variables
Anthropometric indices, blood pressure, lipid profile, mood, glycemic status

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180201038585N10**
Registration date: **2021-04-11, 1400/01/22**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-11, 1400/01/22**
Update count: **0**

Registration date
2021-04-11, 1400/01/22

Registrant information
Name
Karim Parastouei
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-09, 1400/01/20
Expected recruitment end date
2021-05-10, 1400/02/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of jujube consumption on anthropometric indices, lipid parameters, blood pressure, glycemic status, and mood in military personnel with metabolic syndrome referred to Shahid Sadoughi Hospital in Isfahan

Public title
Jujube in metabolic syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Military personnel with metabolic syndrome Age 30-50 years Willing to participate in the study
Exclusion criteria:
Follow special diets Other diseases such as kidney, liver, thyroid and parathyroid, lung, cancer, and heart disease
Age
From **30 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was performed by the block randomization method. Random sequence generation was done using the table of random numbers by a third trained person. Allocation concealment was performed using sealed envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
For blinding, placebo and jujube powder will be placed in the same aluminum package. Then the aluminum packages are placed in paper boxes and will receive a special code from the company. The placebo and jujube powder codes will remain with the company until the end of the study in order to blind the researchers, laboratory staff, and patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Baqiyatallah University of Medical Sciences
Street address
Molla Sadra Ave., Vannak Sq.
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2021-03-02, 1399/12/12
Ethics committee reference number
IR.BMSU.BAQ.REC.1399.063

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
Blood pressure
Timepoint
At the beginning and after 8 weeks of study
Method of measurement
Mercury sphygmomanometer

2

Description
Weight
Timepoint
At the beginning and after 8 weeks of study
Method of measurement
Scale

3

Description
Body mass index
Timepoint
At the beginning and after 8 weeks of study

Method of measurement
Equation, Weight(kg)/[height(m)]2

4

Description
Lipid profile
Timepoint
At the beginning and after 8 weeks of study
Method of measurement
Through intravenous blood samples and commercial kits

5

Description
fasting blood glucose
Timepoint
At the beginning and after 8 weeks of study
Method of measurement
Through intravenous blood samples and commercial kits

6

Description
Waist circumference
Timepoint
At the beginning and after 8 weeks of study
Method of measurement
Tape

Secondary outcomes

1

Description
Depression score
Timepoint
At the beginning and after 8 weeks of study
Method of measurement
DASS-21 questionnaire

2

Description
Stress score
Timepoint
At the beginning and after 8 weeks of study
Method of measurement
DASS-21 questionnaire

3

Description
Anxiety score
Timepoint
At the beginning and after 8 weeks of study
Method of measurement
DASS-21 questionnaire

Intervention groups

1

Description
Intervention group: Patients in the intervention group will receive 30 g packets of jujube powder at the beginning of the study. Patients in the intervention group will be asked to consume a 30-gram packet of jujube powder daily after meals for 8 weeks. Patients will be contacted on a weekly basis to increase compliance.
Category
Treatment - Other

2

Description
Control group: Patients in the control group will receive 30 g packets of wheat flour at the beginning of the study. Patients in the control group will be asked to consume a 30-gram packet of placebo daily after meals for 8 weeks. Patients will be contacted on a weekly basis to increase compliance.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital
Full name of responsible person
Karim Parastouei
Street address
Bozorgmehr Street.
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Isfahan
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Isfehan
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3733181548
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Ali Shiri
Street address
Mollasadra Ave, Vanak Sq,
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Email
shira.reza@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Karim Parastouei

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

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Ph.D.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable