Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of inositol supplementation on sleep quality, fatigue and mood status in women with poor sleep quality: a randomized control trial

Protocol summary

Study aim
Determining the effect of inositol supplement consumption on sleep quality, fatigue, and mood in women with low sleep quality.

Design
A controlled, parallel-group, double-blinded, randomized, clinical trial on 60 patients

Settings and conduct
his study is a randomized, double-blind, placebo-controlled trial conducted on eligible women with low sleep quality. Participants, are randomly allocated into two groups receiving either inositol or placebo daily and take 2 tablets daily for 8 weeks. Assessments include sleep quality, fatigue, and mood at three stages (baseline, week 4, and end of study). Weight, height, and body composition are also measured at the beginning and end of the intervention. All assessments will be performed during the follicular phase of the menstrual cycle.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Women with a (PSQI) score > 5 Body Mass Index (BMI) between 18.5 and 29.9 kg/m². Age between 20-50 years. Exclusion Criteria: General health problems (chronic illnesses or severe psychiatric disorders). Presence of (PCOS). Hyperthyroidism or hypothyroidism. History of disorders affecting sleep quality. Shift work. History of any hormone therapy. Travel to a different time zone within the past 1 month. Consumption of sleep supplements within the last 4 weeks. Menopause. Experiencing a significant stressor within the last 2 weeks. Smoking. Use of medications that may affect cognitive function or sleep within the last month Caffeine intake exceeding 300 mg. Diagnosis of any dementia or neurodegenerative disease. Pregnancy or breastfeeding. Individuals on weight reduction diets. Student examination periods.

Intervention groups
Intervention Group: 1600 mg inositol hexaphosphate daily. Control Group: 1600 mg maltodextrin placebo daily. Both groups: 2 tablets daily after dinner for 8 weeks

Main outcome variables
sleep quality, fatigue mood status

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220208053971N7**
Registration date: **2026-09-04, 1405/06/13**
Registration timing: **prospective**

Last update: **2026-09-04, 1405/06/13**
Update count: **0**

Registration date
2026-09-04, 1405/06/13

Registrant information

Name
Hamed Mohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-23, 1405/08/01

Expected recruitment end date
2028-10-22, 1407/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of inositol supplementation on sleep quality, fatigue and mood status in women with poor sleep quality: a randomized control trial

Public title
The effects of inositol supplementation on sleep quality, fatigue and mood status in women with poor sleep quality
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Women with a Pittsburgh Sleep Quality Index (PSQI) score > 5 indicating poor sleep quality Body mass index (BMI) between 18.5 and 29.9 kg/m² Age between 20 and 50 years
Exclusion criteria:
General health problems (chronic diseases or severe psychiatric disorders) Presence of polycystic ovary syndrome (PCOS) Hyperthyroidism or hypothyroidism History of disorders affecting sleep quality Shift work History of any hormone therapy History of traveling to a different time zone within the past month Use of sleep supplements (magnesium and melatonin) within the past 4 weeks Menopause Experience of an event that caused severe stress within the past 2 weeks Smoking Use of medications that may affect cognitive function or sleep in the past month (sleeping medications, antidepressants), including:• Anticonvulsants• Barbiturates• Benzodiazepines• Antidepressants• Neuroleptics Alcohol consumption Caffeine intake greater than 300 mg Diagnosis of any dementia or neurodegenerative disease Pregnancy or lactation Inability to understand or sign the informed consent form Individuals on weight-loss diets Exam season for students
Age
From **20 years** old to **50 years** old
Gender
Female

Phase
2
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed using permuted block randomization, taking into account the variables age (20–35 and 35–50 years) and body mass index (18.5–24.9 and 25–29.9 kg/m²). Eligible participants will be randomly allocated to either the intervention or placebo group using stratified block randomization based on age group (20–35 and 36–50 years) and body mass index (BMI) (18.5–24.9 and 25–29.9 kg/m²). The randomization sequence will be generated using www.randomization.com. Within each stratum, participants will be allocated to the two study groups in a 1:1 ratio using blocks of four. To maintain blinding, the two study groups will be designated by the codes A and B, and the randomization sequence and group codes will be generated and assigned by an individual independent of the research team.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study will be conducted in a double-blind manner, such that the participants, researcher, and data analyst will be blinded to the type of intervention. The intervention supplement and placebo will be identical in terms of shape, size, packaging, and appearance and will be provided using assigned codes. The codes will be kept by an independent individual until the completion of the statistical analysis.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences
Street address
Tehran, at the end of Keshavarz Boulevard, Imam Khomeini Hospital Complex
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Approval date
2026-08-16, 1405/05/25
Ethics committee reference number
IR.TUMS.IKHC.REC.1405.225

Health conditions studied

1

Description of health condition studied

sleep quality
ICD-10 code
ICD-10 code description

2

Description of health condition studied
fatigue
ICD-10 code
ICD-10 code description

3

Description of health condition studied
mood status
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sleep Quality
Timepoint
Before the start of the intervention, 4 and 8 weeks after
Method of measurement
(Pittsburgh Sleep Quality Index; PSQI)

2

Description
Fatigue
Timepoint
Before the start of the intervention, 4 and 8 weeks after
Method of measurement
(Fatigue Assessment Scale; FAS)

3

Description
Mood status
Timepoint
Before the start of the intervention, 4 and 8 weeks after
Method of measurement
(Beck Anxiety Inventory; BAI) (Beck Depression Inventory–II; BDI-II)(Perceived Stress Scale; PSS)

Secondary outcomes

1

Description
Insomnia Severity
Timepoint
Before the start of the intervention, 4 and 8 weeks after
Method of measurement
(Insomnia Severity Index; ISI)

2

Description
Daytime sleepiness
Timepoint
Before the start of the intervention, 4 and 8 weeks after
Method of measurement
(Epworth Sleepiness Scale; ESS)

3

Description
Body weight
Timepoint
Before the start of the intervention and 8 weeks after
Method of measurement
Digital scale

Intervention groups

1

Description
Intervention group: intervention group will receive 1600 mg of inositol hexaphosphate (IP6) supplement per day, produced by M-Plus. Each participant will take two tablets daily after dinner for a duration of eight weeks.
Category
Other

2

Description
Control group: The control group will receive 1600 mg of maltodextrin daily as a placebo, provided in identical packaging and appearance. Each participant will take two tablets daily after dinner for a duration of eight weeks.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
nutrition and diet therapy clinic of the School of Nutrition, Tehran University of Medical Sciences.
Full name of responsible person
Dr.Hamed Mohammadi
Street address
Dr. Gharib Street, corner of Sadoghi Street, No. 119, Unit 4, First Floor.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr.Hamed Mohammadi
Position
Associate Professor
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Person responsible for updating data

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Latest degree
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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
Because the participants information is confidential, it cannot be published.

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

Analytic Code
Not applicable

Data Dictionary
Not applicable