Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating hedonic eating and its relation with some psychological characteristics and the effect of curcumin supplementation on serum levels of Anandamide and BDNF (Brain-Derived Neurotrophic Factor) and hedonic eating intensity in overweight and obese women

Protocol summary

Study aim

Investigating hedonic eating and its relation with some psychological characteristics and the effect of curcumin supplementation on serum levels of Anandamide and BDNF (Brain-Derived Neurotrophic Factor) and hedonic eating intensity in overweight and obese women

Design

In this double-blind clinical trial (both participants and researchers), patients visiting the nutrition specialist at Imam Reza Hospital will be randomly assigned to two groups. One group will receive oral curcumin supplementation, while the other group will receive an oral placebo capsule. Sleep quality will be compared between the two groups after eight weeks of intervention.

Settings and conduct

In this randomized double-blind clinical trial, participants in two study groups will receive either a 40 mg capsule of nano-micelle curcumin (with 100% encapsulation efficiency, equivalent to 0.8-2 grams of turmeric) or a placebo (containing a mixture of microcrystalline cellulose) with their lunch, for a duration of 8 weeks. Adherence to the intervention will be assessed by counting the number of capsules consumed.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study will consist of apparently healthy women with literacy skills, overweight and obese women, and women over the age of 18. The exclusion criteria will include postmenopausal women, pregnant or breastfeeding women, women with a recent history of weight loss or bariatric surgery, and women who have recently taken supplements or medications affecting sleep.

Intervention groups

In this study, patients who will visit the doctor due to obesity will be intervened. The patients will be randomly divided into two groups. One group will receive oral curcumin supplementation, while the other group will receive an oral placebo capsule. Sleep quality will be compared between the two groups after eight weeks.

Main outcome variables

Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N53**
Registration date: **2025-02-12, 1403/11/24**
Registration timing: **prospective**

Last update: **2025-02-12, 1403/11/24**
Update count: **0**

Registration date

2025-02-12, 1403/11/24

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-17, 1403/11/29

Expected recruitment end date

2026-02-18, 1404/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating hedonic eating and its relation with some psychological characteristics and the effect of curcumin supplementation on serum levels of Anandamide and BDNF (Brain-Derived Neurotrophic Factor) and hedonic eating intensity in overweight and obese women

Public title

The Effect of Curcumin on Hedonic Eating, Anandamide, BDNF (Brain-Derived Neurotrophic Factor) and Psychological Factors in Overweight and Obese Women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Apparently healthy women with literacy skills Overweight and obese women Women over 18 years old

Exclusion criteria:

Postmenopausal women Pregnant or breastfeeding women Women with a recent history of weight loss or bariatric surgery Women who have recently taken supplements or medications affecting sleep

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, with a sample size of 46, patients will be randomly allocated using the block permutation randomization method, which is employed to ensure balance in the number of participants allocated to each group. Six possible blocks are defined, each containing four participants: Block 1 (BBAA), Block 2 (AABB), Block 3 (ABAB), Block 4 (BABA), Block 5 (ABBA), and Block 6 (BAAB). To allocate participants, 12 blocks are needed for 46 individuals. These blocks are generated using the Random Allocation Software, which can create random sequences using the block randomization method. Numbers from 1 to 6 are randomly selected, and for example, if block 6 is selected first and block 2 second, the sequence BAABAABB will be assigned to the participants as they enter the study, from left to right. In the end, participants will be divided into two groups: the intervention group (Group A) and the control group (Group B).

Blinding (investigator's opinion)

Double blinded

Blinding description

The principal investigator and participants will remain unaware of the procedure being performed and will be blinded throughout the study; therefore, this study will be conducted as a double-blind trial. Since participants will be unaware of the type of drug being used, they will not know what type of medication is being administered to other patients in the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2024-12-01, 1403/09/11

Ethics committee reference number

IR.TBZMED.REC.1403.793

Health conditions studied

1

Description of health condition studied

Sleep quality

ICD-10 code

F15.282

ICD-10 code description

Other stimulant dependence with stimulant-induced sleep disorder

Primary outcomes

1

Description

Sleep quality

Timepoint
Twice, before and after the intervention (after eight weeks).
Method of measurement
Using the Pittsburgh Sleep Quality Index (PSQI) questionnaire.

2

Description
Hedonic eating
Timepoint
Twice, before and after the intervention (after eight weeks).
Method of measurement
Using the Power of Food Scale (PFS).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this randomized double-blind clinical trial, participants in the intervention group will receive a 40 mg capsule of nano-micelle curcumin (with 100% encapsulation efficiency, equivalent to 0.8-2 grams of turmeric) with their lunch, for a duration of 8 weeks. Adherence will be assessed by counting the number of capsules consumed. Before the intervention begins and after 8 weeks of supplement or placebo consumption, sleep quality and hedonic eating will be measured.
Category
Treatment - Drugs

2

Description
Control group: In this randomized double-blind clinical trial, participants in the intervention group will receive a placebo capsule (containing a mixture of microcrystalline cellulose) with their lunch, for a duration of 8 weeks. Adherence will be assessed by counting the number of capsules consumed. Before the intervention begins and after 8 weeks of supplement or placebo consumption, sleep quality and hedonic eating will be measured.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Reza Mahdavi
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Azadeh Khalili
Position
PhD candidat in Nutritional Sciences
Latest degree

Master

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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