Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Evening Resistance Training and Nano-Curcumin on Insomnia Severity and Neuroendocrine–Inflammatory Biomarkers

Protocol summary

Study aim

To evaluate the effects of resistance training and nano-curcumin supplementation on insomnia severity and selected sleep-related biomarkers in 18–25-year-old men with chronic Insomnia Disorder

Design

12-week randomized, placebo-controlled, 2×2 factorial, parallel-group clinical trial; n=80; individual randomization; computer-generated block randomization (block size 4) with sequentially numbered opaque sealed envelopes; double-blind supplementation.

Settings and conduct

This study will be conducted at the Health Research Center of islamic azad university shahrekord branch. Participants will be will be randomly allocated with block sizes of four to tree intervention and one control groups. Blinding (using microcrystalline cellulose in control group) will be used to prevent bias.

Participants/Inclusion and exclusion criteria

Inclusion criteria: male aged 18–25 years; Petersburg scale more than 5; clinician-confirmed insomnia disorder more than 3 months with daytime impairment. Exclusion criteria: other diagnosed sleep disorders; shift work; usage of sleep drugs in recent 6 months.

Intervention groups

Intervention group 1: Resistance training (3 sessions/week for 12 weeks; 17:00–19:00) plus nano-curcumin 40 mg (Exir Nano Sina Company, Iran) twice daily for 12 weeks. Intervention group 2: Resistance training plus placebo (microcrystalline cellulose, Barij Essence Pharmaceutical Company, Kashan, Iran) twice daily for 12 weeks. Intervention group 3: Usage of nano-curcumin for 12 weeks. Control group: Usage of placebo for 12 weeks.

Main outcome variables

Insomnia Severity Index total score, Total sleep time, Wake after sleep onset, Sleep efficiency, Urinary 6-sulfatoxymelatonin, Cortisol awakening response, interleukin-6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251112067968N2**
Registration date: **2026-04-01, 1405/01/12**
Registration timing: **registered_while_recruiting**

Last update: **2026-04-01, 1405/01/12**
Update count: **0**

Registration date

2026-04-01, 1405/01/12

Registrant information

Name

Ali Haghighati borujeni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3426 7171

Email address

alihaghighati2002@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-04, 1404/01/15

Expected recruitment end date

2026-07-06, 1405/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Evening Resistance Training and Nano-Curcumin on Insomnia Severity and Neuroendocrine–Inflammatory Biomarkers

Public title
Resistance Training, Nano-Curcumin and Insomnia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Male university students aged 18–25 years Insomnia Severity Index score ≥ 10 Pittsburgh Sleep Quality Index global score ≥ 5 Clinician-confirmed diagnosis of Insomnia Disorder according to DSM-5 criteria with difficulty initiating sleep, difficulty maintaining sleep, and/or early morning awakening occurring ≥ 3 nights per week for ≥ 3 months Presence of clinically meaningful daytime impairment including fatigue, mood disturbance, or cognitive or academic dysfunction No participation in structured resistance training within the previous 6 months Maintenance of regular daytime schedules and stable living conditions during the study period
Exclusion criteria:
Physician-diagnosed sleep disorders other than insomnia including obstructive sleep apnea or restless legs syndrome High risk of obstructive sleep apnea based on STOP-Bang questionnaire Shift work within the previous 3 months Current smoking Alcohol intake greater than 2 standard drinks per week Chronic inflammatory, endocrine, cardiovascular, metabolic, or neurological disease Use of hypnotics, antidepressants, corticosteroids, anti-inflammatory medications, or dietary supplements known to affect sleep or inflammatory status within the prior 3 months
Age
From **18 years** old to **25 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Following completion of baseline assessments, participants were randomly assigned in a 1:1:1:1 ratio to one of four parallel groups: (1) resistance training plus nano-curcumin (RT+NC), (2) resistance training plus placebo (RT+PL), (3) nano-curcumin only (NC), and (4) placebo control (PL). The randomization sequence was generated using computer-generated random numbers (Random.org). Permuted block randomization with fixed block size of four was applied to maintain balanced group sizes throughout recruitment. Within each block, all four possible assignments were randomly ordered, and the blocks were then concatenated to create the final sequence. An independent researcher not involved in enrollment or outcome assessment created and safeguarded the sequence. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes (SNOSE). Each envelope was opened only after a participant was fully enrolled, by a staff member who had no access to the sequence. Supplement allocation was performed under double-blind conditions. Nano-curcumin and placebo capsules were identical in appearance, including size, color, weight, and packaging. Participants, laboratory personnel, and outcome assessors remained blinded to supplementation assignment throughout the study. Due to the nature of the intervention, blinding to resistance-training allocation was not feasible; however, outcome assessment and data analysis were conducted by personnel blinded to group assignments.
Blinding (investigator's opinion)
Double blinded
Blinding description
Supplement allocation was double-blinded. Nano-curcumin and placebo capsules were identical in size, color, weight, and packaging to ensure masking. Participants were blinded to supplementation assignment throughout the study. Laboratory personnel responsible for biomarker analyses and outcome assessors were also blinded to supplementation allocation. Data analysis was performed by personnel who were unaware of group assignments. Due to the nature of the intervention, blinding to resistance training allocation was not feasible. No Data Safety and Monitoring Committee was reported.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islamic Azad University, Shahrekord branch
Street address
Islamic Azad University Shahrekord Branch, Rahmatieh, Shahrekord, Iran
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8818630003
Approval date
2024-06-05, 1403/03/16
Ethics committee reference number
IR.IAU.SHK.REC.1403.068

Health conditions studied

1

Description of health condition studied
Insomnia Disorder
ICD-10 code
F51
ICD-10 code description
Sleep disorders not due to a substance or known physiological condition

Primary outcomes

1

Description
Total score of insomnia severity index
Timepoint
At baseline before randomization and at week12 after completion of the intervention
Method of measurement
Insomnia Severity Index questionnaire

Secondary outcomes

1

Description
Total sleep time
Timepoint
Before intervention and after completing 12 weeks of intervention.
Method of measurement
Consensus Sleep Diary core version

2

Description
Wake after sleep onset
Timepoint
Before intervention and after completing 12 weeks of intervention
Method of measurement
Consensus Sleep Diary core version

3

Description
Sleep efficiency
Timepoint
Before intervention and after completing 12 weeks of intervention
Method of measurement
Consensus Sleep Diary core version

4

Description
Creatinine-normalized overnight urinary 6-sulfatoxymelatonin
Timepoint
Before intervention and after completing 12 weeks of intervention
Method of measurement
Enzyme linked immunoassay for urinary six sulfatoxymelatonin with creatinine normalization

5

Description
Cortisol awakening response
Timepoint
Before intervention and after completing 12 weeks of intervention
Method of measurement
High sensitivity salivary enzyme immunoassay for cortisol

6

Description
Serum interleukin-6 (IL-6) concentration
Timepoint
Before intervention and after completing 12 weeks of intervention
Method of measurement
High sensitivity enzyme linked immunosorbent assay for serum interleukin six

Intervention groups

1

Description
Intervention group 1: Evening resistance training plus nano-curcumin supplementation. Resistance training perform three sessions per week for 12 weeks that were conducted between 17:00 and 19:00. Each session included a 5–10-minute warm-up followed by six exercises that include back squat, Romanian deadlift, bench press, seated row, shoulder press, and abdominal plank hold. Training intensity is 60% 1RM in weeks one to three ; 65% 1RM in weeks four to six; 70% 1RM in weeks seven to ninth; and 75% 1RM in weeks ten to twelve. Each resistance session include 3 sets with 8-12 repetition with 90-120 seconds rest intervals. Also, participants consume nano-curcumin (Exir Nano Sina Company, Iran): 40 mg twice daily (80 mg in total) in morning (after breakfast) and evening (one hour before habitual bedtime) for 12 weeks.
Category
N/A

2

Description
Intervention group 2: Combined evening resistance training plus placebo supplementation. Resistance training perform three sessions per week for 12 weeks that were conducted between 17:00 and 19:00. Each session included a 5–10-minute warm-up followed by six exercises that include back squat, Romanian deadlift, bench press, seated row, shoulder press, and abdominal plank hold. Training intensity is 60% 1RM in weeks one to

three ; 65% 1RM in weeks four to six; 70% 1RM in weeks seven to ninth; and 75% 1RM in weeks ten to twelve. Each resistance session include 3 sets with 8-12 repetition with 90-120 seconds rest intervals. Also, participants consume capsules contained inert microcrystalline cellulose (Barij Essence Pharmaceutical Company, Kashan, Iran) that were identical in appearance and packaging to active capsules; taken twice daily (morning and evening) for 12 weeks.

Category

N/A

3

Description

Intervention group 3: Nano-curcumin supplementation without resistance training. participants consume nano-curcumin (Exir Nano Sina Company, Iran): 40 mg twice daily (80 mg in total) in morning (after breakfast) and evening (one hour before habitual bedtime) for 12 weeks.

Category

N/A

4

Description

Control group: Placebo supplementation without resistance training. Participants consume capsules contained inert microcrystalline cellulose (Barij Essence Pharmaceutical Company, Kashan, Iran) that were identical in appearance and packaging to active capsules; taken twice daily (morning and evening) for 12 weeks.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Islamic Azad University Shahrekord Branch

Full name of responsible person
Mehrdad Yadegari Dekordi

Street address
Islamic Azad University Shahrekord Branch, Rahmatieh, Shahrekord, Iran

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8818630003

Phone
+98 38 3336 1001

Email
mehrdad.yadegari@iau.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Mehrdad Yadegari Dekordi

Street address
Islamic Azad University Shahrekord Branch, Rahmatieh, Shahrekord, Iran

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8818630003

Phone
+98 38 3336 1001

Email
Mehrdad.yadegari@iau.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University

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
Islamic Azad University

Full name of responsible person
Akram Jafari

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
sport physiology

Street address
Islamic Azad University Shahrekord Branch, Rahmatieh, Shahrekord, Iran

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code

8818630003

Phone
+98 38 3336 1001

Email
jafari.akm@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Akram Jafari

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport physiology

Street address
Islamic Azad University Shahrekord Branch, Rahmatieh, Shahrekord, Iran

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8818630003

Phone
+98 38 3336 1001

Email
Jafari.akm@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Akram Jafari

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
sport physiology

Street address
Islamic Azad University Shahrekord Branch, Rahmatieh, Shahrekord, Iran

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8818630003

Phone
+98 38 3336 1001

Email
jafari.akm@gmail.com

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data without participant names

When the data will become available and for how long
6 months after publication of the article

To whom data/document is available
University students and professors

Under which criteria data/document could be used
For future research

From where data/document is obtainable
To the researchers of this study

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

Comments