Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of High-Intensity Interval Training and Sleep Regulation on Immunoglobulin A, IL-6 And IL-1β, hs-CRP, Body Composition, Anaerobic Power, Neuromuscular Coordination and Sleep Quality of Adolescent Girls with Sleep Disorders

Protocol summary

Study aim

The effect of high-intensity interval training and sleep regulation and the combination of the two on some immune system indices (IgA, L-6 and IL-1β, hs-CRP, cortisol), physiological factors (body composition, anaerobic capacity, Neuromuscular coordination) and sleep quality of adolescent girls with sleep disorders.

Design

A randomized, one-blinded, controlled, semi-experimental with a parallel-group design of 80 adolescent females with sleep disorders. A lottery will be used for randomization.

Settings and conduct

This research is an applied quasi-experimental study and includes pre-test and post-test with 4 experimental groups in which the effect of independent variables of high-intensity interval training and sleep regulation and a combination of the two on some immune system indicators, physiological factors and sleep quality in girls 13 to 17 years with sleep disorders will be assessed. The site of the intervention and sports evaluations will be in the club and blood tests will be performed in a specialized laboratory. Collaborative researchers will be blind to pre-test and post-test evaluations and the statistical expert will be blind to how individuals are assigned to the groups.

Participants/Inclusion and exclusion criteria

1- Having sleep disorders using a Pittsburgh questionnaire that was measured by a psychologist. 2. No history of mental illness and hormonal disorders. 3. Do not use sleeping pills. 4- Regular menstrual cycle. 5- No special diet.

Intervention groups

Eighty female students with sleep disorders based on the Pittsburgh Sleep Disorders Questionnaire (score 11 and above), will be identified and selected by convenience sampling method and randomly divided into 4 groups of 20 participants including high-intensity interval training, Sleep Regulation, Combined and Control groups.

Main outcome variables

Some immune system indicators (IgA, IL-6 and IL-1β, hs-CRP, cortisol)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180503039517N12**
Registration date: **2021-12-18, 1400/09/27**
Registration timing: **prospective**

Last update: **2021-12-18, 1400/09/27**
Update count: **0**

Registration date

2021-12-18, 1400/09/27

Registrant information

Name
Soleyman Ansari Kolachahi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-01-15, 1400/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of High-Intensity Interval Training and Sleep Regulation on Immunoglobulin A, IL-6 And IL-1β, hs-CRP, Body Composition, Anaerobic Power, Neuromuscular Coordination and Sleep Quality of Adolescent Girls with Sleep Disorders

Public title

High-intensity interval training and sleep regulation on inflammatory and physical fitness indicators in girls with sleep disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having sleep disorders Regular menstrual cycle No special diet

Exclusion criteria:

Use of sleeping drugs History of mental illness and hormonal disorders being absent for two frequent or 3 consecutive sessions in training program

Age

From **13 years** old to **17 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

80 adolescent girls (who have been diagnosed with sleep disorders based on their medical history) will be selected from schools by available sampling methods. The names of the participants will be written on paper and divided into two experimental and control groups through a random lottery.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this research, responsible for collecting and processing the data, the type of intervention, and the participants in the research groups are unaware.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Islamic Azad University-Rasht Branch

Street address

Lakan Blv

City

Rasht

Province

Guilan

Postal code

41476-54919

Approval date

2021-09-19, 1400/06/28

Ethics committee reference number

IR.IAU.Rasht.REC.1400.026

Health conditions studied

1

Description of health condition studied

sleep disorders

ICD-10 code

G47.9

ICD-10 code description

Sleep disorder, unspecified

Primary outcomes

1

Description

Some immune system indicators (IgA, IL-6 and IL-1β, hs-CRP, cortisol)

Timepoint

48 hours before intervention and 48 hours after 12 weeks of intervention

Method of measurement

Measurement of cytokines using special IL-6 and IL-1β Diaclone kits made in France will be used according to the manufacturer's instructions and ELISA method. hs-CRP will be measured with the kit of Pars-Azmon Company (made in Iran-Karaj) and by enzymatic method. IgA concentration will be measured by turbidometry method and using Pars-Azmon kit made in Iran.

Secondary outcomes

1

Description
Physiological factors (body composition, anaerobic capacity, neuromuscular coordination)
Timepoint
48 hours before intervention and 48 hours after 12 weeks of intervention
Method of measurement
To measure body composition, subjects' BMI will be used by dividing weight by height squared (Kg /m2), for anaerobic power، Wingate test and for neuromuscular coordination، stick test will be utilized.

2

Description
sleep quality
Timepoint
48 hours before intervention and 48 hours after 12 weeks of intervention
Method of measurement
The Pittsburgh Questionnaire will be used.

Intervention groups

1

Description
Intervention group1: high intensity interval training. High intensity interval training group will perform four weeks, three sessions a week, 3 sets of RAST protocol with 3 minutes rest between each set in the first week, to which one set will be added every week and finally in the fourth week will reach six sets. Each set consisted of 6*35-meter sprints with a 10-second break between each repetition. Training sessions will be conducted at morning. Polar heart rate monitor is used to control the intensity of training.
Category
Rehabilitation

2

Description
Intervention group: sleep regulation. Each participant will be given an individualized sleep schedule that sets the time for going to bed, turning off the lights, and waking up for each day. The average time spent going to bed, turning off the lights, and waking up each person reported in her bedroom will be used to calculate these.
Category
Lifestyle

3

Description
Intervention group: combined. The combined group will perform both high intensity interval training and sleep regulation interventions.
Category
Rehabilitation

4

Description
Control group: Participants in this group will not receive any intervention and will continue their daily routine as usual.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Child and Adolescent Psychology Clinic
Full name of responsible person
Soleyman Ansari
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Third floor, Amer Building, Next to the Finance Department, The beginning of Rashtian Street, Jahad square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Islamic Azad University
Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Soleyman Ansari

Position

researcher

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available