

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The Effect of High-Intensity Interval Training and Sleep Regulation on Immunoglobulin A, IL-6 And IL-1 β , 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-1 β , 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-1 β , 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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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-1 β , 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

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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-1 β , 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-1 β 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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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

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

City

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Person responsible for general inquiries

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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