

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The Effect of High-Intensity Interval Training, Sleep Regulation and Combination on Glucose Homeostasis, Growth Hormone, Cortisol, and Lactate Levels, Sleep Quality, Aerobic Power and Reaction Time in Adolescent Girls with Sleep Disorders

Protocol summary

Study aim

Evaluation of the effect of high-intensity periodic exercise and sleep regulation and combination on glucose homeostasis, growth hormone levels, cortisol, lactate, sleep quality and aerobic power during the reaction time 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 Glucose homeostasis, growth hormone, cortisol, and lactate levels, sleep quality, aerobic capacity, and reaction time 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

Having sleep disorders using the Pittsburgh Questionnaire scales, Regular menstrual cycle, No special diet, Use of sleeping drugs, History of mental illness, and hormonal disorders

Intervention groups

High-intensity interval training group (n = 20), Sleep regulation group (n = 20), Combined group (n = 20), Control group (n = 20)

Main outcome variables

Glucose homeostasis, growth hormone, cortisol, and lactate levels, sleep quality, aerobic capacity, and reaction time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180503039517N11**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **prospective**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name

Soleyman Ansari Kolachahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3375 2906

Email address

solomonansari@phd.iaurasht.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-24, 1400/10/03

Expected recruitment end date

2022-01-17, 1400/10/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of High-Intensity Interval Training, Sleep Regulation and Combination on Glucose Homeostasis, Growth Hormone, Cortisol, and Lactate Levels, Sleep Quality, Aerobic Power and Reaction Time in Adolescent Girls with Sleep Disorders

Public title

High-intensity interval training and sleep regulation on glucose homeostasis and growth hormone in girls with sleep disorders

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having sleep disorders using the Pittsburgh Questionnaire scales Regular menstrual cycle No special diet

Exclusion criteria:

Use of sleeping drugs History of mental illness and hormonal disorders Two frequent or 3 consecutive sessions of absence in the training

AgeFrom **13 years** old to **17 years** old**Gender**

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

80 females with sleep disorders will be selected by the available sampling method. Through a lottery (participants' names were written on paper and will be divided into 4 groups (3 intervention and 1 control groups) through 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.1400.027

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**

Glucose homeostasis

Timepoint

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

Method of measurement

the evaluation method of homeostasis model (HOMA-IR) and measuring insulin and glucose (enzyme calorimetric kit of Pars-Azmoun company), fasting was estimated according to the following formula: [$HOMA-IR = \text{insulin (MU} \times \text{lit)} \times \text{glucose (nmol / lit)} \div 22/5$]

Secondary outcomes**1****Description**

aerobic power

Timepoint

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

Method of measurement

Aerobic power in this study will be measured by a shuttle run test.

2

Description

Reaction speed

Timepoint

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

Method of measurement

A two-way general visual reaction time test will be used to measure the dynamic reaction time of the whole body.

3

Description

sleep quality

Timepoint

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

Method of measurement

Pittsburgh Questionnaire

4

Description

Growth hormone

Timepoint

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

Method of measurement

Dbc Canadiangoose Elisa kit

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 3: combined. The combined group will perform both high intensity interval training and sleep regulation interventions.

Category

Treatment - Other

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

Street address

Jahad square. The beginning of Rashtian Street. Next to the Finance Department. Amer Building, third floor

City

Rasht

Province

Guilan

Postal code

4147654919

Phone

+98 13 3358 3940

Email

solomonansari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Alireza Seidavi

Street address

Lakan Blv

City

Rasht

Province

Guilan

Postal code

41476-54919

Phone

+98 13 3342 4071

Email

solomonansari@yahoo.com

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
Street address
Lakan Blv
City
Rasht
Province
Guilan
Postal code
41476-54919
Phone
+98 13 3342 4073
Email
solomonansari@yahoo.com

Person responsible for scientific 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
Street address
Lakan Blv
City
Rasht
Province
Guilan
Postal code
41476-54919
Phone
+98 13 3342 4073
Email
solomonansari@yahoo.com

Person responsible for updating data

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
Street address
Lakan Blv
City
Rasht
Province
Guilan
Postal code
41476-54919
Phone
+98 13 3342 4073
Email
solomonansari@yahoo.com

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

There is no more information.

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