Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

The effectiveness of resistance and aerobic trainings on serum levels of TSH and GH, body composition and cognitive functions indexes in adolescents

Protocol summary

Study aim

The effectiveness of resistance and aerobic trainings on serum levels of TSH and GH, body composition and cognitive functions indexes in adolescents

Design

In the first phase of the study, girls and boys subjects were selected and a relationship was made between the amount of daily physical activity and some of the desired variables. In the second phase of the study, subjects will be randomly divided into 12 groups. The trial did not have a drug intervention and therefore there is no blinding. Stratified randomization will be used for grouping .

Settings and conduct

After the call is published in the first secondary schools of the city and suburbs, subjects will be stratified randomization were selected. Different stages of study will be done in Islamic Azad University of Aliabad Katoul branch.

Participants/Inclusion and exclusion criteria

Entry requirements: - Being between 11 and 15 years old - Studying in one of the first secondary schools of Aliabad city - Consent of the family for their child's participation in the trial - Ability to participate in physical exercises Removal conditions: - Taking a specific drug - Suffering from specific physical or mental diseases - Drug abuse - lack of education

Intervention groups

intervention groups: - Active group (boys and girls) including groups: resistance training, aerobic training, control - Inactive group (boys and girls) including groups: resistance training, aerobic training, control A total of 12 groups

Main outcome variables

Daily physical activity level, TSH and GH hormones, body mass index, body fat, body fat percentage, body fat free mass, body fat free mass percentage, waist circumference, short-term working memory, processing process, reaction time, number of errors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180712040448N2**
Registration date: **2023-06-01, 1402/03/11**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-01, 1402/03/11**
Update count: **0**

Registration date

2023-06-01, 1402/03/11

Registrant information

Name

Reza Rezaeshirazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3323 7714

Email address

Dr.rezaee@aliabadiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of resistance and aerobic trainings on serum levels of TSH and GH, body composition and cognitive functions indexes in adolescents

Public title

The effect of physical exercises on TSH, GH, body composition indices and cognitive functions

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Being between 11 and 15 years old Studying in one of the first secondary schools of Aliabad Katul city Consent of the family for their child's participation in the trial Ability to participate in physical exercises

Exclusion criteria:

Taking a specific drug Suffering from specific physical or mental diseases Drug abuse lack of education

Age

From **11 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **600**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were selected by stratified randommization and will be divided into research groups. Randomization Unit: Individual Randomization tool: Table of Morgan random numbers table The participants will be divided into boy and girl groups and then into active and inactive groups. Then they will be placed in the following groups: aerobic exercise, resistance exercise and control.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University, Aliabad Katul Branch

Street address

Aliabad Katul city - University Blvd - 4941793451

City

Aliabad Katul

Province

Golestan

Postal code

4941793451

Approval date

2023-01-08, 1401/10/18

Ethics committee reference number

IR.IAU.AK.REC.1401.003

Health conditions studied

1

Description of health condition studied

Examining changes in TSH hormone

ICD-10 code

E22.9

ICD-10 code description

Hyperfunction of pituitary gland, unspecified

2

Description of health condition studied

Examining changes in GH hormone

ICD-10 code

E22.9

ICD-10 code description

Hyperfunction of pituitary gland, unspecified

3

Description of health condition studied

Examining changes in body composition indices

ICD-10 code

E66.09

ICD-10 code description

Other obesity due to excess calories

4

Description of health condition studied

Examining changes in cognitive function

ICD-10 code

F99

ICD-10 code description

Mental disorder, not otherwise specified

Primary outcomes

1

Description

TSH blood levels

Timepoint

Measurement of TSH blood levels at the beginning of the second phase study (before the start of the intervention)

and 16 weeks later

Method of measurement

laboratory kit

2

Description

GH blood levels

Timepoint

Measurement of GH blood levels at the beginning of the second phase study (before the start of the intervention) and 16 weeks later

Method of measurement

laboratory kit

3

Description

BMI

Timepoint

At the beginning of the first phase of the study and its end

Method of measurement

BMI Formula

4

Description

Short term working memory

Timepoint

At the beginning of the first phase of the study, the beginning of the second phase of the study and its end

Method of measurement

digit span forward test

5

Description

Amount of daily physical activity

Timepoint

At the beginning of the first phase of the study

Method of measurement

International Physical Activity Questionnaire (IPAQ) – Long Form

6

Description

Body fat percentage

Timepoint

At the beginning of the first phase of the study and its end

Method of measurement

Jackson-Pollock Formula

7

Description

Lean body mass percentage

Timepoint

At the beginning of the first phase of the study and its end

Method of measurement

Jackson Pollock's complementary formula

8

Description

processing speed

Timepoint

At the beginning of the first phase of the study, the beginning of the second phase of the study and its end

Method of measurement

digit-symbol coding test

9

Description

reaction time

Timepoint

At the beginning of the first phase of the study, the beginning of the second phase of the study and its end

Method of measurement

computer modified Stroop color-word test

10

Description

error number

Timepoint

At the beginning of the first phase of the study, the beginning of the second phase of the study and its end

Method of measurement

computer modified Stroop color-word test

11

Description

Body fat mass

Timepoint

At the beginning of the first phase of the study and its end

Method of measurement

FM formula

12

Description

Fat-free body mass

Timepoint

At the beginning of the first phase of the study and its end

Method of measurement

PFFM formula

13

Description

waist circumference

Timepoint

At the beginning of the first phase of the study and its end

Method of measurement

tape measure

Secondary outcomes

1

Description
lipid profile
Timepoint
At the beginning of the second phase the study (before the start of the intervention) and 16 weeks later
Method of measurement
laboratory kit

2

Description
Glucose
Timepoint
At the beginning of the second phase the study (before the start of the intervention) and 16 weeks later
Method of measurement
laboratory kit

3

Description
height
Timepoint
At the beginning of the first phase of the study, at the beginning of the second phase of the study and its end
Method of measurement
tape measure

4

Description
Weight
Timepoint
At the beginning of the first phase of the study, at the beginning of the second phase of the study and its end
Method of measurement
digital Balance

5

Description
blood pressure
Timepoint
At the beginning of the first phase of the study, at the beginning of the second phase of the study and its end
Method of measurement
Sphygmomanometer

6

Description
Muscle strength
Timepoint
At the beginning of the first phase of the study, at the beginning of the second phase of the study and its end
Method of measurement
1 RM Formula

7

Description
aerobic power
Timepoint
At the beginning of the first phase of the study, at the beginning of the second phase of the study and its end
Method of measurement
submaximal treadmill test

8

Description
Personality measurement
Timepoint
At the beginning of the first phase of the study and its end
Method of measurement
Eysenck Eysenck Personality Questionnaire (JEPQ) Questionnaire (JEPQ)

9

Description
academic motivation
Timepoint
At the beginning of the first phase of the study and its end
Method of measurement
Harter's standard academic motivation questionnaire

10

Description
moods
Timepoint
At the beginning of the first phase of the study and its end
Method of measurement
Brunel Mood Scale Questionnaire

11

Description
General Health
Timepoint
At the beginning of the first phase of the study and its end
Method of measurement
General Health Questionare (GHQ-28)

12

Description
Internet Addiction
Timepoint
At the beginning of the first phase of the study and its end
Method of measurement
Young's Internet Addiction Questionnaire

13

Description

Appetite

Timepoint

At the beginning of the first phase of the study and its end

Method of measurement

Adolescent Food Habits Checklist (Johnson & et al)

14

Description

Complete Blood count (CBC)

Timepoint

At the beginning of the second phase the study (before the start of the intervention) and 16 weeks later

Method of measurement

Fluorescece Flow Cytometry

15

Description

Speed

Timepoint

At the beginning of the first phase of the study, at the beginning of the second phase of the study and its end

Method of measurement

60 yard test

16

Description

legs explosive power

Timepoint

At the beginning of the first phase of the study, at the beginning of the second phase of the study and its end

Method of measurement

Sargent Jump Test

17

Description

Hands explosive power

Timepoint

At the beginning of the first phase of the study, at the beginning of the second phase of the study and its end

Method of measurement

Medicine ball throw

18

Description

agility

Timepoint

At the beginning of the first phase of the study, at the beginning of the second phase of the study and its end

Method of measurement

T test

Intervention groups

1

Description

Intervention group: Resistance training: Each participant's 6 repetition maximum (6 RM) will use to estimate their 1 RM using the Brzycki formula (%1RM = 102.78–2.78 * repetitions). This will use to determine the load corresponding to the prescribed intensity (% of 1RM) for the first week of training. The resistance training program will inform by accepted guidelines for resistance training in youth and involved a twice a week progressive periodized program including a variety of exercises for all major muscle groups using resistance machine exercises and free weights (bars and dumbbells), medicine balls, Bosu and Swiss balls. Participants perform between 2 and 4 sets of an exercise with between 30–120 seconds rest between sets. Overall, intensity will increase across the 16 weeks such that during weeks 1–5; 16–20 RM with 30 seconds rest between sets, in weeks 6–10; between 8–14 RM, with between 30–120 seconds inter-set rest, and in weeks 11–16; between 6 and 12 RM with 30–120 seconds inter-set rest.

Category

Lifestyle

2

Description

Intervention group: Aerobic training: The intensity of the sessions was progressively will increase from moderate to vigorous across the course of the intervention. In order to determine the HR range which corresponded to the prescribed intensity, we will estimate maximum heart rate according to the Astrand's formula (HR max = 216.6 –(0.84 x age)). Intensity and duration will progresse across the 16-week program as follows: weeks 1–3; 20 minutes at 65–75% of estimated max HR; weeks 4–6; 30 mins at 65–75%, weeks 7–12; 30 minutes at 70–80%, weeks 13–16; 35 minutes at 70–80%. The principal activities will use in aerobic are variations in straight line and multi directional jogging/running, with obstacles such as cones, hoops and speed ladders. Sessions also include step aerobics and sports orientated sessions incorporating balls.

Category

Lifestyle

3

Description

Control group: They received no intervention without any lifestyle changes.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

First Secondary Schools of Aliabad Katoul ity

Full name of responsible person

Reza Rezaeeshirazi

Street address

Islamic Azad University, Aliabad Katul Branch, University Blvd

City
Aliabad Katoul

Province
Golestan

Postal code
93451-49417

Phone
+98 17 3422 3300

Fax
+98 17 3422 5673

Email
Dr.Rezaee@aliabadiau.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University Aliabad Katoul Branch

Full name of responsible person
Salman Amirkhan

Street address
Islamic Azad University, Aliabad Katul Branch, University Blvd

City
Aliabad Katoul

Province
Golestan

Postal code
93451-49417

Phone
+98 17 3422 3300

Email
salman_amirkhani@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 Aliabad Katoul Branch

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University Aliabad Katoul Branch

Full name of responsible person
Reza Rezaeeshirazi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Physiology

Street address
Aliabad Katul City - University Blvd

City
Aliabad Katoul

Province
Golestan

Postal code
4941793451

Phone
+98 17 3422 2300

Email
Dr.Rezaee@aliabadiau.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University Aliabad Katoul Branch

Full name of responsible person
Reza Rezaeeshirazi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
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Street address
Aliabad Katul City - University Blvd

City
Aliabad Katoul

Province
Golestan

Postal code
4941793451

Phone
+98 17 3422 2300

Email
Dr.Rezaee@aliabadiau.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University Aliabad Katoul Branch

Full name of responsible person
Reza Rezaeeshirazi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Physiology

Street address
Aliabad Katul City - University Blvd

City
Aliabad Katoul
Province
Golestan
Postal code
4941793451
Phone
+98 17 3422 2300
Email
Dr.Rezaee@aliabadiau.ac.ir

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
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All information except statistical data; It can be shared after de-identifying the participants.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
Teaching how to sample, randomize, implement the protocol and use tools and tests
From where data/document is obtainable
Dr. reza Rezaeeshirazi Dr.Rezaee@aliabadiau.ac.ir
What processes are involved for a request to access data/document
The applicant will receive the desired answer two weeks after submitting her/his application via email.
Comments