Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effects of Game-Based Exercise and Wheat Germ Extract on Physical Fitness Indicators, Inflammatory–Stress Biomarkers, and Cognitive Function (Concentration and Attention) in Children with Down Syndrome: A Double-Blind Randomized Controlled Trial

Protocol summary

Study aim
This study was designed to investigate the effect of 8 weeks of game-based training and wheat germ extract on physical fitness indices, inflammatory-stress biomarkers, and cognitive function (concentration and attention) in children with Down syndrome.

Design
Controlled clinical trial with three randomized intervention groups on 60 adolescent boys with Down syndrome

Settings and conduct
Male adolescents with Down syndrome at the Ali Ibn Abi Taleb Center in Kermanshah, if eligible, will be enrolled in the study and divided into 4 groups. This study is designed as a double-blind study, with both participants and researchers unaware of group allocation (supplement/placebo).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Genetic confirmation of Down syndrome diagnosis, absence of severe cardiorespiratory diseases, to ensure the absence of underlying cardiovascular diseases, the following will be applied: careful screening with a complete medical history and physical examination by a pediatrician, ability to perform basic movements, negative celiac test in children
Inclusion criteria: unwillingness to participate in the study, occurrence of any sports injury, inability to complete the steps of the sports protocol

Intervention groups
Intervention group 1: 8 weeks of game-based training (3 sessions per week, 40 minutes each session) + 2.5 grams of NBS supplement daily. Intervention group 2:8 weeks of game-based training (3 sessions per week, 40 minutes each session) + 2.5 grams of placebo (potato starch) daily. Intervention group 3: 2.5 grams of NBS supplement daily for 8 weeks. Control group: 2.5 grams of placebo (potato starch) daily for 8 weeks.

Main outcome variables
Physical fitness indices, inflammatory-stress biomarkers (cortisol/CRP), and cognitive function (concentration and attention)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141228020465N9**
Registration date: **2026-09-14, 1405/06/23**
Registration timing: **prospective**

Last update: **2026-09-14, 1405/06/23**
Update count: **0**

Registration date
2026-09-14, 1405/06/23

Registrant information

Name
Fatemeh Omidali

Name of organization / entity
University of Ayatollah Boroujerdi

Country
Iran (Islamic Republic of)

Phone
+98 66 4246 8320

Email address
f.omidali@abru.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2026-10-10, 1405/07/18

Expected recruitment end date

2026-10-21, 1405/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effects of Game-Based Exercise and Wheat Germ Extract on Physical Fitness Indicators, Inflammatory–Stress Biomarkers, and Cognitive Function (Concentration and Attention) in Children with Down Syndrome: A Double-Blind Randomized Controlled Trial

Public title

The Effects of Game-Based Exercise and Wheat Germ Extract on Physical Fitness, Inflammation, Stress, and Cognitive Function in Children with Down Syndrome

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

Genetic confirmation of Down syndrome diagnosis Absence of severe cardiorespiratory diseases Ability to perform basic movements Negative celiac test

Exclusion criteria:

Unwillingness to participate in the study Occurrence of any sports injury Inability to complete the exercise protocol steps

Age

From **12 years** old to **16 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to the four study groups using a block randomization method. The randomization unit is the individual. Stratified randomization will not be used. The random allocation sequence will be generated using statistical software and by an individual independent of the research team prior to the start of participant allocation. After eligibility is confirmed and baseline assessments are completed, each participant will be assigned to one of the four groups based on the randomization sequence. In order to maintain allocation concealment, the randomization sequence will be maintained by an independent individual and will not be made available to the researchers responsible for recruitment and evaluation until each participant is allocated.

Blinding (investigator's opinion)

Double blinded

Blinding description

This research is designed in a double-blind manner, so that both the participants and the researchers will be unaware of the group allocation (supplement/placebo). The supplement and placebo will be prepared in completely identical packages (in terms of appearance, label and method of consumption) and will be distributed by independent staff of the addiction treatment center who are not involved in other parts of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of the Sports Sciences Research Institute

Street address

Number 3,Fifth Alley -Mir Emad St.-Ostad Motahari St.

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2026-07-18, 1405/04/27

Ethics committee reference number

IR.SSRC.REC.1405.039

Health conditions studied

1

Description of health condition studied

Down syndrome

ICD-10 code

Q90.0

ICD-10 code description

Down syndrome

Primary outcomes

1

Description

Cortisol

Timepoint

Before the intervention and 8 weeks after the end of the intervention

Method of measurement

Saliva sample, ELISA kit, use of ELISA reader

2

Description

C-reactive protein

Timepoint

Before the intervention and 8 weeks after the end of the intervention

Method of measurement

Saliva sample, ELISA kit, use of ELISA reader

3

Description

Cognitive function (IVA-2 test)

Timepoint

Before the intervention and 8 weeks after the end of the intervention

Method of measurement

Integrated Visual and Auditory Continuous Performance Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Game-based training + wheat germ extract. Subjects will participate in game-based training for 8 weeks. The training program will consist of three sessions per week, each session lasting 40 minutes. Each session will consist of a 5-minute warm-up, 30 minutes of game-based training, and a 5-minute cool-down. Game-based training will include aerobic, strength, balance, and coordination activities in the form of games appropriate to the children's abilities. At the same time, subjects will receive 2.5 grams of NBS Superfood supplement containing wheat germ extract orally and dissolved in water daily. The supplement will be provided by NBS Superfood (NBS Organic Company, Turkey).

Category

Lifestyle

2

Description

Intervention Group 2: Game-based training + placebo. Subjects will participate in game-based training for 8 weeks. The training program will consist of three sessions per week, each session lasting 40 minutes, including a 5-minute warm-up, 30 minutes of game-based training, and a 5-minute cool-down. The training will include aerobic, strength, balance, and coordination activities in the form of games appropriate to the children's abilities. At the same time, subjects will receive 2.5 grams of placebo (potato starch) daily orally and dissolved in water.

Category

Lifestyle

3

Description

Intervention Group 3: No training + wheat germ extract. Subjects will receive 2.5 grams of NBS Superfood supplement containing wheat germ extract orally and dissolved in water daily for 8 weeks. The supplement will be provided by NBS Superfood (NBS Organic Company, Turkey).

Category

Lifestyle

4

Description

Control group: No training + placebo. Subjects will receive 2.5 grams of placebo (potato starch) orally dissolved in water daily for 8 weeks. This group will not participate in any exercise program and will continue their usual lifestyle during the study period.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ebn Abi Taleb

Full name of responsible person

Mahnaz Karami Mal Amiri

Street address

No. 15, Jalal Najafi Street, Shahid Boulevard, Elahiyeh

City

Kermanshah

Province

Kermanshah

Postal code

6711-6713-6714

Phone

+98 83 3814 0793

Email

Zohreelahi3949@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ayatollah Boroujerdi University

Full name of responsible person

Ali Godaki

Street address
Khorramabad Road.3rd kilometer
City
Boroujerd
Province
Lorestan
Postal code
6919756756
Phone
+98 66 4246 8322
Email
ajoodaki@abru.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Ayatollah Boroujerdi 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
Ayatolah Bourujerdy University
Full name of responsible person
Negin Kordi
Position
Consultant
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Kilometer 3, Khorramabad Road
City
Bourujerd
Province
Lorestan
Postal code
69199-69737
Phone
+98 66 4246 8320
Fax
Email
K_negin_69@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Ayatollah Boroujerdi
Full name of responsible person
Negin Kordi
Position
Consultant
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Kilometer 3, Khorramabad Road
City
Bourujerd
Province
Lorestan
Postal code
69199-69737
Phone
+98 66 4246 8320
Fax
+98 66 4246 8223
Email
K_negin_69@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
University of Ayatollah Boroujerdi
Full name of responsible person
Fatemeh Omidali
Position
Consultant
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Kilometer 3, Khorramabad Road
City
Bourujerd
Province
Lorestan
Postal code
69199-69737
Phone
+98 66 4246 8320
Fax
+98 66 4246 8223
Email
f.omidali@abru.ac.ir

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable