Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect and durability of a course of Exercise Program and sport Game on Actual Motor Competence and Physical Performance of Adolescents with Intellectual Impairment

Protocol summary

Study aim

The purpose is comparison of the effect and durability of a course of exercise program and sport game on actual motor competence and physical performance of people with intellectual disabilities.

Design

A clinical trial with a control group, with parallel groups, double-blind, simple randomized on 45 people with intellectual impairment, which was used for randomization from the random numbers table.

Settings and conduct

The letter of introduction was sent to the management of Exceptional Education in Zanjan province by the university. By studying the medical records of the subjects, and the necessary conditions and criteria for entering and not entering the research, simple randomization will be done first, and then people will be randomly divided into three groups. The study will be double blinded. First, the dependent variables will be evaluated first. Then the interventions will be implemented and re-evaluated for 8 weeks. Finally, after 3 months, the effect and durability of the interventions will be evaluated for the third time.

Participants/Inclusion and exclusion criteria

Children and adolescents with mild intellectual impairment, male or female, and obtaining the consent of their parents and guardians, who are between the ages of 7 and 14 years old and do not have a history of injury or surgery of the lower limbs or neuromuscular diseases and also have the necessary ability to have the implementation of exercise programs.

Intervention groups

Three groups of exercise, sports game and control; the exercise group performs 8 weeks of aerobic and resistance exercises; the sports game group performs 8 weeks of football and basketball game exercise; the control group will not implement exercise programs.

Main outcome variables

Test of gross motor development (Ulrich version-2); gait; functional balance; Static balance

General information

Reason for update

Acronym

ID / II

IRCT registration information

IRCT registration number: **IRCT20230407057840N1**
Registration date: **2023-06-06, 1402/03/16**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-06, 1402/03/16**
Update count: **0**

Registration date

2023-06-06, 1402/03/16

Registrant information

Name
Milad Fadaei Dehcheshmeh
Name of organization / entity
University of Guilan
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect and durability of a course of Exercise Program and sport Game on Actual Motor Competence and Physical Performance of Adolescents with Intellectual Impairment

Public title
Comparison of the effect and durability of a course of Exercise Program and sport Game on Motor Competence and Physical Performance of Adolescents with Intellectual Impairment
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Intellectual Disability (Intellectual Impairment) Being in the group of educable Intellectual Disability (IQ 50-75) The ability to participate in exercise sessions regularly (maximum absence of three sessions during the exercise period) Being in the age range between 7 and 14 years Ability to implement exercise programs The satisfaction of the subjects, their families and their guardians for cooperation in the research
Exclusion criteria:
Not being excessive overweight or obese No history of doing sports and exercises for at least 1 year Avoiding exercises or intense activities during the research Absence of severe structural abnormalities Participation in rehabilitation and occupational therapy courses that have an effect on the exercise program Taking special drugs that affect motor and cognitive function
Age
From **7 years** old to **14 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
In this research, the subjects were selected in an accessible and purposeful way and according to the desired criteria and by simple randomization, using a random numbers table, and Online randomization and using Numbered containers with a random sequence in groups Intervention (exercises and sports games) and control will be divided.
Blinding (investigator's opinion)
Double blinded
Blinding description
People with Intellectual Impairment will be divided according to the simple randomization method (intervention or Control groups). The randomization method is done by one of the researchers and the clinical caregivers, evaluators, participants and data analyzer are blinded.
Placebo
Not used
Assignment
Parallel
Other design features
The present research, after the implementation of 8 weeks of intervention (sports exercises and sports games), in order to evaluate the sustainability of the interventions, after 3 months, the dependent variables will be evaluated again.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Sport Sciences Research Institute (SSRI)
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran
City
Tehran
Province
Tehran
Postal code
4515933156
Approval date
2023-04-19, 1402/01/30
Ethics committee reference number
IR.SSRC.REC.1402.023

Health conditions studied

1

Description of health condition studied
People with intellectual impairment (intellectual disabilities)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

Actual motor competence that expresses fundamental motor skills.

Timepoint

Measurements in the pre-test and before the implementation of the protocol, post-test and after the implementation of the protocol and after 3 months of the implementation of the protocol

Method of measurement

Using test of gross motor development Ulrich version-2

2

Description

Physical performance that includes gait and functional and static balances.

Timepoint

Measurements in the pre-test and before the implementation of the protocol, post-test and after the implementation of the protocol and after 3 months of the implementation of the protocol

Method of measurement

gait using Kinovea software, functional balance using the timed up & go test (TUG) and static balance using the standing stork test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 8-week course (three sessions per week) of exercise with a combination of aerobic and resistance exercises designed for people with intellectual impairment (modeling from similar studies and considering the abilities of people with intellectual impairment) will perform.

Category

Rehabilitation

2

Description

Intervention group: 8-week course (three sessions per week) of sports games with a combination of football and basketball, based on similar studies and according to the abilities of people with intellectual impairment, as well as interest and available facilities, will be designed and implemented.

Category

Rehabilitation

3

Description

Control group: During the period of receiving the protocols by the intervention groups, they continue their normal life and refrain from participating in any regular sports activities.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Exceptional Education of Zanjan Province

Full name of responsible person

Milad Fadaei Dehcheshmeh

Street address

P. 96, Laleh second st, Laleh town

City

Zanjan

Province

Zanjan

Postal code

4515933156

Phone

+98 24 3377 8942

Email

miladfadaei71@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Guilan

Full name of responsible person

Dr. Reza Ebrahimi Atani

Street address

5th Kilometer of Persian Gulf Highway, Faculty of Physical Education, Rasht, Guilan Province

City

Rasht

Province

Guilan

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4199613776

Phone

+98 13 3369 0348

Email

rebrahimi@guilan.ac.ir

Web page address

https://resvp.guilan.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Guilan

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

University of Guilan

Full name of responsible person

Milad Fadaei Dehcheshmeh

Position

Ph.D Candidate

Latest degree

Ph.D.

Other areas of specialty/work

Sport injury and Corrective exercise

Street address

P. 96, Laleh second st, Laleh town

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

No - There is not a plan to make this available

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

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

Data Dictionary

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

Title and more details about the data/document

Only a part of the data, such as the information related to the main outcome or the like, can be shared after the completion of the project.

When the data will become available and for how long

The access period starts 9 months after the publication of the results and articles.

To whom data/document is available

The data will be available to researchers.

Under which criteria data/document could be used

The detailed information of the study can be provided to competent researchers interested in the field of intellectual impairment.

From where data/document is obtainable

Contact by email: miladfadaei71@gmail.com

What processes are involved for a request to access data/document

Competent and interested researchers can receive data documentation after publication of the work from the corresponding author by providing their academic information and identification.

Comments

This clinical trial with the title "Comparison of the effect and durability of a course of Exercise Program and sport Game on Actual Motor Competence and Physical Performance of Adolescents with Intellectual Impairment" has not been previously registered anywhere else and has not been sent anywhere else at the same time. We are very happy to register our clinical trial with IRCT. Thank you. Wishing you health and happy moments.