Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of a course of local adaptive games on basic skills, cognitive and behavioral characteristics in mentally retarded people.

Protocol summary

Study aim

The main purpose of this research is to investigate the effect of a training course of local adaptive games on motor skills, cognitive and behavioral characteristics in mentally retarded people. Determining the effect of a training course of local adaptive games on self-efficacy, aggression, adaptive behavior and motor skills of mentally retarded children.

Design

A clinical trial with a control group, with a parallel experimental group with a blind evaluator, randomized on 40 participants, was used to randomize the Random Allocation software.

Settings and conduct

This study will be held in schools for exceptional children in Chaharmahal and Bakhtiari province, where the evaluator will be blinded and will not know the results of the tests: the classes of the experimental group will be held for 3 months. Classes will include rhythmic games with music, local games.

Participants/Inclusion and exclusion criteria

Conditions for entering the intervention: children 8 to 12 years old studying in elementary schools for exceptional children in Chaharmahal and Bakhtiari provinces. Conditions for not entering the intervention: children over 12 years old and higher than elementary school.

Intervention groups

The group of experimental interventions has three sessions per week for 12 weeks and the duration of the training is based on the complexity of the games, the amount of execution of the initial position, the range of movements, the distance and the amount of rest between exercises of 90 minutes. The control group will continue their routine life and only participate in the pre-test and post-test.

Main outcome variables

Raven's intelligence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220920055996N1**
Registration date: **2022-10-18, 1401/07/26**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-18, 1401/07/26**
Update count: **0**

Registration date

2022-10-18, 1401/07/26

Registrant information

Name

Fakhroldin Asadi Farsani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3535 4001

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-15, 1401/07/23

Expected recruitment end date

2023-01-13, 1401/10/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a course of local adaptive games on basic skills, cognitive and behavioral characteristics in mentally retarded people.

Public title

The effect of a course of local adaptive games on basic skills, cognitive and behavioral characteristics in mentally retarded people.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Absence of cardiovascular disease Not having any neurological disorder Not having movement problems and walking independently Education in primary schools for exceptional children in Chaharmahal and Bakhtiari province Having the criteria for diagnosing the disorder based on the cutoff score Parental consent Age 8 to 12 years

Exclusion criteria:

The occurrence of orthopedic problems for the participants Parents' unwillingness to cooperate despite initial consent Failure to attend the post-examination on time The number of absences of more than 3 sessions during the exercise protocol

Age

From **8 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to two experimental groups and a control group with a 1:1 allocation ratio. Block randomization method will be used for random allocation of participants. The name of the software is random allocation software. We put the data into the software and then the software does it.

Blinding (investigator's opinion)

Single blinded

Blinding description

After allocation it was not possible to keep the trainer bilnd to each participant's allocated intervention. But the evalutor remained bilnd. According to the evaluator's opinion, this study was blinded in order not to enter incorrect information or borrowing that may occur in any person, so that it can be done without information about the purpose of this research and the purpose of the tests.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Azad University of Khorasgan branch

Street address

University Blvd, Arghavanieh Ave, Eastern Jey Str, Esfahan Town

City

Esfahan

Province

Isfehan

Postal code

8155139998

Approval date

2019-06-25, 1398/04/04

Ethics committee reference number

IR.IAU.KHUISF.1398.097

Health conditions studied

1

Description of health condition studied

Mentally retarded children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The IQ of mentally retarded children

Timepoint

The first session will be taken at the beginning of the pre-test intervention and the post-test will be taken after 12 weeks of the end of the intervention.

Method of measurement

Using Raven's progressive matrices test in adult form

Secondary outcomes

1

Description

The level of self-efficacy of mentally retarded children

Timepoint

A pre-test will be taken in the first session and a post-test will be taken after 12 weeks of intervention.

Method of measurement

Wheeler and Led questionnaire will be used to measure self-efficacy.

2

Description
The level of aggression of mentally retarded children
Timepoint
A pre-test will be taken in the first session and a post-test will be taken after 12 weeks of intervention.
Method of measurement
Aggression questionnaire of mentally retarded children was used.

Intervention groups

1

Description
Intervention group: The experimental intervention group participated in the local indigenous exercises and games and rhythmic games and participated in the pre-test in the first session of the intervention and will participate in the post-test after 12 weeks at the end of the intervention.
Category
Rehabilitation

2

Description
Control group: In this group, there are no interventions and only at the beginning of the interventions, the intervention group will participate in the pre-test and after 12 weeks they will participate in the post-test.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Student Martyrs Sports Complex
Full name of responsible person
Alireza Talebi
Street address
Student Martyrs Sports Complex, Shohada Str, North Farabi Blvd, Shahre Kord
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Majid Toghiyani
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University Blvd, Arghavanieh Ave, Estern Jey Str, Esfahan Town
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Fakhruddin Asadi Farsani
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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Fakhroldin Asadi Farsani
Position
Student
Latest degree
Master
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Person responsible for scientific inquiries

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Latest degree
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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
Yes - There is 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The data file of the participants is in the form of a complete Excel, in which the children's history, underlying disease and surgical history, and the degree of mental retardation are fully stated. The informed consent form will be designed and available to each participant. After completing the intervention steps, a complete report of the clinical interventions will be prepared and documented in an accessible file.

When the data will become available and for how long
All the documentary files will be available after the interventions and after the results and approval of the relevant judges and professors and after printing.

To whom data/document is available
People related to this research will be allowed to access, such as supervisors and advisors and referees, in addition to the details of the participants, other researchers working in academic and scientific institutions will have the necessary access.

Under which criteria data/document could be used
Access to all parts of this study will be granted solely for treatment and to supplement and improve research.

From where data/document is obtainable
To get information, you can refer to the email address fakhroldin.asadi@yahoo.com.

What processes are involved for a request to access data/document
Applicants can access the information after one working week after entering the email to the entered email address.

Comments