Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Brailletonik exercises, treadmill and computer games on executive functions, motor and social skills of mentally retarded children

Protocol summary

Study aim

evaluate the effectiveness of brailletonik, treadmill and computer games exercises on executive functions, social and motor skills of mentally retarded children.

Design

The statistical sample of this study will be selected from mentally retarded children referring to Kahrizak Rehabilitation Center in Alborz province in the academic year of 97-98. This study will be consisted of 32 educable girls with intellectual disability that randomly are placed into 4 groups of computer games, brailletonik exercises, treadmill exercises and control. A game that included a variety of puzzles will be presented to the computer game group for 45 minutes. The brailletonik team will perform exercises such as warm-up, use of coding, use of six squares, and cooling over 45 minutes. The treadmill group will do warm-up, children's treadmill exercises, and cooled down for 45 minutes.

Settings and conduct

All stages of this research will be carried out from sample selection to data collection at Kahrizak Rehabilitation Center in Alborz province in the academic year 98-97.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Diagnosis of mentally retarded disorder of educational type (IQ score between 50 and 70) 2. Female gender 3. Age range from 8 to 11 years 4- Being matched in terms of motor development

Intervention groups

A game that included a variety of puzzles will be presented to the computer game group for 45 minutes. The brailletonik team will perform exercises such as warm-up, use of coding, use of six squares, and cooling over 45 minutes. The treadmill group will do warm-up, children's treadmill exercises, and cooled down for 45 minutes.

Main outcome variables

executive functions, social and motor skills of mentally retarded children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190802044406N1**
Registration date: **2020-01-16, 1398/10/26**
Registration timing: **retrospective**

Last update: **2020-01-16, 1398/10/26**
Update count: **0**

Registration date

2020-01-16, 1398/10/26

Registrant information

Name

Manizhe Ghassemi

Name of organization / entity

Khurazmi university of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 26 3457 5014

Email address

std_ghassemi.m93@khu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of Brailletonik exercises, treadmill and computer games on executive functions, motor and social skills of mentally retarded children

Public title
The effect of Brailletonik exercises, treadmill and computer games on executive functions, motor and social skills

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of Educable Mental Disability (IQ score between 50 and 70) Female gender Age range from 8 to 11 years Peer in terms of motor development

Exclusion criteria:
Diagnosis of any illness or mental and physical disorder (other than mental retardation) that may affect research results, such as the diagnosis of head trauma or symptoms of psychosis.

Age
From **8 years** old to **11 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be based on randomized block design with block size 4 (using table of random permutations) and assignment ratio of 1: 1. To ensure that the assignment to each group will be kept confidential, after randomization, participants' codes will be covered by closed envelopes by a person who that unaware of the purpose of study. Until the intervention of the researcher and the participant, he or she will do not know in which group he will be placed. Subjects will be randomly divided into four groups of eight (8 in the Brailltonic group, 8 in the treadmill group, 8 in the computer game group, and 8 in the control group).

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 Tarbiat Modarres University

Street address
Jalal Ale Ahmad

City
Tehran

Province
Tehran

Postal code
14115-111

Approval date
2019-05-06, 1398/02/16

Ethics committee reference number
IR.MODARES.REC.1398.025

Health conditions studied

1

Description of health condition studied
Mental retardation

ICD-10 code
F70

ICD-10 code description
Mild mental retardation

Primary outcomes

1

Description
Executive functions

Timepoint
At baseline and 60 days later

Method of measurement
stroop

2

Description
Motor skills

Timepoint
At baseline and 60 days later

Method of measurement
Continuous Performance Test

3

Description
social skill

Timepoint
At baseline and 60 days later

Method of measurement
Vineland Adaptive Behavior Scale

Secondary outcomes

empty

Intervention groups

1

Description
In this group, Brailletonic exercises will be used for intervention. Brighton exercises such as warm-up, coding, using six squares, and cooling will be performed for 45 minutes. In general, the warm-up is 10 minutes, the training is 30 minutes, and the general body cooling is 5 minutes. Exercise intensity start with 50-60% of maximal heart rate and at the end of the eighth week it will be tried to reach 70-80% of maximal heart rate based on research findings using Polar pacemaker.

Category
Rehabilitation

2

Description
In this group, treadmill exercises will be used for intervention. The group Ventures warm-ups, treadmill training, and cooling down for 45 minutes. In general, the warm-up is 10 minutes, the training is 30 minutes, and the general body cooling is 5 minutes. Exercise intensity start with 50-60% of maximal heart rate and at the end of the eighth week it will be tried to reach 70-80% of maximal heart rate based on research findings using Polar pacemaker.

Category
Rehabilitation

3

Description
In this group, the intervention will be a computer game. Computer gaming is a type of interactive entertainment performed by an electronic device equipped with a processor or micro controller. These types of games based on the style of play and graphics are divided into different forms, such as educational, racing, sports, etc. In this group, the game will be adapted from a puzzle game of type Farm and Castles 1.2 8.5473.21-2 for 45 minutes.

Category
Rehabilitation

4

Description
The control group will received no intervention and its members will be performed the same routine procedure as the center.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Kahrizak Rehabilitation Center

Full name of responsible person
Manizhe Ghasemi

Street address
Mohammad Shahr, end of Golestanak street, at the beginning of Esfahani street

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Mohammadshahr

Province
Alborz

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31845-167

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Email
Kahraj@kahrizak.com

Web page address
http://kahrizak.com/contact-us/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Khurazmi university of Tehran

Full name of responsible person
Manizhe Ghasemi

Street address
Khurazmi university

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Karaj

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Alborz

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15719-14911

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info@khu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
دانشگاه خوارزمی

Proportion provided by this source
10

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
Kharazmi University of Tehran
Full name of responsible person
Manizhe Ghasemi
Position
Phd student
Latest degree
Ph.D.
Other areas of specialty/work
Physical Education
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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