

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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 Brailletonic 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

#### City

Mohammadshahr

#### Province

Alborz

#### Postal code

31845-167

#### Phone

+98 26 3630 9171

#### Fax

+98 26 3630 1859

#### 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

##### City

Karaj

##### Province

Alborz

##### Postal code

15719-14911

##### Phone

+98 21 8832 9222

##### Fax

+98 21 8832 9222

##### Email

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

**Street address**

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std-Ghasemi.m93@khu.ac.ir

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Kharazmi University of Tehran

**Full name of responsible person**

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**Position**

PhD student

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**Email**

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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