

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of balance with gross motor exercises on gross motor and balance function in children with mental retardation

Protocol summary

Summary

Motor perceptual abilities are based on motor functions and conceptual growth. Therefore, given that the perceptual-motor abilities are weak in mental retarded children; paying attention to motor problems in these children will be a useful step to eliminate the problems of learning and to improve their function activities at school, home and society. Our purpose in this study is to investigate the effect of the balance along with gross movement exercises on gross movement and balance function in these children. In this study, using a simple non-probability sampling method, based on a pilot sample and the sample size formula were considered 10 children in the treatment group and 10 children in the control group. Inclusion criteria include Educable Down Syndrome children with conform diagnosis by clinical psychologist, Educable Down Syndrome children without significant skeletal, neurological and mental illness and the age group is between 4.5 and 14.5 years. Exclusion criteria include non-cooperative child, Child injury accident in the length of treatment and Absence more than one session. Treatment group for 10 weeks, 3 sessions per week for 30-minute exercises; balance training (15 minutes) and gross motor (15 minutes) are taught. Control group were without intervention. After that, all the subjects will be retested. After statistical analysis, the effectiveness of the treatment on balance and gross motor function will be investigated. The survey is single blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012072510387N1**

Registration date: **2013-06-03, 1392/03/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-06-03, 1392/03/13

Registrant information

Name

Shahla Rafiee

Name of organization / entity

Tehran University Rehabilitation College

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences, 4th Floor, Tehran University Central Building, Keshavarz Blvd, Tehran, Iran.

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of balance with gross motor exercises on gross motor and balance function in children with mental retardation

Public title

The effect of balance and gross motor exercises on gross

motor and balance function

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria: - Educable Mental Retarded children with conform diagnosis by clinical psychologist - Educable Mental Retarded children without significant skeletal, neurological and mental illness, significant attention deficit disorder, epilepsy and other disease such as musculoskeletal and neurological disease and fractures and so on. - The age group is between 4.5 and 14.5 Exclusion criteria: - Non-cooperative child - Child injury accident in the length of treatment - Absence more than one session

Age
From **5 years** old to **14 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features
In this study, simple random sampling was used to determine the intervention and control groups. Study is a blind test and Examiners of whether a student belongs to the control group or the intervention group are unaware.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Tehran University of Medical Sciences

Street address

4th Floor, Tehran University of Medical Sciences
Central Building, Keshavarz Blvd

City

Tehran

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1545913487

Approval date

2012-09-10, 1391/06/20

Ethics committee reference number

17961

Health conditions studied

1

Description of health condition studied

Mental Retardation

ICD-10 code

F70

ICD-10 code description

Approximate IQ range of 50 to 69 (in adults, mental age from 9 to 12 years). Likely to result in some learning difficulties in school. Many adults will be able to work and maintain good social relationships and contribute to society.

Primary outcomes

1

Description

Balance skills

Timepoint

Before and after intervention

Method of measurement

Bruininks RH. Bruininks _Oseretsky Test

2

Description

Gross motor skills

Timepoint

Before and after intervention

Method of measurement

Bruininks RH. Bruininks _Oseretsky Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention included Balance and gross motor exercise. These exercises are designed from easy to hard. Subjects for 10 weeks, 3 sessions per week for 30-minute exercises; balance training (15 minutes), gross motor (15 minutes) are taught.

Category

Rehabilitation

2

Description

control group: Control group without intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghods Special School

Full name of responsible person

Ghamari Narges

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No

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr Fotouhi

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4th Floor, Tehran University Central Building, Keshavarz Blvd

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Tehran

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Education and Training

Full name of responsible person

Ghamari Narges

Position

Occupational therapist/Occupational Therapy

Other areas of specialty/work

Street address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rehabilitation Faculty, Tehran University of Medical Sciences

Full name of responsible person

Rafiee Shahla

Position

Master of Health Education

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Rafiee Shahla

Position

Mentor-Master of Science

Other areas of specialty/work

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No

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty