

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The study of the effect of progressive resistance exercise in 8-11 years old children with down syndrome, with use of Bruininks Oseretsky Test

Protocol summary

Summary

The purpose of this study is the effect of progressive resistance exercise on balance of 8-11 years old children with down syndrome. This study is an intervention study. By going to exceptional schools introduced by exceptional education and gaining the school officials' approval, 8-11 years old children with down syndrome with an IQ of 50-70 and with the mentioned conditions will appear in the study: 1- disparticipation of cases in the strength exercises in the last 3 months 2- not consuming any drugs which have effects on the muscles' strength 3- having normal optical & hearing abilities with/without auxiliary equipment Any kind of non cooperation discovered from the child or his/her parents will lead to the exclusion of the child from the study. Twenty children with down syndrome are divided in two control and intervention groups randomly. The cases in the intervention group have to participate in for 3 days per week, for 6 weeks. Every session takes 20 min. The cases in the control group will continue their regular activities followed at school. Before and after the intervention the child's strength and balance will be evaluated and these data will be collected and assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204199517N1**

Registration date: **2012-07-06, 1391/04/16**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-07-06, 1391/04/16

Registrant information

Name

Tayebeh Sayadinezhad

Name of organization / entity

Tehran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8474 1538

Email address

sayadinezhad@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2012-11-21, 1391/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the effect of progressive resistance exercise in 8-11 years old children with down syndrome, with use of Bruininks Oseretsky Test

Public title

The effect of progressive resistance exercise on children with down syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- age between 8 to 11 years old; 2-IQ between 50 to 70; 3- disparticipation of cases in the strength exercises in the last 3 months; 4- not consuming any drugs which have effects on the muscles'

strength; 5- having normal optical & hearing abilities with/without auxiliary equipment; 6- not having any cardio_vascular disorders and 7- not having any neurology disorders Exclusion criterion: any kind of non cooperation discovered from the child or his/her parents.

Age

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

Gender

Both

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)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran university of medical sciences

Street address

The center of students research, School of Medical Sciences, the third floor, Poursina street, Quds street, Enqelab Street

City

Tehran

Postal code

Approval date

2012-06-19, 1391/03/30

Ethics committee reference number

91-01-61-16981-56814

Health conditions studied

1

Description of health condition studied

down syndrome

ICD-10 code

f70

ICD-10 code description

Mild mental retardation

Primary outcomes

1

Description

Hip abductor and knee extensor muscles isometric strengths

Timepoint

Every 2 week

Method of measurement

Nicholas manual muscle test

2

Description

Balance

Timepoint

Pre and post intervention

Method of measurement

Balance subscale of Bruininks Oseretsky Test of Motor Proficiency

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: The subjects participated three times per week in a six-week, progressive, free-weight, strengthening programme. Free weights were used to provide resistance for the strength training in the form of adjustable weight cuffs attached by Velcro straps. For training, the children were positioned as for muscle strength testing with free weights. The training weight (TW) used in this study was 65% of the mean maximum isometric muscle strength value for each individual. Maximum strength was re-measured every two weeks during the six-week programme and the TW reset at 65% of the new value. At each TW the children progressed from three sets of five repetitions, to four sets of five, then three sets of ten as the number of repetitions became easy.

Category

Rehabilitation

2

Description

control group: will continue their regular activities followed at school

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Piruzi Center
Full name of responsible person
Mis . Khedmeti
Street address
Valiasr street, Pesyan street,Ardabili street
City
Tehran

2

Recruitment center
Name of recruitment center
Sayad shirazi Center
Full name of responsible person
Street address
City
Tehran

3

Recruitment center
Name of recruitment center
Ershad center
Full name of responsible person
Mr. Moqadam
Street address
Bridge Gisha, Patris lobumba street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Akbar Fotuhi
Street address
Vice chancellor for research, Tehran University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Tehran University of Medical Sciences
Full name of responsible person
Sayadinezhad Tayebbeh
Position
MSc candidate
Other areas of specialty/work
Street address
The center for students research, School of Medical Sciences, The third floor, Poursina street, Quds street, Enqelab Street
City
Tehran
Postal code
Phone
+98 936 744 6507
Fax
Email
sayadinezhad@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sayadinezhad Tayebbeh
Position
MSc candidate
Other areas of specialty/work
Street address
The center for students research, School of Medical Sciences, The third floor, Poursina street, Quds street, Enqelab Street
City
Tehran
Postal code
Phone
+98 936 744 6507
Fax
Email
sayadinezhad@razi.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sayadinezhad Tayebbeh
Position
MSc candidate
Other areas of specialty/work
Street address

The center for students research, School of Medical Sciences, The third floor, Poursina street, Quds street, Enqelab Street

City

Tehran

Postal code

Phone

+98 936 744 6507

Fax

Email

sayadinezhad@razi.tums.ac.ir

Web page address

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