

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Effect 12 weeks group progressive resistance exercise with musical background on gross motor function and Participation in activity sports children with cerebral palsy of spastic

#### Protocol summary

##### Summary

1- objective: Muscle weakness is a common disorder in children with cerebral palsy of spastic Which can be causes problems in performing skills such as standing, walking and running. The objective of the present study was to the effects 12 weeks group progressive resistance exercise with musical background on gross motor function and Participation in sport activity of children with cerebral palsy of spastic diplegia. Design: Twenty - Seven ambulation children with spastic CP Occupational therapy clinics and special schools Alborz of Province which include nine girls & eighteen boys with a mean age of girls (10/5 years) and boys (11 years) were divided into an intervention & control group randomly. 3-Setting and conduct: intervention group performed group progressive resistance exercise with musical background for 12 weeks (3 sessions per week and each session lasted for 55 min) that focused on lower limb muscles. In order to measure of gross motor function was used the dimension D (standing) & E (walking, running and jumping) GMFM test & for measure Participation in activity sports was used the The Children's Assessment of Participation and Enjoyment questionnaire (CAPE). 4- Participants . major criteria of entry into the study: Spastic diplegia cerebral palsy; Ability to stand and walk independently at home or without auxiliary equipment; No obvious limitation in the lower extremity passive range; Ability to understand commands and collaboration during the test 5. major eligibility criteria of Exit the Study: any Diseases such as heart disease, diabetes, seizure, etc ; any lower limb fixation; orthopedic surgery and botulinum toxin injections in the 6 months before the intervention (or as planned during the study); do not practice Strength at least 3 months before the intervention; using medications that can help muscle tone or muscle strength Influenced by the occurrence of orthopedic

events during the study; the lack of cooperation between the child and the parents. 5- Interventions: intervention group performed group progressive resistance exercise with musical background for 12 weeks (3 sessions per week and each session lasted for 55 min). 6- main outcome measures variables: gross motor function- sports participation

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017090836095N1**

Registration date: **2017-11-07, 1396/08/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-07, 1396/08/16

##### Registrant information

###### Name

Hamidreza Sajadi

###### Name of organization / entity

Kharazmi

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 5241 7410

###### Email address

hamidrezasajadi68@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research of deputy of School of Physical Education, Kharazmi University of Tehran

**Expected recruitment start date**

2014-09-23, 1393/07/01

**Expected recruitment end date**

2014-11-22, 1393/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect 12 weeks group progressive resistance exercise with musical background on gross motor function and Participation in activity sports children with cerebral palsy of spastic

**Public title**

Effect 12 weeks group progressive resistance exercise with musical background on gross motor function and Participation in activity sports children with cerebral palsy of spastic

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

The criteria for entering the study include: 1- Spastic diplegia cerebral palsy; 2- Ability to stand and walk independently at home or without auxiliary equipment (children at the level of GMFCS I-III); 3. No obvious limitation in the lower limb's passive range; - Ability to understand commands and collaboration during the test. Exit criteria include: 1- Any illnesses such as heart disease, diabetes, seizure, etc. 2- Any deformity fixed in the lower extremity; 3. Orthopedic surgery and botulinum toxin injection in the 6 months before the intervention (or Scheduled form during the study); 4) failure to exercise strength for at least 3 months before the intervention; 5) use of medications that may affect muscle tone or strength; 6) the occurrence of orthopedic events during the study; And 7. The lack of cooperation between children and parents.

**Age**

From **85 years** old to **79 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **28**

**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**

Ethics Committee, Faculty of Physical Education, Kharazmi University of Tehran

**Street address**

Shahid Beheshti St, Hesarak Sqare, Alborz, Iran. Motor Behavior Department, Physical Education Faculty, Kharazmi University

**City**

karaj

**Postal code**

03197937551

**Approval date**

2017-09-06, 1396/06/15

**Ethics committee reference number**

letter number: t64/83

**Health conditions studied****1****Description of health condition studied**

cerebral palsy

**ICD-10 code**

G00-G99

**ICD-10 code description**

Nervous system disease (tremor, neurological discomfort, flea ...)

**Primary outcomes****1****Description**

Gross motor function

**Timepoint**

After 12 weeks

**Method of measurement**

with gross motor function test (GMFM-66)

**2****Description**

Participation in activity sports

**Timepoint**

After 12 weeks

**Method of measurement**

with The Children's Assessment of Participation and Enjoyment questionnaire (CAPE).

**Secondary outcomes**

## 1

### Description

Ability to walk fast

### Timepoint

After the end of 12 weeks

### Method of measurement

1-Minute fast walk test

## Intervention groups

## 1

### Description

The training program includes 12 weeks, 3 sessions per week and 60 minutes per session (with a rest day between each training session). The training program included 10 minutes of warming and stretching, 40 minutes of exercise and 10 minutes of cool and tensile style movements. The amount of exercise load (severity) increased gradually based on the ability of individuals. In this study, the principles of increasing NCSA and ASCM resistance training were used. In order to get the weight of the training, the participants was initially weared a body vest and Foot lift, with the weight of half and a kilogram in front and back equal in this vest. In order to determine the amount of exercise load, the child started with 6 repetitions with a weight of less than one maximum repetition and based on the number of repetitions and based on the weight of the carried amount was calculated a maximum repetition . Resistance training is performed in a group with exciting and motivational music such as disco, rock, pop, which is common in gym clubs. An exciting, fast-paced music with loud rhythm patterns and temptations ranging from 124 to 128 bpm (multiples per minute) was used to increase the children's stimulus and excitement to further engaging in exercises. The exercise was conducted by the leader of the group and gave the members of the group instructions for modifying movements and increasing motivation. The coach encouraged the participants to participate more during the session, and at the end of each week the training would also be awards for the participants.

### Category

Rehabilitation

## 2

### Description

Control group: The control group received only ordinary daily care and did not participate in any resistance training program during 12 weeks. No intervention was performed on them.

### Category

Rehabilitation

## Recruitment centers

## 1

### Recruitment center

### Name of recruitment center

Sun clinic

### Full name of responsible person

Mrs. Azar

### Street address

Plate 1, Block 3, Phase 3, 13th West Street, Revolution Boulevard, Gohardasht, Karaj

### City

Karaj

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Vice Chancellor for Research of deputy of School of Physical Education, Kharazmi University of Tehra

#### Full name of responsible person

Dr. Haidar Sadeghi

#### Street address

Shahid Beheshti St, Hesarak Sqare, Alborz, Iran. Motor Behavior Department, Physical Education Faculty, Kharazmi University

#### City

Karaj

#### Grant name

شماره راهنما: پ ت ر، ۴۱۰۰/۳۰۰۰

#### Grant code / Reference number

شماره مدرک: پ۴۱۰۳۰۰/۴۱۰۳

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

Yes

#### Title of funding source

Vice Chancellor for Research of deputy of School of Physical Education, Kharazmi University of Tehra

#### Proportion provided by this source

#### 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

## 2

### Sponsor

#### Name of organization / entity

Department of Welfare of Alborz Province

#### Full name of responsible person

Dariush Bayat Nejad

#### Street address

Culture St, Taleghani Sqare, Cooperative Blvd, Alborz, Iran

#### City

karaj

#### Grant name

شماره راهنما: پ ت ر، ۴۱۰۰/۳۰۰۰

#### Grant code / Reference number

Document number:410300/410p

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

Yes

**Title of funding source**

Department of Welfare of Alborz Province

**Proportion provided by this source**

**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**

Kharazmi University

**Full name of responsible person**

Hamid Reza Sajjadi

**Position**

M.A

**Other areas of specialty/work**

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**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*