Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 devideded 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
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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 . Ressistance 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،۴۱۰/۳۰۰۰
Grant code / Reference number
شماره مدرک:پ410300/410
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،۴۱۰/۳۰۰۰
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