Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of exercise therapy with Swiss ball on the trunk control and balance in children with spastic cerebral palsy

Protocol summary

Study aim

To determine the effect of exercise therapy with Swiss ball on the trunk control and balance in children with spastic cerebral palsy

Design

This study is 2-armed, double-blind RCT with one to one allocation in two groups (group 1: exercise with Swiss ball, group 2: trunk control exercise on the floor) in children with spastic cerebral palsy , where the person evaluating the outcome measures will be completely blind to the type of exercise each group will have receive. Additionally, participants will be blind because there is no difference between the two groups in terms of exercise positions, and duration treatment sessions.

Settings and conduct

The intervention is performed in the community rehabilitation and the finder. In this study, both the participants and the assessor are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria include diagnosis of spastic hemiplegia/ diplegia, Having age range between 6 and 12 years old and Having motor function at levels between 1 and 3 exclusion criteria include occurrence orthopedic events during treatment having body mass index above 25 and Ability to active straight leg raise and maintain the position until the abdominal muscle image is recorded

Intervention groups

participants in intervention group, will receive "exercise with Swiss ball" and in control group, they will receive " trunk control exercise on floor" 5 weeks, three sessions per week.

Main outcome variables

trunk control score

General information

Reason for update

In the inclusion criteria, the ability to raise the straight leg actively and maintain it when the ultrasound instrument records the abdominal muscle image is added. because during the study, it will be hard to record the image of the abdominal muscles in the hip flexion position by sonography instrument for children who do not have this ability. Moreover, Due to the decrease in the severity of the corona pandemic, the treatment at the patient's home is eliminated because the patients are referred to the Community Rehabilitation and the Finder for receiving physiotherapy services. Also, this center is added to the patient reception center. Additionally, in the sample randomization section, "cerebral palsy type" has been replaced by "gross motor function classification scale" because during the pilot study we realized that cerebral palsy children with moderate motor impairment severity (grade 3 of the gross motor function classification scale) who are able to perform hip flexion, and maintain it when the ultrasound instrument records the abdominal muscle image are rare.

Acronym

IRCT registration information

IRCT registration number: **IRCT20140222016680N8**
Registration date: **2021-05-14, 1400/02/24**
Registration timing: **prospective**

Last update: **2022-09-03, 1401/06/12**
Update count: **1**

Registration date

2021-05-14, 1400/02/24

Registrant information

Name

Shohreh Noorizadeh Dehkordi

Name of organization / entity

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-08-01, 1400/05/10
Expected recruitment end date
2022-09-22, 1401/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of exercise therapy with Swiss ball on the trunk control and balance in children with spastic cerebral palsy

Public title
The effect of exercise therapy with ball in children with cerebral palsy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Have a diagnosis of spastic diplegia / hemiplegia as determined by a pediatric neurologist Having age range between 6 and 12 years old Having motor function at levels between 1 and 3 based on the "Gross Motor Function Classification Scale" Ability to understand and follow verbal instructions No severe visual or hearing impairment Having a score above 70 in the "SPARCLE "questionnaire Ability to active straight leg raise and maintain it when the ultrasound instrument records the abdominal muscle image
Exclusion criteria:
Having a seizure is not controlled Having a body mass index above 25 due to reduced reliability of ultrasonography images
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Stratification and Random blocks with four blocks will be used for randomization. The randomization type using the stratification method will be performed in four classes: cerebral palsy type of diplegia and hemiplegia, the age range between 6 to 9 years and 9 to 12 years using 4 blocks. For concealment in the randomization process, a unique code will be used on each envelope.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study ,Assessor who evaluates the outcome measures of study and the participants in the study will be blind to the allocation of the two treatment groups. Additionally the data also will be evaluated by a person who is blind to the allocation and treatment of groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Iran University of Medical Sciences
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Iran University of Medical Sciences, Hemmat Expressway, Tehran, Iran
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۱۴۴۹۶۱۴۵۳۵
Approval date
2021-04-18, 1400/01/29
Ethics committee reference number
IR.IUMS.REC.1400.041

Health conditions studied

1

Description of health condition studied
spastic cerebral palsy
ICD-10 code
G80
ICD-10 code description
Cerebral palsy

Primary outcomes

1

Description
Trunk control score
Timepoint
Measurement of trunk control before intervention, after

intervention and one month after the end of the intervention

Method of measurement

"Trunk Control Measurement Scale"

Secondary outcomes

1

Description

Balance score

Timepoint

Before intervention, after intervention and one month after the end of the intervention

Method of measurement

"Pediatric Balance Scale"

2

Description

Gross Motor Function Score

Timepoint

Before intervention, after intervention and one month after the end of the intervention

Method of measurement

Levels of D and E of the "Gross Motor Function Measurement"

3

Description

Functional Mobility Score

Timepoint

Before intervention, after intervention and one month after the end of the intervention

Method of measurement

"Pediatric Evaluation of Disability inventory"

4

Description

Abdominal Muscles Thickness

Timepoint

Before intervention, after intervention and one month after the end of the intervention

Method of measurement

Sonography

Intervention groups

1

Description

Intervention group: In this group, exercises with Swiss ball, will be given in a period of 5 weeks, three sessions per week. Each treatment session starts with warming up and then special exercises are given with focus on improving trunk control in supine, prone, sitting, quadruped and standing positions and then it ends with cooling down. Each treatment session, depending on the patient needs to rest, lasts approximately 45 minutes. Required equipment are mats and gymnastics ball. Trunk control score, pediatric balance score, gross motor function score, functional mobility score, abdominal muscle thickness(internal oblique, external oblique and transverse abdomen) at rest and hip flexion will be measured before the intervention, the last session of treatment and one month after the end of intervention.

Category

Rehabilitation

2

Description

Control group: Intervention group: In this group, trunk control exercises on floor, will be given in a period of 5 weeks, three sessions per week. Each treatment session starts with warming up and then conventional exercises are given with focus on improving trunk control in supine, prone, sitting, quadruped and standing positions and then it ends with cooling down. Each treatment session, depending on the patient needs to rest, lasts approximately 45 minutes. Required equipment are mats and chairs. Trunk control score, pediatric balance score, gross motor function score, functional mobility score, abdominal muscle thickness(internal oblique, external oblique and transverse abdomen) at rest and hip flexion will be measured before the intervention, the last session of treatment and one month after the end of intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurological physiotherapy Clinic, School of Rehabilitation Sciences, Iran University of Medical sci

Full name of responsible person

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2

Recruitment center

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
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

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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