

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Additionally, in the sample randomization section, "cerebral palsy type" has been replaced by "gross motor function classification scale" because during the pilot study we realized that cerebral palsy children with moderate motor impairment severity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

Iran University of Medical Sciences, School of Rehabilitation Sciences

Country

Iran (Islamic Republic of)

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Email address

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

Street address

Iran University of Medical Sciences, Hemmat Expressway, Tehran, Iran

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۱۴۳۹۶۱۴۵۳۵

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

Shohreh Noorizadeh Dehkordi

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School of Rehabilitation Sciences, Madadkaran Street, Shahnazari Street, Madar Square, Mirdamad, Tehran, Iran

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2

Recruitment center

Name of recruitment center

Community Rehabilitation and the Finder

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Shohreh Noorizadeh Dehkordi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

Physiotherapy

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Latest degree

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Other areas of specialty/work

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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