

# 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

Iran University of Medical Sciences, School of Rehabilitation Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 7124

##### 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

**City**

Tehran

**Province**

Tehran

**Postal code**

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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

15459-13487

**Phone**

+98 21 2222 7124

**Fax**

**Email**

noorizadeh.sh@iums.ac.ir

**Web page address**

http://www.iums.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**

Community Rehabilitation and the Finder

**Full name of responsible person**

Shohreh Noorizadeh Dehkordi

**Street address**

Community Rehabilitation and the Finder, Jafar Zadehan Street, Kargar Shomali Street, Enghelab Square, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1418815665

**Phone**

+98 21 6693 5124

**Email**

noorizadeh.sh@iums.ac.ir

**Web page address**<https://ehyagroup.ir>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Seyyed Abbas Motevalian

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 8670 4704

**Fax**

+98 21 8862 2707

**Email**

amotevalian@iums.ac.ir

**Web page address**<https://vcr.iums.ac.ir/>**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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

15459-13487

**Phone**

+98 21 2222 7124

**Email**

noorizadeh.sh@iums.ac.ir

**Person responsible for scientific 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**

Physiotherapy

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

15459-13487

**Phone**

+98 21 2222 7124

**Email**

noorizadeh.sh@iums.ac.ir

## Person responsible for updating data

noorizadeh.sh@iums.ac.ir

### 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**

Physiotherapy

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

15459-13487

**Phone**

+98 21 2222 7124

**Email**

## 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