

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effects of Horse Riding Simulator on the Balance, postural control and Hip Adductor Spasticity in Children with Bilateral Spastic Cerebral Palsy: A Single Blind Randomized Control Trial

#### Protocol summary

##### Study aim

Investigating the effect of simulated horse riding on balance, postural control and spasticity of thigh adductor muscles in children with spastic bilateral cerebral palsy: a single-blind clinical trial study

##### Design

A clinical trial with a control group with parallel groups and a blind strain and randomization of blocks on 36 patients and randomization by stratification method will be done in two groups.

##### Settings and conduct

Samples will be collected from occupational therapy clinics in the field of children. The evaluator will be unaware of all the steps of the implementation.

##### Participants/Inclusion and exclusion criteria

The child has been diagnosed with spastic cerebral palsy by a neurologist. The child must be in one of the levels II and III of the classification system of gross movements on the saddle. The child's IQ score, which will be measured by Sparkle, should be above 70.;Unwillingness of the family or the child to continue the interventions.

##### Intervention groups

In the therapist intervention group, in addition to routine occupational therapy interventions, the simulated horse-riding device is also used to In order to benefit from simulated hippotherapy will be used. In this way, out of 45 minutes of occupational therapy, the therapist spends half an hour on common and routine occupational therapy treatments and spends the last 15 minutes on simulated hippotherapy. In the control group, during the 45-minute occupational therapy sessions, the therapist will only use common and routine occupational therapy treatments, including stretching exercises, strength exercises, vestibular and sensory stimulations.

##### Main outcome variables

balance ; postural control ; spasticity ; gross motor function ; functional mobility ; range of motion

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230626058589N1**

Registration date: **2023-07-23, 1402/05/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-07-23, 1402/05/01**

Update count: **0**

##### Registration date

2023-07-23, 1402/05/01

##### Registrant information

##### Name

Kiana Ramezani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7756 1721

##### Email address

kianaramezani@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-01, 1402/04/10

##### Expected recruitment end date

2023-08-01, 1402/05/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The Effects of Horse Riding Simulator on the Balance, postural control and Hip Adductor Spasticity in Children with Bilateral Spastic Cerebral Palsy: A Single Blind Randomized Control Trial

**Public title**

The Effects of Horse Riding Simulator on the Balance, postural control and Hip in Children with Bilateral Spastic Cerebral Palsy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The child has been diagnosed with spastic cerebral palsy (diplegia, double hemiplegia, and quadriplegia) by a neurologist. The child must be in one of the levels II and III of the classification system of gross movements so that they have the ability to sit and can hold themselves on the saddle. The child does not have behavioral problems and can tolerate sitting on the simulated horse (assessed by interviewing the parents and observing). The child's IQ score, which will be measured by Sparkle, should be above 70. The child has not performed any surgery on the adductors and does not intend to perform it during the implementation of interventions. The child has not received botox injection in the last 6 months and does not intend to do it during the implementation of interventions. Children should not have dislocation or subluxation in the pelvis. The child does not have seizures, especially uncontrolled seizures or epilepsy. The child does not have problems with the vestibular system (children who cannot tolerate vestibular stimulation, which is determined by clinical evaluation by the therapist and interview.) The child does not have a history of receiving any hippotherapy or simulated hippotherapy services during the past year. have received a spasticity score of 1 and +1 in MAS

**Exclusion criteria:****Age**

From **5 years** old to **9 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **36**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The present study is a randomized clinical trial of one sucure. The number of 36 children with spastic cerebral palsy was selected from the available population and after filling the consent form, using the block randomization method and considering the number of samples required from the sample size formula. People are divided into two equal groups. (group receiving simulated hippotherapy along with routine treatment and control group receiving routine treatment). In children

with GMFCS II, III levels, children with GMFCS II will be in one group and children with GMFCS III will be placed in a separate group. Then 9 people from each group are selected randomly and using envelopes and randomly enter the control and intervention groups to make sure that an equal number of each GMFCS will be placed in each group. In this method, we select a number of cards as the intervention group and the same number of cards for the control group, then we mix the cards together and spend one card, and its allocation is recorded, and after spending the card, it is returned to the group of other cards. Then the cards are merged again and we take out another card. This process continues until reaching a random sequence according to the sample size. This method will be done separately for both groups with different levels of GMFCS. In this research, the control and intervention group meetings are held on different days so that children and families remain unaware of the child's presence in the control and intervention groups. Also, the occupational therapist who did the evaluations is not aware of the classification of the patients.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The evaluator will be completely blinded to the individuals of each group in all phases of evaluation, including initial evaluation, post-treatment evaluation, and follow-up.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

**Street address**

Shahid Beheshti University of Medical Sciences, Damavand Street, Imam Hossein Square, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1616913111

**Approval date**

2023-06-11, 1402/03/21

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1402.160

## Health conditions studied

### 1

#### Description of health condition studied

Children with Bilateral Spastic Cerebral Palsy

#### ICD-10 code

G80

#### ICD-10 code description

Cerebral palsy

## Primary outcomes

### 1

#### Description

balance

#### Timepoint

At the beginning of the study, 30 days after the start of the intervention and 60 days after the end of the intervention

#### Method of measurement

Pediatric Balance Scale

### 2

#### Description

Postural control of the trunk

#### Timepoint

At the beginning of the study, 30 days after the start of the intervention and 60 days after the end of the intervention

#### Method of measurement

Trunk Control Measurement Scale

### 3

#### Description

spasticity

#### Timepoint

At the beginning of the study, 30 days after the start of the intervention and 60 days after the end of the intervention

#### Method of measurement

Modified Ashworth Scale

## Secondary outcomes

### 1

#### Description

Gross motor function

#### Timepoint

At the beginning of the study, 30 days after the start of the intervention and 60 days after the end of the intervention

#### Method of measurement

Gross Motor Function Measure

### 2

#### Description

Functional mobility

#### Timepoint

At the beginning of the study, 30 days after the start of the intervention and 60 days after the end of the intervention

#### Method of measurement

Pediatric Evaluation of Disability Inventory

### 3

#### Description

Joint range of motion

#### Timepoint

At the beginning of the study, 30 days after the start of the intervention and 60 days after the end of the intervention

#### Method of measurement

Goniometry

## Intervention groups

### 1

#### Description

Intervention group: In the therapist intervention group, in addition to routine occupational therapy interventions, there are common treatments for children with cerebral palsy, which include traditional neurodevelopmental approaches (Bobath), Rood, sensory integration, splints, and strength-enhancing exercises. The simulated horse riding device will also be used in order to benefit from simulated hippotherapy. In this way, out of the 45 minutes of occupational therapy, the therapist will spend half an hour on common treatments and occupational therapy routines, and the last 15 minutes will be spent using simulated hippotherapy.

#### Category

Rehabilitation

### 2

#### Description

Control group: In the control group, during the 45-minute occupational therapy sessions, the therapist will only use common and routine occupational therapy treatments, including stretching exercises, strength exercises, vestibular and sensory stimulations.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tavanyab Association

##### Full name of responsible person

sahar firozbakht

##### Street address

No. 2, Shahid Jafarzadegan Alley, after Fasat Street, North Kargar St., Elkhebal Square, Tehran

**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
0000000000  
**Phone**  
+98 21 6693 5533  
**Email**  
anjoman.ehya1@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Mino Kalantari  
**Street address**  
Shahid Beheshti University of Medical Sciences,  
Damavand Street, Imam Hossein Square, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1616913111  
**Phone**  
+98 21 7756 1721  
**Email**  
info@sbmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti 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**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Kiana Ramezani  
**Position**  
Student  
**Latest degree**

Bachelor  
**Other areas of specialty/work**  
Occupational Therapy  
**Street address**  
Shahid Beheshti University of Medical Sciences,  
Damavand Street, Imam Hossein Square, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1616913111  
**Phone**  
+98 21 7756 1721  
**Fax**  
**Email**  
kianaramezani@sbmu.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Kiana Ramezani  
**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Occupational Therapy  
**Street address**  
Shahid Beheshti University of Medical Sciences,  
Damavand Street, Imam Hossein Square, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1616913111  
**Phone**  
+98 21 7756 1721  
**Fax**  
**Email**  
kianaramezani@sbmu.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Kiana Ramezani  
**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Occupational Therapy  
**Street address**  
Shahid Beheshti University of Medical Sciences,

Damavand Street, Imam Hossein Square, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1616913111

**Phone**

+98 21 7756 1721

**Fax**

**Email**

kianaramezani@sbmu.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

To comply with the principle of trust

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The data will be published in accordance with the principle of confidentiality and without mentioning the names of the participants.

**When the data will become available and for how long**

2 months after printing the results

**To whom data/document is available**

Participants in this study and researchers and people working in this field

**Under which criteria data/document could be used**

There is no further information

**From where data/document is obtainable**

Kiana Ramezani kianaramezanib@gmail.com

**What processes are involved for a request to access data/document**

The confidential information of the participants will be published only if they have a letter from the relevant center (Shahid Beheshti University of Medical Sciences) and other health centers.

**Comments**