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
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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 sucur. 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

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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
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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
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
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Position
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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