Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative effectiveness of usual treadmill therapy and waterwalk on mobility, walking balance and occupational performance in children with spastic cerebral palsy

Protocol summary

Study aim

The overall aim of this study was to compare the effect of waterway and conventional treadmill therapy on gait balance and work performance in children with spastic cerebral palsy.

Design

Clinical trial with control and comparison group, parallel, randomized with computer system

Settings and conduct

In the study, participants are randomly divided into specified groups after evaluation. The intervention is performed in 6 weeks and 3 sessions per week for 30 minutes. The intervention will be performed at Ofogh Occupational Therapy Clinic located in Tehran.

Participants/Inclusion and exclusion criteria

Participants: Children with spastic cerebral palsy Inclusion criteria: Has a diagnosis of spastic cerebral palsy by a neurologist No surgery or injection of dysport in the last 6 months in the lower extremities Ability to stand independently for at least 30 seconds Proper commandability and cooperation Age range 6 to 12 years exclusion criteria: Lack of cooperation (such as fear of water or apparatus) the child during the evaluation and intervention process Participate in similar interventions during this study Inability to control urination and defecation

Intervention groups

In this study, participants were studied in three، main intervention groups (intervention with a watermark device that provides walking on a treadmill and in the water), a sub-intervention group (walking with a normal treadmill) and a control group (routine rehabilitation interventions) are studied.

Main outcome variables

Gait balance, Static balance, occupational performance, Step length, Width step, Cadence, Walking speed, Acceleration of motion, Mobility, Severity of spasticity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210219050414N1**
Registration date: **2021-08-03, 1400/05/12**
Registration timing: **prospective**

Last update: **2021-08-03, 1400/05/12**
Update count: **0**

Registration date

2021-08-03, 1400/05/12

Registrant information

Name

Mansour Noori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4438 8409

Email address

ot.noori@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative effectiveness of usual treadmill therapy and waterwalk on mobility, walking balance and occupational performance in children with spastic cerebral palsy

Public title
treadmill therapy in children with cerebral palsy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Has a diagnosis of spastic cerebral palsy by a neurologist No surgery or injection of dysport in the last 6 months in the lower extremities Ability to stand independently for at least 30 seconds Proper commandability and cooperation Age range 6 to 12 years
Exclusion criteria:
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **27**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling method Sampling is available in this study. The samples are then randomly divided into three groups by computer method (by random sequence generation software): intervention whaterwalk, intervention with normal treadmill and control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of University of Social Welfare and Rehabilitation
Street address
kodakyar Ave., Daneshjo Blvd.,Evin
City
Tehran
Province
Tehran
Postal code
1985713871
Approval date
2019-09-16, 1398/06/25
Ethics committee reference number
IR.USWR.REC.1398.079

Health conditions studied

1

Description of health condition studied
Cerebral Palsy
ICD-10 code
G80.9
ICD-10 code description
Cerebral palsy, unspecified

Primary outcomes

1

Description
Score of Berg Balance Scale for "Walking Balance"
Timepoint
Measuring the Level of Balance at the Beginning and End of the 6-week Intervention
Method of measurement
Berg Balance Scale

2

Description
Scale of Mobility Questionnaire
Timepoint
Measuring the Level of Mobility at the Beginning and End of the 6-week Intervention
Method of measurement
Mobility Questionnaire

3

Description
Scale of Occupational Performance Based on Pediatric Evaluation Of Disability Inventory
Timepoint
Measuring the Level of Occupational Performance at the Beginning and End of the 6-week Intervention
Method of measurement
Pediatric Evaluation Of Disability Inventory

4

Description
Rate of Speed, Velocity, Step Length and Step Width While Walking
Timepoint
Beginning and End of the 6-week Intervention
Method of measurement
Balance Master System

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first intervention group included children who are intervened with waterwalk or under water treadmill for 6 weeks and 3 sessions of 30 minutes each week.
Category
Rehabilitation

2

Description
Intervention group: The second intervention group included children who are intervened with usual treadmill for 6 weeks and 3 sessions of 30 minutes each week.
Category
Rehabilitation

3

Description
Control group: They do not receive any intervention
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ofogh Occupational Therapy Center
Full name of responsible person
Behzad Amini
Street address
No. 2, Eleven Ave, Balochestan Street, Nasr blvd
City
Tehran
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Tehran
Postal code
1446964552
Phone
+98 21 8823 5046
Email
behzad.ot@gmail.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Dr Hamidreza Khorramkhorshid
Street address
Kodakyar Ave., Daneshjo Blvd.,Evin
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Postal code
1985713871
Phone
+98 21 2218 0083
Email
international_affairs@uswr.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
Mansour Noori
Position
Phd Student
Latest degree
Master
Other areas of specialty/work
Occupational Therapy
Street address
No. 34, Golestan 6, Nahid Street, Marzdaran Blvd
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Person responsible for scientific inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Mansour Noori

Position
Phd Student

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
Yes - There is 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
At the end of the study, all data will be shared after the samples are not identified.

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
In order to cooperate with researchers related to the field in order to promote and advance scientific studies related to the project and the target patients

From where data/document is obtainable
Direct communication with the main researcher of the project. Mr. Mansour Nouri. email:ot.noori@gmail.com/ mobile number: 09128504790

What processes are involved for a request to access data/document
6 months after the publication of the project results, applicants will be able to submit an application with an official request from the institution or university under employment. After receiving and reviewing the request, the request will be answered within a maximum of 2 working weeks.

Comments