

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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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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

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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

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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

Person responsible for updating data

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Mansour Noori

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Latest degree

Master

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