

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Province

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

#### City

Tehran

#### Province

Tehran

#### 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1461673156

##### Phone

+98 21 4438 8409

##### Fax

##### Email

ot.noori@gmail.com

## 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

**Latest degree**

Master

**Other areas of specialty/work**

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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

**Position**

Phd Student

**Latest degree**

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