

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jul 2026

### The effect of conventional physiotherapy plus ankle kinesiotaping on walking and balance in children with spastic diplegia (a randomized clinical trial)

#### Protocol summary

##### Study aim

Determining the effect of conventional physiotherapy plus kinesiotape on walking and balance in children with spastic diplegia

##### Design

Clinical trial with control group (10 in each treatment group), double blinded, randomized (simple randomization with coin

##### Settings and conduct

In initiation, the end of treatment and follow-up (6 weeks after the end of the treatment sessions) outcomes are evaluated by GMFM and MTUG and PBS. according to subject's group, routine physiotherapy/routine physiotherapy plus ankle kinesiotaping are performed at the Physiotherapy Clinic of the Faculty of Rehabilitation, Jundishapur University of Ahwaz for 4 weeks. subject due to age and data analyzer will be blind of intervention type and grouping.

##### Participants/Inclusion and exclusion criteria

spastic diplegia children/ age less than 9 years, ability to stand and walk, Diagnosis of spastic diplegia by the physician, Ability to understand the therapist's commands/ History of surgery or botulinum toxin injection up to 6 months before starting treatment, Allergy to kinesiotape, Lack of parenting with the plan, Tumoral lesions, History of any lower limb corrective surgery

##### Intervention groups

Control group: Routine physiotherapy treatment include Gastrosoleus & hip adductors stretch, Tibialis anterior & knee extensors strengthening with FES and postural & walking training/Intervention group: Routine physiotherapy treatment plus ankle kinesiotaping with the aim of correcting equinus

##### Main outcome variables

walking and balance of spastic diplegia children

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181211041931N1**

Registration date: **2019-03-11, 1397/12/20**

Registration timing: **prospective**

Last update: **2019-03-11, 1397/12/20**

Update count: **0**

##### Registration date

2019-03-11, 1397/12/20

##### Registrant information

##### Name

Bahare Ziaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3374 3108

##### Email address

ziaei.b@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-21, 1398/02/01

##### Expected recruitment end date

2020-04-20, 1399/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of conventional physiotherapy plus ankle kinesiotaping on walking and balance in children with spastic diplegia (a randomized clinical trial)

## Public title

The effect of conventional physiotherapy plus ankle kinesiotaping on walking and balance in children with spastic diplegia (a randomized clinical trial)

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age less than 9 years Ability to stand and walk independently or with auxiliary equipment Diagnosis of spastic diplegia by the physician The cognitive ability to follow verbal commands and instructions for testing

### Exclusion criteria:

History of surgery or botulinum toxin injection up to 6 months before starting treatment Allergy to kinesiotape Lack of parental support with the child's treatment plan Tumor lesions Damage to the central nervous system following any trauma History of any lower limb corrective surgery

## Age

To 9 years old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Data analyser

## Sample size

Target sample size: 20

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization by Coin. The heads in order to place the patient in the treatment group and the tails means the patient is in the control group

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participants and analyzer are unaware of the type of treatment

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

Ethics committee

## Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

## Street address

Golestan

## City

Ahvaz

## Province

Khouzestan

## Postal code

15794-61357

## Approval date

2019-02-02, 1397/11/13

## Ethics committee reference number

IR.AJUMS.REC.1397.820

## Health conditions studied

### 1

#### Description of health condition studied

spastic diplegic cerebral palsy

#### ICD-10 code

G80.1

#### ICD-10 code description

Spastic diplegic cerebral palsy

## Primary outcomes

### 1

#### Description

Score of gross motor function measure test

#### Timepoint

At the beginning of the study, the end of the study (4 weeks), 6 weeks after the end of the study

#### Method of measurement

Level of walking and standing performance

### 2

#### Description

Score of modified time up and go test

#### Timepoint

At the beginning of the study, the end of the study (4 weeks), 6 weeks after the end of the study

#### Method of measurement

Time to get up and walk a certain distance

### 3

#### Description

Score of pediatric balance scale test

#### Timepoint

At the beginning of the study, the end of the study (4 weeks), 6 weeks after the end of the study

#### Method of measurement

Performing static and dynamic equilibrium activities

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: conventional physiotherapy

#### Category

Rehabilitation

### 2

#### Description

Intervention group: conventional physiotherapy plus ankle kinesiotape

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Physiotherapy Clinic of Ahvaz Jundishapur University of Medical Sciences

##### Full name of responsible person

Gholamhossein nassadj

##### Street address

Golestan

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

61357-15794

##### Phone

+98 61 3743 1013

##### Email

nassadj@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mohammad badavi

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Golestan

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+98 61 3336 2414

##### Fax

+98 61 3336 1544

##### Email

itc@ajums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Gholamhossein nassadj

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Physiotherapy

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## Person responsible for scientific inquiries

#### Contact

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Assistant Professor

##### Latest degree

Ph.D.

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## Person responsible for updating data

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Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Bahare Ziaei  
**Position**  
Masters student  
**Latest degree**  
Bachelor  
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**Email**  
ziaei.b@ajums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Undecided - It is not yet known if there will be 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**  
Undecided - It is not yet known if there will be a plan to make this available  
**Clinical Study Report**  
Undecided - It is not yet known if there will be a plan to make this available  
**Analytic Code**  
Not applicable  
**Data Dictionary**  
Undecided - It is not yet known if there will be a plan to make this available  
**Title and more details about the data/document**  
The whole potential data is unpublished after being unidentifiable  
**When the data will become available and for how long**  
6 months after printing results  
**To whom data/document is available**  
Data will only be available to researchers working in academic and academic institutions  
**Under which criteria data/document could be used**  
If someone wants to do the same research project  
**From where data/document is obtainable**  
Executor of plan: Dr.Gholamhossein nassadj E-mail: nassadj@yahoo.com  
**What processes are involved for a request to access data/document**  
By sending an E-mail with a full explanation of the reason for requesting the documentation and the purpose of having it.  
**Comments**