Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of occupational therapy home program versus no therapy on gross and fine motor development in children with cerebral palsy: a single blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of occupational therapy home program versus no therapy on gross and fine motor development in children with cerebral palsy. Design: a single blind randomized clinical trial. Setting and conduct: The eligible children with cerebral palsy who will refer to the treatment centers of University of Social Welfare and Rehabilitation Sciences during the study period will be enrolled into the trial. Inclusion criteria: (a) age of 5 to 10 years; (b) affected with cerebral palsy; (c) score of 3 to 5 based on GMFCS system; (d) mother of child had at least ability to read and write; (e) the mother does not care another disable child simultaneously. Exclusion criteria: (a) the child undergoes surgery or receiving Botox during study period; (b) having multiple disability such as blindness, deafness, congenital hip dislocation, and drug resistance seizure. Intervention group: a two hour educational session for caregivers who will care the children cerebral pals plus receiving routine care. Control group: only receiving routine care. Primary outcome: (a) assessing fine motor development before and 3 months after intervention using Bruininks-Oseretsky Test; (b) assessing gross motor development before and 3 months after intervention using Gross Motor Function Measure (GMFM). Secondary outcome: nothing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507139014N71**
Registration date: **2015-08-06, 1394/05/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-08-06, 1394/05/15

Registrant information

Name
Jalal Poorolajal
Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 81 1838 0090
Email address
poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of occupational therapy home program versus no therapy on gross and fine motor development in children with cerebral palsy: a single blind randomized clinical trial

Public title

Effect of occupational therapy home program versus no therapy on gross and fine motor development in children with cerebral palsy

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: (a) age of 5 to 10 years; (b) affected with cerebral palsy; (c) score of 3 to 5 based on GMFCS system; (d) mother of child had at least ability to read and write; (e) the mother does not care another disable child simultaneously. Exclusion criteria: (a) the child undergoes surgery or receiving Botox during study period; (b) having multiple disability such as blindness, deafness, congenital hip dislocation, and drug resistance seizure.

Age
From **5 years** old to **10 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization: The children will be randomly assigned to intervention and control groups through drawing of lots. Blinding: The patients will be aware of the type of intervention. However, the examiner who will examine the patients will be someone else who will not be aware of the intervention. Therefore, the trial will be run as single blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committee of Tehran University of Medical Sciences

Street address
Vice-chancellor for Research the Technology, Tehran University of Medical Sciences, Enghelab Ave

City
Tehran

Postal code

Approval date
2012-07-26, 1391/05/05

Ethics committee reference number
91/801/9/1/7389

Health conditions studied

1

Description of health condition studied
Cerebral palsy

ICD-10 code
G80

ICD-10 code description
Cerebral palsy

Primary outcomes

1

Description
assessing fine motor development

Timepoint
before and 3 months after intervention

Method of measurement
using Bruininks-Oseretsky Test

2

Description
assessing gross motor development

Timepoint
before and 3 months after intervention

Method of measurement
using Gross Motor Function Measure (GMFM)

Secondary outcomes

1

Description
Nothing

Timepoint
Nothing

Method of measurement
Nothing

Intervention groups

1

Description
a two hour educational session for caregivers who will care the children cerebral pals plus receiving routine care

Category
Treatment - Other

2

Description

only receiving routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Sahar Johari

Street address

University of Social Welfare and Rehabilitation Sciences, Koodakyar Alley, Daneshjoo Bulvar, Evin

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology, Tehran University of Medical Sciences

Full name of responsible person

Dr Albar Fotouhi

Street address

Tehran University of Medical Sciences, Enghelab Ave

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research the Technology, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Sahar Johari

Position

Rehabilitation Student

Other areas of specialty/work

Street address

University of Social Welfare and Rehabilitation Sciences, Koodakyar Alley, Daneshjoo Bulvar, Evin

City

Tehran

Postal code

Phone

+98 21 2218 0086

Fax

Email

saharjohari85@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Sahar Johari

Position

Rehabilitation Student

Other areas of specialty/work

Street address

University of Social Welfare and Rehabilitation Sciences, Koodakyar Alley, Daneshjoo Bulvar, Evin

City

Tehran

Postal code

Phone

+98 21 2218 0086

Fax

Email

saharjohari85@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Sahar Johari

Position

Rehabilitation Student

Other areas of specialty/work

Street address

University of Social Welfare and Rehabilitation Sciences, Koodakyar Alley, Daneshjoo Bulvar, Evin

City

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Postal code

Phone

+98 21 2218 0086

Fax

Email

saharjohari85@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty