

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effects of group-based education of handling skills for parents with children with cerebral palsy on family empowerment and child's functional mobility

Protocol summary

Study aim

The present study is designed to investigate the effect of teaching the family how to use handling techniques on their empowerment and also the functional mobility of the child.

Design

A clinical trial with a control group and an intervention group in parallel, which is randomized in a single-blind and stratified method. The study has one phase and the sample size of each group is 23 people.

Settings and conduct

The place of conducting the study is Tavanyab NGO and the method of conducting the study was explained in detail. The primary evaluator is subjected to the blinding process as a blind strain.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The child has been diagnosed with spastic cerebral palsy by a neurologist; The child does not have vision problems; The child's family does not intend to perform any surgery during the implementation of interventions; The mother of the child can be present as a parent of the participant in the study; The mother (participant's parent) must be fluent in Persian and able to read.

Intervention groups

Control group: The members of this group receive common occupational therapy interventions. The duration of providing common occupational therapy interventions commonly between the intervention and control groups will be 2 months (2 sessions per week and 45 minutes per session). Intervention group: The members of this group, while receiving common occupational therapy interventions, they also benefit from 5 related workshop sessions in case of increasing family awareness of their child's condition and training appropriate techniques for handling and positioning him.

Main outcome variables

Family empowerment; Gross motor function; Functional mobility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220630055330N1**

Registration date: **2022-10-25, 1401/08/03**

Registration timing: **retrospective**

Last update: **2022-10-25, 1401/08/03**

Update count: **0**

Registration date

2022-10-25, 1401/08/03

Registrant information

Name

Pooya Reaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effects of group-based education of handling skills for parents with children with cerebral palsy on family empowerment and child's functional mobility

Public title
The effects of group-based education of handling skills for parents with children with cerebral palsy on family empowerment and child's functional mobility

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
The child has been diagnosed with spastic cerebral palsy by a neurologist The child does not have vision problems The child's family does not intend to perform any surgery during the implementation of interventions The mother of the child can be present as a parent of the participant in the study The mother (participant's parent) must be fluent in Persian and able to read
Exclusion criteria:
The age of the child is less than 3 years or more than 10 years.

Age
From **3 years** old to **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
We plan to divide people based on the score of the GMFCS questionnaire into three categories with scores 1 and 2, with score 3 and with scores 4 and 5, and then to perform randomization in a way to select a number of samples from each of these categories almost equally in the intervention and control groups. First, by drawing a two-by-two table, we specify all the placement situations of the samples in the final groups: 1) intervention/control 2) control/intervention 3) intervention/intervention/control/control. Then, by lottery, one of these arrangement methods is selected and we exceed to the next step. In the next step, the ID of all the samples in the form of a code along with their GMFCS questionnaire scores are written on separate sheets and arranged randomly. Then in three envelopes (based on the scores of the GMFCS questionnaire, which had three categories with scores 1 and 2, with score 3 and with scores 4 and 5), on the sheets of the sorting system that was determined earlier (for example, intervention/intervention/control/control) In the same way, it is written separately and repetitively and placed

inside triple envelopes. Then the sheets related to the ID of the samples (which apart from their ID code, also includes their GMFCS score) are revealed in order, and based on their GMFCS scores, we go to the desired envelope and take out the sorted sheets from inside it. Based on the writing on the pages inside the envelope (intervention or control), the target sample is randomly placed in one of the intervention or control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluator will not know which group each sample belongs to in all stages of the evaluation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Science

Street address

Unit 3, No. 3, 3rd Piroozi Alley, Nikzare Ave., 22nd Bahman Ave., Ashrafi Esfahani Blvd., Bagh Feiz

City

Tehran

Province

Tehran

Postal code

1473178434

Approval date

2022-06-21, 1401/03/31

Ethics committee reference number

IR.IUMS.REC.1401.246

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

Family empowerment score in the Family Empowerment Scale

Timepoint

Measuring family empowerment score for the first time at the beginning of the study, for the second time one month after the start of the study, for the third time two months after the start of the study (at the end of the interventions), for the fourth time one month after the end of the interventions and for the fifth time two months after the end of the Interventions

Method of measurement

Family Empowerment Scale

2

Description

Gross motor function score in the Gross Motor Function Measurement

Timepoint

Measuring Gross motor function score for the first time at the beginning of the study, for the second time one month after the start of the study, for the third time two months after the start of the study (at the end of the interventions), for the fourth time one month after the end of the interventions and for the fifth time two months after the end of the Interventions

Method of measurement

Gross Motor Function Measurement - 88

3

Description

Functional mobility score in the Mobility subscale of the Pediatric Evaluation of Disability Inventory

Timepoint

Measuring Functional mobility score for the first time at the beginning of the study, for the second time one month after the start of the study, for the third time two months after the start of the study (at the end of the interventions), for the fourth time one month after the end of the interventions and for the fifth time two months after the end of the Interventions

Method of measurement

Mobility subscale of the Pediatric Evaluation of Disability Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The members of this group, while receiving common occupational therapy interventions including active and passive stretching exercises to improve range of motion and adjust muscle tone, facilitate gross and fine movement patterns in the form of developmental patterns and facilitate the child's movement functions with purposeful activities, they also benefit from 5 related workshop sessions in case of increasing family awareness of their child's condition and training appropriate techniques for handling and

positioning him, the content of which is described in detail below. The first group session: During this one-hour session, the researcher will provide information on the nature of cerebral palsy, its causes, types and symptoms of each, functional levels, prognosis and related disorders, in addition to the introduction of drugs used to reduce spasticity and control convulsions and occupational therapy common interventions, through PowerPoint. The second group session: In this session, the researcher guides the parents to discuss and exchange opinions about the handling problems of their children, their musculoskeletal pain, the decrease in the quality of life of parents due to the child's illness, the decrease in the quality of the parent's health, the disruption of their occupational balance and related topics. The third group session: this session will be about children's functional problems in general; In this way, first the researcher explains the areas of occupational performance in the form of PowerPoint, and then parents are invited to express their challenges and the child's challenges in the introduced areas. 4th and 5th group session: By analyzing the discussions of the previous three group sessions that have been explained up to this point, the researcher has identified the basic problems that families are facing and prepares interventions for group training to parents in the form of PowerPoint, which will be presented in the fourth and fifth group sessions. It should be noted that there will be a suitable platform for discussion and exchange of parent's opinions, just like the previous group sessions.

Category

Rehabilitation

2

Description

Control group: The members of this group receive common occupational therapy interventions, including active and passive stretching exercises to improve the range of motion and adjust muscle tone, facilitate gross and fine movement patterns in the form of developmental patterns, and facilitate the child's movement functions with purposeful and appropriate activities. The duration of providing common occupational therapy interventions commonly between the intervention and control groups will be 2 months (2 sessions per week and 45 minutes per session).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tavanyab Association

Full name of responsible person

Khosrow Mansourian

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No. 2, Martyr Jafarzadegan Alley, North Kargar Ave., Enqelab Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences
Full name of responsible person
Pooya Reaei
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Occupational Therapy
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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available