# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 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)

**Phone**

+98 21 4442 3675

**Email address**

reaei.po@iums.ac.ir


**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

**Street address**

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

**City**
Tehran
**Province**
Tehran
**Postal code**
1418815665
**Phone**
+98 21 6693 5533
**Fax**
+98 21 6693 5124
**Email**
anjoman.ehya1@gmail.com
**Web page address**
https://www.tavanyabngo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Hossein Keyvani
**Street address**
Iran University of Medical Science, next to Milad tower, Hemmat Expressway, Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
1449614535
**Phone**
+98 21 86701
**Email**
info@iums.ac.ir
**Web page address**
https://www.iums.ac.ir
**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
**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
**Phone**
+98 21 4442 3675
**Email**
pooya369@yahoo.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Malek Amini
**Position**
Associate professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Occupational Therapy
**Street address**
School of Rehabilitation Science, Madadkaran St., Shahid Shah Nazari St., Mother Square, Mirdamad Blvd.
**City**
Tehran
**Province**
Tehran
**Postal code**
1545913487
**Phone**
+98 21 2222 8051
**Email**
amini.m@iums.ac.ir

## Person responsible for updating data

**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

**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

**Phone**

+98 21 4442 3675

**Email**

pooya369@yahoo.com

## 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