

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of the effects of maternal handling training on occupational performance of children with cerebral palsy and family caregiving satisfaction in Arak city.

Protocol summary

Summary

Abstract: The aim of this study is the comparison of the effects of maternal handling training on occupational performance of children with cerebral palsy (CP) and family caregiving satisfaction in Arak city. This research is an experimental, clinical trial study; fifty children with CP (4-12 years old) in the levels of III-IV Gross Motor Function Measure Expanded & Revised (GMFM E&R) recruit based on convincing sampling method and divided randomly into two groups of intervention and control. The caregivers in intervention group determine maternal handling training priorities and receive specific educations in this regards by an occupational therapist. In the first pre-test, Intervention & control group receive routine occupational therapy interventions for 4 weeks. After that, caregivers of the intervention group, perform maternal handling training interventions based on detecting priorities for children with CP for three months. A demographic information questionnaire and Canadian Occupational Performance Measure (COPM) use to collect data. Then, data, analyze in three phases; pretest, before interventions and after interventions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015031521478N1**

Registration date: **2015-07-10, 1394/04/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-10, 1394/04/19

Registrant information

Name

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Name of organization / entity

Arakk University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of maternal handling training on occupational performance of children with cerebral palsy and family caregiving satisfaction in Arak city.

Public title

Maternal handling training

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: children with cerebral palsy (CP) be diagnose by pediatric neurologist ; children with CP aged between 4-12 years old ; children with CP in levels of III-V

Gross Motor Function Classification System Expanded & Revised (GMFCS E&R). Exclusion criteria: CP children with refractory seizure ; CP children with Muscular - skeleton surgery.

Age

From **4 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

School of Rehabilitation, Medical science building number 2; Golestan town, Mostafakhomeini Street.

City

Arak

Postal code

381-869-3395

Approval date

2015-05-02, 1394/02/12

Ethics committee reference number

93-176-31

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

Occupational Performance of children with CP & Caregiver Satisfaction

Timepoint

Data gather in three phases; pre-test (4 weeks before intervention), before interventions and 3 month after interventions.

Method of measurement

Occupational Performance of children with CP and Caregiver Satisfaction (both) measure with Canadian Occupational Performance Measure (COPM)

Secondary outcomes

1

Description

Maternal Handling Training

Timepoint

Before and 3 months after intervention

Method of measurement

Canadian Occupational Performance Measure (COPM)

Intervention groups

1

Description

Interventions; for intervention group perform in four phases; pretest, before intervention, intervention and after intervention. Pretest phase: Intervention group receive routine occupational therapy interventions for 4 weeks. Occupational performance for children with CP and level of satisfaction for caregivers assess with COPM. This period is for determine the effectiveness of routine occupational therapy without maternal handling therapy. Before intervention phase: Again, we use COPM for identifying of maternal handling training priorities, occupational performance for children with CP and level of satisfaction for caregivers for intervening group. Intervention phase: A 2-hour maternal handling training workshop held for caregivers of the intervention group based on identifying priorities in COPM. During this session, caregivers acquaint with educations for special care of children with CP. After that, a hand book entitled "knowing more about our children and acting better" and video CD in this regard gifts to the caregivers for studying. , Moreover, Over the 3-month period of intervention, intervention group kept on their routine occupational therapy interventions. After intervention phase: Differences between occupational performance for children with CP and level of satisfaction for caregivers assess with COPM after 3 month intervention.

Category

Treatment - Other

2

Description

Interventions; for control group perform in four phases; pretest, before intervention, intervention and after intervention. Pretest phase: Control group receive routine occupational therapy interventions for 4 weeks. This period is for determine the effectiveness of routine occupational therapy without maternal handling therapy. Occupational performance for children with CP and level of satisfaction for caregivers assess with COPM. Before intervention phase: Again, we use COPM for identifying of maternal handling training priorities, occupational performance for children with CP and level of satisfaction for caregivers for control group. Intervention phase: During three month intervention, control group do not receive maternal handling training, but they kept on their routine occupational therapy interventions. After intervention phase: Differences between occupational performance for children with CP and level of satisfaction for caregivers assess with COPM after 3 month intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation

Full name of responsible person

Dr. Hamid Dalvand

Street address

School of Rehabilitation, Medical science building number 2; Golestan town, Mostafakhomeini Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice- chancellor of Research and Technology, Arak University of Medical Sciences

Full name of responsible person

Dr. Mohammad Rafeie

Street address

School of Medicine, Medical science building number 2; Golestan town, Mostafakhomeini Street

City

Arak

Grant name

Grant code / Reference number

93/176/13

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

Yes

Title of funding source

Vice- chancellor of Research and Technology, Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr. Hamid Dalvand

Position

PhD of Occupational Therapy / Assisstant Professor

Other areas of specialty/work

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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