

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Effectiveness of Pediatric care education for children with cerebral palsy on anxiety and depression in mothers

Protocol summary

Study aim

Determining the Effect of Care Education of Mothers of Children with Cerebral Palsy on their maternal Depression and Anxiety

Design

This is a quasi-experimental study that is conducted with researcher intervention and care education of mothers of children with cerebral palsy. The study population consisted of all referred mothers as inpatient and outpatient with a cerebral palsy child, under the age 15 years. It is conducted at Bahaonar hospital in Karaj. The sampling method was based on the objective sampling method and divided into two groups as randomly selected and each participant is assigned a code.

Settings and conduct

This study was conducted with a demographic inventory to collect data. That includes some questions such age, level of education and economic status of the mothers. To collect data on the status of caring for a child with cerebral palsy a six-part checklist was used that provides information about; 1- the mode of transportation of the body; 2- the correct positioning; 3- dressing and dressing up; 4- feeding; 5- going to bed; and 6- bathing. That was leveled in good, moderate or poor by answers as yes, to some extent or no. They will be given a Beck anxiety and depressing inventory to answer. The location of the study is Bahaonar hospital, Karaj

Participants/Inclusion and exclusion criteria

The mother with a child with cerebral palsy under the age of 15 ; The mother is literate ; The child has no other chronic illness ;The father of the family is not addicted or unemployed; There is no record of divorce in the family; The primary responsibility for caring for the child with cerebral palsy lies with the mother; The mother cares for only one disabled child Only one child cerebral palsy in the family; There is no history of caring for a child with cerebral palsy; Non of the main members of the family of medical personnel The mother is not in a mental state for mental health

Intervention groups

The intervention group consisted of 30 mothers of children with cerebral palsy, cerebral palsy caregiver training them for classes in six half-hour sessions over 2 weeks are. The training program will be implemented by lecture method in 6 half-hour sessions for 2 weeks and will be implemented by using teaching aids such as Pamphlet and Slid Training at the appropriate place in the hospital in the form of group training (in groups of up to 5 people). The training will be provided theoretically and practically by means of a puddle. After that, the checklist for the health and care of children with cerebral palsy is filled with observation by the researcher and the mothers' skills in helping the child to carry out daily life activities in the six areas mentioned one week after training, Beck Anxiety Inventory (BAI) and Beck Depression Inventory will be provided to the units under study. In case of discharge, the child will be completed by the mothers by returning to the home. In the control group, which consisted of 30 mothers of children with cerebral palsy is only routine training program receive.

Main outcome variables

In this research, caring for children with cerebral palsy to independent mothers will be independent and the level of anxiety and depression in dependent mothers with variable cerebral palsy is dependent.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170725035308N2**

Registration date: **2018-02-07, 1396/11/18**

Registration timing: **retrospective**

Last update: **2018-02-07, 1396/11/18**

Update count: **0**

Registration date

2018-02-07, 1396/11/18

Registrant information**Name**

Laila Panahi

Name of organization / entity**Country**

Iran (Islamic Republic of)

Phone

+98 21 2200 6666

Email address

falaee@iautmu.ac.ir

Recruitment status**Recruitment complete****Funding source**

Islamic Azad University, Tehran Medical Branch

Expected recruitment start date

2017-11-03, 1396/08/12

Expected recruitment end date

2017-12-03, 1396/09/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Pediatric care education for children with cerebral palsy on anxiety and depression in mothers

Public title

The Effect of Care Education on Anxiety and Depression in Mothers of Children with Cerebral palsy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The mother with a child with cerebral palsy under the age of 15 The mother is literate The child has no other chronic illness The father of the family is not addicted or unemployed There is no record of divorce in the family The primary responsibility for caring for the child with cerebral palsy lies with the mother The mother cares for only one disabled child Only one child cerebral palsy in the family There is no history of caring for a child with cerebral palsy. Non of the main members of the family of medical personnel The mother is not in a mental state for mental health

Exclusion criteria:

Do research in one center only

Age

From **1 month** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics Committee of Islamic Azad University, Tehran Medical Branch. Tehran, Iran. Islamic Azad U

Street address

Zargande avn, Shariati avn

City

Tehran

Province

Tehran

Postal code

1916893813

Approval date

2017-07-26, 1396/05/04

Ethics committee reference number

IR.IAU.TMU.REC.1396.92

Health conditions studied**1****Description of health condition studied**

anxiety

ICD-10 code

F50-F59

ICD-10 code description

Behavioural syndromes associated with physiological disturbances and physical factors

2**Description of health condition studied**

Depresion

ICD-10 code

F50-F59

ICD-10 code description

Behavioural syndromes associated with physiological disturbances and physical factors

3**Description of health condition studied**

Cerebral Palsy
ICD-10 code
G80-G83
ICD-10 code description
Cerebral palsy and other paralytic syndromes

Primary outcomes

1

Description

Depression and anxiety

Timepoint

Before the intervention, one month after the intervention

Method of measurement

پرسشنامه افسردگی و اضطراب بک. چک لیست

Secondary outcomes

empty

Intervention groups

1

Description

Group intervention in this group of mothers of children with cerebral palsy care education for classes in six half-hour sessions will be conducted within 2 weeks.

Category

Lifestyle

2

Description

En Control group: in this group just routine teaching were received

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahonar hospital

Full name of responsible person

Leila Panahi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Shirin Hejazi

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Fateme alae karahroudy

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Fatemeh Alae Karahroudy
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

this reaserch is not completed

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