

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Investigation of the effect of psychoeducation program on anxiety, depression and Quality of life of caregivers of children with cerebral palsy

Protocol summary

Study aim

Investigation of the effect of psychoeducation program on anxiety, depression and Quality of life of caregivers of children with cerebral palsy

Design

Clinical trial, without control group, pre/post design

Settings and conduct

The present study will be conducted at the Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences. In this clinical trial, 15 carers of children with cerebral palsy referred to occupational therapy clinics of Semnan city will be selected by simple random method. After selecting participants for research and obtaining informed consent, evaluations of anxiety, depression and quality of life will be made from the participants. The evaluations will be carried out in two other sessions, immediately after the completion of the treatment sessions, and after a 2 month follow-up period. The protocol of the psychoeducation program is 5 sessions of a group intervention program including training programs and supportive group therapy.

Participants/Inclusion and exclusion criteria

The inclusion criteria for these carers are as follows:1: The age range of these carers will be between 25 and 40 years old.2: Children's age range will be 2-7 years old. 3: Children at movement level 3 or 4 or 5 (GFMCF). 4: Carers have at least a fifth grade elementary degree. 5:Detection of cerebral palsy is definite. Exclusion criteria includes of absence of a participant in a session of the sum of psychological training sessions and unwillingness to stay in research

Intervention groups

The intervention group includes caregivers for children with cerebral palsy.

Main outcome variables

Anxiety level; Depression; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181130041807N1**

Registration date: **2019-02-07, 1397/11/18**

Registration timing: **prospective**

Last update: **2019-02-07, 1397/11/18**

Update count: **0**

Registration date

2019-02-07, 1397/11/18

Registrant information

Name

Hossein Alibakhshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4180

Email address

alibakhshi@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of psychoeducation program on anxiety, depression and Quality of life of caregivers of children with cerebral palsy

Public title

The effectiveness of psychoeducation on caregivers of children with cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The age range of these carers will be between 25 and 40 years old. Children's age range will be 2-7 years old Children will be at the level of 3,4 or 5 of the Gross Motor Function Classification System (GMFCS) Carers have at least a fifth grade elementary degree. Detection of cerebral palsy is definite

Exclusion criteria:

Absence of a participant in a session of the sum of psychoeducational sessions Unwillingness to stay in research

Age

From **25 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd., Semnan

City

Semnan

Province

Semnan

Postal code

3519899951

Approval date

2019-01-15, 1397/10/25

Ethics committee reference number

IR.SEMUMS.REC.1397.259

Health conditions studied

1

Description of health condition studied

Depression , Anxiety , Cerebral palsy

ICD-10 code

G80

ICD-10 code description

Cerebral palsy

Primary outcomes

1

Description

Anxiety: A score that is obtained using the Beck Anxiety Scale.

Timepoint

Before the intervention, immediately after the intervention and after a 2 month follow-up period

Method of measurement

Beck Anxiety questionnaire

2

Description

Depression: The score used by the Beck Depression questionnaire.

Timepoint

Before the intervention, immediately after the intervention and after a 2 month follow-up period

Method of measurement

Beck Depression questionnaire

3

Description

Quality of Life: The score obtained using the SF36 questionnaire.

Timepoint

Before the intervention, immediately after the intervention and after a 2 month follow-up period

Method of measurement

SF36 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After providing initial information about the participants and obtaining informed consent, anxiety, depression and quality of life will be assessed by Beck Anxiety Inventory, Beck Depression Inventory and SF36 Form. These evaluations will be resumed after the completion of the treatment sessions and after a follow-up period of 2 months. The psychoeducation protocol includes 5 sessions of the group psychoeducational program, including educational programs and supportive group therapy.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabatabaei Rehabilitation Clinic, Semnan

Full name of responsible person

Hossein Alibakhshi

Street address

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1234567890

Phone

+98 23 3334 0867

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halibakhshi.m@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

دکتر پرویز کوخایی

Street address

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+98 23 3344 1022

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p_kokha@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Alibakhshi Hossein

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available