

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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 (GFMC). 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**

Ghods

**City**

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**Province**

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**Postal code**

1234567890

**Phone**

+98 23 3334 0867

**Email**

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**

Basij Blvd.

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**Province**

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**Phone**

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**Email**

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

**Street address**

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**Phone**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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