

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Relaxation on Depression and Anxiety in Mothers of Children with Cerebral Palsy.(The Clinical Trial)

Protocol summary

Study aim

Determination of The Effect of Relaxation on Depression and Anxiety in Mothers of Children with Cerebral Palsy

Design

Clinical trial with control group, parallel group, single blind, randomized with simple randomization technique using Random Digits Table.

Settings and conduct

This study was conducted a demographic inventory and Depression Anxiety Stress Scale-21(DASS-21) to collect data.The location of the study are the rehabilitation centers in Urmia city.In order to blind the study for sampling steps, random allocation of samples to two intervention and control groups, intervention and data collection before and after the study, two trained clinical psychologists with a master's degree in clinical psychology are used. In this way, the main researcher and the analyst in this study are blinded. They are unaware of the grouping. Groups are provided with A and B.

Participants/Inclusion and exclusion criteria

Inclusion criteria:The mothers with a child with cerebral palsy between 6 month to above -DASS score in mothers:depression between 10 to 28 and anxiety between 8 to 20 -To be content to participate in the study -ability to understand Persian language Exclusion criteria:- Chronic or incurable disease in a family member - Severe stress in the last year. - Unemployment or addiction of the spouse - History of severe anxiety, major depression, or other mental disorders before a child is diagnosed with cerebral palsy

Intervention groups

Intervention group: 30 mothers of children with cerebral palsy, 6 weeks Relaxation in home Control group:30 mothers of children with cerebral palsy, No Intervention

Main outcome variables

Depression levels of mothers with children with cerebral palsy based on the scale of depression, anxiety and stress (DASS-21) The level of anxiety of mothers with

children with cerebral palsy based on the scale of depression, anxiety and stress (DASS-21)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200211046457N1**

Registration date: **2020-06-02, 1399/03/13**

Registration timing: **prospective**

Last update: **2020-06-02, 1399/03/13**

Update count: **0**

Registration date

2020-06-02, 1399/03/13

Registrant information

Name

Maryam Shahrifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3336 9416

Email address

m.shahrifar@iaurmia.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-02, 1399/04/12

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Relaxation on Depression and Anxiety in Mothers of Children with Cerebral Palsy.(The Clinical Trial)

Public title

The Effect of Relaxation on Depression and Anxiety in Mothers of Children with Cerebral Palsy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The mothers with a child with cerebral palsy between 6 month to above DASS score in mothers:depression between 10 to 28 and anxiety between 8 to 20 To be content to participate in the study ability to understand Persian language

Exclusion criteria:

Chronic disease in one of the members of family Severe stress (death, hard disease, divorce ...) Unemployment or addiction in husband Record of Anxiety, major Depression, Addiction or other Mental Disorder in mother Psychology Drugs user

Age

From **15 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are randomly into two groups of intervention and control, with simple randomization technique using Random Digits Table.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to blind the study for sampling steps, random allocation of samples to two intervention and control groups, intervention and data collection before and after the study, two trained clinical psychologists with a master's degree in clinical psychology are used.In this way, the main researcher and the analyst in this study are blinded. They are unaware of the grouping. Groups are provided with A and B.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Islamic Azad University Urmia Branch

Street address

(Ayatollah Rafsanjani Complex), On then 2th Kilometer of Airport Rd, Urmia Islamic Azad University

City

urmia

Province

West Azarbaijan

Postal code

57169-63896

Approval date

2018-11-05, 1397/08/14

Ethics committee reference number

IR.IAU.URMIA.REC.1397.011

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

depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

2**Description of health condition studied**

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

3**Description of health condition studied**

Cerebral Palsy

ICD-10 code

G80

ICD-10 code description

Cerebral palsy

Primary outcomes**1****Description**

Depression: The score used by the DASS -21 questionnaire

Timepoint

Before the intervention, six weeks after the intervention

Method of measurement

Depression- Anxiety- Stress Scale (DASS -21)

2**Description**

Anxiety: The score used by the DASS -21 questionnaire

Timepoint

Before the intervention, six weeks after the intervention

Method of measurement

Depression- Anxiety- Stress Scale (DASS -21)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 6 weeks Relaxation in home - Based on the individual lesson plan, Progressive Muscle Relaxation Techniques, Deep Breathing and Mental Imagery techniques will be taught individually in 3 to 4 one-hour sessions at intervals of 3 to 5 days. A compact disc containing the first and second steps of relaxation and an educational booklet taken from the book Relaxation in Zarfa written by Bahadoran and Pournaseh will be provided to the test group. Each relaxation step takes about 15 minutes The test group is asked to perform relaxation exercises once a day according to the program set at home. In order to ensure the correct implementation of relaxation according to the plan, along with the training booklet, the general stress registration form is given to the test group before and after the relaxation and they are asked to perform their general stress based on scale 1 to 10 before and after. Record sedation each time. According to this form, only those who have completed at least 70% of the developed program will be evaluated and the rest will be excluded from the study.

Category

Behavior

2**Description**

Control group: No Intervention

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sheykh Raees Rehabilitation center

Full name of responsible person

Romina Baghi Zade

Street address

No.106, Mandegar Commercial Center, Hasani Ave

City

Urmia

Province

West Azarbaijan

Postal code

5715859423

Phone

+98 44 3348 4586

Email

sheykhoraeesreha312@yahoo.com

2**Recruitment center****Name of recruitment center**

Ehsan Rehabilitation Center

Full name of responsible person

Naser Zare

Street address

Santa Maria Clinic, Abolfathi St, 8 Shahrivar Ave

City

Urmia

Province

West Azarbaijan

Postal code

5716144772

Phone

+98 44 3348 1927

Email

ojeerob@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Mahdi Zavaree

Street address

Urmia Islamic Azad University, on then 2th Kilometer of Airport Rd

City

Urmia

Province

West Azarbaijan

Postal code

5716963896

Phone

+98 44 3180 3000

Email

info@iaurmia.ac.ir

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
10
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
Islamic Azad University
Full name of responsible person
Maryam Shahrifar
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
NO.91,Tamkinvash St,Nabovat Blvd
City
Urmia
Province
West Azarbaijan
Postal code
5719854669
Phone
009833369416
Email
m.shahrifar@iaurmia.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Maryam Shahrifar
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
NO.91,Tamkinvash St,Nabovat Blvd
City
Urmia
Province

West Azarbaijan
Postal code
5719854669
Phone
+98 44 3336 9416
Fax
Email
m.shahrifar@iaurmia.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Maryam Shahrifar
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
NO.91,Tamkinvash St,Nabovat Blvd
City
Urmia
Province
West Azarbaijan
Postal code
5719854669
Phone
009833369416
Email
m.shahrifar@iaurmia.ac.ir

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