

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparing the Effectiveness of Training in Cognitive Behavior Therapy (CBT) and Acceptance and Commitment Therapy (ACT) on Anxiety and Depression among the Mothers with Premature Infants and Assessment of the Prevalence Rate of these Disorders

Protocol summary

Summary

Objective: To compare the effectiveness of CBT and ACT therapies education on depression and anxiety of mothers with preterm infants Study design: Random (shuffle bags method), without placebo control, single central. Experimental population: all fertility females in aged 18-45 years Inclusion criteria: alive premature infants; the baby will be single; Lack of comorbidities; non-use drug and psychotropic drug abuse and not using alcoholic beverages; having ability of write and read; non-use of drug; three days have passed since childbirth Exclusion criteria: absence of two or more in treatment sessions; lack of answer to five or more question of the questionnaire. Sample size, intervention, intervention time and outcome of the study: sample size of this study is 45 persons will be divided into three groups with 15 persons (2 groups are intervention and one group is control). First intervention group (CBT- cognitive behavioral therapy): Treatment sessions in 10 sessions (1 session per week, each session about 60 minutes during 2 months) will be performed according to the protocol (Kennedy et al, 2012). The measurements will be perform in before and after treatment. Second intervention group (ACT- Acceptance and commitment treatment): Treatment sessions in 10 sessions (1 session per week, each session about 60 minutes during 2 months) will be performed according to the protocol (Forman & Herbert, 2008). The measurements will be perform in before and after treatment. Control group: In the control group (15 persons) will not performed any intervention just the results compared with experimental group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017073125732N21**

Registration date: **2017-08-25, 1396/06/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-25, 1396/06/03

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Semnan Branch, Islamic Azad University

Expected recruitment start date

2017-07-25, 1396/05/03

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effectiveness of Training in Cognitive Behavior Therapy (CBT) and Acceptance and Commitment Therapy (ACT) on Anxiety and Depression among the Mothers with Premature Infants and Assessment of the Prevalence Rate of these Disorders

Public title

Comparing the Effectiveness of Training in Cognitive Behavior Therapy (CBT) and Acceptance and Commitment Therapy (ACT) on Anxiety and Depression among the Mothers with Premature Infants and Assessment of the Prevalence Rate of these Disorders

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: alive premature infants; the baby will be single; Lack of comorbidities; non-use drug and psychotropic drug abuse and not using alcoholic beverages; having ability of write and read; non-use of drug; three days have passed since childbirth Exclusion criteria: absence of two or more in treatment sessions; lack of answer to five or more question of the questionnaire.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

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

Ethics Committee, Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Postal code

3514799442

Approval date

2017-07-24, 1396/05/02

Ethics committee reference number

IR.semums.REC.1396.103

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Depression

Timepoint

Before and after intervention

Method of measurement

Questionnaire Postpartum depression, Edinburgh

2

Description

Anxiety

Timepoint

Before and after intervention

Method of measurement

Questionnaire Anxiety zank

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group (CBT- cognitive behavioral therapy): Treatment sessions in 10 sessions (1 session per week, each session about 60 minutes during 2 months) will be performed according to the protocol (Kennedy et al, 2012). The measurements will be perform in before and after treatment.

Category

Diagnosis

2

Description

Second intervention group (ACT- Acceptance and commitment treatment): Treatment sessions in 10

sessions (1 session per week, each session about 60 minutes during 2 months) will be performed according to the protocol (Forman & Herbert, 2008). The measurements will be performed before and after treatment.

Category

Diagnosis

3**Description**

Control group: In the control group (15 persons) will not performed any intervention just the results compared with experimental group.

Category

Diagnosis

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

Amir Hospital

Full name of responsible person

Roghayeh Omrani

Street address

Blvd Mostafa Khomeini, Semnan

City

Semnan

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

Vice chancellor for research, Semnan University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Asgari

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Semnan University of Medical Sciences, Basij Blvd, Semnan

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Semnan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Semnan 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**

Semnan Branch, Islamic Azad University

Full name of responsible person

Abolfazl Karami

Position

PhD in Psychology

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Web page address

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