Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effectiveness of cognitive behavioral training and positive psychology training on psychological health in pregnant women with pregnancy anxiety

Protocol summary

Study aim
The aim of this research is comparing the effectiveness of cognitive behavioral training and positive psychology training on psychological health in pregnant women with pregnancy anxiety.

Design
Clinical trial with 2 experimental group (n=15) and one control group (n=15), parallel groups, randomized by random assignment in groups

Settings and conduct
The study will perform in 8 educational session to both experimental groups way in Ahar without blinding

Participants/Inclusion and exclusion criteria
Inclusion criteria: 3-6 mounts pregnant; age 20-35; at least diploma Exclusion criteria: having physical and psychological diseases in past

Intervention groups
Experimental group 1: 8 1-hour sessions of cognitive behavioral training for 1 month; Experimental group 2: 8 1-hour sessions of positive psychology training for 1 month; control group: without training

Main outcome variables
Pregnancy anxiety؛ anxiety sensitivity؛ resilience؛ quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171212037852N1**
Registration date: **2019-03-16, 1397/12/25**
Registration timing: **retrospective**

Last update: **2019-03-16, 1397/12/25**
Update count: **0**

Registration date
2019-03-16, 1397/12/25

Registrant information

Name
Mahdieh Jafari

Name of organization / entity
University of Mohaghegh Ardabili

Country
Iran (Islamic Republic of)

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+98 45 3150 5000

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-06-21, 1397/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of cognitive behavioral training and positive psychology training on psychological health in pregnant women with pregnancy anxiety

Public title
The effectiveness of cognitive behavioral training and positive psychology training on psychological health

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

3-6 mounts pregnant at least diploma age 20-35

Exclusion criteria:

Record of physical and psychological illnesses

Age

From **20 years** old to **35 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

The member of sample assigned in the experimental and control group by lottery.

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 of Ardabil University of Medical Scienses

Street address

Daneshgah Ave.

City

Ardabil

Province

Ardabil

Postal code

5451917961

Approval date

2017-10-04, 1396/07/12

Ethics committee reference number

IR.ARUMS.REC.1396.112

Health conditions studied

1

Description of health condition studied

Pregnancy Anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pregnancy Anxiety

Timepoint

Before the training and 1 week after the training

Method of measurement

Prenatal Distress Questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

Before the training and 1 week after the training

Method of measurement

WHOQ-BREF

2

Description

Anxiety sensitivity

Timepoint

Before the training and 1 week after the training

Method of measurement

Anxiety sensitivity inventory

3

Description

Resistance

Timepoint

Before the training and 1 week after the training

Method of measurement

Resistance scale

Intervention groups

1

Description

Intervention group 1: 8 1-hour sessions of cognitive behavioral training for 1 month including: 1. introducing of participants, pre-test, explanation about nature of anxiety during pregnancy, 2. presentation of basic information about CBT, 3. The ways of realizing automatic thoughts, 4. evaluation of worries, 5. mindfulness training, 6. relaxation training, 7. the ways of problem solving, 8. review and post-test.

Category

Behavior

2

Description

Intervention group 2 : 8 1-hour sessions of positive

psychology training for 1 month including: 1. introducing of participants, pre-test, explanation about nature of anxiety during pregnancy, 2. introduction of positive psychology, 3. recognizing strengths, 4. gratitude training, 5. satisfying versus maximizing training, 6. hope and optimism, 7. savoring, 8. review and post-test.

Category
Behavior

3

Description
Control group: without training

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Health care centers in Ahar

Full name of responsible person
Mahdieh Jafari

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Shahrdari Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Mohaqeq Ardabili

Full name of responsible person
Mohammad Narimani

Street address
Faculty of Education & Psychology, University of Mohaqeq Ardabili, university street, Ardabil

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5698725761

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narimani@uma.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
University of Mohaqeq Ardabili

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
University of Mohaghegh Ardabili

Full name of responsible person
Mahdieh Jafari

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Faculty of Education & Psychology, University of Mohaqeq Ardabili, University street, Ardabil

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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