

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the effect of counseling with positivity approach and routine care on anxiety in pregnant women over 35 years

Protocol summary

Study aim

Determining the effect of positive psychological counseling on anxiety in pregnant women over 35 years

Design

A randomized controlled clinical trial with parallel groups will be performed on 46 patients

Settings and conduct

The study population will be selected from pregnant mothers over 35 years of age referring to comprehensive health centers in Zanjan. There is no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: be literate; gestational age 24-35 weeks; no history of known psychiatric disorders being treated in the mother based on personal statements and evidence in the file; willingness to participate in the study; no history of drug and psychotropic use; age over 35 years old; no stressful events in the last 6 months (accidents, death of a loved one, separation from a spouse, bankruptcy, severe disputes, immigration); no history of high-risk delivery; not having a child with congenital problems or cerebral palsy. Exclusion criteria: do not attend more than one training session; leave the training class before completing it; occurrence of stressful events in the research process (accidents, death of a loved one, separation from a spouse, bankruptcy, severe disputes, immigration); high-risk pregnancies such as multiple births and diabetes, HTN and IUGR; informing the mother of fetal anomalies; abortion.

Intervention groups

In the 24th to 35th weeks of pregnancy, positive psychology interventions will be held in eight virtual 70-90 minute sessions individually two days a week, and the control group will receive routine pregnancy care training.

Main outcome variables

Pregnancy anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160521027994N7**

Registration date: **2021-07-18, 1400/04/27**

Registration timing: **prospective**

Last update: **2021-07-18, 1400/04/27**

Update count: **0**

Registration date

2021-07-18, 1400/04/27

Registrant information

Name

Taraneh Emamgholi khooshehchin

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3314 8318

Email address

khoosheh@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of counseling with positivity approach and routine care on anxiety in pregnant women over 35 years

Public title

The effect of counseling on pregnancy anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age 24 to 35 weeks Be literate Willingness to participate in the study Age over 35 years Internet access and Android phone

Exclusion criteria:

Existence of a history of known psychiatric disorders in the mother based on individual statements and evidence in the file History of drug and psychotropic use Child with congenital problems or cerebral palsy Child with congenital problems or cerebral palsy

Age

From **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, first, the easy sampling method will be used and then individuals with inclusion criteria will be divided into two groups of intervention and control using random block division. In this way, first, using 4 blocks, the arrangement of people next to each other in each block will be determined, and then a number will be assigned to each block, and 12 blocks will be determined to provide the required number of samples. Then, using the table of random numbers, the sequence of using the blocks will be determined. Entry to each group in each block will be done by the number of selected blocks and the arrangement inside the block, respectively. The number of people in each group will be 23.

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

Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azadi Square

City

Zanjan

Province

Zanjan

Postal code

4513665758

Approval date

2021-06-16, 1400/03/26

Ethics committee reference number

IR.ZUMS.REC.1400.110

Health conditions studied

1

Description of health condition studied

Pregnancy anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Pregnancy anxiety

Timepoint

Before the intervention, the last consultation session and two months after the intervention

Method of measurement

Pregnancy Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in addition to the positive psychology approach for the intervention group will be held in 8 sessions of 70-90 minutes twice a week and at the end of each session homework will be given to participants.

Category

Other

2

Description

Control group: For the control group, routine pregnancy care will be performed. Finally, after the intervention, if

desired, the members of the control group will be provided with a description of counseling sessions.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health department

Full name of responsible person

Hadis Jalilvand

Street address

Azadi Square, Zanjan University of Medical Sciences

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4513956113

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+98 21 3338 3629

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hadis.j120@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Alireza Shoghli

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Hadis Jalilvand

Position

Master student in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Taraneh Emamgholi khooshehchin

Position

Faculty

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Hadis Jalilvand

Position

Master student in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Title and more details about the data/document

The release schedule is not yet known.

When the data will become available and for how long

The release schedule is not yet known.

To whom data/document is available

The release schedule is not yet known.

Under which criteria data/document could be used

The release schedule is not yet known.

From where data/document is obtainable

The release schedule is not yet known.

What processes are involved for a request to access data/document

The release schedule is not yet known.

Comments