

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of Solution-Focused group counseling on anxiety in pregnant women

Protocol summary

Study aim

Investigation of the effect of Solution-Focused group counseling on anxiety in pregnant women

Design

Controlled randomized counseling intervention, with pre-test-post-test design and with control and intervention group, single blind , block randomization method (20 to 4 blocks), in each block two allocations for the control group and two allocations for the group Intervention. Random sequence generation using site (<https://www.sealedenvelope.com>) Sequence concealment was used centrally 40 people in the intervention group and 40 people in the control group

Settings and conduct

After obtaining permission from the ethics committee of Arak University of Medical Sciences and the necessary coordination, convenience sampling is done from all health centers affiliated to Arak University of Medical Sciences as well as Ayatollah Taleghani Health Center, so that the researcher (student) after attending the mentioned places Examines pregnant clients for inclusion criteria. .Classes are held in 5 sessions of 60 to 90 minutes per week for the intervention group in the pregnant classrooms of Ayatollah Taleghani Hospital and the control group does not receive any intervention. Blinding is single.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: gestational age 29-22 weeks and age 18-35 years. Exclusion criteria: unwillingness to continue participating in the study after the start of the study, absence of more than one session.

Intervention groups

The participants of the intervention group receive 5 sessions of 60 to 90 minutes once a week for the solution approach consultation in groups of 10 people. Individuals in the control group do not receive intervention.

Main outcome variables

pregnancy anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220125053827N1**

Registration date: **2022-02-26, 1400/12/07**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-26, 1400/12/07**

Update count: **0**

Registration date

2022-02-26, 1400/12/07

Registrant information

Name

Fatemeh Mazraeifarahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3425 3295

Email address

f.mazraeifarahani@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-27, 1400/11/07

Expected recruitment end date

2022-04-19, 1401/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Solution-Focused group counseling on anxiety in pregnant women		Completion of the questionnaire in the post-test stage is done by interviewers who are unaware of how people are placed in the two groups and do not know the statistical consultant.	
Public title	Investigating the effect of Solution-Focused group counseling on anxiety in pregnant women	Placebo	Not used
Purpose	Education/Guidance	Assignment	Other
Inclusion/Exclusion criteria	Inclusion criteria: Age range 18-35 years, at least fifth elementary education, gestational age (29-32) weeks, obtaining a score of 18 from the short form of the revised Pregnancy Anxiety Questionnaire Edition 2, singleton pregnancy, no history of infertility and use of assisted reproductive techniques , Pregnant mother's desire to participate in research, no smoking, alcohol and drug addiction, no history of hospitalization in the psychiatric ward, no use of psychiatric drugs at present and during the intervention, no use of propranolol, no participation in similar intervention , No occurrence of stressful events during the last 6 months, resident of Arak city and no diseases or medical records and disorders that make pregnancy high risk. Exclusion criteria: Reluctance to cooperate, absence from more than one session, experience of stressful events (death of a spouse, death of a loved one), occurrence of any complications that make pregnancy dangerous (gestational diabetes, preeclampsia, preterm (onset of labor pains before 37 weeks Complete pregnancy), bleeding, intrauterine death).	Other design features	Examining the interventions performed to reduce pregnancy anxiety, whether solution-oriented, etc., it was found that in these studies, a specific population of pregnant women were studied, for example, Noli Par women who were afraid of childbirth or Noli Par women. Many of these studies also used general anxiety questionnaires to measure pregnancy anxiety, such as the Spielberger Anxiety Inventory, the Hamilton Anxiety Rating Scale, the Cohen Perceived Stress Scale, and the Beck General Anxiety Inventory. It is clear that the study of multiparous women, as a large proportion of pregnant women, has been neglected, while the results of a study showed that multiparous women were 36% more anxious than nulliparous women. Another important point is to use a special questionnaire to measure pregnancy anxiety. General Anxiety Questionnaires are designed to measure general anxiety and their items are not able to measure pregnancy-related anxiety. Therefore, there is a need to conduct studies that include women with multiple pregnancies and a specific questionnaire of appropriate pregnancy anxiety has been used. Therefore, in this study, the short form of the revised Pregnancy Anxiety Questionnaire Edition 2 (PRAQ-R2) was used and the study population includes nulliparous and multiparred women.
Age	From 18 years old to 35 years old	Secondary Ids	empty
Gender	Female	Ethics committees	1
Phase	N/A	Ethics committee	Name of ethics committee
Groups that have been masked	Data analyser		Ethics Committee of Arak University of Medical Sciences
Sample size	Target sample size: 80		Street address
Randomization (investigator's opinion)	Randomized		Slaughterhouse Street, Shahid Vahidollah Rezaei Alley, Postal Code 3816787916
Randomization description	In the present study, the block randomization method will be used (20 to 4 blocks), in each block, two allocations for the control group and two allocations for the intervention group are considered. Random sequence generation will be done using the site (https://www.sealedenvelope.com) . The list of random allocation sequences is then made available to an individual outside the research team. As soon as a person is eligible to attend the study, the sampler contacts the person with the random assignment sequence and, in turn, according to the sequence list, gives the participants a code to enter the study, thus hiding the sequence. Will be the central method		City
Blinding (investigator's opinion)	Single blinded		Arak
Blinding description			Province
			Markazi
			Postal code
			3816787916
		Approval date	2022-01-15, 1400/10/25
		Ethics committee reference number	IR.ARAKMU.REC.1400.277

Health conditions studied

1

Description of health condition studied

Pregnancy Anxiety

ICD-10 code

O99.345

ICD-10 code description

Other mental disorders complicating the puerperium

Primary outcomes

1

Description

Pregnancy Anxiety

Timepoint

Before and immediately after the intervention

Method of measurement

Using the Revised Pregnancy Anxiety Questionnaire Form 2 (PRAQ-R2)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: The intervention group will receive 5 sessions of solution-oriented group counseling, one session per week on an even day of the week (Saturday or Monday or Wednesday) for 5 consecutive weeks. Each session will last 90 minutes. Since the consultation is held in groups, the number of people in each group is 10 and we will have a total of 4 groups of 10 people (40 people). Solution-oriented group counseling sessions will be in accordance with the solution-oriented treatment protocol (including: introduction - goal setting - eliminating the disruptive pattern of behavior with miraculous questions - creating solutions - consolidating solutions - summarizing and concluding) They do not receive any intervention.

Category

N/A

2

Description

Control group: The control group did not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers affiliated with Arak University of Medical Sciences and Ayatollah Taleghani Hospital

Full name of responsible person

Fatemeh Mazraei Farahani

Street address

Koshtargah street, Shahid Vahidollah Rezaei alley

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3816787916

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f.mazraeifarahani@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamani

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Sardasht Street

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Grant name

No

Grant code / Reference number

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

No

Title of funding source

No

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

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Mazraei Farahani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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

Arak University of Medical Sciences

Full name of responsible person

fatemeh mazraei farahani

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for updating data**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

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Position

Student

Latest degree

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Other areas of specialty/work

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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