

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness of "supportive" midwifery counseling on stress and anxiety Due to the Covid 19 epidemic in pregnant women.

Protocol summary

Study aim

Determining the effectiveness of midwifery counseling in a "supportive" way on stress and anxiety caused by the Covid 19 epidemic in pregnant women.

Design

This study is a parallel clinical trial with a control group on 100 pregnant women And using the allocation sequence, which is produced based on the block method of volume 4, the participants are randomly assigned to two groups.

Settings and conduct

First, Gorgan city is divided into three classes in terms of socio-economic status and two health centers are randomly selected from each floor and according to the volume covered by each class, participants are randomly selected from among pregnant women referring to the centers.

Participants/Inclusion and exclusion criteria

Having a health record in health centers Pregnant women with a gestational age of 6 to 32 weeks age range 35-18 Primary education level up Wanting to get pregnant Mental disability No hearing or vision problems No addiction to cigarettes, drugs and alcohol No recurrent miscarriage and history of infertility Ability to participate in training classes if classes are held virtually Access to cyberspace and the Internet High-risk pregnancy) History of serious psychiatric illness History of anxiety problems

Intervention groups

Referral pregnant women will be randomly assigned to two A / B groups (intervention A and control B); In the control group, except for completing the questionnaires and receiving routine pregnancy care, the intervention center will not do it, and in the intervention group, they will be consulted individually and face to face by the project manager in a room in the same center; Support counseling during two 60-minute sessions; The goals of support counseling include a) improving self-esteem b) improving self-efficacy c) and maximizing adaptive skills.

Main outcome variables

Covid 19 stress and anxiety in pregnant women.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210120050092N1**

Registration date: **2021-02-19, 1399/12/01**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-19, 1399/12/01**

Update count: **0**

Registration date

2021-02-19, 1399/12/01

Registrant information

Name

Mina Eteraf

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

mina_eteraf26@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of "supportive" midwifery counseling on stress and anxiety Due to the Covid 19 epidemic in pregnant women.

Public title

Evaluation of stress and anxiety due to Covid 19 epidemic in pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a health record in health centers Pregnant women with a gestational age of 6 to 32 weeks age range 35-18Sa Primary education level up Wanting to get pregnant Mental disability No hearing or vision problems No addiction to cigarettes, drugs and alcohol No recurrent miscarriage and history of infertility Ability to participate in training classes if classes are held virtually Access to cyberspace and the Internet

Exclusion criteria:

High-risk pregnancy (twin or multiple, threat of miscarriage, recurrent miscarriage, history of infertility, history of preterm or threatened preterm delivery, gestational diabetes, preeclampsia, bleeding) History of serious psychiatric illness History of anxiety problems

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

Using the allocation sequence, which is generated based on the block method of volume 4, participants are randomly assigned to two groups. This method was used because people enter the study over time and in order to be assigned to the groups in proportion to the accident over time, and also by assigning one person to one group, it is not possible to guess which group the next person will belong to. After generating the assignment sequence, each sequence letter (A, B) corresponds to a group. As participants enter the study from different centers, the central concealment method is used. The assignment sequence is placed in the hands of someone outside the research team. For each eligible person, after registering and entering the study, the desired person will be contacted and thus entered in a central list and will receive an identification code and assigned to the desired group. • 1, 4, 1, Group B • 1, 4, 2, Group B • 1, 4, 3, Group A • 1, 4, 4, Group A • 2, 4, 1, Group B • 2, 4, 2, Group A • 2, 4, 3, Group A • 2, 4, 4, Group B • 3, 4, 1, Group A • 3, 4, 2, Group B • 3, 4, 3, Group B • 3, 4, 4,

Group A • 4, 4, 1, Group A • 4, 4, 2, Group B • 4, 4, 3, Group B • 4, 4, 4, Group A • 5, 4, 1, Group B • 5, 4, 2, Group B • 5, 4, 3, Group A • 5, 4, 4, Group A • 6, 4, 1, Group A • 6, 4, 2, Group B • 6, 4, 3, Group B • 6, 4, 4, Group A • 7, 4, 1, Group B • 7, 4, 2, Group A • 7, 4, 3, Group A • 7, 4, 4, Group B • 8, 4, 1, Group B • 8, 4, 2, Group B • 8, 4, 3, Group A • 8, 4, 4, Group A • 9, 4, 1, Group B • 9, 4, 2, Group B • 9, 4, 3, Group A • 9, 4, 4, Group A • 10, 4, 1, Group B • 10, 4, 2, Group A • 10, 4, 3, Group B • 10, 4, 4, Group A • 11, 4, 1, Group B • 11, 4, 2, Group A • 11, 4, 3, Group B • 11, 4, 4, Group A • 12, 4, 1, Group B • 12, 4, 2, Group A • 12, 4, 3, Group A • 12, 4, 4, Group B • 13, 4, 1, Group A • 13, 4, 2, Group B • 13, 4, 3, Group A • 13, 4, 4, Group B • 14, 4, 1, Group A • 14, 4, 2, Group A • 14, 4, 3, Group B • 14, 4, 4, Group B • 15, 4, 1, Group A • 15, 4, 2, Group A • 15, 4, 3, Group B • 15, 4, 4, Group B • 16, 4, 1, Group B • 16, 4, 2, Group A • 16, 4, 3, Group B • 16, 4, 4, Group A • 17, 4, 1, Group B • 17, 4, 2, Group A • 17, 4, 3, Group A • 17, 4, 4, Group B • 18, 4, 1, Group B • 18, 4, 2, Group B • 18, 4, 3, Group A • 18, 4, 4, Group A • 19, 4, 1, Group B • 19, 4, 2, Group B • 19, 4, 3, Group A • 19, 4, 4, Group A • 20, 4, 1, Group A • 20, 4, 2, Group A • 20, 4, 3, Group B • 20, 4, 4, Group B • 21, 4, 1, Group A • 21, 4, 2, Group B • 21, 4, 3, Group B • 21, 4, 4, Group A • 22, 4, 1, Group B • 22, 4, 2, Group A • 22, 4, 3, Group A • 22, 4, 4, Group B • 23, 4, 1, Group B • 23, 4, 2, Group A • 23, 4, 3, Group A • 23, 4, 4, Group B • 24, 4, 1, Group A • 24, 4, 2, Group A • 24, 4, 3, Group B • 24, 4, 4, Group B • 25, 4, 1, Group B • 25, 4, 2, Group B • 25, 4, 3, Group A • 25, 4, 4, Group A

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 Shahrood University of Medical Sciences

Street address

Shahrood University of Medical Sciences and Health Services- 7th of Tir Square- Shahrood

City

shahrood

Province

Semnan

Postal code

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Approval date

2021-02-07, 1399/11/19

Ethics committee reference number

IR.SHMU.REC.1399.172

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

Stress caused by the Covid epidemic in pregnant women

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Anxiety caused by the Covid epidemic in pregnant women

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Covid 19 stress in pregnant women

Timepoint

First before the intervention and then 4 weeks after the end of the intervention.

Method of measurement

Corona Virus Stress Scale Questionnaire

2**Description**

Anxiety caused by Covid 19 in pregnant women

Timepoint

First before the intervention and then 4 weeks after the end of the intervention.

Method of measurement

Coronavirus Anxiety Scale Questionnaire

Secondary outcomes

empty

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

Intervention group: pregnant women

Category

N/A

2**Description**

Control group:

Category

N/A

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

Comprehensive health service centers of Gorgan city.

Full name of responsible person

mina eteraf

Street addressNext to the Islamic Propaganda Organization, Razi St.-
Shahid Rajaei St, Martyrs Square**City**

gorgan

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Golestan

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Email

Info@goums.ac.ir

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

Shahroud University of Medical Sciences

Full name of responsible person

mohammad hasan emamiyan

Street addressShahroud University of Medical Sciences and Health
Services - 7th of Tir Squar - Shahroude**City**

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emamian@shmu.ac.ir

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

Yes

Title of funding source

Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
mina eteraf
Position
Master student in midwifery counseling
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

Contact

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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Regarding participants' personal data, information about the initial outcome is shared.

When the data will become available and for how long

Access time 6 months after the results are published.

To whom data/document is available

Researchers are allowed to receive data.

Under which criteria data/document could be used

The use of available pain data to advance the objectives of the study is permitted.

From where data/document is obtainable

They can be contacted via the following email to receive information. mina_eteraf26@yahoo.com

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

The applicant's request will be answered within a week.

Comments