

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Telephone Counseling on Covid-19-related Health Anxiety in Pregnant Women: A randomized controlled trial

Protocol summary

Study aim

Determining the effect of telephone counseling on COVID-19-related health anxiety in pregnant women referred to Saveh health centers

Design

This study was a randomized controlled clinical trial. Simple random sampling was performed among pregnant women referring to Saveh Health Center (5 centers) who provided midwifery services. Then they were divided into intervention (A) and control (B) by block randomization method.

Settings and conduct

After sampling and random allocation of samples, they were asked to complete a demographic and health anxiety questionnaire. Then the intervention group was given telephone counseling and the control group was not given counseling. After one month, the test post was taken by telephone from both groups. The counseling session consisted of two 30-minute telephone calls. Each sample in the intervention group received telephone counseling at least twice, one to two weeks apart. The consultation was conducted by a senior midwifery consultant who has a history of counseling.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No family conflicts or mental and psychological problems, no history of any psychological disease, no history of using antidepressants and psychiatric medications, and access to the telephone. Exclusion criteria: unwillingness to continue participation in the study and the happening of any crisis and stressful situation for the mother during the study

Intervention groups

Pregnant Mothers

Main outcome variables

Health Anxiety Rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220531055038N1**

Registration date: **2022-06-13, 1401/03/23**

Registration timing: **retrospective**

Last update: **2022-06-13, 1401/03/23**

Update count: **0**

Registration date

2022-06-13, 1401/03/23

Registrant information

Name

Sahar Yazdi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-04-09, 1401/01/20

Actual recruitment start date

2022-03-01, 1400/12/10

Actual recruitment end date

2022-04-19, 1401/01/30

Trial completion date

2022-04-30, 1401/02/10

Scientific title

The Effect of Telephone Counseling on Covid-19-related Health Anxiety in Pregnant Women: A randomized controlled trial

Public title

The effect of counseling on coronary anxiety in pregnant women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant women who refer to selected health centers
Willing to participate in the study

Exclusion criteria:

Inclusion criteria were willingness to participate in the study, no family conflicts or mental and psychological problems no history of any psychological disease no history of using antidepressants and psychiatric medications, and access to the telephone

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **85**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

This study was performed on 85 pregnant women referred to Saveh health centers. After obtaining the necessary approvals and attracting the participants, the objectives of the research were explained to them and the mothers were asked to sign their written consent. Random sampling was performed by participants from all five health centers in Saveh that provided midwifery services. First, a list of pregnant mothers was prepared and then, using a random number table, participants from each center (proportional to the number of mothers covered by them) were selected from among the eligible inclusion criteria. Then they were divided into intervention (A) and control (B) by block randomization method. First, 17 blocks of 5 are listed as follows: AAAAB, AAABB, AABBB, ABBBB,... Then these blocks were arranged using a table of random numbers and individuals were assigned to two groups according to A and B.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the study (counseling and training), which was not possible for the researcher and participant to be blinded, the analyzer and evaluator were given codes A and B. The intervention group received code A and control code B and had no information about the type of study and groups.

Placebo

Not used

Assignment

Other

Other design features

The consultation session consisted of two 30-minute phone conversations consisting of three parts. In part one, explanations were provided about coronavirus epidemiology in the region, definition and symptoms of the disease, how to care for pregnant women and protect them during the pandemic, how to schedule telephone counseling sessions and visits with gynecologists (to avoid unnecessary visits), providing the necessary information about the maternal-fetal transmission of the virus, answering to ambiguities around the choice of the right person who would follow the instructions during delivery, how to choose the safest place for delivery, how to breastfeed during the pandemic time, and how to care for the baby in the hospital and at home during the coronavirus era. Part two was dedicated to teaching relaxation techniques, which was accompanied by sending a file containing training about these techniques for ensuring better knowledge and practice. Finally, the 5-minute part three was considered for answering questions, following up for needs, and obviating the problems of the participant.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Saveh University of Medical Sciences

Street address

Saveh university , Behest Ave, Fahmideh Blvd

City

Saveh

Province

Markazi

Postal code

3919953649

Approval date

2020-12-23, 1399/10/03

Ethics committee reference number

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

-

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Primary outcome: health anxiety rate; In this study, the effect of telephone counseling on COVID-19-related health anxiety in pregnant women was investigated. The level of health anxiety was assessed using the Salkovskis and Warwick's health anxiety questionnaire by telephone before and after the intervention.

Timepoint

1 Month

Method of measurement

demographic checklist and the health anxiety Salkowski & Warwick questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants were initially requested to complete a demographic checklist and the health anxiety questionnaire. The consultation session consisted of two 30-minute phone conversations consisting of three parts. In part one, explanations were provided about coronavirus epidemiology in the region, definition and symptoms of the disease, how to care for pregnant women and protect them during the pandemic, how to schedule telephone counseling sessions and visits with gynecologists (to avoid unnecessary visits), providing the necessary information about the maternal-fetal transmission of the virus, answering to ambiguities around the choose of the right person who would follow the instructions during delivery, how to choose the safest place for delivery, how to breastfeed during the pandemic time, and how to care for the baby in the hospital and at home during the coronavirus era. Part two was dedicated to teaching relaxation techniques, which was accompanied by sending a file containing training about these techniques for ensuring better knowledge and practice. Finally, the 5-minute part three was considered for answering questions, following up for needs, and obviating the problems of the participant. ONE - Two week after intervention, the health anxiety questionnaire was completed again via making phone calls to the participants.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

health Care Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

1399-027

Grant code / Reference number

1399-02.

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

Yes

Title of funding source

Saveh 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
Saveh University of Medical Sciences

Full name of responsible person
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Position
Lecturer

Latest degree
Master

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participant data is confidential.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The e-mail of the responsible author will be included in the article and the subscribers will be provided with shareable items at the request of the audience.

When the data will become available and for how long

There is no time limit.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The results of the project can be obtained and extracted only by mentioning the source.

From where data/document is obtainable

Author

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

Email to the responsible author

Comments

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