

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of effect of crisis counseling on anxiety, Decision-Making Style and Strategies in women with unplanned pregnancy in intervention (receive crisis counseling) with control (do not receive crisis counseling) groups

Protocol summary

Summary

This is an experimental study with the aim of determining the Impact of crisis counseling on anxiety, decision-making style and strategies of women with unplanned pregnancy. Study setting was family physician centers and obstetricians and midwifery offices of the city of Qaemshahr, North of Iran. The statistical population includes 15-49 year-old women with unplanned pregnancy referred to these centers. The sample size is 70 women (35 women in each group). Blinding is not possible. Random allocation to two groups will be done by using Random Number Generator software. Two series in 35 random number will be taken. Women who come to these centers for a pregnancy test and do not have a planned pregnancy, also, women who refer to the centers for asking pregnancy test and have positive pregnancy tests during the past four weeks will be invited to participate in the project. Women, who did not have a plan for childbearing, requested Pregnancy test or had a positive pregnancy test within 4 weeks ago were recruited. Inclusion criteria was reproductive age; have at least one child; Iranian; married; ability to communicate; having general health and positive β hcg. After receiving written consent, Spielberger's anxiety inventory and style and decision-making strategies of women in the unplanned pregnancy questionnaires will be complete by the participant. If the level of anxiety are high and women with an inappropriate decision style, the phone number will be obtained. Participants will be randomly allocated to one of the two groups based on sequential referring to the centers. In the intervention group, the first session will be held as soon as possible within 4 weeks of the pregnancy confirmation. A total of 4 individual 120-150 minutes counseling sessions are provided. The first 3 sessions will be held at intervals of 3-4 days and the last session will be held one month

after the last session. The control group will not receive crisis counseling. Then, two groups' anxiety and style and decision-making strategies in unplanned pregnancy will be compared.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017100231117N5**

Registration date: **2017-11-11, 1396/08/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-11, 1396/08/20

Registrant information

Name

Soghra Khani

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2017-11-01, 1396/08/10

Expected recruitment end date

2018-04-30, 1397/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of crisis counseling on anxiety, Decision-Making Style and Strategies in women with unplanned pregnancy in intervention (receive crisis counseling) with control (do not receive crisis counseling) groups

Public title

Effect of crisis counseling on anxiety, Decision-Making Style and Strategies in Women with unplanned pregnancy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Reproductive age; have at least one child; Iranian; married and currently living with her legal spouse; ability to communicate; having general health (lack of diseases including diabetes, high blood pressure and any known chronic disease, such as cardiovascular, kidney and liver diseases); have a positive Pregnancy test (β hcg). Exclusion criteria: Appearing of high risk pregnancy symptoms such as bleeding, leaking of liquid through the vagina, existing of suicidal thoughts; severe and major psychiatric disorders; Having a psychosis; Participation in other psychiatric treatment protocols in the last 6 months; Unwilling to participate in the study.

AgeFrom **15 years** old to **49 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **70****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Random table numbers will be used for random allocating of two groups.

Secondary Ids

empty

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

Ethics committee of Mazandaran University of Medical Sciences

Street address

vice chancellor for research of Mazandaran University of Medical Sciences, Moalem Square.

City

Sari

Postal code**Approval date**

2017-06-10, 1396/03/20

Ethics committee reference number

IR.MAZUMS.REC.95. 3181

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

unwanted pregnancy

ICD-10 code

F64.0

ICD-10 code description

Problems related to unwanted pregnancy

Primary outcomes**1****Description**

Anxiety

Timepoint

before intervention, 4 week after intervention

Method of measurement

wendenburg pregnancy related anxiety questionnaire; Spielberger Anxiety; GHQ-28;

Secondary outcomes**1****Description**

decision-making style and strategies about unplanned pregnancy

Timepoint

before and one month after intervention

Method of measurement

decision-making style and strategies of women with unplanned pregnancy questionnaire

Intervention groups

1

Description

Intervention group: The first session will conduct as soon as possible within a maximum of 4 weeks after the pregnancy test, and a total of 4 120-120 minutes solitary confinement sessions will done according to the Robert's seven-step model, 3 first sessions with a 3-4 day interval and the last session (follow up) will held one month later.

Category

Behavior

2

Description

Control group: This group will not receive the intervention (crisis counseling).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

The centers of the urban family physician and obstetricians and midwifery offices.

Full name of responsible person

Dr Mohammad Geran

Street address

City

Qaemshahr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

Dr M. Saeidi

Street address

vice chansellor for research of Mazandaran University of Medical Sciences, Moalem squire

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences, Sexual and Reproductive Health Research Center

Full name of responsible person

Dr Soghra Khani

Position

PhD, Moderator (owner) of project

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr soghra Khani

Position

Modarator (owner) of [project/ PhD]

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr Soghra Khani

Position

PhD/moderator (owner) of project

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty