

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the effectiveness of couple counseling based on cognitive-behavioral and Solution-focused approaches to prevention of postpartum blues and depression in pregnant women .

Protocol summary

Study aim

Comparison of the effectiveness of paired counseling with two cognitive-behavioral and decision-based approaches in the prevention of postpartum distress and postpartum depression in pregnant women. If counseling is effective in reducing postpartum depression, these sessions can be considered.

Design

Clinical practice is a non-randomized, cross-sectional one-blind clinical trial.

Settings and conduct

At first, grief questionnaires, postpartum depression, and DOS depression questionnaire by couples, which are needed for matching, are given to people who are referred to Mobinini Hospital in Sabzevar, and then eligible wives of their spouses in the counseling classes are present at the intervention sessions.

Participants/Inclusion and exclusion criteria

Minimal primary education ,No history of previous mental illnesses , Failure of the physician to rest absolutely , No illness Chronic ,Do not addict, Earn score below 15 in the DASS questionnaire by yourself and the spouse. ;The occurrence of any stressful incident for a patient or class members of a pregnant woman, diagnosis of mental illness and psychiatric disorders, dissatisfaction and lack of interest in continued cooperation, absence of more than 2 sessions in counseling sessions, abnormalities and deaths.Abnormalities and fetal death

Intervention groups

Includes two groups: 1. An intervention group that must participate in conjugal counseling classes in addition to attending birth-preparation classes. 2. The attending group attending prepayment classes. Ultimately this We compare the two groups together.

Main outcome variables

Cognitive-qualitative-nominal-independent-grouping-has or not. Qualitative-nominal solution-Independent -group-

Ordinary or not. Distress after childbirth - a little bit of continuity - no doubt - and a questionnaire-an issue Postpartum depression - Continuously-Nonspecific-Affected-Grouping-Neutral

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190204042622N1**

Registration date: **2019-07-16, 1398/04/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-16, 1398/04/25**

Update count: **0**

Registration date

2019-07-16, 1398/04/25

Registrant information

Name

Atefe Beyhaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3752 3023

Email address

abeyhaghi76@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-05, 1398/03/15

Expected recruitment end date

2020-04-03, 1399/01/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of couple counseling based on cognitive-behavioral and Solution-focused approaches to prevention of postpartum blues and depression in pregnant women .

Public title
Comparison of the effectiveness of couple counseling based on cognitive-behavioral and Solution-focused approaches to prevention of postpartum blues and depression in pregnant women .

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
1-Minimum Elementary Education 2. Not a history of mental illness in the past, such as schizophrenia, depression, anxiety and ... 3. Participation in childbirth classes 4. Failure of the physician to rest absolutely absolute 5. The absence of chronic diseases 6. Non-addiction 7- Earn score below 15 in the DASS questionnaire by yourself and the spouse 8. The absence of mental illness in a spouse.
Exclusion criteria:
The occurrence of any stressful incident for a patient or class members of a pregnant woman's family Diagnosis of mental illness and psychiatric disorders (mood disorders such as depression, anxiety disorder and the diagnosis of a patient's illness and any other illness during the study) Dissatisfaction and lack of interest in continued cooperation Missing more than 2 sessions in counseling sessions Abnormalities and fetal deaths and termination of pregnancy before the end of counseling sessions

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: 45

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
First, in person by interviewing pregnant women and filling out the questionnaire of sadness and depression by pregnant women, as well as filling the DASS depression questionnaire by couples, qualified people to attend counseling classes, and by telephone to obtain

their consent for participation It was done in classes. Using the six-point block table, the samples were grouped into three groups and equalized, and by matching the score of 15 couples in the DASS questionnaire, this would be matched. In this study, all participants were asked how they assigned the group They are unaware of the fact that the investigator, the safety committee and the supervisors are aware of how the people are assigned.

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sabzevar University of Medical Sciences

Street address

Tohid Town, Above Anonymous Martyrs, Campus Medical Sciences Complex

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Approval date

2019-05-24, 1398/03/03

Ethics committee reference number

IR.MEDSAB.REC. 1398.018

Health conditions studied

1

Description of health condition studied

blues and postpartum depression

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Cognitive-qualitative-nominal-independent-grouping-has or not. Qualitative-nominal solution-Independent -group-Ordinary or not. Distress after childbirth - a little bit of continuity - no doubt - and a questionnaire-an issue . Postpartum depression - Continuously-Nonspecific-Affected-Grouping-Neutral . Mental health is a little continuously a disturbing proportion of the score

questionnaire.

Timepoint

Death grief questionnaire after Stein's birth during 3-5 days after childbirth. Postpartum diaphysmicity questionnaire in Edinburgh on the 15th day after childbirth.

Method of measurement

Death grief questionnaire after Stein's birth during 3-5 days after childbirth. Postpartum diaper delivery questionnaire on the 15th day after childbirth. Dos depression questionnaire for couples before counseling.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to participating in childbirth classes, intervention groups are accompanied by a spouse in interventional sessions. The Cognitive-Behavioral Counseling Group will participate in 4 1-hour sessions and an Axis Solutions in 3 1-hour sessions.

Category

Prevention

2

Description

Control group: Witnesses attend routine classes for childbirth. Due to the increasing sample size, each group of people is in the subgroups of 8 to 12 people.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahidan Mobini Hospital in Sabzevar

Full name of responsible person

Masoumeh Sharifzadeh

Street address

North Kashfi Avenue

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mobini.h@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Masoumeh Sharifzadeh

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Blvd. Tohid Shahr, above the unknown martyrs, Campus building

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Masoumeh Sharifzadeh

Position

professor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Position

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Latest degree

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

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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