

# 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

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9613873136

##### Phone

+98 51 4423 8103

##### Email

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

##### Street address

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

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9613873136

##### Email

info@medsab.ac.ir

#### 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

##### Street address

Shahidan Mobini Hospital in Sabzevar

##### City

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##### Province

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##### Phone

+98 935 678 0225

**Email**

msharifzade@yahoo.com

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

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**Position**

professor

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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

Sabzevar University of Medical Sciences

**Full name of responsible person**

Atefeh Bayhaghi

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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**Province**

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**Postal code**

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**Phone**

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**Email**

abeyhaghi76@gmail.com

**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