

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The effectiveness of couples counseling with cognitive-behavioral approach on the severity of labor pain and prevention of postpartum blues and depression in pregnant women

Protocol summary

Study aim

To determine the effectiveness of couple counseling with cognitive-behavioral approach on the severity of labor pain and prevention of postpartum grief and depression in pregnant women.

Design

Clinical trial with two groups of intervention and control with parallel groups, without blinding, randomized. The website <https://www.sealedenvelope.com/simple-randomiser/v1/lits> was used for the crash.

Settings and conduct

Random sampling will be done in the clinic from mothers referring to Musa Ibn Al-Jaafar, Bint Al-Huda, Mehr, Madar, Mehregan, Umm Al-Banin, Pasteur hospitals in Mashhad. One-hour cognitive-behavioral counseling sessions are held for spouses. Finally, during labor, the severity of labor pain and postpartum grief and postpartum depression are measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No history of mental illness in the past - No chronic physical illness - No addiction - No history of mental illness in the spouse - Noli Parita Exclusion criteria : Twins, diagnosis of mental illness and psychiatric disorders and diagnosis of the patient with any incurable disease, etc. During the study, dissatisfaction and lack of interest in continuing cooperation.

Intervention groups

In addition to attending childbirth preparation classes, intervention groups also attend intervention sessions with their spouses. The cognitive-behavioral counseling group will participate in 4 1-hour sessions. The control group will participate in routine childbirth preparation classes. Each group of individuals is placed in subgroups of 8 to 12 people. At the beginning of counseling classes, the informed consent form, demographic characteristics

and questionnaire of the plan including grief and depression are completed.

Main outcome variables

Postpartum blues and depression, the severity of labor pains

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190204042622N2**

Registration date: **2021-09-08, 1400/06/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-08, 1400/06/17**

Update count: **0**

Registration date

2021-09-08, 1400/06/17

Registrant information

Name

Atefe Beyhaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3752 3023

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of couples counseling with cognitive-behavioral approach on the severity of labor pain and prevention of postpartum blues and depression in pregnant women

Public title

The effect of couple counseling with cognitive-behavioral approach on severe labor pain and postpartum blues and depression

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

1- Having at least primary education 2- Not having a history of mental illnesses in the past such as schizophrenia, depression, anxiety, etc. 3- Participating in childbirth preparation classes 4- Lack of doctor's instructions for absolute rest 5- Absence of chronic physical illnesses 6- Absence Addiction 7- No history of mental illness in the spouse.8_Noli Parita

Exclusion criteria:

Occurrence of any stressful event for the patient or first-degree members of the pregnant woman's family, diagnosis of mental illness and psychiatric disorders (mood disorders such as depression, anxiety disorder and diagnosis of the patient with any incurable disease, etc.) during the study), Dissatisfaction and unwillingness to continue cooperation, absence of more than 2 sessions in counseling sessions, abnormalities and fetal death and termination of pregnancy before the end of counseling sessions, multiple ,Emergency cesarean section

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

Quadruple blocks. In this study, we will use the Restricted randomization method of block randomization. The size of all blocks is equal and we in this two-group experiment of 4 blocks (including 2 participants in We will have an intervention group and 2 participants in the control group). The method of hiding the sequence of allocating white envelopes is used. Using the website <https://www.sealedenvelope.com/simple-randomiser/v1/lists> and with the help of the methodology consultant, the

allocation sequence was generated.

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**

Shahroud University of Medical Sciences

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

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shahroud

Province

Semnan

Postal code

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Approval date

2021-09-01, 1400/06/10

Ethics committee reference number

IR.SHMU.REC.1400.118

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

Postpartum blues and depression

ICD-10 code

F53

ICD-10 code description

Mental and behavioural disorders associated with the puerperium

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

Postpartum blues

Timepoint

Filling out the grief questionnaire by a pregnant woman before the start of counseling sessions. After the counseling sessions, the post-delivery grief questionnaire is filled in 3 to 5 days after delivery.

Method of measurement

Stein Postpartum Grief Questionnaire

2

Description

Postpartum depression

Timepoint

Completing the Postpartum Depression Questionnaire by a pregnant woman before the start of counseling sessions. After the counseling sessions, the Edinburgh Postpartum Depression Inventory will be completed on the 15th day after delivery.

Method of measurement

Edinburgh Postpartum Depression Inventory

3

Description

Intensity of labor pain

Timepoint

Intensity of labor pain during the active phase of labor (dilation 4 cm) is filled in three stages.

Method of measurement

Visual scale of pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to attending childbirth preparation classes, intervention groups also attend cognitive-behavioral counseling sessions with their spouse. The Cognitive Behavioral Counseling Group will participate in 4 1-hour sessions. Due to the increase in the sample size, each group of people are placed in groups of 8 to 12 people for counseling. At the beginning of counseling classes, the informed consent form is completed in writing and the demographic profile form and the design questionnaire including grief and depression are completed. A Brief Description of Cognitive-Behavioral Couple Sessions in Research (Cognitive Therapy Techniques by Robert Lee Hee): Session 1: Establishing a good relationship and getting acquainted with the principles and goals of cognitive-behavioral couple therapy, examining and recognizing the goals of members participating in the sessions. Session 2: Identifying unrealistic beliefs and expectations of couples by providing cognitive skills Session 3: Correcting mistakes Cognitive (thinking all or nothing, exaggerated generalization, subjective filtering, neglect of the positive, hasty conclusions, mind reading, prediction, magnification, emotional reasoning, do's and don'ts, labeling, personalization and blame.), Clearing up misunderstandings Due to misconceptions or differences from each other - Replacing realistic beliefs and expectations (cognitive skills) Session 4: Teaching effective communication skills between couples (verbal and non-verbal communication, empathetic understanding and active listening) Recognizing patterns of reinforcement and punishment of each Spouses,

Increasing Positive Reinforcers and Increasing Positive Behavioral Exchanges (Behavioral Skills). Homework: We teach couples in any intense and annoying emotional situation they have experienced the feelings of inefficiency that come to mind at that moment. And in the next step, when they learned Shakhty mistakes, thinking n Write the effect next to that sense, then write the alternative thinking we have taught them against this inefficient thought, and finally write their sense after substituting the alternative thought and express what percentage of them feel better.

Category

Prevention

2

Description

Control group: Control group: The control group will participate in childbirth preparation classes routinely. Due to the increase in the sample size, each group of people are placed in groups of 8 to 12 people for counseling.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Musa Ibn Al-Jaafar, Bint Al-Huda, Mehr, Madar, Mehregan, Umm Al-Banin, Pasteur Hospitals, Mashhad

Full name of responsible person

Atefe beyhaghi

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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**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

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Position

Student

Latest degree

Master

Other areas of specialty/work

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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