Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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/lists 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

Email address

abeyhaghi76@gmail.com

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
Street address
Shahroud, 7th of Tir Square - Shahroud University of Medical Sciences and Health Services
City
shahroud
Province
Semnan
Postal code
۳۶۱۴۷-۷۳۹۴۳
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
Street address
Mashhad - Bahar Street - next to the gas station
City
Mashhad
Province
Razavi Khorasan
Postal code
9174685157
Phone
+98 51 3859 0051
Email
bentolhodahospital@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Atefe beyhaghi
Street address
Shahroud University of Medical Sciences
City
Shahroud

Province
Semnan
Postal code
3614773943
Phone
+98 23 3239 5054
Email
info@shmu.ac.ir
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
Atefe beyhaghi
Position
Student
Latest degree
Master
Other areas of specialty/work
Midwifery
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shahroud
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
Atefe beyhaghi
Position
Student
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact
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Full name of responsible person
Atefe beyhaghi
Position
Student
Latest degree
Master
Other areas of specialty/work
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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary