Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of midwifery counseling (positive psychology based intervention) on happiness and labor pain coping behaviors of pregnant women

Protocol summary

Study aim
The effectiveness of midwifery counseling (positive psychology based intervention) on happiness and labor pain coping behaviors of pregnant women

Design
This double blind Randomize control trial conducts, with two groups. Randomization was centralized and computerized with concealed randomization .Pretest questionnaire will be fill for both groups. The Control group will receive only 8 sessions of childbirth preparation classes and intervention group will receive 8 counselling sessions weekly in addition childbirth preparation classes.At the end of classes , post test questionnaire will be fill for both groups again. At the active phase of labor,mothers are completed coping behavioral questionnaire .

Settings and conduct
childbirth preparation and counselling Classes conduct at Mobinabi Hospital. Primigravida who Have inclusion , Invited to enter the study.The participants of each group do not aware about Existence of another group. questionnaires will complete by another person except researcher.The analyzor does not aware about groups .

Participants/Inclusion and exclusion criteria
age (18 -35), primigravida, no exposure to grief or lost of siblings during last year, Non-addiction and substance abuse, Literacy reading and writing, Tendency to normal delivery, Lack of mental and medical illness, Have a low-risk pregnancy, Non-indication for cesarean section, absence of auditory and verbal problems witch prohibit communication with researcher.

Intervention groups
This double blind Randomize control trial conducts, with two groups. The Control group will receive only 8 sessions of childbirth preparation classes and intervention group will receive 8 counselling sessions weekly in addition childbirth preparation classes.

Main outcome variables
Coping behaviors with labor pain - happiness level of pregnant women

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190311043004N1**
Registration date: **2019-07-14, 1398/04/23**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-14, 1398/04/23**
Update count: **0**

Registration date
2019-07-14, 1398/04/23

Registrant information

Name
azam keyvanloo

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4429 4209

Email address
azam.k1looshah@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-30, 1398/02/10

Expected recruitment end date
2019-08-23, 1398/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of midwifery counseling (positive psychology based intervention) on happiness and labor pain coping behaviors of pregnant women

Public title
The effectiveness of counseling (positive psychology based intervention) on happiness and labor pain coping behaviors of pregnant women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
age (18 -35) Being primiparous Literacy reading and writing Having a low-grade risk pregnancy Tendency to normal delivery
Exclusion criteria:
had experienced grief or death of a loved one until past year Suffering from addiction and drug abuse having Mental or medical illness have indication for cesarean section Having verbal and hearing problems as a communication barrier to the researcher
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
The blocking method (quadrilateral blocks) is used for random assignment. in this method Block list is written and numbers assigned to them. Finally, the allocation of treatment is based on random numbers.To do this, the random blocked website is used. A random sequence of blocking is given to a specific person outside the research team who is responsible for random assignment.
Blinding (investigator's opinion)
Double blinded
Blinding description
Both groups participate in the 8 sessions of the class with the content of childbirth preparedness sessions and the intervention group will participate in positive psychological sessions in addition to participating in these 8 sessions (preparedness of childbirth). The scheduling of the sessions is planned in such a way that the control and intervention groups do not interact and the content of each meeting is not known. The analyst is also unaware of the person's ability to control the group or intervention. Exposure assessment is also provided by the trained person who does not know the allocation of people to the control and intervention teams. However, due to the fact that the consultation is carried out by the researcher himself, the researcher will not be blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrood University of Medical Sciences
Street address
7th tir square, shahrood University of Medical Sciences
City
shahroud
Province
Tehran
Postal code
3614773947
Approval date
2019-03-16, 1397/12/25
Ethics committee reference number
IR. SHMU. REC.1397.224

Health conditions studied

1

Description of health condition studied
Happiness
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Coping behaviors with labor pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Happiness refers to the judgment of the individual about the desirability of the quality of life as a whole, which is

scored by the Oxford Happiness Questionnaire. The Oxford Happiness Questionnaire (OHI) has 29 sentences, each containing 4 sentences, the first term is zero, the second is the score 1 , The third phrase marks 2 and the fourth expression takes the score of 3. Finally, a person earns a score between 0 and 87.Higher scores mean more happiness.

Timepoint

Beginning of the study (before intervention) and after intervention

Method of measurement

Oxford Happiness questionnaire

Secondary outcomes

1

Description

Coping behaviors with labor pain

Timepoint

After the intervention (the onset of the active phase of labor)

Method of measurement

Coping behaviors with labor pain questionnaire

Intervention groups

1

Description

Intervention group: A group of interventions is a group of pregnant women who participate in positive psychological counseling sessions in addition to participating in childbirth classes, who participate in 8 sessions of 90 minutes in 8 weeks. The intervention is based on Frederick Ben Nin's positive cognitive-behavioral therapy. The general objectives of the sessions are: the first session (familiarity with the concept of positivism), the second session (social happiness and awareness), the third week (the introduction of the exemption process model), the fourth week (introducing the appreciation concept), the fifth week (explanation of optimism) Sixth Week (The Concept of Hope and Hope), Seventh Week (Explaining Self-esteem and Valuable Feeling), Eighth Week (The Importance of Life and Trust in God).

Category

N/A

2

Description

Control group: The control group only participates in classes with the content of the classes of childbirth preparation (8 sessions) and do not receive any other intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahidan Mobinini Hospital of Sabzevar

Full name of responsible person

gholamabbas kafi

Street address

Kashefi Ave

City

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Azam.k1looshah@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hasan Emamian

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Fax

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Email

vcr@shmu.ac.ir

Web page address

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
Azam Keyvanloo shahrestanaky
Position
Midwife
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
puplishable data include thesis interpreted results and papers and protocol if needed
When the data will become available and for how long
Access from 2020
To whom data/document is available
Data are access for all researchers in scientific institutes
Under which criteria data/document could be used
In case of Author's permission
From where data/document is obtainable
To corresponding author or executive author
What processes are involved for a request to access data/document
By contact with the departmant or send an email to authors
Comments