

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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 analyzer 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

AgeFrom **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 sizeTarget 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

shahrood

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

Sabzevar

Province

Razavi Khorasan

Postal code

9613675955

Phone

+98 51 4423 8100

Email

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

Street address

7th tir square, Shahroud University of Medical Sciences

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷۷۳۹۵۵

Phone

+98 23 3239 6714

Fax

+98 23 3239 4852

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
Street address
17 plaqu ,No 1, Sarcheshme Ave
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613675955
Phone
+98 51 4429 4209
Email
Azam.k1looshah@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
azam keyvanloo shahrestanaky
Position
postgraduate Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
17 plaqu ,No 1, Sarcheshme Ave
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613675955
Phone
+98 51 4429 4209
Email
Azam.k1looshah@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Azam keyvanloo shahrestanky
Position
Post Graduate Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
17 plaqu ,No 1, Sarcheshme Ave
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613675955
Phone
+98 51 4429 4209
Email
Azam.k1looshah@gmail.com

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

publishable 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