

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effectiveness of midwifery counseling based on cognitive-behavioral approach on anxiety and maternal - fetal attachment among mothers with past history abortion referring prenatal care shahid Sadoughi center Yazd

Protocol summary

Study aim

Determining the effect of midwifery counseling with cognitive-behavioral approach on maternal.fetal attachment and anxiety in mothers with abortion history

Design

This study was a randomized clinical trial with two groups (test and control). There are 33 pregnant women with abortion history that are available in each group. Blind is on the side.

Settings and conduct

The prenatal center of Shahid Sadoughi Hospital in Yazd is based on objective sampling

Participants/Inclusion and exclusion criteria

teria for entering the study: Mothers who have literacy and reading skills, mothers with pre-pregnancy and abortion, gestational age 27-30 weeks, and physiologically and physically healthy, are able to attend and participate actively in the classroom, have an anxiety score. Low to moderate (80-20) based on Spielberger anxiety scale; Exit criteria: having recurrent abortions, having acute obstetric problems associated with pregnancy, and having a history of serious psychiatric disorders, unwillingness to participate in research, use of psychoactive drugs before From pregnancy and during pregnancy by couples, it is suddenly taken To abnormal stress due to life-threatening events in the last 1 month, multiple pregnancies

Intervention groups

The statistical population of this study is all pregnant women with a history of abortion and childbirth and 27-30 weeks pregnancy referred to the prenatal center of Shahid Sadoughi Hospital in Yazd. If the conditions for entering the research were divided into two groups, the control group was randomly divided into 33 groups each group. The midwifery counseling group with a cognitive-

behavioral approach was held during 6 sessions and the control group received routine prenatal care They give.

Main outcome variables

Anxiety; maternal. fetal attachment

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20170802035446N2**

Registration date: **2018-10-17, 1397/07/25**

Registration timing: **retrospective**

Last update: **2018-10-17, 1397/07/25**

Update count: **0**

Registration date

2018-10-17, 1397/07/25

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3252 6897

Email address

arianmokhtari2@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-10, 1396/09/19

Expected recruitment end date

2018-06-19, 1397/03/29
Actual recruitment start date
 2018-02-09, 1396/11/20
Actual recruitment end date
 2018-06-10, 1397/03/20
Trial completion date
 1988-09-01, 1367/06/10

Scientific title
 The effectiveness of midwifery counseling based on cognitive-behavioral approach on anxiety and maternal - fetal attachment among mothers with past history abortion referring prenatal care shahid Sadoughi center Yazd

Public title
 Investigating the effect of counseling with cognitive-behavioral approach on maternal attachment-anxiety in mothers with abortion history

Purpose
 Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 -Madrid who are literate to read and write. Pregnant mothers, without children, and abortions 3- Gestational age 27-30 weeks 4. Mothers who were physiologically and physically able to attend and participate actively in the classroom (vision, hearing, etc.). Having low to moderate anxiety score (80-20) based on Spielberger anxiety scale
Exclusion criteria:
 Having repeated abortions 2- Acute obstetric and pregnancy related problems (severe gestational infertility, bladder pains, bleeding ...) 3. Having a history of serious psychiatric disorders 5- The use of psychotropic drugs before pregnancy and during pregnancy by couples 6. Sudden onset of abnormal stress caused by unpleasant events of life in the last 1 month, such as: the death of a spouse, divorce, separation and disgust with a spouse, the death of a close member of a family 7. Multiple pregnancy

Age
 No age limit

Gender
 Female

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **66**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Among them, the mothers who have entered the study (goal-based sampling) are selected as the sample and randomly divided into two groups (test and control). The random allocation rule is the simplest method of randomization. This method represents a large block for the entire sample size, which means that the balance in the number of people assigned to each of the groups will

be at the end of the study. To do this, first determine a total sample size and then randomly assign a set of them to Group A and assign the remainder to Group B. This method is applicable to trials in two or more groups.

Blinding (investigator's opinion)
 Single blinded

Blinding description
 he population of this study is pregnant women referred to the prenatal center of Shahid Sadoughi Hospital in Yazd. Among them, the mothers who are eligible for inclusion in the study are selected as a research sample (simple sampling based on the goal) and randomly assigned to two groups. To select the samples, the researcher is first and foremost in the prenatal center of Shahid Sadoughi Hospital in Yazd. After identifying the eligible patients, they will be asked to enter the study after explaining the goals of the plan and obtaining written consent from their mothers and their wives. At the next stage, mothers are asked to complete the Spielberger Anxiety Scale questionnaire. Spielberger's Anxiety Scale Scale (Low to Moderate Scale) is one of the requirements for entering the study. Mothers who receive Spielberger's Scale of Inferiority Scale (20-80) are asked to complete demographic information and maternal and cranial attachment questionnaires. They will be referred to a psychiatrist if they have a higher anxiety score. . Mothers participate in 6 counseling sessions in the test group. At the same time, counseling groups are being set up in five, while in the control group there is no intervention and routine pregnancy care and a physiological delivery class are provided. At the end of the intervention (one week after the last counseling session), both groups completed the Cranly questionnaire and the Spielberger anxiety scale again. Finally, the data will be analyzed by SPSS software and the results will be reported.

Placebo
 Not used

Assignment
 Parallel

Other design features
 Study of the effect of midwifery counseling on psychological approach

Secondary Ids
 empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Yazd University of Medical Sciences
Street address
 Central Office of Shahid Sadoughi University of Medical Sciences and Health Services of Yazd, Shahid Bahonar Square, Yazd,
City
 Yazd

Province
Yazd
Postal code
8916978477
Approval date
2017-10-10, 1396/07/18
Ethics committee reference number
ir.ssu.rec.1396.115

Health conditions studied

1

Description of health condition studied

Mother's attachment to fetus

ICD-10 code

F53.8

ICD-10 code description

Other mental and behavioural disorders associated with the puerperium, not elsewhere classified

2

Description of health condition studied

anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Maternal attachment score

Timepoint

Before the intervention and one week after the end of the last counseling session

Method of measurement

Cranelian questionnaire

2

Description

anxiety score

Timepoint

Before the intervention and one week after the end of the last counseling session

Method of measurement

Spielberger questionnaire

Secondary outcomes

1

Description

Quality Score

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Short-Form Health Survey Ware: Sherbourne questionnaire

Intervention groups

1

Description

Intervention group: Mothers who have anxiety scores of low to moderate anxiety scores and other entry conditions are enrolled in the study and their counseling classes are grouped in six sessions of 1.5 hours.

Category

Behavior

2

Description

Control group: Control group: The control group included 33 people who only receive routine center of maternity care services and physiological delivery classes.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital, Abnecenna Blvd, Shahid Ghandi Boulevard, Yazd

Full name of responsible person

Zohreh Shayegh

Street address

Abnecenna Blvd

City

Yazd

Province

Yazd

Postal code

8916886931

Phone

+98 35 3822 4000

Fax

+98 35 3822 4100

Email

Shayegh0203@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr Masood Mirzaie

Street address

Yazd, Central Office of Shahid Sadoughi University of Medical Sciences and Health Services Yazd, Shahid

Bahonar Square
City
 Yazd
Province
 Yazd
Postal code
 8915993830
Phone
 +98 35 3827 8568
Email
 shayegh0203@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Yazd 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
 Yazd University of Medical Sciences
Full name of responsible person
 Zohreh Shayegh
Position
 Midwife
Latest degree
 Bachelor
Other areas of specialty/work
 Midwifery
Street address
 the third Alley of Hojjat, Kashani street
City
 Yazd
Province
 Yazd
Postal code
 8915993830
Phone
 +98 35 3827 8568
Email
 Shayegh0203@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
 Yazd University of Medical Sciences

Full name of responsible person
 Shahnaz Mojahed
Position
 Professor and faculty member of the university
Latest degree
 Master
Other areas of specialty/work
 Midwifery
Street address
 Faculty of Midwifery, Bouali Ave.,Safaieh
City
 Yazd
Province
 Yazd
Postal code
 8949333865
Phone
 +98 35 2824 9704
Email
 sh_mojahed@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
 Yazd University of Medical Sciences
Full name of responsible person
 Zohreh Shayegh
Position
 Midwife
Latest degree
 Bachelor
Other areas of specialty/work
 Midwifery
Street address
 Hojat Third Alley, Kashani Street
City
 Yazd
Province
 Yazd
Postal code
 8915993830
Phone
 +98 35 3827 8568
Email
 shayegh0203@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
 No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
 According to the opinion of the university and the supervisor.
Study Protocol
 No - There is not a plan to make this available
Statistical Analysis Plan
 No - There is not a plan to make this available
Informed Consent Form
 No - There is not a plan to make this available
Clinical Study Report
 No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available