

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of cognitive counseling on the fear of childbirth and depression in pregnant women: a randomized controlled clinical trial

Protocol summary

Study aim

Determining the effect of cognitive counseling on the fear of childbirth and depression of pregnant women

Design

Randomized, double-blind, with parallel group controlled clinical trials on 120 women for randomization from www.random.org through blockchain with quadruple blocks and 1: 1 assignment ratio to counseling and control groups

Settings and conduct

The study is performed in Kermanshah health centers by selecting and inviting pregnant women. Women who score higher than 66 on the Fear of Childbirth Questionnaire (W-DEQ) and score 12 or lower on the Edinburgh Depression are included in the study. Participants will be assigned to two groups of counseling and control through random blocking. Due to the lack of knowledge of the statistical analyst about the assignment of individuals to groups, lack of knowledge of participants about the nature of control or intervention of groups and differences in interventions, the study will be double-blind. Mothers in both groups will receive routine prenatal care by the health team. At the end of the research and one month after the last intervention session, the questionnaires will be completed again by the samples in both groups.

Participants/Inclusion and exclusion criteria

Pregnant women 18 to 35 years old with a singleton pregnancy and with a gestational age of more than 20 weeks without a history of chronic disease, infertility and high-risk pregnancy

Intervention groups

The intervention group will receive counseling with cognitive therapy approach and the control group will receive routine pregnancy care.

Main outcome variables

The variables of fear of childbirth and depression in pregnancy that will be measured at the end of the intervention and 4 weeks after the last intervention

session will be measured using the questionnaire of fear of childbirth and the Edinburgh Depression Scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170116031977N2**

Registration date: **2022-02-23, 1400/12/04**

Registration timing: **prospective**

Last update: **2022-02-23, 1400/12/04**

Update count: **0**

Registration date

2022-02-23, 1400/12/04

Registrant information

Name

Aazam Bakhteh

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

کرمانشاه

Email address

aa_bakhteh@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of cognitive counseling on the fear of childbirth and depression in pregnant women: a randomized controlled clinical trial

Public title
The effect of cognitive counseling on fear of childbirth and depression in pregnant women

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 All pregnant women who have a singleton pregnancy
 Pregnant women over 20 weeks of gestation
 Pregnant women should be literate (at least elementary)
 Pregnant women who have the ability to call and follow up
 Pregnant women with a Vajima score above 66
Exclusion criteria:
 Pregnant women with chronic diseases (such as diabetes, etc.)
 Pregnant women with a history of infertility
 Pregnant women with high-risk pregnancies
 Pregnant women with psychiatric disorders
 Pregnant women taking certain medications

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to execute random allocation, random sequencing will be created by the method of "random allocation law". This method consists of a large block for the entire sample size, so that the balance in the number of people assigned to each group is achieved at the end of the study. After determining the sample size by the researcher, in the first stage, the specified number will be selected from the people who meet the inclusion criteria and have signed the informed consent form, if desired. Pregnant women who complete the pre-test questionnaires will be randomly assigned to two groups (60 in the counseling intervention group and 60 in the control group) using a computer-generated random number table at random.org. To conceal the allocation, the type of intervention was written on paper and placed inside opaque and numbered envelopes. The envelopes will be opened in order of entry and pregnant women will be in the intervention or control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the lack of a person allocating ethnic resources, the lack of knowledge of the statistical analyst about the allocation of individuals to the groups, the lack of knowledge of the participants about the nature of control or intervention of groups A and B and the difference between trainings / interventions will be a double-blind study. Due to the nature of psychological interventions, it is not possible to blind learners. Questionnaires will be completed before assigning participants to intervention and control groups, using sealed envelopes (blinding participants) and presenting the intervention at a time other than the presentation of routine programs and submitting a questionnaire to the intervention group on a non-day From the day of submission to the control group. After the intervention, the people collecting the questionnaires and entering the information were not aware of the group of people and the data analyst would not be from the group of people providing the intervention (information blinding and analysis).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Shahroud University of Medical Sciences
Street address
 Seventh Tir Square, Shahroud University of Medical Sciences and Health Services, Vice Chancellor for Research and Technology
City
 Shahroud
Province
 Semnan
Postal code
Approval date
 2020-12-23, 1399/10/03
Ethics committee reference number
 IR.SHMU.REC.1399.135

Health conditions studied

1

Description of health condition studied
 Fear of childbirth
ICD-10 code
 F40.9
ICD-10 code description
 Phobic anxiety disorder, unspecified

2

Description of health condition studied

Depression in pregnancy

ICD-10 code

F53.0

ICD-10 code description

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

Primary outcomes

1

Description

Fear of childbirth

Timepoint

Before the intervention, after the intervention and 1 month after the last intervention session

Method of measurement

Wijma Delivery Expectancy Questionnaire (W-DEQ)

2

Description

Depression

Timepoint

Before the intervention, after the intervention and 1 month after the last intervention session

Method of measurement

Edinburgh Postpartum Depression Scale

Secondary outcomes

1

Description

childbirth Satisfaction

Timepoint

1-3 days after delivery

Method of measurement

Mackey Childbirth Satisfaction Rating Scale

2

Description

Delivery method

Timepoint

After childbirth

Method of measurement

medical documents

Intervention groups

1

Description

Intervention group: For the intervention group, counseling in the form of groups of 10 people with a cognitive approach is performed in 6 sessions of 90-60 minutes in one of the health centers of Kermanshah that has suitable conditions.

Category

Behavior

2

Description

Control group: The control group will receive routine prenatal care and, in addition, a training session will be held after the end of the second phase of the assessment.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah health centers

Full name of responsible person

azam bakhteh

Street address

Department of Reproductive Health, School of Nursing and Midwifery, Dolatabad Blvd., Isar Sq

City

Kermanshah

Province

Kermanshah

Postal code

6719884586

Phone

+98 83 3816 2559

Email

aa_bakhteh@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Nasrin Jaber Ghaderi

Street address

Central building of Kermanshah University of Medical Sciences, Shahid Beheshti St., Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 84 3442 3968

Fax

Email

n_jaberghaderi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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 Bakhteh

Position

PhD student in Reproductive Health

Latest degree

Master

Other areas of specialty/work

Reproductive Health

Street addressSchool of Midwifery Nursing, Haft Tir Square,
Shahroud**City**

Shahroud

Province

Semnan

Postal code

3614773955

Phone

+98 23 3239 1609

Email

aa_bakhteh@kums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

Zahra Motaghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street addressShahroud University of Medical Sciences and Health
Services, Hafte Tir Square, Shahroud**City**

Sharoud

Province

Semnan

Postal code

3614773955

Phone

+98 23 3239 1609

Email

zhromotaghi@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

Azam Bakhteh

Position

PhD student in Reproductive Health

Latest degree

Master

Other areas of specialty/work

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3614773955

Phone

+98 23 3239 1609

Email

aa_bakhteh@kums.ac.ir

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

There is no more information

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