

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluating effectiveness of dialectic behavioral therapy on fear of childbirth and preferred mode of delivery

Protocol summary

Study aim

Evaluation the effectiveness of dialectical behavioral therapy on the fear of childbirth and preferred mode of delivery

Design

The clinical trial was conducted in two groups of intervention and control, Double blind, Randomized

Settings and conduct

Five counselling sessions are conducted for the intervention group in Mashhad's center for comprehensive health services. For blinding, neither the participants nor the analyzer know which participants belong to the control group, nor the intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Participation in childbirth classes, Singleton pregnancy, low risk pregnancy, Cut off score of fear of delivery above 28, Gestational age 22 to 24 weeks, Desire to participate in study. Exclusion criteria: Not addicted to drugs

Intervention groups

The intervention group will receive consultation, weekly in five session. The control group will receive usual education for childbirth classes.

Main outcome variables

The primary outcome is fear of delivery that measured before and after intervention (counselling) and one month after intervention. The secondary outcome is the preference mode of delivery, which is measured after intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180131038579N1**

Registration date: **2018-06-30, 1397/04/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-30, 1397/04/09**

Update count: **0**

Registration date

2018-06-30, 1397/04/09

Registrant information

Name

Zahra Ghasempour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3603 3219

Email address

zahraghasempour1367@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating effectiveness of dialectic behavioral therapy on fear of childbirth and preferred mode of delivery

Public title

Evaluating effectiveness of dialectic behavioral therapy on fear of childbirth and preferred mode of delivery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Ability to speak persian Participate in childbirth classes
Singleton pregnancy Having low risk pregnancy Cut off
scores fear of delivery above 28 No history of mental
disorders and psychotropic drugs Gestational age 22 to
24 weeks

Exclusion criteria:

Drug abuse Missing consent of the pregnant mother to
collaborate in the study

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: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization, Statistical software

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding, neither the participants nor the analyzer
know which participants belong to the control group, nor
the test group. all Participants participate in childbirth
classes but test group benefit from receiving counselling
session in addition to usual classes.

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 university of medical sciences, 7th of Tir
square

City

Shahroud

Province

Semnan

Postal code

36147-73947

Approval date

2018-03-06, 1396/12/15

Ethics committee reference number

IR.SHMU.REC.1396.159

Health conditions studied

1

Description of health condition studied

Dialectic behavioral therapy

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Preference of mode of delivery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Scores of fear in Harman's childbirth attitude
questionnaire (CAQ)

Timepoint

Second (22-24 wk) and third trimester (32-36 wk) of
pregnancy

Method of measurement

Harman's childbirth attitude questionnaire (CAQ)

Secondary outcomes

1

Description

Preferred mode of delivery

Timepoint

Third trimester of pregnancy 32-36 week

Method of measurement

Pregnant women's preferences for mode of delivery
questionnaire

Intervention groups

1

Description

Intervention group: counselling

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for comprehensive health services

Full name of responsible person

Zahra Ghasempoor

Street address

Sanabad St.,Mashhad Town

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Mashhad

Province

Razavi Khorasan

Postal code

9185684538

Phone

+98 51 3841 5001

Email

zahraghasempour1367@gmail.com

Web page address**Full name of responsible person**

Zahra Ghasempoor

Position

midwife

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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No.87,Behvarz 3/6.,Falahi Blvd.,Mashhad town

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Email

zahraghasempour1367@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

Shahroud University of Medical Sciences Vice
chancellor of research and technology

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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

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

Shahroud University of Medical Sciences

Full name of responsible person

Zahra Ghasempoor

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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

Shahroud University of Medical Sciences

Full name of responsible person

Zahra Ghasempoor

Position

midwife

Latest degree

Bachelor

Other areas of specialty/work

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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

Data Dictionary

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