# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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 Ghasempoor
**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: conselling

**Category**

N/A

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Center for comprehensive health services

**Full name of responsible person**

Zahra Ghasempoor

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Sanabad St.,Mashhad Town
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## 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
**Street address**
7th of Tir squere.,Shahroud Town
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**Fax**
+98 23 3239 5009
**Email**
info@shmu.ac.ir
**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**
Zahra Ghasempoor
**Position**
midwife
**Latest degree**
Bachelor
**Other areas of specialty/work**
Midwifery
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## Person responsible for scientific inquiries

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Student
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## Person responsible for updating data

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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