

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### The effectiveness of meta-cognitive therapy group on intense fear of normal vaginal delivery in primiparous pregnant women

#### Protocol summary

##### Study aim

Effectiveness of meta-cognitive therapy on reducing the fear of delivery in primipara women

##### Design

The sample size was 35 people in each group according to the opinion of the statistical advisor. Sampling method was simple combination of cluster and random sampling. Among 15 health centers in Abadan, eight centers were selected as cluster and samples from these centers will be selected randomly.

##### Settings and conduct

Sampling method was simple combination of cluster and random sampling. Among 15 health centers in Abadan, eight centers were selected as cluster and samples from these centers will be selected randomly.

##### Participants/Inclusion and exclusion criteria

Entry requirements: First pregnancy  
Conditions of non-arrival: second pregnancy

##### Intervention groups

This is a clinical trial of 70 primiparous women. Each group includes 35 people. The case group undergoes eight sessions of meta-cognitive group therapy and control group under routine pregnancy care.

##### Main outcome variables

The fear of normal delivery is described as anxiety due to possible fear of natural delivery. The present study was designed to investigate the effectiveness of meta-cognitive therapies on reducing the fear of delivery in nulliparous women.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180520039729N1**

Registration date: **2018-05-24, 1397/03/03**

Registration timing: **prospective**

Last update: **2018-05-24, 1397/03/03**

Update count: **0**

##### Registration date

2018-05-24, 1397/03/03

##### Registrant information

###### Name

Maryam Nikbina

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 5338 4004

###### Email address

nikbina\_m@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-22, 1397/04/01

##### Expected recruitment end date

2018-10-22, 1397/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effectiveness of meta-cognitive therapy group on intense fear of normal vaginal delivery in primiparous pregnant women

##### Public title

The effectiveness of meta-cognitive therapy group on intense fear of normal vaginal delivery

##### Purpose

Education/Guidance

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

primiparous

**Exclusion criteria:**

multiparous

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: 70

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

clustered

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This is a clinical trial of 70 primiparous women. Each group includes 35 people. The case group undergoes eight sessions of metacognitive therapy and a control group under routine pregnancy. In this exercise, the participant does not know which of the two control or test groups belong

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Abadan University of Medical Sciences

**Street address**

Thirty Metric Approvals, Abadan University of Medical Sciences

**City**

Abadan

**Province**

Khuzestan

**Postal code**

6319811154

**Approval date**

2016-11-30, 1395/09/10

**Ethics committee reference number**

187

**Health conditions studied****1****Description of health condition studied**

fear of normal vaginal delivery

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

fear

**Timepoint**

At the beginning of the study, one month after the intervention, after delivery

**Method of measurement**

Beck Anxiety Inventory, Fear of Maternity Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In the meta-cognitive therapy, anxiety, depression and related beliefs are considered and treatment is focused on modifying these anxious and depressed thoughts and beliefs. In this trial, the intervention group undergo eight 90-minute sessions of cognitive therapy with a 6-day interval Placed.

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Abadan University of Medical Sciences

**Full name of responsible person**

Friba khavyet

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Thirty Meter Zolfaghar - Abadan University of Medical Sciences

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nikbina.maryam@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Abadan University of Medical Sciences

**Full name of responsible person**

fariba khavayet

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Thirty Meter Zolfaghar - Abadan University of Medical Sciences

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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**

Abadan 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**

Abadan University of Medical Sciences

**Full name of responsible person**

fariba khavayet

**Position**

Assistant Professor of Midwifery, Abadan University of Medical Sciences

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

### Contact

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Assistant Professor of Midwifery, Abadan University of Medical Sciences

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Abadan University of Medical Sciences

**Full name of responsible person**

Maryam Nikbina

**Position**

Teacher

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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## 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

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

### Title and more details about the data/document

Information on the main consequence of sharing is possible

### When the data will become available and for how long

Start the access period 6 months after printing the results

### To whom data/document is available

For scholars working in academia and academia

### Under which criteria data/document could be used

It can be used to improve the health of mothers within the framework of the rules

### From where data/document is obtainable

nikbina.maryam@gmail.com

### What processes are involved for a request to access data/document

The principle of the plan that the applicant intends to do, along with the names of the authors, the university or sponsoring organizations

### Comments