Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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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
Khouzestan
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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Sponsors / Funding sources

1

Sponsor

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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
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Person responsible for updating data

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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