Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigate the impact of counseling with an approach based on acceptance and commitment therapy to the fear, attitude and intention of choosing the type of delivery in primigravid women

Protocol summary

Study aim

Determine the impact of counseling with an approach based on acceptance and commitment therapy to the fear, attitude and intention of choosing the type of delivery in primigravid women

Design

Clinical trials with control group and parallel groups without blindness ; and Randomized with Random numbers .

Settings and conduct

Place: Health centers No. 1 and 3 of Mashhad. In each selected health center, an intervention and control group will be selected and the samples will be randomly assigned to the control or intervention group. At the beginning of the study, the questionnaire for fear, attitude and intention to select the type of delivery will be completed by samples. Then, after intervention, for 4 consecutive sessions of acceptance and commitment based counseling within 4 consecutive weeks, again immediately and then one week after the intervention, the questionnaires will be completed by the intervention and control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Having no hearing and mental problems in the mother that prevents communication with the researcher 2- Age between 18 and 35 years. 3- Gestational age between 28 weeks and 32 weeks. 4- low-risk singleton pregnancies and is showing head. 5- Being primigravid. 6. Do not have a history of infertility. 7- Not having a medical cause for cesarean section, such as a transverse position, previous uterine surgery, etc. Non-entry terms: 1- Earn more than 85 scores from Vijma's fears questionnaire. 2- She or her husband should be employed by the hospital staff. 3- In the last 6 months, she has severe mental problems.

Intervention groups

Intervention group: group counseling sessions for 4 consecutive weeks Control group: Routine care of childbirth classes

Main outcome variables

Fear, Attitude, Intention to choose a type of delivery, Social support, Self-efficacy, Decision conflict, Subjective norms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180901040916N1**
Registration date: **2019-05-13, 1398/02/23**
Registration timing: **retrospective**

Last update: **2019-05-13, 1398/02/23**
Update count: **0**

Registration date

2019-05-13, 1398/02/23

Registrant information

Name

Raha Shoja

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5412 3311

Email address

shojar9@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-02, 1397/07/10

Expected recruitment end date

2019-03-30, 1398/01/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigate the impact of counseling with an approach based on acceptance and commitment therapy to the fear, attitude and intention of choosing the type of delivery in primigravid women

Public title
Investigate the impact of counseling on acceptance and commitment therapy to the fear, attitude and intention of choosing the type of delivery

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
1- Residence in Mashhad 2- Access to Telephone 3- Having at least elementary education 4- Do not have a mother's hearing and speech problems that can not communicate with a researcher 5- Age between 18 and 35 6- Gestational age between 28 weeks to 32 weeks 7- Single and low-risk pregnancy 8- Primigravid 9- Willingness to cooperate 10- The sample has no history of infertility 11- The sample does not have a medical cause for cesarean section (such as a transverse or transverse placement, an uterine surgeon, etc.).

Exclusion criteria:
1- Do not be staffed by a hospital 2- She has not had severe mental problems in the last 6 months 3- In the Vijma's fear questionnaire, she scored less than 85 points

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized method: simple using random numbers. At first, the researcher selects a number from the table with a blind eye, and then the numbers are given in the order of the row, the first number is assigned to the control group, and the second number assigned to the intervention group and so on. Random unit: Individual Randomization Tool:Random numbers Hiding: no

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee on Environmental Research

Street address
No.1, West Hijab Ave., Hijab1

City
Mashhad

Province
Razavi Khorasan

Postal code
9189917155

Approval date
2018-07-31, 1397/05/09

Ethics committee reference number
IR.MUMS.NURSE.REC.1397.026

Health conditions studied

1

Description of health condition studied
Fear of delivery, Attitude of delivery , Intent to choose the type of delivery

ICD-10 code
O75.0

ICD-10 code description
Maternal distress during labour and delivery

Primary outcomes

1

Description
Fear of delivery

Timepoint
At the beginning of the study, then immediately and one week after the intervention

Method of measurement
Vijma's fear of delivery Questionnaire; Version A

2

Description
Attitude towards delivery

Timepoint
At the beginning of the study and then immediately and one week after the intervention.

Method of measurement
Attitude to the type of delivery questionnaire

3

Description
Intent to choose the type of delivery
Timepoint
At the beginning of the study and then immediately and one week after the intervention.
Method of measurement
Intent selection choose the type of delivery checklist

4

Description
Social support
Timepoint
At the beginning of the study
Method of measurement
Modified Cassidy Social Support Assessment Questionnaire

5

Description
Decision Conflict
Timepoint
At the beginning of the study
Method of measurement
Decision Conflict Questionnaire

6

Description
Self-efficacy of delivery
Timepoint
At the beginning of the study
Method of measurement
Maternal self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving 4 consultation sessions with an approach base on acceptance and commitment therapy in group ,any week ,a meeting with a duration of 90 to 120 minute up to 4 weeks. Session content: First Session: Introduction , determination the escape and avoidance of client strategies and determination of specify the dumps and bugs, Forecasts and evaluation of client about fear of childbirth. Second session: Education of control is problem not solution, Separating the judgments of person experiences and see thoughts without judging them. Third session: Help to client for determination of judgments about himself such as be cowardly, be weakly and so on. The education of mindfulness and help to client for identification values of himself and their classification. Fourth session: Presentation of practical approach for action and commitment about decided.
Category
Other

2

Description
Control group: Routine Care Pregnancy Classes which lasts from 23 to 38 weeks of pregnancy for 8 sessions of 90 minutes.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Najafi Health Center
Full name of responsible person
Simin Gazani
Street address
Shahid Haghshenas4, Piroozi18, Piroozi Blvd
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2

Recruitment center
Name of recruitment center
Imam Hassan Health Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi

Street address
Vice-President of Research and Technology University-Mashhad University of Medical Sciences-Facing ,West Daneshgah, Daneshgah 18-Mashhad-Ave. University-Khorasan Razavi

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http://v-research.mums.ac.ir/index.php/component/content/article/62-vcresearch/1236-tafaghodim2

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Mahboobeh firoozi

Position
Teacher

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Mahboobeh firoozi

Position
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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shojar9@mums.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
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