Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of psychological immunization strategy on fear of childbirth in childparents primiparous woman

Protocol summary

Study aim
The effect of psychological immunization strategy on fear of childbirth in childparents primiparous woman

Design
sixty four people with inclusion criteria will be included in the study and will be divided into two equal groups including A (intervention group) and B (control group). Individuals will enter to groups randomly using blocks with size of 4 and through a table of random numbers.

Settings and conduct
The study site will be health centers affiliated to Qom University of Medical Sciences. Using the information of the Sib system, the researcher will select the centers that have the highest number of references of childparents for sampling. For the intervention group, ten sessions of mental safety training classes plus 8 sessions of childbirth preparation classes will be held, and for the control group, only 8 sessions of childbirth preparation classes will be held. In this study, there is no possibility of blindness.

Participants/Inclusion and exclusion criteria
inclusion criteria: Willingness to participate in the study؛ Be literate؛Smartphone access20 ؛ weeks gestational age؛ Singleton؛ Absence of pregnancy complications such as bleeding and preeclampsia؛primiparous؛ mother age less than 18 years؛ Participate in childbirth preparation classes، Exclusion criteria: history of infertility؛ having chronic diseases؛ having known mental illness

Intervention groups
The intervention group includes pregnant mothers under 18 years of age who will receive ten sessions of mental immunization training classes in addition to 8 sessions of childbirth preparation classes. The control group includes pregnant mothers under 18 years of age (child-parent) who will receive the intervention including 8 sessions of childbirth preparation classes.

Main outcome variables
fear of childbrith

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160821029446N10**
Registration date: **2022-01-15, 1400/10/25**
Registration timing: **prospective**

Last update: **2022-01-15, 1400/10/25**
Update count: **0**

Registration date
2022-01-15, 1400/10/25

Registrant information

Name
Maryam Damghanian
Name of organization / entity
Nursing and Midwifery Faculty, Tehran University of Medical Science
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-05-22, 1401/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of psychological immunization strategy on fear of childbirth in childparents primiparous woman

Public title
The effect of psychological immunization strategy on fear of childbirth
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Be literate Smartphone access 20 weeks gestational age Singleton Absence of pregnancy complications such as bleeding and preeclampsia primiparous mother age less than 18 years Participate in childbirth preparation classes
Exclusion criteria:
history of infertility having chronic diseases having known mental illness
Age
To **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Assignment of samples to intervention (A) and control (B) groups (32 people in each group) will be done using blocks with size of 4. In this way, 6 possible modes will be considered using a table of random numbers. These 6 modes are written on 6 separate cards and the cards will be placed in a black bag (for concealment) . A card will be issued for 16 times to finally get 64 letters written as the sample size. The intervention group will be the group that will receive psychological immunization training sessions in addition to childbirth preparation classes, and the control group will be the group that will receive only childbirth preparation classes.
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 of the School of Nursing and Midwifery, Tehran University of Medical Sciences
Street address
Tohid square,Dr. Mirkhani Street (eastern nosrat)
City
tehran
Province
Tehran
Postal code
1419733171
Approval date
2021-11-04, 1400/08/13
Ethics committee reference number
IR.TUMS.FNM.REC.1400.145

Health conditions studied

1

Description of health condition studied
fear of childbirth
ICD-10 code
F40.232
ICD-10 code description
Fear of other medical care

Primary outcomes

1

Description
Fear of childbirth score in Vijma questionnaire
Timepoint
At the beginning of the study and after the intervention
Method of measurement
Vijama Maternity Fear / Expectation Questionnaire Version A

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:the intervention group will be given Ten sessions of mental immunization training. These sessions will be held two one-hour sessions per week (five weeks in total) from the twentieth week of pregnancy. Psychological immunization sessions will be conducted in the form of individual interviews (In the form of talking in class), Perform relaxation techniques, Examining mothers' opinions and fears about childbirth, Examination of environmental and internal stressors and Factors that cause fear in mothers, Answer all these symptoms, Teaching relaxation techniques,Teaching coping techniques against stress, Giving correct information to mothers, Assessing mothers' sense of adequacy and teaching them the necessary points,

Expressing mothers' feelings and fears and etc. So far in Iran, the education with this technique has not been performed on mothers. These interventions are designed to evaluate the effectiveness of this technique in the primiparous child parent woman. None of this is covered in childbirth preparation classes.

Category

Behavior

2

Description

Control group: No action is taken for members of the control group. These people receive routine pregnancy care. Once before the intervention in the intervention group and once after the training sessions in the intervention group, the Vijma questionnaire will be filled out by the control group at the same time as the intervention group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Qom health centers

Full name of responsible person

Najmeh Taghian

Street address

School of Nursing & Midwifery, Tehran University of Medical sciences. Tohis sq, Tehram, Ian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

dr homan shahsavari

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

najmeh taghiyan

Position

دانشجوی کارشناس ارشد مامایی

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Other areas of specialty/work

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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

there isnt 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