

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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 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

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)

Phone

+98 21 6692 7171

Email address

m-damghanian@sina.tums.ac.ir

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 Vija 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, lan

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4222

Email

najm9276@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

dr homan shahsavari

Street address

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

City

tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

Email

fnm@tums.ac.ir

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

Street address

School of Nursing & Midwifery, tehran university of medical science, tohid sq, Twhran, Iran

City

tehran

Province

Tehran

Postal code

1499733171

Phone

+98 21 6692 7171

Email

najm9276@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Maryam Damghanian

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of Nursing & Midwifery, Tehran University of
Medical sciences, Tohid sq, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733172

Phone

+98 21 6105 4000

Email

maryam_damghanian@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

maryam damghanian

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of Nursing & Midwifery, Tehran University of
Medical Sciences, tohid sq, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733172

Phone

+98 21 6692 7171

Email

maryam_damghanian@yahoo.com

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