

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Design, implementation, and evaluation of educational program based on salutogenesis theory on fear of childbirth and choice of delivery method among nulliparous women: a sequential-exploratory mixed methods design

Protocol summary

Study aim

Design, implementation, and evaluation of educational program based on salutogenesis theory on fear of childbirth and choice of delivery method among nulliparous women

Design

Eligible women are randomly selected based on their electronic health records. Blocked randomization will be used to assign participants to two groups. Envelopes are used to allocate concealment.

Settings and conduct

The educational intervention is held in 4 training sessions of at least 30 minutes in 4 groups of 6 people and 2 groups of 7 people, one day a week for each group at the Health Comprehensive Service Centers of Bostanabad city of East Azerbaijan by the researcher in face to face. All of the training sessions will be completed by the 16th-week gestation.

Participants/Inclusion and exclusion criteria

Primiparous pregnant women / Inclusion criteria: first trimester of pregnancy, 18-35 years, no history of self-reported depression or chronic illness, singleton pregnancy, ultrasound confirmation of fetal health, no history of miscarriage or stillbirth, lack of contraindications of vaginal delivery to termination of pregnancy, lack of midwifery base and related fields of study, having consent to participate in the study. Exclusion criteria: preterm delivery due to an emergency, indications of cesarean section, history of cesarean section, history of infertility, lack of continuous presence of pregnant women in training sessions, failure to complete the questionnaire, lack of access to the participant for any unpredictable reason.

Intervention groups

The intervention group will receive intervention designed based on the content of education obtained from the

qualitative and review phases using lectures, group discussions, collaborative learning, a problem-solving workshop. The Control group will receive routine pregnancy care.

Main outcome variables

Fear of childbirth and vaginal delivery choice

General information

Reason for update

The fourth letter (u) of the Latin word salutogenesis was omitted.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210506051202N1**

Registration date: **2021-08-21, 1400/05/30**

Registration timing: **prospective**

Last update: **2025-04-28, 1404/02/08**

Update count: **2**

Registration date

2021-08-21, 1400/05/30

Registrant information

Name

Safieh Kananikandeh

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 45 3278 1289

Email address

s.kananikandeh@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

2022-11-01, 1401/08/10

Actual recruitment end date

2023-07-01, 1402/04/10

Trial completion date

empty

Scientific title

Design, implementation, and evaluation of educational program based on saltuogenesis theory on fear of childbirth and choice of delivery method among nulliparous women: a sequential-exploratory mixed methods design

Public title

Saltuogenesis theory on fear of childbirth

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

All primiparous pregnant women in the first trimester of pregnancy 18-35 years High school and university No history of self-reported depression or chronic illness Singleton pregnancy Ultrasound confirmation of fetal health No history of miscarriage or stillbirth Lack of contraindications of vaginal delivery to termination of pregnancy Lack of midwifery base and related fields of study Having consent to participate in the study

Exclusion criteria:

Preterm delivery due to an emergency Indications for cesarean section History of cesarean section History of infertility Lack of continuous presence of pregnant women in training sessions Failure to complete the questionnaire Lack of access to the participant for any unpredictable reason

AgeFrom **18 years** old to **35 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget sample size: **76**Actual sample size reached: **63****Randomization (investigator's opinion)**

Randomized

Randomization description

For assigning participants to the two groups of intervention and control will be used blocked randomization method with the size of 4 and 6 blocks. To allocate concealment, the type of intervention is written on paper by a person who has no role in sampling and analyzing the data. These sheets of paper are placed inside identical matte envelopes in an appearance that

will be numbered in order. Upon arrival at the center, each participant receives an envelope from one of the coordinated health personnel.

Blinding (investigator's opinion)

Single blinded

Blinding description

To allocate concealment, the type of group will be written on a piece of paper by a person who will have no role in sampling and analyzing the data. These sheets are placed inside identical matte envelopes that will be numbered sequentially. Upon arrival at the center, each participant receives an envelope from one of the coordinated health personnel. In this way, each person will be in one of the control or intervention groups without knowing their group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of Tarbiat Modares University

Street address

Jalal AleAhmad Ave

City

Tehran

Province

Tehran

Postal code

14115-111

Approval date

2021-06-26, 1400/04/05

Ethics committee reference number

IR.MODARES.REC.1400.097

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

Fear of childbirth

ICD-10 code

F40

ICD-10 code description

Phobic anxiety disorders

Primary outcomes**1****Description**

Reduce fear of childbirth

Timepoint
Before the intervention, immediately after the intervention and 6 months after the intervention

Method of measurement
Wijma Delivery Expectancy/Experience Questionnaire- A

2

Description
Choice of natural childbirth

Timepoint
Before the intervention, immediately after the intervention and 6 months after the intervention

Method of measurement
Checklist for choosing the delivery method

Secondary outcomes

1

Description
Sense of coherence

Timepoint
Before the intervention, immediately after the intervention and 6 months after the intervention

Method of measurement
Antonovsky Coherence Scale (SOC-13)

Intervention groups

1

Description
Educational content is prepared based on the main factors obtained from qualitative and review stages on the fear of childbirth in nulliparous women. Teaching methods include lecturing, group discussion, question and answer and collaborative learning, problem-solving, talking about positive experiences, and brainstorming. Educational tools include books, posters, brochures, photos, videos, educational slides, recollection of memories, problem-solving workshop, formation of virtual groups and membership of participants in social networking groups, the reflection of values, motivations, needs, and desires of participants about pregnancy and childbirth on a piece of paper and discussion, description and sharing participants' personal skills, and drawing participants pictures of their family (for identifying their role and support in the family). If possible, the educational intervention is held in 4 training sessions of at least 30 minutes in 4 groups of 6 people and 2 groups of 7 people, one day a week for each group at the Health Comprehensive Service Centers of Bostanabad city of East Azerbaijan by the researcher in face to face. A reminder text message is sent to participants about the time and place of the meeting before each meeting. All of the training sessions will be completed by the 16th-week gestation. The evaluation of the educational intervention will be done in two phases; immediately and 6 months after the end of the educational intervention. Participants will re-complete the initial assessment tool.

After birth, the method of delivery and the reason for choosing are recorded.

Category
Behavior

2

Description
Control group: This group will receive routine pregnancy care.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Health Comprehensive Service Centers

Full name of responsible person
Ramak Zavar Kaabeh

Street address
Bostanabad Health Network, Imam Khomeini Ave

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kanani.safieh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tarbiat Modares University

Full name of responsible person
Yaghoub Fatollahi

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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

Tarbiat Modares University
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
Tarbiat Modares University
Full name of responsible person
Safieh Kananikandeh
Position
Student
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The demographic characteristics of the participants are confidential, but information about other variables will be shared.
When the data will become available and for how long
Six months after the publication of the paper
To whom data/document is available
Researchers in scientific and academic institutions, Health Education and Health Promotion Unit of the Ministry of Health and Family Health Unit of the Ministry of Health
Under which criteria data/document could be used

Educational and research use is allowed with the permission of the ethics committee of the Tarbiat Modares University of Tehran. The request should be made through the Vice Chancellor for Research of Medical Universities.

From where data/document is obtainable

Corresponding author - Dr. Farkhondeh Aminshokravi

aminsh_f@modares.ac.ir

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

Up to one week receiving a request via email to the responsible study corresponding author

Comments