Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Aug 2026

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

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
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Name of organization / entity
Tarbiat Modares Universuty
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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
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

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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

Latest degree

Ph.D.

Other areas of specialty/work

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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