

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of educational program based on PRECEDE-PROCEED model on professional skills of midwives and promotion of breast cancer control behavior in women

Protocol summary

Study aim

the effect of educational program based on the PRECEDE / PROCEED model on professional skills of midwives and promotion of breast cancer control behavior in women in Kabul city.

Design

This protocol is a clinical trial with a single-blind control group and runs in two steps. To randomly allocate midwives to randomized quadrilateral blocks, interventional and control groups are used. For each intervention and control group, 45 people were recruited. In the women's group, 200 are in the intervention group and 200 in the control group.

Settings and conduct

Implementation of training program for midwives: Designed training programs will be implemented through workshops with 15 participants in 3 groups for 3 days. Training sessions for midwives participating in the intervention group will be held at the Women's Health Center. Women's Training Stage: This section will be conducted by trained midwives from the first stage. Study of a blinded (female participants)

Participants/Inclusion and exclusion criteria

Including criteria for first stage (Midwives): 1. Employed at one of the private and public hospitals in Kabul city. 2. Have not completed the course before, according to the research unit. 3. Have a tendency to participate in the project. Including criteria for second stage (Women): 1. Be Between the ages of 20-64. 2. Strong tendency to attend a classroom. 3. Be residents of Kabul. 4. Do not have breast cancer. Exclusion criteria: having one of the types of existing cancers or having pathologic specimens suspected of breast cancer as documented during the study.

Intervention groups

Midwives and women in Kabul city community

Main outcome variables

Promoting the professional development of midwifery professionals through the development of an educational program will help in the form of a workshop for midwives, and if progress is made, it will be conducted throughout Afghanistan.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025743N2**

Registration date: **2020-04-23, 1399/02/04**

Registration timing: **retrospective**

Last update: **2020-04-23, 1399/02/04**

Update count: **0**

Registration date

2020-04-23, 1399/02/04

Registrant information

Name

Nesa Mohammadi

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-01-21, 1397/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of educational program based on PRECEDE-PROCEED model on professional skills of midwives and promotion of breast cancer control behavior in women

Public title
Evaluation of educational program based on PRECEDE-PROCEED model on professional skills of midwives and promotion of breast cancer control behavior in women

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Including criteria for first stage (Midwives):1. Employed at one of the private and public hospitals in Kabul city. 2. Have not completed the course before, according to the research unit. 3. Have a tendency to participate in the project. Including criteria for second stage (Women): 1. Be Between the ages of 20-64. 2. Strong tendency to attend a classroom. 3. Be residents of Kabul. 4. Do not have breast cancer.
Exclusion criteria:
Exclusion criteria: having one of the types of existing cancers or having pathologic specimens suspected of breast cancer as documented during the study.

Age
From **20 years** old to **64 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomly allocate midwives to randomized quadrilateral blocks, interventional and control groups are used. Thus, blocks AABB, ABAA, ABBA, BABA, BBAA, BAAB are written on 6 cards and since the sample size of 90 midwives is estimated, 23 times randomly extracted from a card of one card and replaced by a replacement method Repeating. The extracted words are followed by a written statement and placed in 90 closed envelopes. Then the midwives are numbered from 1 to 90, and the first envelope, the second envelope, and the second, are divided into individuals. To randomly assign women to Kabul urban community, randomly assigned quadrilateral blocks are used to intervene and control groups. Thus, blocks AABB, ABAA, ABBA, BABA, BBAA, BAAB are written on 6 cards, and since the sample size is 400 women, 100

times randomly extracted from a card of one card and replaced by a repeat replacement method we do. The letters extracted are followed by a single letter and enclosed in 400 closed envelopes. Then the women are numbered from 1 to 400, and the first envelope, the second envelope, and the second, are divided into individuals.

Blinding (investigator's opinion)

Single blinded

Blinding description

just the participant will be informed about how the people will be placed in the intervention and control group

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tarbiat Modares University of Medical Sciences

Street address

Tehran, Jalal Al Ahmad highway, Beside to Shariati Hospital, Tarbiat Modares University

City

Tehran

Province

Tehran

Postal code

3976171664

Approval date

2017-09-19, 1396/06/28

Ethics committee reference number

IR.TMU.REC.1396.618

Health conditions studied

1

Description of health condition studied

Evaluation of educational program based on PRECEDE-PROCEED model on professional skills of midwives and promotion of breast cancer control behavior in women of Kabul city community.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

determining the effect of educational program based on the PRECEDE / PROCEED model on professional skills of midwives and promotion of breast cancer control behavior in women in Kabul city.

Timepoint

oct 2018 - APR2019

Method of measurement

The method of data collection in all stages of the study is using the following questionnaires. Researcher-made questionnaire on demographic and fertility variables, Midwifery practical skill checklist, Chmpion standard health questionnaire, Knowledge standard questionnaire, Self-efficacy standard questionnaire, Researcher-made checklist for women self-examination self observation, Self-report self-report self-report form of breast self-examination.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Implementation of training program for midwives: Designed training programs will be implemented through workshops with 15 participants in 3 groups for 3 days. Training sessions for midwives participating in the intervention group will be held at the Women's Health Center. Educational tools include educational slides, educational posters, moles for breast examination, and practical skills for breast examinations to improve practical skills for midwives. During the implementation of the workshop, interactive and question-and-answer training will take place. A complimentary pamphlet will be provided for them to read on their own. Before the intervention, the questionnaires and the checklist for the first stage of midwifery education will be completed in this section. After completing the training sessions again, the same questionnaires and a checklist of the midwives participating in the workshops will be evaluated. To determine the effectiveness of the Women's Health Support Center, the Focus Group will be discussed in each of the 3 groups of 15 midwives (intervention group). To determine the system efficiency, the Focus Group database will be discussed in each of the 3 groups of 15 midwives (intervention group). Women's Training Stage: This section will be conducted by trained midwives from the first stage. The midwives' skills of breast examination will be double checked by a breast cancer specialist. Methodology: 400 women aged 20-64 years were selected and randomly assigned to intervention and control groups. In the intervention group 200 women and in the control group, 200 women will be included in the study. The method of women's education in the Focus Group and in the groups of 5 people will be taught and questioned by each trained midwife according to the curriculum. Before the intervention, the educational program of knowledge,

belief, performance, health beliefs, self-efficacy and monthly self-report self-examination checklist of the breast were completed in this section (pre-test) and two months after the training again, the same questionnaires were provided to research units Placed and completed (post test). In order to encourage the participation in educational sessions for women, a researcher and midwife responsible for training the contact number and email will be provided to the intervention team for any questions. In relation to both control groups, no training is provided according to the program, and they receive only ordinary general education.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

مرکز حمایتی زنان

Full name of responsible person

نساء محمدی

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Tarbiat Modares

Full name of responsible person

دکتر مینور لمیعیان

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Jalal Al-Ahmad Highway, beside to Shariati Hospital, Tarbiat Modares University

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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

The University of Tarbiat Modares

Proportion provided by this source

50

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**

The University of Tarbiat Modares

Full name of responsible person

Minor Lamiyan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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

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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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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available