

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Studying the effect of education based on Pender's health promotion models on successful breastfeeding in pregnant women

Protocol summary

2018-11-10, 1397/08/19

Study aim

Studying the effect of education based on Pender's health promotion models on successful breastfeeding in pregnant women in selected health centers of Shiraz

Design

In this research, 40 pregnant women (with pregnancy duration more than 32 weeks) were chosen. Then, Participants were randomly divided into two control and intervention groups and a code was allocated to each one of them.

Settings and conduct

This is a two-blind clinical trial that will be carried out in Shiraz's comprehensive health centers so that there will be 6 sessions for the intervention group and there will be no intervention for the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria for admission in this study is pregnant women with pregnancy duration more than 32 weeks and the exclusion criteria for this study, non-participation in more than one session.

Intervention groups

For the intervention group, 6 sessions will be held. The control group will receive no intervention.

Main outcome variables

successful breastfeeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160404027216N6**

Registration date: **2018-11-10, 1397/08/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-10, 1397/08/19**

Update count: **0**

Registration date

Registrant information

Name

Fatemeh Vizeshfir

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4258

Email address

vizeshfarf@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-07, 1397/07/15

Expected recruitment end date

2019-01-05, 1397/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of education based on Pender's health promotion models on successful breastfeeding in pregnant women

Public title

Successful breastfeeding training

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women whose duration of their pregnancy is more than 32 weeks. Lack of breastfeeding prohibition

for any reasons. Ability to read, write and understand and using the trainings.

Exclusion criteria:

Absence more than one session in the training program. Mother's relinquishment of participating in the research at each stage of the researching. Former participation at breastfeeding training classes

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

4 social health centers will be chosen by clustering method, subsequently two centers will be assigned as intervention centers and two of them as control ones, based on draw lot method and randomly.

Blinding (investigator's opinion)

Double blinded

Blinding description

Since the questionnaire will given to all participants, no one is aware of being in the control or intervention group, also participant's identity will be unbeknownst to the person who is analyzing the data.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

opposite Phalestine Street, Zand Blvd, Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2018-10-02, 1397/07/10

Ethics committee reference number

IR.Sums.REC.1397.600

Health conditions studied

1

Description of health condition studied

Other problems related to education and literacy

ICD-10 code

Z55.8

ICD-10 code description

Other problems related to education and literacy

Primary outcomes

1

Description

successful breastfeeding

Timepoint

Pre- intervention, Post- intervention, Two months after the intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The implementation of 6 sessions

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Community Health Centers

Full name of responsible person

Maryam Saberi

Street address

Namazi Square - School of Nursing and Midwifery- Shiraz- Fars-Iran

City

Shiraz

Province

Fars

Postal code

71936-13119

Phone

+98 71 3647 4252

Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

Shiraz University of Medical Sciences, Zand Blvd.,
Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3235 7282

Email

vcrdep@sums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Saberi

Position

Bachelore

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Namazi Square - School of Nursing and Midwifery-
Shiraz- Iran

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4254

Email

saberi.mari.71@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Fatmeh Vizeshfir

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Namazi Square - School of Nursing and Midwifery-
Shiraz- Fars- Iran

City

Shiraz

Province

Fars

Postal code

71936-13119

Phone

+98 71364742548

Email

vizeshfir@sums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Shiraz

Position

Bachelor of science

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Namazi Square - School of Nursing and Midwifery-
Shiraz- Iran

City

Shiraz

Province

Fars

Postal code

71936-13119

Phone

+98 71364742548

Email

saberi.mari.71@gmail.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

Due to the confidentiality of the data

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Publish in domestic and foreign publications and present in credible seminars

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Research team members

Under which criteria data/document could be used

As statistical data in research such as meta-analysis, which requires these data.

From where data/document is obtainable

Maryam Saberi

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

Send an email to the public responsible

Comments