

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation The Effect of Self-Care Educational Intervention on Empowerment of Primigravida Pregnant Women covered by The Family Doctor Program of Estahban City: an Application of The Pender Health Promotion Model

Protocol summary

Study aim

Determining the effect of self-care educational intervention on the empowerment of primigravida pregnant women covered by the family doctor program of Estehban city

Design

The present semi-experimental study on a sample of 40 primigravida pregnant women in the form of an intervention group who refer to the centers covered by the family doctor program in Estehban city to receive services, with the aim of improving their capabilities based on the Pender health promotion model, in a way direct (face-to-face consultation), during 6 sessions of 90 minutes and two sessions per week for the intervention group. Questionnaires will be completed by the samples before and one month after the intervention.

Settings and conduct

In one of the health centers, the educational program will be held in the form of 6 sessions for the intervention group.

Participants/Inclusion and exclusion criteria

Interested in participating in the study Pregnant mothers participating in the research must have at least reading and writing (primary) literacy. Have listening and speaking skills to participate in the study. be Iranian Without any known physical or mental illness that would prevent the pregnant woman from participating in the study. Do not belong to the high-risk group. Have not participated in childbirth preparation classes. Including pregnant women with a gestational age of 14-28 weeks Be primigravida

Intervention groups

Primigravida pregnant women in two control and intervention groups in separate health centers

Main outcome variables

Empowerment and its subscales (self-efficacy, future

image, self-esteem, perceived social support, joy of being added to the family)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131014015015N23**

Registration date: **2023-11-10, 1402/08/19**

Registration timing: **prospective**

Last update: **2023-11-10, 1402/08/19**

Update count: **0**

Registration date

2023-11-10, 1402/08/19

Registrant information

Name

Leila Ghahremani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

Email address

ghahramanl@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-21, 1402/08/30

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation The Effect of Self-Care Educational Intervention on Empowerment of Primigravida Pregnant Women covered by The Family Doctor Program of Estahban City: an Application of The Pender Health Promotion Model

Public title

Effect of Self-Care Education on Empowerment of Primigravida Pregnant Women

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Interested in participating in the study Pregnant mothers participating in the research must have at least reading and writing (primary) literacy Have listening and speaking skills to participate in the study Be Iranian Without any known physical or mental illness that would prevent the pregnant woman from participating in the study Do not belong to the high-risk group Have not participated in childbirth preparation classes Including pregnant women with a gestational age of 14-28 weeks Be primigravida

Exclusion criteria:**Age**From **15 years** old to **49 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

For the generalizability of the study results and to reduce the socio-economic differences as much as possible, the samples of the two control and experimental groups were selected from 4 established health centers, completely randomly, 2 centers along with covered centers as the control group and two other health centers. It will be selected as the test group along with the covered centers. In the selected centers, the names of eligible people are listed from the apple system, and among the mothers eligible to enter the study, 40 people will be randomly selected as the control group and 40 people will be considered as the experimental group.

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 Shiraz University of Medical Sciences

Street address

Central building of Shiraz University of Medical Sciences, Zand St. Shiraz

City

Shiraz

Province

Fars

Postal code

71345-1978

Approval date

2023-11-02, 1402/08/11

Ethics committee reference number

IR.SUMS.SCHEANUT.REC.1402.000

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

Empowerment of primigravida pregnant women

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Empowerment

Timepoint

in two periods: before the intervention and one month after the intervention

Method of measurement

Kamda empowerment questionnaire

Secondary outcomes**1****Description**

Self-efficacy

Timepoint

in two periods: before and one month after the educational intervention

Method of measurement

2**Description**

future image

Timepoint

in two periods: before and one month after the educational intervention

Method of measurement

Kameda empowerment questionnaire

3**Description**

self-esteem

Timepoint

in two periods: before and one month after the educational intervention

Method of measurement

Kameda empowerment questionnaire

4**Description**

perceived social support

Timepoint

in two periods: before and one month after the educational intervention

Method of measurement

Kameda empowerment questionnaire

5**Description**

joy of being added to the family

Timepoint

in two periods: before and one month after the educational intervention

Method of measurement

Kameda empowerment questionnaire

Intervention groups**1****Description**

Intervention group: will be invited to participate in the study and the objectives of the study will be explained to them, after assuring them of the confidentiality of the information, informed consent will be obtained from them. will be brought in this study, for the purpose of educational intervention, in the intervention group, the implementation of the educational program will be conducted face-to-face and by the method of short lectures, group discussions, questions and answers according to the structures of the Pender model and using educational aids such as (pamphlets, showing educational clips). Pregnant women will be divided into small groups of 5 people and will receive 6 training sessions of 90 minutes. Questionnaires will be provided to them again one month later.

Category**2****Description**

Control group: They will not receive training during this period. Although, in order to comply with ethical considerations, the control group will be assured that after the completion of the research process, they will also receive this educational intervention. A month later, the questionnaires will be provided to them again.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Centers covered by the family doctor program of Estehban city

Full name of responsible person

Leila Ghahremani

Street address

Vakil Abad, health and treatment network of Estehban city

City

Estehban

Province

Fars

Postal code

74518-73981

Phone

+98 71 5324 2036

Email

estahbansh@sums.ac.ir

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

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hashem Hashempour

Street address

Research and Technology Deputy; 7th Floor; Central Building of Shiraz University of Medical Sciences; Zand Street

City

Shiraz

Province

Fars

Postal code**Phone**

+98 71 3234 7966

Email

hashempurm@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

Leila Ghahramani

Position

Faculty member of Shiraz University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

First floor; building number one; School of Public Health; in front of Electricity Club; Razi Blvd.

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 3725 1001

Email

lghahraman@gmail.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Leila Ghahramani

Position

Faculty member of Shiraz University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Health; in front of Electricity Club; Razi Blvd.

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 3725 1001

Email

lghahraman@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Leila Ghahramani

Position

Faculty member of Shiraz University of Medical Sciences

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71345-1978

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+98 71 3725 1001

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lghahraman@gmail.com

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