

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Evaluation of the effectiveness of a self care program based on the teach back model on postpartum quality of life in women who visited health care centers

Protocol summary

Summary

Objective: This study is to determine the effect determine effect of a self care program based on the teach back model on postpartum quality of life. This study population comprised women on days 2-3 after delivery. The participants will be divided into two groups by using sealed envelope. The sample size concludes of 40 patients in the intervention group and 40 patients control group. For each sample in the test group, a sample will be chosen in the control group whose individuals have been matched in terms of the mother's age (± 2 years), the infant's gender, the mother's educational level, the mother's employment status (employed or housewife), and monthly income of the family. Inclusion criteria: They should be nulliparous; They should have a singleton, term and vaginal delivery; They should have given birth to an alive, healthy child resulting from a wanted pregnancy and weighing 2500 to 4000 grams; have a low-risk pregnancy. Exclusion criteria: Their infant is in need of special care; Mothers who have postpartum depression (using the Edinburgh Postnatal Depression Scale (EPDS)); They do not breastfeed their baby; They have encountered a stressful event during the time period of the study. In intervention group counseling will be done in two sessions of self-care teaching which each session for one hour based on the teach back model. In this study primary outcome variable is postpartum quality of life before and after education .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012820854N1**

Registration date: **2015-12-12, 1394/09/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-12, 1394/09/21

Registrant information

Name

Hedyeh Riazi

Name of organization / entity

Shahid Beheshti University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 912 386 5612

Email address

h.riazi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Behesht University of Medical Sciences

Expected recruitment start date

2015-10-12, 1394/07/20

Expected recruitment end date

2016-03-15, 1394/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of a self care program based on the teach back model on postpartum quality of life in women who visited health care centers

Public title

The Effect of a Self Care Program on Postpartum Quality of Life

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Women who are willing to participate in the study; They should be living in Darreh Shahr County; They should be nulliparous;; They should have a singleton, term and vaginal delivery; They should have given birth to an alive, healthy child resulting from a wanted pregnancy and weighing 2500 to 4000 grams; They should not have a history of primary infertility; They should have received prenatal care, they should not smoke, and they should not use any narcotic drugs; They should not have any recognized psychological, medical and obstetric; have a low-risk pregnancy; They should not have a difficult delivery (dystocia, instrumental delivery with forceps and vacuum); They should not have encountered any stressful events during the last 9 months (leaving of their spouse or divorce, death of one of their first-degree relatives, accident, burglary, horrible illness of the person or one of her close relatives); They should not have experienced any intrapartum or early postpartum complications, such as: severe hemorrhage. Exclusion criteria: The researcher's accessibility to the participant is not possible for any reasons, such as: moving to a different place to live; Their infant is in need of special care; Mothers who have postpartum depression (using the Edinburgh Postnatal Depression Scale (EPDS)); They do not breastfeed their baby.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The participants will be divided into two groups by using sealed envelope.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

St Velenjak, Shahid Chamran Highway, Shahid Beheshti University Of Medical Sciences, Tehran, Iran

City

Tehran

Postal code

Approval date

2015-08-16, 1394/05/25

Ethics committee reference number

SBMU2.REC.1394.67

Health conditions studied

1

Description of health condition studied

Postpartum Quality of Life

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Postpartum Quality of Life

Timepoint

The second or third days after birth before intervention, 6 to 8 weeks after delivery after intervention

Method of measurement

postpartum quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the postpartum care teaching is done individually and face-to-face, according to the defined plan, the intervention consists of two sessions of self-care teaching based on the teach back model in accordance with the postpartum educational package, so that the first session will be held on days 2-3 and the second session on days 10-15 after delivery, respectively. Each session will be held one hour.

Category

Lifestyle

2

Description

Control group: The control group will receive training routine postpartum.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care center Mo'ayyeri

Full name of responsible person

Ghiasvand Fatemeh

Street address

City

Darreh Shahr

2

Recruitment center

Name of recruitment center

Health care center koi Taleghani

Full name of responsible person

Ghiasvand Fatemeh

Street address

City

Darreh Shahr

3

Recruitment center

Name of recruitment center

Health care center Ghaleh Tasmeh

Full name of responsible person

Ghiasvand Fatemeh

Street address

City

Darreh Shahr

4

Recruitment center

Name of recruitment center

Health care center Ermou

Full name of responsible person

Ghiasvand Fatemeh

Street address

City

Darreh Shahr

5

Recruitment center

Name of recruitment center

Health care center Mazhin

Full name of responsible person

Ghiasvand Fatemeh

Street address

City

Darreh Shahr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research and Technology, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Ashin Rezgi

Street address

Vice chancellor for Research and Technology, Shahid Beheshti University Of Medical Sciences, Velenjak Ave, Chamran Highway, Tehran, Iran

City

Tehran

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for Research and Technology, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Science

Full name of responsible person

Ghiasvand Fatemeh

Position

Bachelor of Midwifery/ MA student midwifery

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Shahid Beheshti University of Medical Science, Valiasr Ave, Tehran, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Science

Full name of responsible person

Dr Hedyeh Riazi

Position

Ph.D in Reproductive Health/ Midwifery and Health
Academic member of Nursing & Midwifery

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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Shahid Beheshti University of Medical Science

Full name of responsible person

Ghiasvand Fatemeh

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty