

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Sep 2026

Assessing Postpartum Care Needs: Designing, Implementing, and Evaluating a Need-Based Program in Bojnourd

Protocol summary

Study aim

the training program on the mother and spouse and a key supporter in the postpartum period

Design

The study is quasi-experimental. 100 mothers, spouses, and key supporters in the intervention group received training, and 100 in the control group received only postpartum outcome questionnaires. Health centers were randomly divided into intervention and control groups.

Settings and conduct

The intervention was performed in Bojnourd Health Center and Hospital and included four training sessions for mothers, wives and key sponsors. The first session was held virtually during pregnancy and the third and fourth sessions were postpartum, but the second session was held in the hospital on the first day after delivery. A WhatsApp group in which all research units were members also answered the questions of the research samples 24 hours a day.

Participants/Inclusion and exclusion criteria

residents of Bojnourd and having literacy and first pregnancy. And any of the research units that wanted to leave the research during the study could be excluded from the study.

Intervention groups

The intervention group included education of mothers and wives and key supporters who entered the study from the third trimester of pregnancy. The control group also completed only the questionnaires.

Main outcome variables

The results of the study were Awareness in the third trimester and eight weeks after delivery the rate of breastfeeding in the first and second months after delivery and the level of satisfaction with postpartum care in the eighth week after delivery and the quality of life, postpartum depression and social support and the mother's performance in caring for herself and her baby.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180715040477N1**

Registration date: **2021-01-10, 1399/10/21**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-10, 1399/10/21**

Update count: **0**

Registration date

2021-01-10, 1399/10/21

Registrant information

Name

Sakineh Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 5376

Email address

s4.nazari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing Postpartum Care Needs: Designing, Implementing, and Evaluating a Need-Based Program in Bojnourd	
Public title	Postpartum Care
Purpose	Education/Guidance
Inclusion/Exclusion criteria	
Inclusion criteria:	Be a resident of Bojnourd Have the ability to read and write Persian Be the first pregnancy. Have no history of physical or mental illness Mothers are 18 to 45 years old
Exclusion criteria:	Not wanting to continue research
Age	From 18 years old to 45 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 200
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization was done in such a way that health centers in Bojnourd city were first classified into two classes with economic benefits and low economic benefits, and then from each floor by drawing a health center as an intervention group and a health center to The title of the control group was selected
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Other
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of Medical Sciences
Street address	Department of Reproductive Health and Midwifery (2th floor), School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Cross of Vali-Asr and Neiaiesh Highway, Opposite to Rajaee Heart Hospital, Tehran, Iran
City	tehran
Province	Tehran
Postal code	1996835119
Approval date	2019-06-10, 1398/03/20
Ethics committee reference number	IR.SBMU.PHARMACY.REC.1398.089
Health conditions studied	
<u>1</u>	
Description of health condition studied	Postpartum care and examination
ICD-10 code	Z39
ICD-10 code description	Encounter for maternal postpartum care and examination
Primary outcomes	
<u>1</u>	
Description	Breastfeeding
Timepoint	The first and second after delivery
Method of measurement	Self made Questionnaire and checklist
<u>2</u>	
Description	Postpartum satisfaction
Timepoint	Eight weeks after delivery
Method of measurement	Self made Questionnaire
<u>3</u>	
Description	social support
Timepoint	two and Eight weeks after delivery
Method of measurement	Hapkinz Social Support questionnaire
<u>4</u>	
Description	Quality of Life
Timepoint	two and Eight weeks after delivery
Method of measurement	Postpartum Quality of life questionnaire

5

Description

postpartum depression

Timepoint

two and Eight weeks after delivery

Method of measurement

Edinburgh Postnatal Depression

6

Description

Function The mother takes care of the baby and herself

Timepoint

two and Eight weeks after delivery

Method of measurement

Self made Questionnaire

7

Description

Awareness of postpartum care

Timepoint

Third trimester in pregnancy and eight weeks after delivery

Method of measurement

Self made Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Considering that in the first phase of research in the fan panel of the nominal group of social support strategy for the able Motherhood in the postpartum period in the city of Bojnourd gained the most points. We considered the simultaneous education of mother and wife and a key supporter. Mothers were selected in the third trimester after delivery and an online training session was held for the mother and spouse and a key sponsor about the postpartum period. On the first day after delivery, a training session was held for the mother and wife and a key supporter in the hospital in person on maternal and infant care and breastfeeding. And two more virtual sessions for participants in the second week and the first month after delivery with a focus on mental health and physical activity of the mother and care of the baby. All research units in the WhatsApp Q&A group were also present to answer their questionsh

Category

Prevention

2

Description

Control group: 100 mothers, spouses and key sponsors whoWho do not receive any training completed the questionnaires in the third trimester of pregnancy, two

weeks after delivery and eight weeks after delivery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Bint Al-Huda Hospital in Bojnourd

Full name of responsible person

Sakineh Nazari

Street address

Department of Reproductive Health and Midwifery (2th floor), School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Cross of Vali-Asr and Neiaiesh Highway, Opposite to Rajaee Heart Hospital, Tehran, Iran

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2

Recruitment center

Name of recruitment center

Bojnourd city health centers

Full name of responsible person

Sakineh Nazari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Syed Ali Ziae

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Department of Reproductive Health and Midwifery
(2th floor), School of Nursing and Midwifery, Shahid
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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

Shahid Beheshti 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

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sakineh Nazari

Position

Reproductive Health PhD Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Asr and Neiaiesh Highway, Opposite to Rajaee Heart
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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for general inquiries

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Full name of responsible person

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Position

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Latest degree

Master

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After the study, the main results of the research can be shared without mentioning the names of the research

samples

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The data will be available to researchers working in medical universities

Under which criteria data/document could be used

If data are used, the names of the authors of this research should also be mentioned

From where data/document is obtainable

Applicants can refer to the Vice Chancellor for Research of Shahid Beheshti University of Medical Sciences or send an email to s4.nazari@gmail.com.

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

Applicants can request documents by writing to the Vice Chancellor for Research of Shahid Beheshti University of Medical Sciences or emailing s4.nazari@gmail.com six months after the publication of the articles

Comments