Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Presenting a Pattern of Postpartum Care at Home and Its Effects on the Health of the Mother and the Suckling

Protocol summary

Summary

Objective: Presenting a pattern of postpartum care at home and its effects on the health of the mother and suckling. Method: This interventional study is a randomized trial. First, we reach a unique pattern by summarizing data from the study of the pattern of postpartum care at home in different countries. Then by gathering journalists' and stakeholders' comments there will be changes in accordance with the needs of the country. The study population is woman who have given birth in Shohada, Imam Hossein, Taleqani and Mahdieh hospitals. After obtaining consent, 270 eligible mothers are elected successively, we allocate 90 people in intervention group and 180 people in control group. Inclusion criteria: Iranian nationality; no gestational hypertension and Diabetes; single embryo with normal birth weight; having a score less than 14 in Edinburg questionnaire. Exclusion criteria: unwillingness to continue the study for any reason; immigration from the areas of study. The type of intervention for both groups is providing service in accordance with the approved pattern at home and to visit in days of 3-5 and 13-15 after the delivery.The control group won't be provided with home service.The review of the results will be conducted on days 42-60 and mother and suckling health indices between two groups will be compared. These indices include using supplementation by mother and suckling, postpartum depression, mother hospitalization due to the complications after childbirth, exclusive feeding with breast milk, infant hospitalization after the first 28 days of childbirth and common physical complications in mothers in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013060313565N1**

Registration date: **2013-12-07, 1392/09/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-07, 1392/09/16

Registrant information

Name

Parastoo Amiri

Name of organization / entity

Shaheed Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2220 2563

Email address

amiri.parasto@gmail.com

Recruitment status

Recruitment complete

Funding source

Shaheed Beheshti University of Medical Sciences

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2014-01-05, 1392/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Presenting a Pattern of Postpartum Care at Home and Its Effects on the Health of the Mother and the Suckling

Public title

Effects of Postpartum Care at Home on the Health of the

Mother and Suckling

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Iranian nationality; no gestational hypertension, preeclampsia and gestational diabetes; single embryo with normal birth weight;no congenital anomalies; having a score less than 14 in Edinburg questionnaire. Exclusion criteria: unwillingness to continue the study for any reason; immigration from the areas of study

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **270**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Shaheed Beheshti University of Medical Sciences

Street address

Velenjak , Shahid Chamran Highway

City

Tehran

Postal code

Approval date

2012-11-11, 1391/08/21

Ethics committee reference number

0308/11470

Health conditions studied

1

Description of health condition studied

Postpartum Period

ICD-10 code

Z39.1, Z39

ICD-10 code description

Care and examination of lactating mother, Routine postpartum follow-up

Primary outcomes

1

Description

Using supplementation in mother in intervention and control groups

Timepoint

42-60 days after intervention

Method of measurement

questionarie

2

Description

Using supplementation in suckling in intervention and control groups

Timepoint

42-60 days after intervention

Method of measurement

questionarie

3

Description

Using the contraceptive methods in intervention and control groups

Timepoint

42-60 days after intervention

Method of measurement

questionarie

4

Description

Incidence of Postpartum depression in intervention and control groups

Timepoint

42-60 days after intervention

Method of measurement

Edinburg questionarie

5

Description

Mother hospitalization due to complications after childbirth in intervention and control groups

Timepoint

42-60 days after intervention

Method of measurement

questionarie

6

Description

Exclusive feeding with breast milk in intervention and control groups

Timepoint

42-60 days after intervention

Method of measurement

questionarie

7

Description

Breast problems in intervention and control groups

Timepoint

42-60 days after intervention

Method of measurement

questionarie

8

Description

Constipation in intervention and control groups

Timepoint

42-60 days after intervention

Method of measurement

questionarie

9

Description

Hemorrhoids in intervention and control groups

Timepoint

42-60 days after intervention

Method of measurement

questionarie

10

Description

Backache and lumbago in intervention and control groups

Timepoint

42-60 days after intervention

Method of measurement

questionarie

11

Description

Fatigue in intervention and control groups

Timepoint

42-60 days after intervention

Method of measurement

questionarie

Secondary outcomes

1

Description

Satisfaction rate in intervention and control groups

Timepoint

42-60 days after intervention

Method of measurement

questionares

Intervention groups

1

Description

The type of intervention for both groups is providing service in accordance with the approved pattern at home and to visit in days of 3-5 and 13-15 after the delivery. Visits are done by trained midwives or nurses. The average time of visit is considered between 30-45 minutes, which is flexible according to mothers' demands.The service provider's phone number is given to mothers in case of any problems. Caregivers will be trained before the intervention, so there will be integration in the caring method.

Category

Prevention

2

Description

The control group won't be provided with home service.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdie Hospital

Full name of responsible person

Dr. Mehrdad Izadi , Hospital administration

Street address

Shoosh ".Sq." ,Fadaeian Eslam".Av."

City

Tehran

2

Recruitment center

Name of recruitment center

Emam Hossein Hospital

Full name of responsible person

Ḍr.seid Mohammad Taghi Hosseini Tabatabae, Hospital administration

Street address

Tehran, Shaheed Madani Avenue

City

Tehran

3

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Dr. Abbas Haj Fathali , Hospital administration

Street address

Velenjak, shahid chamran highway

City

Tehran

4

Recruitment center

Name of recruitment center

Shohada Hospital

Full name of responsible person

Dr.Badiozaman Radpey, Hospital administration

Street address

Tajrish, Qods ".Sq."

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shaheed Beheshti University of Medical Sciences

Full name of responsible person

Dr.Hossein Goodarzi

Street address

Velenjak, Shahid Chamran Highway

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, Shaheed 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

Shaheed Beheshti university of Medical Sciences

Full name of responsible person

Parastoo Amiri

Position

Resident of Community medicine

Other areas of specialty/work

Street address

Velenjak,Shaheed Beheshti Faculty of medicine,Eighth floor,Public health & Community medicine department

City

Tehran

Postal code

Phone

+98 21 2243 9936

Fax

Email

Amiri.Parasto@gmail.com ; Amiri_Parasto@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shaheed Beheshti university of Medical Sciences

Full name of responsible person

Dr.Hourieh Shamshiri Milani

Position

assistant professor

Other areas of specialty/work

Street address

Velenjak,Shaheed Beheshti Faculty of medicine,Eighth floor,Public health & Community medicine department

City

Tehran

Postal code

Phone

+98 21 2243 9936

Fax

Email

Hourieh_Milani@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shaheed Beheshti University of Medical Sciences

Full name of responsible person

Parastoo Amiri

Position

Resident Of Community Medicine

Other areas of specialty/work

Street address

Velenjak,Shaheed Beheshti Faculty of medicine,Eighth floor,Public health & Community medicine department

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Tehran

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Phone

+98 21 2243 9936

Fax

Email

Amiri.Parasto@gmail.com ; Amiri_Parasto@yahoo.com

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