

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Assessment the effect of Orem's self-care counselling on the postpartum self- evaluation of primiparous women

Protocol summary

Study aim

Evaluation the the effect of Orem's self-care counselling on the post partum self- evaluation of primiparous women

Design

A randomized controlled clinical trial with a parallel group design of 58 participants

Settings and conduct

Research population comprise postpartum women of Mohammadshahr in the Alborz province. A sample of 58 eligible mothers will be selected by simple random. In intervention group, participants will attend weekly in group counselling session for 3 sessions (90 minutes) in groups of six people, according the Orem's model. The participants will be evaluated before and 6 weeks after the intervention by postpartum self-evaluation questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being Iranian, being literated, primipara, low risk pregnancy, absence of physical and mental illness, absence of postpartum Depression, absence of postpartum complications, being interested to contribute in the study. Exclusion criteria: Neonatal illness, Neonatal Hospitalisation.

Intervention groups

"Intervention group" will receive group counselling in 3 sessions (90 minutes)weekly. "Control group" will not receive any counselling.

Main outcome variables

Postpartum self-evaluation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160424027557N8**

Registration date: **2018-10-13, 1397/07/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-13, 1397/07/21**

Update count: **0**

Registration date

2018-10-13, 1397/07/21

Registrant information

Name

Mahnaz Akbari Kamrani

Name of organization / entity

Alborz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3433 6007

Email address

dr.akbarikamrani@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of Orem's self-care counselling on the postpartum self- evaluation of primiparous women

Public title

Effect of counselling on the postpartum self- evaluation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Being Iranian Being literated Being married Being primiparous Having single pregnancy Having low risk pregnancy Having term newborn Absence of physical and mental illness Absence of postpartum Depression Absence of postpartum complications Being interested to contribute in the study

Exclusion criteria:

Neonatal illness Neonatal Hospitalisation

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

The block sampling was used for random allocation using Excel software to form the groups. Samples were divided into intervention and control groups by quadruple random blocks. There were six possibilities for blocking (BAAB, ABAB, AABB, ABBA, BBAA, BABA). First, one of the blocks was selected and four of the participants in that block were selected. As a result, the number A belongs to the intervention group and the number B belongs to the control 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 Alborz University of Medical Sciences

Street address

Vice-Chancellor for Research and Technology, Alborz University of Medical Sciences, above Taleghani Square, Taleghani Square

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2018-02-24, 1396/12/05

Ethics committee reference number

IR.ABZUMS.REC.1396.203

Health conditions studied

1

Description of health condition studied

Routine postpartum follow-up

ICD-10 code

Z39.2

ICD-10 code description

Routine postpartum follow-up

Primary outcomes

1

Description

Postpartum self-evaluation

Timepoint

Before and after intervention

Method of measurement

Postpartum self-evaluation questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants will attend in group counselling (90 minutes) for 3 sessions in groups of six people weekly, according the Orem's model. Counselling content includes: the purpose of the study, general health, developmental health and illness.

Category

Lifestyle

2

Description

Control group: Participants will not receive any intervention. After the study, a booklet containing the content of the consultation will be given to them.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Alborz University of Medical Sciences

Full name of responsible person

Maryam Chamangasht

Street address

Bakhtiari Ave., Tabatabaie Comprehensive Health Services Center

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Mohammadshahr

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3198764653

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khcalborz@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Noorisepehr

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Research@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alborz 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

Alborz University of Medical Sciences

Full name of responsible person

Maryam Chamangasht

Position

student

Latest degree

Master

Other areas of specialty/work

counseling in midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Dr. Mahnaz Akbari Kamrani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

Contact

Name of organization / entity

Alborz University of Medical Sciences

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Position

Assistant Professor

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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

All collected variables

When the data will become available and for how long

From 2019

To whom data/document is available

It will be available only for people working in academic institutions.

Under which criteria data/document could be used

No Criterion

From where data/document is obtainable

By Email: Dr.akbarikamrani@abzums.ac.ir and Dr. Mahnaz Akbari Kamrani would be responsive

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

By Email

Comments