

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Effect of Tele continuous Care on Postpartum Adaptation and Neonate Perception among Primiparous women

Protocol summary

Study aim

Evaluating the Effect of Tele continuous care on Postpartum Adaptation and Neonate Perception among Primiparous women.

Design

Randomized controlled field trial on 48 samples. 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.

Settings and conduct

The research population are among primiparous women hospitalized in the postpartum department of the selected Maternity and Gynecology center of east of Tehran. The intervention group will receive tele-continuous care during six weeks after delivery while the control group only benefits from the routine three separated postpartum care given in Health centers.

Participants/Inclusion and exclusion criteria

Eligible participants include Iranian primiparous women aged 18 years old or older who are able to communicate with mobile phones and messaging apps and only the singleton mothers whose gestational age is over 37 weeks with their baby's weight > 2500 gr and the APGAR score > 7 immediately after birth, will be enrolled. Getting a score of 15 or more from the Edinburgh Postpartum Depression Scale or occurring any serious health problem in mothers or their babies, are the exclusions criteria.

Intervention groups

The continuous postpartum care involved postnatal support by a midwife at first visit in the hospital and a six week follow-up after delivery providing health education and midwifery counseling based on the individual needs and conditions of each client via phone calls and messaging apps to send videos and educational content during the postpartum period. The control group will only benefit from routine postpartum care provided in comprehensive health centers after discharge from

hospital.

Main outcome variables

Postpartum adaptation and neonatal perception in primiparous women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160424027557N9**

Registration date: **2022-12-20, 1401/09/29**

Registration timing: **prospective**

Last update: **2022-12-20, 1401/09/29**

Update count: **0**

Registration date

2022-12-20, 1401/09/29

Registrant information

Name

Mahnaz Akbari Kamrani

Name of organization / entity

Alborz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-04-09, 1402/01/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Tele continuous Care on Postpartum Adaptation and Neonate Perception among Primiparous women

Public title
Effect of Tele continuous Care on Postpartum Adaptation and Neonate Perception

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Primiparous women Iranian nationality and proficiency in Persian language Ability to use cell phones and messaging apps Being married Age over 18 years old Delivering single birth Birth of a healthy and full term baby Absence of known medical or mental disease according to self statement Not being addicted and not having the history of opioids, amphetamines and alcohol use Signing the informed voluntary consent form
Exclusion criteria:
 Occurring any serious medical complications in mother or neonate during the study Obtaining a 15 or higher depression score from the Edinburgh Postpartum Depression Questionnaire

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
The block sampling was used for random allocation using Excel software to form the groups. Samples are divided into intervention and control groups by quadruple random blocks. There are six possibilities for blocking (BAAB, ABAB, AABB, ABBA, BBAA, BABA). First, one of the blocks is selected and four of the participants in that block will be 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

Reaearch Ethics committees of Alborz University of Medical Science

Street address

Research Ethics Committees of Alborz University of Medical Siences Taleghani square, north Taleghani boulevard, Karaj, Alborz Medical University

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2022-12-03, 1401/09/12

Ethics committee reference number

IR.ABZUMS.REC.1401.246

Health conditions studied

1

Description of health condition studied

Continuous postpartum follow up

ICD-10 code

Z39.2

ICD-10 code description

Encounter for routine postpartum follow-up

Primary outcomes

1

Description

Postpartum adaptation score

Timepoint

Assessment the postpartum adaptation score within the second and sixth weeks after delivery

Method of measurement

Barkin Index of Maternal Functioning

2

Description

Neonate perception score

Timepoint

Assessment the neonate perception score within the second and sixth weeks postpartum

Method of measurement

The Newborn Perception Scale Broussard and Hanter 1971

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Primiparous Iranian women aged >18 giving birth to a single healthy full-term newborn. After the first visit at the postpartum department of the chosen hospital and providing the health tips and breastfeeding consultation to the new mothers and obtaining the consent form and completing the demographic questionnaire, the intervention group will undergo a six week follow up via phone calls and messaging apps in order to provide the relevant health educations such as Neonatal Screening programs, postnatal examinations in health centers, diagnosing the warning signs in mother or baby and providing the individual consultations involving lactating and feeding problems, baby care, complement use, taking care of the stump, baby sleep tips, safely bathing and massaging the baby, telling helpful tips to relieve colic pains, emphasizing on husband support, sexual health and family planning consultations, scoring the postpartum depression scale and responding to the questions and health concerns of the mother and so on. In the second and sixth weeks post delivery, the postpartum adaptation and neonatal perception questionnaires will be asked from participants.

Category

Lifestyle

2

Description

Control group: Primiparous Iranian women aged >18 giving birth to a single healthy full-term newborn. After the first visit at the postpartum department of the chosen hospital and providing the health tips and breastfeeding consultation to the new mothers and obtaining the consent form and completing the demographic questionnaire, the control group will only benefits from the routine separate postnatal visits in health centers. In the second and sixth weeks post delivery, the postpartum adaptation and neonatal perception questionnaires will be asked from participants.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women Hospital

Full name of responsible person

Fateme Arank

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No.162 Ave, Baghdarnia St, Tehranpars

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr Razieh Lotfi

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Vice-Chancellor for Reaserch and Technology, Alborz University of Medical Sciences, North Taleghani Square, Karaj

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Grant name

Grant code / Reference number

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

No

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

Fateme Arank

Position

Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Dr. Mahnaz Akbari Kamrani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Associate professor

Latest degree

Ph.D.

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 2023

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

Person responsible for updating data

Contact