Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of a Care Model Based on Orem's Theory on Self-Efficacy and Attachment in Mothers of Infants Attending Health Centers in Shahrekord: A Clinical Trial

Protocol summary

Study aim

Determine the effect of implementing Orem’s self-care model on maternal self-efficacy and mother–infant bonding

Design

This randomized controlled trial with parallel groups includes primiparous mothers with infants under 6 months. Sample size is based on study objectives, and participants are randomly allocated 1:1 to intervention or control using random numbers. The intervention is an Orem-based educational program.

Settings and conduct

This study was conducted in Shahrekord health centers, with eligible mothers randomly assigned (1:1) to Orem-based education or control after consent. Participant/provider blinding was not feasible, but the outcome assessor was blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Primiparous mothers with a term infant aged 0–6 months, no chronic or psychiatric disorders, Persian literacy, residence in Shahrekord or suburbs, and signed informed consent. Exclusion criteria: Absence from more than one session, infant hospitalization, onset of acute maternal illness, or voluntary withdrawal.

Intervention groups

The Orem model will be delivered to the intervention group in 6 weekly 60–90 minute sessions, in person or virtually, to empower mothers in infant care, including feeding, daily care, danger signs, developmental needs, maternal self-care, and home assignments..

Main outcome variables

Maternal self-efficacy score measured by the Maternal Self-Efficacy Questionnaire; mother–infant bonding score measured by the Postpartum Bonding Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180722040555N6**
Registration date: **2026-05-18, 1405/02/28**
Registration timing: **prospective**

Last update: **2026-05-18, 1405/02/28**
Update count: **0**

Registration date

2026-05-18, 1405/02/28

Registrant information

Name

Zohreh Karimiankakolaki

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-11, 1405/05/20

Expected recruitment end date

2027-03-10, 1405/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of a Care Model Based on Orem's Theory on Self-Efficacy and Attachment in Mothers of Infants Attending Health Centers in Shahrekord: A Clinical Trial

Public title
Effect of Orem-Based Care on Mothers' Self-Efficacy and Mother–Infant Bonding

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Primiparous mothers (first-time mothers) Having an infant aged 0 to 6 months Infant without any chronic disease, congenital anomaly, or neurological problem Infant born at term (gestational age 37–42 weeks No known psychiatric disorders in the mother (based on health records or self-report) No history of hospitalization of the mother or infant during the postpartum period due to serious medical conditions Ability to read and write in Persian (for completing questionnaires) Residence in Shahrekord or its suburbs (for accessibility and follow-up) Willingness to participate and completion of the informed consent form No concurrent participation in other similar studies No use of psychotropic medications

Exclusion criteria:
Absence from more than one educational session Hospitalization of the infant during the study period Development of acute mental or physical illness in the mother during the study Voluntary withdrawal from participation in the study

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly allocated into intervention and control groups after completing the baseline questionnaire. Randomization will be performed using a random number table. Each participant will be assigned a specific code, and based on the random numbers, she will be allocated to either the intervention or control group. Allocation will be performed with an equal ratio (1:1) between the two groups. To reduce selection bias, group allocation will be carried out by a person other than the main researcher/intervention provider.Allocation concealment will be achieved using sequentially numbered, opaque, sealed envelopes. Due to the nature of the educational/supportive intervention, blinding of participants and the intervention provider is not feasible. However, if possible, the outcome assessor/data analyst will be kept unaware of group allocation.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Implementation of Orem's self-care model for the intervention group is designed as a six-session program. Each session lasts 60 to 90 minutes and is held weekly at the comprehensive health service center or, based on the mother's preference, either face-to-face at the health centers (in compliance with health protocols) or in a virtual or hybrid format according to the mothers' choice.The content of the sessions is structured based on the three levels of Orem's nursing system wholly compensatory, partly compensatory, and supportive educative and aims to empower mothers in caring for their infants.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Islamic Azad University Shahrekord Branch

Street address
Rahmatieh, Islamic Azad University of Shahrekord

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Chahar-Mahal-va-Bakhtiari

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8813733395

Approval date
2026-04-08, 1405/01/19

Ethics committee reference number
IR.IAU.SHK.REC.1405.010

Health conditions studied

1

Description of health condition studied
Maternal self-care Maternal, self-efficacy Mother–infant, bonding Orem's self-care theory–based, education Maternal and child health / infant care

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Maternal self-efficacy score measured by the Maternal Self-Efficacy Questionnaire at the end of the intervention,

assessing the mother's ability to care for her infant. Mother–infant bonding score measured by the Postpartum Bonding Questionnaire at the end of the intervention, evaluating the emotional connection between mother and infant.

Timepoint

At the baseline, before the intervention begins,At the end of the intervention after completion of the educational sessions.

Method of measurement

Maternal self-efficacy is measured using the Maternal Self-Efficacy Questionnaire, a validated tool assessing the mother's confidence in caring for her infant.Mother–infant bonding is measured using the Postpartum Bonding Questionnaire, a standardized instrument evaluating the emotional connection between mother and infant.

Secondary outcomes

1

Description

This secondary outcome assesses the mother's quality of life after the educational intervention, measured by a validated questionnaire covering physical, emotional, and mental health aspects.

Timepoint

At baseline before the intervention,At the end of the intervention.

Method of measurement

The secondary outcome of quality of life is measured using the Short Form Health Survey with 12 questions, which assesses the mother's physical and mental health.

Intervention groups

1

Description

Intervention group: The intervention consists of implementing Orem's self-care model through six weekly sessions, each lasting 60 to 90 minutes, delivered in person or virtually. The sessions aim to empower primiparous mothers in infant care, including education on feeding, daily care, recognition of danger signs, infant developmental needs, maternal self-care, and anxiety reduction. Educational booklets and weekly home practice assignments complement the sessions.

Category

Other

2

Description

Control group: In this study, mothers in the control group will receive only the routine care provided by health centers, and no additional educational intervention will be administered to them during the study period. Routine care includes the standard maternal and infant care services delivered according to the current guidelines of the national health system at comprehensive health service centers. To address ethical considerations and ensure equal access to educational materials, an educational booklet related to the study topic will be provided to the mothers in the control group after the completion of the intervention period and data collection.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahrekord County Health Center

Full name of responsible person
Dr Somaye Javadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Private

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
Islamic Azad University

Full name of responsible person
Forogh Okhovat

Position
student in phd

Latest degree
Master

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data include questionnaire results and clinical information. If shared, only de-identified data and possibly a subset related to primary outcomes will be made available. Final decision will be made after study completion.

When the data will become available and for how long

Data and documents will be made available after the study completion and publication of main results, if sharing is decided. The exact start time of access will be announced after analyses are finalized.

To whom data/document is available

If data and documents are shared, access will be granted only to researchers and individuals who submit requests for legitimate scientific and research purposes. Access for those outside academic and research institutions will be subject to ethical and scientific review.

Under which criteria data/document could be used

Use of the data and documents is permitted solely for legitimate scientific and research purposes. Requesters must provide an approved research proposal outlining specific objectives for data use. Any commercial or non-scientific use is prohibited. Access will require signing a non-disclosure agreement (NDA) and compliance with ethical standards and participant confidentiality. Data use must adhere to relevant ethical guidelines and regulations.

From where data/document is obtainable

Applicants interested in accessing the study data and documents should first contact the principal investigator or project manager. Requests can be submitted via email to: [investigator’s email address]. For formal correspondence, postal mail can be sent to: For further coordination, telephone number: [phone number] and fax number: [fax number] are also available.

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

The process for requesting data is as follows: the applicant submits a written request to the principal investigator. After scientific and ethical review, if approved, the applicant must provide a confidentiality agreement (NDA) and a research proposal. Upon final approval, de-identified data will be prepared and shared. This process usually takes 3 to 6 weeks, and the applicant can follow up during this period.

Comments