

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of multimedia film and booklet on mother self-efficacy and healthy newborn care behavior in primipara mothers: A randomized controlled trial

Protocol summary

Summary

Objectives: This study aims to compare the effects of multimedia film and educational booklet on self-efficacy and care behavior of healthy newborn in primipara mothers. **Design:** A single-blind Randomized Controlled Trial. **Setting and conduct:** This study will be conducted in health centers of Miandoab city. Eligible women will be selected with convenience sampling and will be randomly assigned into 3 groups of 126 subjects with block sizes of 3 and 6. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelopes will be used for allocation concealment. **Participants:** 126 primipara pregnant women with gestational age of 36 to 38 weeks. **Interventions:** The first intervention groups will receive the educational CD and the second intervention group will receive educational booklet. Educational CD has been developed by the Ministry of Health. The booklet also will set by researcher with the same educational content. The control group also will receive postpartum routine care. **Main outcome measures** include Maternal self efficacy and newborn care behavior and secondary outcomes include knowledge of newborn care and maternal self-confidence that will be evaluated before and 4 weeks after childbirth.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071410324N23**
Registration date: **2015-08-06, 1394/05/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-06, 1394/05/15

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2015-08-01, 1394/05/10

Expected recruitment end date

2015-12-01, 1394/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of multimedia film and booklet on mother self-efficacy and healthy newborn care behavior in primipara mothers: A randomized controlled trial

Public title

Comparison of the effect of multimedia film and booklet on mother self-efficacy and healthy newborn care behavior in primipara mothers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Desire to participate in the study; Having at least secondary school education; Being nulliparous and having singleton pregnancy, Term healthy child; Having the ability to see and hear; Having a computer or a DVD. Exclusion criteria: Existence of mental –psychological diseases according to mother expression; High-risk pregnancy according to prenatal care records; Hospitalized newborns in NICU or malformed newborn.

Age

To 50 years old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 126

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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 Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan

City

Tabriz

Postal code**Approval date**

2015-07-06, 1394/04/15

Ethics committee reference number

TBZMED.REC.1394.344

Health conditions studied**1****Description of health condition studied**

Newborn care

ICD-10 code

Z76.2

ICD-10 code description

Health supervision and care of other healthy infant and child

Primary outcomes**1****Description**

Maternal self efficacy

Timepoint

Baseline and 4 weeks after childbirth

Method of measurement

Maternal self efficacy questionnaire

2**Description**

Infant care behavior

Timepoint

Baseline and 4 weeks after childbirth

Method of measurement

A researcher made questionnaire

Secondary outcomes**1****Description**

Knowledge of newborn care

Timepoint

Baseline and 4 weeks after childbirth

Method of measurement

A researcher made questionnaire

2**Description**

Maternal self-confidence

Timepoint

Baseline and 4 weeks after childbirth

Method of measurement

Self-confidence questionnaire

Intervention groups**1****Description**

The first intervention group will receive education by multimedia film. Educational film has been developed by the Ministry of Health that will be provided to participants at 36-38 weeks of pregnancy.

Category

Behavior

2

Description

The control group will receive postpartum routine care.

Category

N/A

3

Description

The second intervention group will receive education by educational booklet. Educational booklet has been developed by the researcher with same contents of educational film that will be provided to participants at 36-38 weeks of pregnancy.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Miandoab City

Full name of responsible person

Somayeh Jamalivand

Street address

City

Miandoab

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Rashidi Mohammad Reza

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Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz

City

Tabriz

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, Tabriz 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

Tabriz University of Medical Sciences, Nursing & Midwifery Faculty

Full name of responsible person

Somayeh Jamalivand

Position

MSc student in Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

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PhD of Reproductive Health

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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