

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1479 6969

###### Email address

mirghafourvandm@tbzmed.ac.ir

##### 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

#### Street address

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

#### Street address

Nursing & Midwifery Faculty, South Shariati Street

#### City

Tabriz

#### Postal code

3417174914

#### Phone

+98 41 3331 2679

#### Fax

#### Email

Jamalivandsomayeh@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Science, Nursing & Midwifery Faculty

#### Full name of responsible person

Mojgan Mirghafourvand

#### Position

PhD of Reproductive Health

#### Other areas of specialty/work

#### Street address

Nursing & Midwifery Faculty, South Shariati Street

#### City

Tabriz

#### Postal code

34751745

#### Phone

+98 41 1479 6770

#### Fax

#### Email

Mirghafourvandm@tbzmed.ac.ir;  
mirg1385@yahoo.com

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Tabriz University of Medical Science, Nursing &

Midwifery Faculty  
**Full name of responsible person**  
Mojgan Mirghafourvand  
**Position**  
PhD of Reproductive Health  
**Other areas of specialty/work**  
**Street address**  
Nursing & Midwifery Faculty, South Shariati Street  
**City**  
Tabriz  
**Postal code**  
34751745  
**Phone**  
+98 41 3479 6770  
**Fax**  
**Email**  
Mirghafourvandm@tbzmed.ac.ir;  
mirg1385@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*