

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effectiveness of two methods of ring band & nipple massage on successes of breastfeeding among mothers with nipple problems

#### Protocol summary

##### Summary

Objective: Comparing effectiveness of two methods of ring band & nipple massage on successful breastfeeding among mothers with nipple problems. Design: Randomized controlled clinical trial. Method: It will be conducted in hospitals of Tabriz (Al- Zahra and Taleghani). The qualified individuals will randomly be allocated to three groups of 33 persons with blocks of 6 and 9. One of the members of research team who is not involved in sample selection, will determine random allocation sequence using the computer program. The closed opaque envelopes will be scored respectively and used to hide the allocation. Intervention will begin 0.5 and 3 hours after vaginal delivery and cesarean section respectively, after mothers' physical stability. Mothers in the intervention groups will receive: 1 (ring band at the base of nipple which obtained from condom brim), 2 (massage of nipple or Hoffman massage) and 3 as control group (receive nipple's shield as the routine method of maternity ward). The variables of main outcome: The number of infants' breast feeding during 1, 7 and 15 days, the ratio of infants' bounding and the frequency of adverse events in mother and infants will be measured at groups of study during 1 and 15 days after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201512078170N9**

Registration date: **2016-03-13, 1394/12/23**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-03-13, 1394/12/23

#### Registrant information

##### Name

Jamileh Malakouti

##### Name of organization / entity

Nursing Faculty

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1477 2699

##### Email address

malakoutij@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

#### Expected recruitment start date

2016-02-22, 1394/12/03

#### Expected recruitment end date

2016-10-01, 1395/07/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effectiveness of two methods of ring band & nipple massage on successes of breastfeeding among mothers with nipple problems

#### Public title

Successful breastfeeding with inverted nipples

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria: Aged between 18-40; willingness of women to participate at study; ability to read and write Persian; infant birth weight between 2000 and 4000 gr;

mothers with flat or inverted nipple problem; phone number for follow-up Exclusion criteria:Using pumps; caps or any other devices to facilitate breastfeeding; mothers' infants with physiological; anatomical and other abnormalities no able to feed orally; history of physical and mental illness of the mother (epilepsy; gastrointestinal disorders; cardiovascular; kidney); having stressful accidents 1 month ago such as divorce; death of family members; using effective drugs during breastfeeding (to increase and decrease milk and hormones); presence of a disease or disorder affecting the attachment of the baby on mother

#### **Age**

From **18 years** old to **40 years** old

#### **Gender**

Female

#### **Phase**

2

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **99**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **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 Tabriz University of Medical Sciences

###### **Street address**

Azadi st; Golgasht Street ; Tabriz University of Medical Sciences Research & Technology

###### **City**

Tabriz

###### **Postal code**

51665118

##### **Approval date**

2015-11-26, 1394/09/05

##### **Ethics committee reference number**

rec.1394/779

### **Health conditions studied**

#### 1

##### **Description of health condition studied**

Breast-feeding problems

##### **ICD-10 code**

92.5

##### **ICD-10 code description**

Neonatal difficulty in feeding at breast

### **Primary outcomes**

#### 1

##### **Description**

The number of infants' breast-feeding

##### **Timepoint**

1, 7, 15

##### **Method of measurement**

Device for weight gain

#### 2

##### **Description**

Comparing the number of infants' breast-feeding during 1, 7 and 15 days at massage group

##### **Timepoint**

1, 7 and 15

##### **Method of measurement**

Calculating the number of infants' breast-feeding and device for weight gain

#### 3

##### **Description**

Comparing the number of infants breast-feeding during 1, 7 and 15 days at 3 groups

##### **Timepoint**

1, 7, 15

##### **Method of measurement**

Calculating the number of infants' breast-feeding and device for weight gain

### **Secondary outcomes**

#### 1

##### **Description**

Mother-infant bonding

##### **Timepoint**

Day 1 and 15 after intervention

##### **Method of measurement**

Maternal-fetal bonding scale

#### 2

##### **Description**

Determining the frequency of adverse events in mother and infant at groups of study

##### **Timepoint**

1-14 after intervention

##### **Method of measurement**

Self- designed check List

## Intervention groups

### 1

#### Description

The first group of intervention will receive ring bond at the base of nipple which cut from condom brim for successful breast-feeding

#### Category

Prevention

### 2

#### Description

The second group of intervention will receive massage of nipple or Hoffman massage for successful breast-feeding

#### Category

Prevention

### 3

#### Description

The control group will receive nipple's shield as the routine method of maternity ward for successful breast-feeding

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alzahra Hospital

##### Full name of responsible person

Maryam Kahfroshan

##### Street address

South Artesh street

##### City

Tabriz

### 2

#### Recruitment center

##### Name of recruitment center

Shahid Khanly

##### Full name of responsible person

Afkham Fazel Fard

##### Street address

Shahid Khanly: Health Center of Supporting Breast-Feeding Mothers; Beheshti st

##### City

Tabriz

### 3

#### Recruitment center

##### Name of recruitment center

Talegani Hospital

##### Full name of responsible person

Shakiba Poor Asad

##### Street address

Rah Ahan st

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research, Tabriz University of Medical Sciences

##### Full name of responsible person

Mohammad Reza Rashidi

##### Street address

Number 2; Third floor; Golgasht Street; Azadi Avenue; Central Construction; Research department; Tabriz Medical Science University; 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

Faculty of Nursing and Midwifery, Tabriz Medical Science University

##### Full name of responsible person

Jamileh Malakouti

##### Position

Academic member; Faculty of Nursing and Midwifery; Tabriz

##### Other areas of specialty/work

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*