

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the Effect of Two Educational Methods Booklet and Role-Playing on Mother's Knowledge and Perception of Self-Efficacy Regarding Infant Pain Management

Protocol summary

Study aim

Determining and comparing knowledge and Perception of Mothers' Self-Efficacy about infant Pain Management in the Control, Booklet and Role playing Groups before and after the Intervention.

Design

Quasi-experimental Study with control group, with parallel groups, on 75 infants

Settings and conduct

In the intervention group, an educational booklet containing contents in the field of management in the infant is given to the mother. Then, in two one and a half hour sessions, the researcher discusses the contents of the booklet face to face with the mother. In the intervention group, two educational contents will be taught to the mother through role-playing in two sessions of one and a half hours. For this purpose, individual sessions will be held in coordination with the mother and according to her wishes in the baby's bed. In the control group, they will receive routine training. These exercises are oral and include generalities about calming the baby, such as non-nutritious cuddling and sucking with the mother's finger.

Participants/Inclusion and exclusion criteria

Their babies are full-time and are fed under the mother's breast. The mother should live next to the baby; Mothers with a history of pain management education. Changes in the baby's clinical condition

Intervention groups

Three intervention groups. One Group will receive a pain management training booklet in addition to routine care. In addition to routine care, the second group receives pain management training through role-playing, and the third group receives only routine training.

Main outcome variables

Knowledge; Perception of Mothers' Self-Efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100823004617N17**

Registration date: **2021-01-27, 1399/11/08**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-27, 1399/11/08**

Update count: **0**

Registration date

2021-01-27, 1399/11/08

Registrant information

Name

Mahnaz Jabraeili

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Two Educational Methods Booklet and Role-Playing on Mother's Knowledge and Perception of Self-Efficacy Regarding Infant Pain Management

Public title

Comparison of the Effect of Two Educational Methods Booklet and Role-Playing on Mother's Knowledge and Perception of Self-Efficacy Regarding Infant Pain Management

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Their babies are full-term and are fed under the mother's breast 48 hours after the baby was admitted to the ward. The mother resides with the baby. The mother is physically and mentally healthy The mother is literate. The baby has no history of hospitalization.

Exclusion criteria:

The mother is an employee of the health care system Mothers with a history of pain management education. Discharge or death of the baby or transfer of the baby to other medical centers Withdrawal from continuing to participate in the study Changes in the baby's clinical condition and malaise

Age

From **14 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Not 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

Tabriz University of Medical Sciences.,Attar Neyshabouri St., Golghasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-11-02, 1399/08/12

Ethics committee reference number

IR.TBZMED.REC.1399.771

Health conditions studied

1

Description of health condition studied

Infants Pain Management

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

Mothers' knowledge about Infant Pain Management

Timepoint

Before the Intervention and 72 Hours after The Intervention

Method of measurement

Using a Researcher-Made Questionnaire

2

Description

Understanding Mothers' Self-Efficacy in Infant Pain Management

Timepoint

Before the Intervention and 72 Hours after The Intervention

Method of measurement

Using a Researcher-Made Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The control group will receive routine ward training. These exercises are oral and include generalizations about calming the baby, such as non-nutritious cuddling and sucking with the mother's finger. These trainings are

usually given to the mother before performing a painful procedure such as blood sampling, venipuncture, etc., or the baby's pain following bloating.

Category

Treatment - Other

2**Description**

In intervention second group , in addition to routine care, an educational booklet will be given to mothers. This booklet contains content on the definition of pain, pain symptoms in infants, management methods in infants and in particular common non-pharmacological methods in pain management (skin-to-skin care, non-nutritious sucking, sucrose and breast milk) . After reading the content by the mother, the researcher will discuss the contents of the booklet face to face with the mother in two one and a half hour sessions in order to answer any questions or ambiguities in the content of the booklet. With the coordination of the mother and according to her desire, it will be formed in the baby's bed. In this method, to ensure the mother's learning, scenarios will be prepared by the researcher and mothers will be asked to explain how to control and manage pain in the baby. For example, the mother is asked to 'explain the correct amount and method of giving sucrose to a baby weighing 3 kg'. During the intervention, the mother's strengths and weaknesses are fed to her by the researcher.

Category

Treatment - Other

3**Description**

In the third intervention group, in addition to routine care, the educational content will be taught to the mother through role-playing in two sessions of one and a half hours. For this purpose, individual sessions will be held in coordination with the mother and according to her wishes in the baby's bed. The image will be used to better understand theoretical issues such as pain symptoms in the baby. Common non-pharmacological methods of pain management, such as skin-to-skin care, non-nutritious sucking, oral sucrose, and practical breastfeeding, will be taught to the mother. For this purpose, depending on the circumstances, the mannequin or the baby (if the baby is asleep from the mannequin) will be used to educate the mother. To ensure the mother's learning, scenarios will be developed by the researcher and mothers will be asked to demonstrate how to control and manage pain in the baby using the methods described on the baby / mannequin. For example, the mother is asked to 'determine the amount of sucrose received for a baby weighing 3 kg and show the correct way to give sucrose to the baby'. During the intervention, the mother's strengths and weaknesses are fed to her by the researcher.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz Children's Hospital

Full name of responsible person

Dr. Mahnaz Jabraeili

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Children's Hospital., Shesgelan Street., Tabriz

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kodakanhospital@tbzmed.ac.ir

Web page address

<https://childrenhospital.tbzmed.ac.ir/>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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No. 2 Central Building, Research Deputy of Tabriz University of Medical Sciences., Golgasht Street., Tabriz

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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

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Mahnaz Jabraeili

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available