Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 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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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

Street address
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
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Full name of responsible person
Mahnaz Jabraeili
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Assistant Professor
Latest degree
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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