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
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

**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

**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 Jabraeiil

**Street address**: Children's Hospital, Shesgelan Street, Tabriz

**City**: Tabriz

**Province**: East Azarbaijan

**Postal code**: 5136735886

**Phone**: +98 413 526 2255

**Email**: 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

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

**City**: Tabriz

**Province**: East Azarbaijan

**Postal code**: 5165665931

**Phone**: +98 413 3334 4280

**Email**: research-vice@tbzmed.ac.ir

**Web page address**: https://www.tbzmed.ac.ir/

**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: East Azarbaijan
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
Street address: School of Nursing and Midwifery., Shariati Street., Tabriz
City: Tabriz
Province: East Azarbaijan
Postal code: 5166614766
Phone: +98 41 3336 4658
Email: jabraelim@gmail.com

Person responsible for scientific 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
Street address: School of Nursing and Midwifery., Shariati Street., Tabriz
City: Tabriz
Province: East Azarbaijan
Postal code: 5166614766
Phone: 0098 41 3364658
Email: jabraelim@gmail.com

Person responsible for updating data

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
Street address: School of Nursing and Midwifery., Shariati Street., Tabriz
City: Tabriz
Province: East Azarbaijan
Postal code: 5166614766
Phone: 0098 41 3364658
Email: jabraelim@gmail.com

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