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Original Research Article

A study to assess the effectiveness of breast feeding on pain level among infants during immunization at selected health and wellness centre, Daman

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ABSTRACT

Background: Pain is a global health problem experienced from birth to the last stages of life. It has been proven that infants are able to feel painful stimuli during immunization. Multiple adverse effects of pharmacological agents due to their side effects prevent providers from adequately addressing procedural pain. Breast feeding should be the first-choice analgesic during painful procedures in neonates. Aim was to assess the effectiveness of breast feeding on pain level among infants during immunization at a selected health and wellness center, Daman.
Methods: A quasi-experimental, non-equivalent control group post-test-only design was adopted. 60 infants were selected using a non-probability convenient sampling technique; 30 were assigned to the control group and 30 to the experimental group.
Results: The mean pain score in the control group was 7.50 and in the experimental group was 2.70, with a mean difference of 4.800. The calculated unpaired "t" value of 12.829 was higher than the table value of 1.672 at $p<0.05$ level of significance, demonstrating the effectiveness of breast feeding in reducing pain during immunization.
Conclusions: Breast feeding is a simple, safe, cost-effective, and easy-to-administer pain intervention during immunization. It should be incorporated in all immunization centres as a pain management measure.

Keywords: Breast feeding, Pain level, Infants, Immunization, FLACC scale

INTRODUCTION

"The best way to make children good is to make them happy"-Oscar Wilde.

An infant is a word derived from the Latin word "infants," meaning unable to speak or speechless a very young offspring of a human.[1] An infant is the most super-sensitive, delicate, and susceptible form that can be easily harmed if not carefully cared for. Infant health comprises physical, mental, and social wellbeing. Regular checkups by health care professionals are essential for keeping children healthy.[2]

The triad problems poverty, population explosion, and environmental stress-are great threats to child health in developing countries. Better nutrition, education, and family planning are essential aspects for improving child health.[2]

Children are the future leaders of India. Immunization is one of the most important preventive measures in children's lives, providing protection against the most dangerous childhood diseases. The development and administration of immunization is a greater achievement of the 20th century, having an enormous positive impact on disease prevention. Approximately 14 vaccines are

currently recommended by the Centre for Disease Control and Prevention before the age of two years.[3]

Pain is a universal experience. Infants are more sensitive to pain than older children and adults because they are still in the process of development, both physically and mentally. Many infants undergo painful procedures without pain-relieving medication; vaccination is one such procedure.[4]

Heine and Barrett proved that breast milk contains a higher concentration of tryptophan, a precursor of melatonin. Melatonin increases the concentration of beta endorphins and could possibly be one of the mechanisms for the nociceptive effects of breast milk. Breast feeding/breast milk is a natural, easily available, easy-to-use, and potentially risk-free intervention.[5]

Melzack and Wall's Gate Control Theory explains the pain-blocking mechanism: when non-nociceptive touch fibres are stimulated, the substantia gelatinase "closes the gate" to pain impulses entering the spinal cord. This mechanism can result in little or no pain perception regardless of the intensity of the painful stimuli.[6]

During the invasive procedure the neonates were separated from parents for various investigations and further it increases the pain. In some private hospital babies are handled by untrained and unskilled health professionals who also increase the pain for the baby.[7]

Need for the study

Pain is a global health problem experienced from birth to the last stages of life. According to WHO 2022, 77.2% of rural and 80% of urban children in India receive vaccines annually; however, vaccinated infants experience severe to moderate pain. The majority of health care professionals recognize the lack of interventions to decrease the unpleasantness of procedural pain. Knowledge of alternative techniques in pain management can improve infant care and satisfaction.[1]

Breast feeding should be the first-choice analgesic during painful procedures in neonates. Raylene M. Phillips concluded that breast feeding is more analgesic than non-maternal holding with pacifier use, suggesting that maternal holding itself has an analgesic effect. This motivated the investigator to assess the effectiveness of breast feeding on pain level during immunization among infants.[8]

Breast feeding in infants under age 6 months of age and use of sucrose or lidocaine in children aged 6 to 48 months has significantly reduced crying time and pain scores. A prospective controlled study was conducted among 243 children between age 0 and 48 months receiving their routine vaccinations at Well Child Unit in Turkey were randomly assigned to the study groups to investigate the interventions that affect pain reduction during vaccination.[10]

Statement of the problem

A study to assess the effectiveness of breast feeding on pain level among infants during immunization at selected health and wellness center, Daman.

Objectives

Objectives were to assess the pain level among infants during immunization in control group and experimental group, to assess the effectiveness of breast feeding on pain level among infants during immunization in experimental group and to find out the association between pain level among infants of control group with selected demographical variables.

Hypothesis

The following hypotheses were tested at <0.05 level of significance:

H_1

There will be a significant mean difference in pain level among infants during immunization in the control group and experimental group.

H_2

There will be a significant association between pain level among infants of the control group with selected demographic variables.

Variables

Independent variable was breast feeding, dependent variable was pain and demographic variables were age, sex, education of mother, occupational status of mother, and type of vaccination.

Operational definitions

Effectiveness

Refers to a reduction in pain perception of infants due to administration of breast-feeding during the immunization.

Breast feeding

Refers to the act of feeding a baby directly from the mother's breast during immunization.

Pain

An uncomfortable sensation experienced by infants during immunization, measured by the modified FLACC

(Face, legs, activity, cry and consolability) behavioural pain assessment scale.

Immunization

A way to create immunity to protect individuals from certain diseases, specifically pentavalent vaccination in this study.

Infant

Children of age 6, 10, and 14 weeks attending the immunization clinic at Daman.

Conceptual framework

Study is based on Modified Melzack and Wall's Gate control theory of pain. When non-nociceptive touch fibres are stimulated (as occurs during breast feeding), gate tends to close, thereby preventing the transmission of pain impulses.[11] The experimental group received breast feeding 2 minutes before, at time of stopping (to prevent aspiration), and for 5 minutes immediately after immunization injection, thus stimulating pain receptors' blocking mechanism and reducing pain perception. Pain was assessed in both groups using modified FLACC behaviaral pain assessment scale (Figure 1).[4]

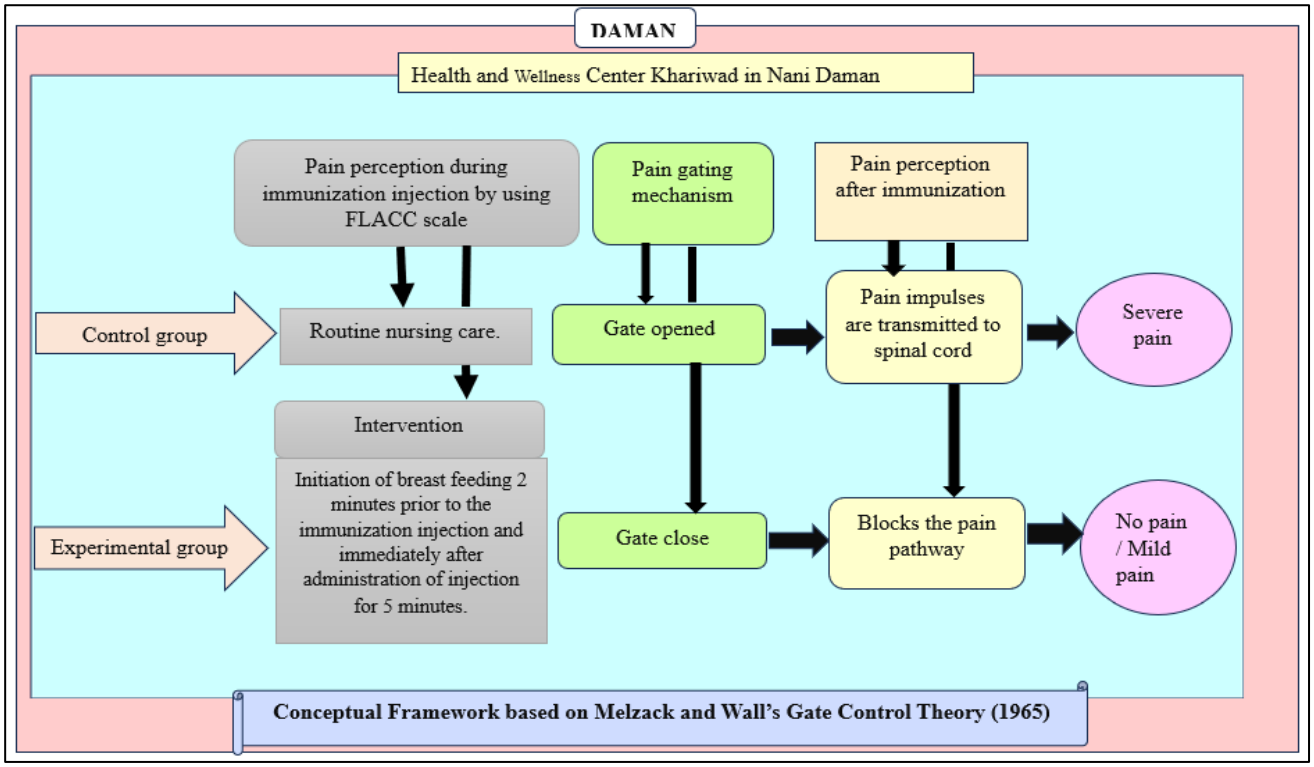

Figure 1: Conceptual framework.

METHODS

Research approach and design

A quasi-experimental, non-equivalent control group post-test-only design was adopted for this study. An evaluative research approach was used to assess the effectiveness of breast feeding on pain level among infants during pentavalent immunization.

Control group:- =O_1 and experimental group: XO_1. Where O_1=pain assessment post-test; X=breast feeding intervention;- =no intervention.

Setting/place

The study was conducted at the Health and Wellness Center, Khariwad, Nani Daman. The pilot study was conducted at Health and Wellness Center, Dholar, Moti Daman.

Duration of data collection

Data collection period is One moth for this study data Was collected from 03.10.2023 to 03.11.2023. and it completed in 27 December 2023

Population and sample

The population comprised all infants aged 6, 10, and 14 weeks attending for pentavalent immunization at the Health and Wellness Center, Nani Daman. A sample of 60 infants was selected using a non-probability convenient sampling technique; 30 were assigned to the control group and 30 to the experimental group.

Inclusion criteria

Infants undergoing immunization, infants aged 6, 10, or 14 weeks, infants on breast feeding and infants having mother as bystander were included in the study.

Exclusion criteria

Very sick infants, infants weighing less than 2.5 kg, infants with congenital malformations or cleft lip/palate and mothers not willing to participate were excluded from the study.

Ethical considerations

Ethical clearance was obtained from the institutional ethics committee of NAMO Medical Education and Research Institute and Shri Vinoba Bhave Civil Hospital, Dadra and Nagar Haveli, and Daman and Diu. Formal administrative permission was obtained from the Chief Medical Officer, Dr. Shailesh Arlekar. Informed consent was obtained from all participants. Confidentiality was assured.

Tool/ instrument

The data collection instrument consisted of two sections:

Section A

Demographic variables (age in weeks, gender, education of mother, occupation of mother and type of vaccination).

Section B

Modified FLACC (Face, legs, activity, cry and consolability) behavioural pain assessment scale. Scoring: 0=no pain; 1-3=mild pain; 4-6=moderate pain; ≥7=severe pain. Maximum score=10.

Validity and reliability

Content validity was established by two nursing experts (MSc Nursing, Child Health Nursing) and two medical experts (Paediatricians). The tool was modified based on their feedback. Reliability was established by the inter-rater method (r=0.08), indicating high reliability.

Data collection procedure

For the experimental group, mothers were seated comfortably in a chair and asked to breast feed the infant for 2 minutes before immunization. Feeding was stopped at the time of injection (to prevent aspiration) and resumed for 5 minutes immediately after injection. For the control group, routine nursing care was provided without the breast-feeding intervention. Pain was assessed using the FLACC scale immediately after immunization.

Data analysis

Data were analysed using descriptive statistics (frequency, percentage, mean, standard deviation) and inferential statistics. An unpaired t test was used to determine the effectiveness of breast feeding on pain level. A chi-square test was used to find the association between pain level and selected demographic variables.

RESULTS

In the control group, the majority of infants (53%) were in the 10-week age group. Males comprised 56%. Most mothers had primary education (43%) and were unemployed (66%). All 30 infants received pentavalent vaccination. Similar distribution was observed in the experimental group.

In the control group, 22 (73%) infants experienced severe pain, 7 (23%) moderate pain, and 1 (3%) mild pain. In the experimental group (breast feeding), 19 (63%) had mild pain and 11 (37%) moderate pain; none had severe pain (Figure 2).

The mean pain score was 7.50 in the control group and 2.70 in the experimental group (mean difference=4.800). The unpaired t=12.829 was statistically significant at $p<0.05$ (table value 1.672), confirming that breast feeding significantly reduces pain during immunization. Thus, hypothesis H_1 was accepted (Figure 3).

Age in weeks, education of mother, and occupation of mother showed significant association with pain level in control group. Gender was not significantly associated with pain level. Hypothesis H_2 accepted for 3 variables.

Table 1: Frequency and percentage distribution of demographic variables, (n=60).

Demographic variables	Control group		Experimental group	
	N	%	N	%
Age (in weeks)				
6	8	26	12	40
10	16	53	12	40
14	6	20	6	20
Gender				
Male	17	56	20	66
Female	13	43	10	33

Continued.

Demographic variables	Control group		Experimental group	
	N	%		N
Education of mother				
Post graduate	4	13	1	3
Higher secondary education	3	10	3	10
Secondar education	10	33	8	26
Primary education	13	43	17	56
Illiterate	0	0	1	3
Occupation of mother				
Professional	2	6	0	0
Clerical	3	10	0	0
Skilled	2	6	2	6
Semiskilled	3	10	1	3
Unemployed	20	66	27	90
Type of vaccination				
Pentavalent	30	100	30	100

Table 2: Pain level among infants during immunization in control and experimental groups, (n=60).

Pain level	Control group	Experimental group
No pain	0 (0%)	0 (0%)
Mild pain (1-3)	1 (3%)	19 (63%)
Moderate pain (4-6)	7 (23%)	11 (37%)
Severe pain (≥7)	22 (73%)	0 (0%)
Total	30 (100%)	30 (100%)

Table 3: Effectiveness of breast feeding on pain level during immunization, (n=60).

Groups	Mean	Mean difference	SD	SE	Df	't' value (calculated)	Tabulated value	Inference
Control	7.50	4.800	1.614	0.295	58	12.829	1.672	S*
Experimental	2.70		1.264	0.231				

S*=Significant at p<0.05 level.

Table 4: Association between pain level and selected demographic variables in control group.

Demographic variables	FLACC score			Chi- square value, df, Table value	Level of significance
	Mild pain	Moderate pain	Severe pain		
Age (in weeks)				χ^2=7.751 df=2 Table valve=2.920	p≤0.05 S*
6	0	10	2		
10	0	4	8		
14	0	5	1		
Gender				χ^2=0.287 df=1 Table value=6.314	p≤0.05 NS
Male	0	12	8		
Female	0	7	3		
Education of mother				χ^2=4.669 df=4 Table value=2.132	p≤0.05 S*
post graduate	0	0	1		
higher secondary education	0	3	0		
secondar education	0	4	4		
primary education	0	11	6		
Illiterate	0	1	0		
Occupation of mother				χ^2=1.063 df=2 Table value=2.920	p≤0.05 S*
Professional	0	0	0		
Clerical	0	0	0		
Skilled	0	1	1		
Semiskilled	0	1	0		
Unemployed	0	17	10		
Type of vaccination				-	-
Pentavalent	0	19	11		

S*=Significant at p<0.05; NS=Not significant.

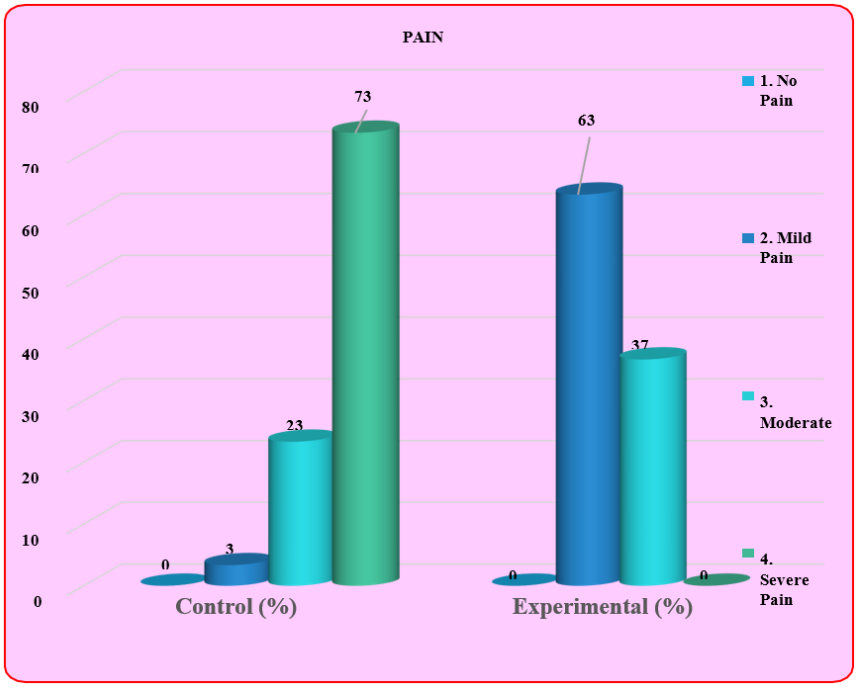

Figure 2: Percentage distribution of pain level during immunization in control and experimental groups.

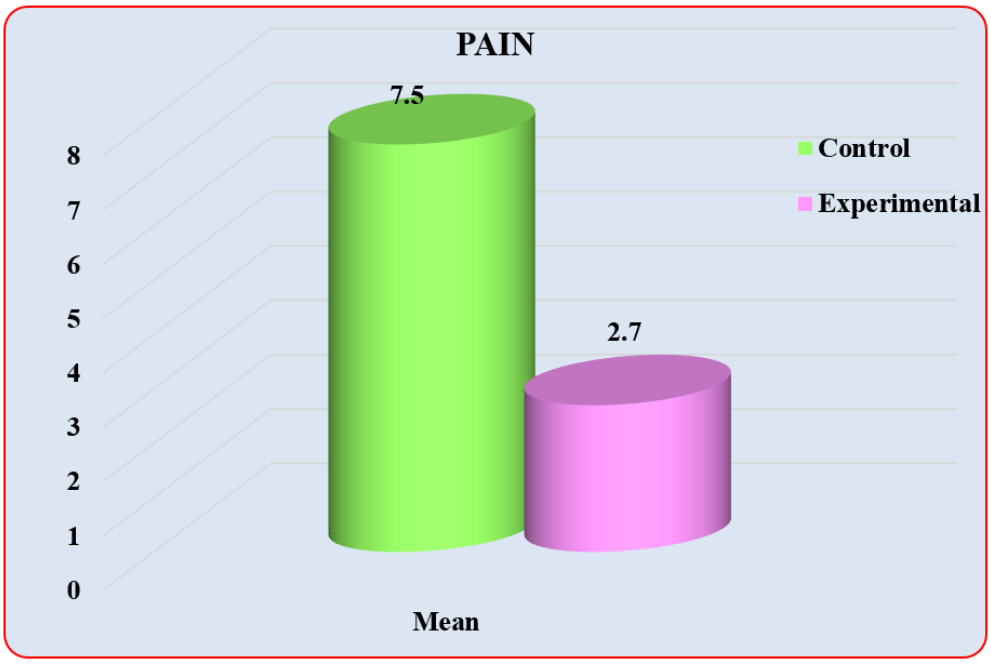

Figure 3: Mean pain score comparison between control and experimental groups.

DISCUSSION

The primary aim of the study is to assess the effectiveness of breastfeeding on pain level among the infant during the immunization at selected health and wellness center Khariwad at Nani Daman. The finding of the present study is discussing under the following heading.

Assess the frequency and percentage distribution of samples according to the demographic variables among infants in control group and experimental group

In this study from control group majority of infants 16 (53%) belonged to the age group of 10 weeks whereas 8 (26%) of infants belong to age group of 6 weeks and 6 (20%) belong to age group of 14 weeks. There were 17 (56%) males whereas 13 (43%) were female.

The majority 13 (43%) of infant's mother pursued primary education, whereas 10 (33%) mother pursued secondary education, 3 (10%) of them pursued higher secondary education, 4 (13%) of them pursued post-graduation, only 0% belonged to the illiterate education.

The majority 20 (66%) of infant's mother were unemployed, whereas 3 (10%) of mother were semiskilled, 3 (10% 0 of them had clerical, whereas 2 (6%) of them were professional, only 2 (6%) of them were skilled mothers. The majority 30 (100%) of infants has pentavalent vaccination.

In experimental group, majority 12 (40%) belonged to the age group of 10 weeks whereas 12 (40%) of infants belong to age group of 6 weeks and 6 (20%) belong to age group of 14 weeks. There were 20 (66%) males whereas 10 (33%) were female.

The majority 17 (56%) of infant's mother pursued primary education, whereas 8 (26%) mother pursued secondary education, 3 (10%) of them pursued higher secondary education, 1 (3%) of them pursued post-graduation, only 1 (3%) belonged to the illiterate education.

The similar study was conducted in 2012 by Mrs. Nesa Sathya Satchi, Chennai. In which similar demographic variable were associated with the control group and experimental group were males (60%, 40%) in the age group of 1-2 months (63%,66.7%).[3]

The similar study was conducted in 2010 by Coimbatore in That in which similar demographic variable were associated with the majority of the (86.67%) control group and experimental group was (93.3%) in group of 1-3 months. And majority (60%) of the infants were male in experimental group and female in control group. And Educational status the level of education of mother ranged from illiterate to graduation. Six mother (40%) in experimental group were graduates and 6 mothers in the control group (40%) had higher secondary education.[8]

Assess the pain level among infants during immunization in control group and experimental group

In this study from majority control group majority 22 (73%) of infants had severe level of pain during immunization. Seven (23%) infants had moderate pain, 1 (3%) infant had mild pain and none of the infants belonged to the category of no pain. Whereas in experimental group after breast feeding majority 19 (63%) infants had mild pain, 11 (37%) of infants had moderate pain and none of the infants were categorized into severe pain and no pain.

The similar study was conducted by Mrs. Nesa Sathya Satchi, Chennai. That all the infants in the control group had severe pain during immunization, where as in the experimental group majority of the infants had mild pain (73.3%).[3]

Assess the effectiveness of breast feeding on pain level among infants during immunization

In this study from the control group mean score during immunization among infants was 7.50 and in the experimental group the mean score was 2.70 with mean deference of 4.800. However, both the groups were statistically significant but there is a huge mean difference between control group and experimental group that clearly shows the successfulness of the breast feeding.

The mean score during immunization in control group, shows that the SD was 1.614 and in experimental group S.D was 1.264. The calculated unpaired "t" value was 12.829 which was found to be statistically significant at $p<0.05$ level. This clearly indicates that after the administration of breast-feeding during immunization among infants in the Experimental group shows that there was a significant reduction in the level of pain during immunization than the control group.

The similar study was conducted by Mrs. Nesa Sathya Saatchi, Chennai. That the mean and standard deviation of the control group is M=6.1, SD=0.907 and of experimental group is M=3.16, SD=0.687, The obtained "t" value 13.9 is greater than the table value 3.46 at <0.001.[3]

Assess between pain level among infants during immunization of control group with selected demographical variables

In this study was association of the experimental infant during the immunization with their selected demographical variables such as age, sex, education of the mother, occupational status of the mother, and type of vaccination. Among all these variables, only three. Age in weeks, education of the mother, and occupation of the mother. have a significant association with the control group of infants.

The similar study was conducted at Hong Kong is in line with the finding of That with their selected demographical variables such as age, sex, education of the mother, occupational status of the mother, and type of vaccination. Among all these variables, only three. Age in weeks, education of the mother, and sex. have a significant association with the control group of infants.[9]

Limitations

The study findings may be limited in terms of applicability, as the non-probability convenience sampling technique was employed for sample selection. The research was exclusively conducted in Khariwad, Nani Daman, and the study period was limited to 6, 10,

and 14 weeks. The sample consisted of 60 participants, with 30 in the control group and 30 in the experimental group during the immunization phase.

CONCLUSION

Based on the findings of the study the following conclusion are drawn. Effectiveness of during immunization administration of breast feeding reduce the pain in infants. The findings of the study indicated that the breast feeding is simple, safe, cost effective and easy to administer then any other pharmacological or non-pharmacological pain intervention. So, breast feeding must be incorporated in all immunization centres as a pain intervention measure.

Recommendations

Based on the findings of the present study, the following recommendations are proposed for future research: Replicate the study on a larger scale. Conduct the same study with a larger sample size to enhance result generalization. Replicate the study in different settings. Explore the application of the same study for pain management during other invasive procedures. Utilize different pain scales to assess pain scores in the study. Investigate pain among neonates during BCG vaccination and heel prick procedures. Conduct a comparative study to assess the effectiveness of breastfeeding compared to other interventions, such as oral sucrose administration, during immunization injections.

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