SOUTH EAST ASIA NURSING RESEARCH
Available on : https://jurnal.unimus.ac.id/index.php/SEANR

Research article

Check for updates

Effect of recorded maternal voice on procedure pain - a double blinded randomized controlled trial

Deeksha Patel[1], Cecilia M.S.[1], Aditi Prashant Sinha[1], Sameer Bakhshi[2]

[1] College of nursing, All India Institute of Medical Sciences, New Delhi, India
[2] Medical Oncology, All India Institute of Medical Sciences, New Delhi, India

Article Info

Article History:
Submitted: July 3rd 2023
Accepted: July 17th 2024
Published: July 19th 2024

Keywords:
Bone Marrow Aspiration; Bone Marrow Biopsy; Child's Cooperation Procedural Pain; Maternal Voice; Pain Perception

Abstract

This double-blinded randomized controlled trial included 46 children between 4 to 12 years of age with haematological malignancy, scheduled for bone marrow examination at tertiary care hospital of India. Subjects were enrolled into two groups (23 each) by stratified random sampling based on the type of procedure scheduled to them. The maternal voice was recorded for 3 minutes before the procedure and headphones was placed during the procedure, for all children but maternal voice was played only to intervention group by another person to blind the researcher. Child's cooperation for the entire procedure was recorded as video by researcher and later video was rated using FLACC behavioural scale. Pain perception was rated by children using Wong-Baker faces pain rating scale. The results showed a significant difference in the level of child's cooperation with mean (SD) distress score of 7(2) in control group and 4.52(2.15) in the intervention group (p=0.0002). There was no significant difference in pain perception of control and intervention groups. Significant moderate positive correlation (0.31) was found in the child's distress and pain perception levels (p=0.03). There was significant negative association of age was found with the child's distress (-0.30) and pain perception level (-0.33) at (p=0.04, 0.02) respectively. In cconclusion, recorded maternal voice can significantly decrease the child's distress level thus improve the child's cooperation during bone marrow examination along with local anaesthesia. As the child's cooperation increased, the child perceived less pain during the procedure. Older children were more cooperative and perceived less pain as compared to younger ones. Nurses are at an ideal position to implement this cost-effective, non-pharmacological intervention for children undergoing bone marrow examination.

INTRODUCTION

Cancer in children is less common as compared to adults. In children, cancers usually occur suddenly, without early symptoms, and have a high rate of cure. Irrespective of the type of cancer, pain is one among the most frequently reported symptoms. Cancer pain is a complex pain and various mechanisms are responsible for it. When cancer is diagnosed at early stages, then children usually experience pain due to

Corresponding author:
Cecilia M. S.
cecilia.aiims@gmail.com
South East Asia Nursing Research, Vol 6 No 2, July 2024
ISSN:2685-032X
DOI: https://doi.org/10.26714/seanr.6.2.2024.61-69

diagnostic and therapeutic procedures. However, at the advanced stage the pain is usually due to the progression of cancer itself.[1]

Paediatric oncology patients have reported pain as a greater problem from diagnostic and treatment procedure than pain from the malignant disease itself.

As per the 2018 world demographic profile, children (0-14 years) account 25.4% which is around 1.95 billion of total world population. Based on international association of cancer registry (IACR) paediatrics dataset of last decade, approximately 11.4% of the total cases, comes under age group of 0-14 years, out of which 1.7% covered by south Asia (India). In children (0-14 years), the leading cancers in all regions are leukaemia, lymphoma and CNS tumours. The incidence of cancer increased from 124 to 140 per million per years over the last decade.[2] As per the Indian cancer registries, out of total childhood (0-14) cancers, around 40-50% are leukaemia, and 15-20 % are lymphoma.[3]

To diagnose and follow up the hematological disorders, bone marrow examination is considered an essential tool.[4] Bone marrow examination consists of bone marrow aspiration (BMA) and bone marrow biopsy (BMB) which are invasive procedures. Many times, only bone marrow aspiration is needed like in leukemia, but in lymphoma both the procedures are preferred. Deep, dull, and aching pain felt when liquid portion of bone marrow is withdrawn by syringe whereas severe pain and pressure felt when biopsy needle inserted in the bone. Both bone marrow aspiration and biopsy are associated with morbidity, discomfort and pain.

Anxiety, fear and pain related to procedure are more in children. The pain and anxiety manifests as distress or lack of cooperation by the child which hinder, the success and timely completion of the procedure.[4]

Anxiety, fear and pain related to procedure are affected by other variables such as frequency of the procedure performed, procedure type. Anxiety and distress subsequently can affect the clinical parameters such as blood pressure and heart rate.[5] Despite being performed for many years, using different protocols, the procedure remains painful for patients.[6] Invasive procedures have been reported as the most difficult part of cancer treatment, leading to post traumatic stress symptoms in long term survivors.[7]

General anesthesia or combination of analgesia and sedative drugs are recommended during painful procedures in pediatric oncology by The World Health Organization and the American Academy of Pediatrics (AAP)[8] but general anesthesia require additional time such as preparation time before the procedure, recovery time afterward and require additional trained personnel such as anesthesiologist. All these factors increase the cost of the procedure and make the institute less likely to use sedation and general anesthesia if they can avoid it. Along with all these issues sedation and general anesthesia carry small risk of post procedural adverse reactions and complications like vomiting, agitation and headache.

Due to less actual time for bone marrow aspiration and biopsy procedure, Infiltration of Local anaesthesia used as the main form of analgesia in most of the health care settings. As the children are awake, they demand to be accompanied with parents inside the procedural room but parental presence is not possible in every setting. Separation from parents creates considerable distress, leads to un-cooperativeness during the entire procedure.

Nonpharmacological factors play an important role in influencing pain and distress level during the invasive procedures.[9] Recorded Maternal voice can be the effective non-pharmacological

intervention to control child's distress and make them cooperative during the procedure, which is less costly and can be administered by nurses.[10]

Study aimed to assess the effectiveness of recorded maternal voice on the child's cooperation and pain perception during bone marrow examination.

METHODS

This study has a quantitative approach through double blinded randomized controlled group design.

Recruitment and Setting

Participants were recruited through stratified random sampling. Children scheduled for bone marrow examination were assessed for eligibility based on inclusion and exclusion criteria in the medical oncology OPD, As shown in table 1. Patients were divided into two strata, bone marrow aspiration and biopsy on the basis of procedure type scheduled to them. The basis for dividing into strata was the pain level during the procedure. Bone marrow biopsy is more painful procedure than aspiration. If patient was scheduled for both the procedures then they were kept in biopsy strata. Separate random tables were generated for both the strata. Just before the procedure patient's group allocation was communicated to third person who administers the intervention to the patients. Recorded maternal voice was played to only intervention group of children but the headphones were kept for all the children by the third person to blind the researcher and the other patients. The allocation and randomization are shown in figure 1.

Bone marrow examination is mostly an OPD procedure for cancer patients who are taking treatment under medical oncology department. It is conducted in procedure room of OPD, of Dr. B.R.A Institute-Rotary Cancer Hospital (IRCH), AIIMS. Procedure room resembles an operating room with two tables, one monitor and articles required for procedure. Out of two, one table which is towards the monitor is preferred for pediatric cases. All the procedures are performed from Monday to Friday every week. Chairs are placed outside the room where patient and relatives can wait. A side room is available near the room, and it was utilized for recording.

Table 1
Inclusion and Exclusion criteria

Inclusion Criteria	Exclusion Criteria
1. Accompanied with mother	1. Children with significant hearing deficits.
2. Mother is able to speak and understand HINDI/ENGLISH	2. Children diagnosed with cognitive disability.
3. Willing to participate.	3. Children with critical illness.

Data collection

Data collection was done by using three different tools, out of which FLACC behavioural scale and Wong-Baker faces pain rating scale were standardized tools and socio-demographic with clinical profile was the structured tool. Socio-demographic profile consists of age, sex, birth order, education of mother, area of residence, family monthly income and child attend school. Clinical profile consists of diagnosis, procedure type, frequency of the procedure performed, heart rate, blood pressure and oxygen saturation.

Other than tools devices like mobile phones and headphones were used to record and implement the intervention during the study.

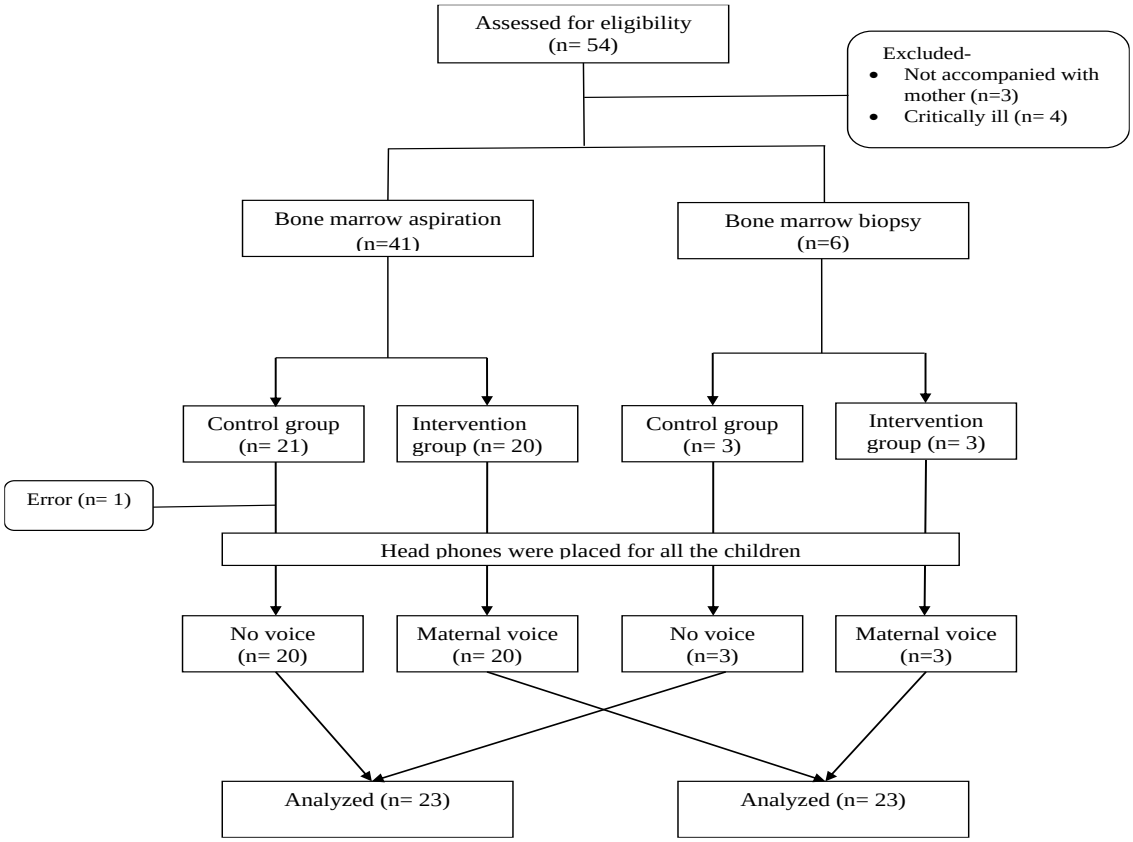

Figure 1
Consort Diagram

Intervention

Recorded maternal voice was used as intervention for the study. For recording the maternal voice of respective child, they were called to the side room to give instructions before recording, where content for the voice recording was explained to the mothers with the help of a downloaded procedural video. Time was given to think and once the mothers were ready, recorder was set with the instruction 'start'. Talk was recorded for 3 minutes, and after 3 minutes the voice recorder was turned off and mothers were instructed to 'stop'. The recorded voice was checked for clarity and content and then saved to memory card with the serial number of the respective child.

Administration of the intervention

Once the child laid down on the procedural table, the recorded maternal voice of their respective mother was played to the child of intervention group whereas headphone without any voice was placed to the child of control group for the entire procedure to blind the researcher.

Procedure for data collection

Once the eligibility criteria assessed, socio-demographic data were collected and maternal voice was recorded for all the children by the researcher. Subjects were randomly allocated into control and interventional group with the help of computer-generated random table by second person who was not in the contact with the patients. Recorded maternal voice were handed over to the third person who was administering the intervention. Once the child laid on procedural table, headphone was placed for all children by the third person and voice was played to interventional group while the control group was not heard any voice. Vitals were measured before and just after the procedure for all children. Child's

cooperation for the entire procedure was recorded as video by the researcher and later on, video recording of the procedure was rated using FLACC behaviour scale. Whereas pain perception of the child was assessed after the procedure by asking subjectively to rate the scale.

Data analysis

All recorded data were coded and scored into Microsoft Excel 2007 spread sheet. All the entries were checked for errors. STATA 14 version was used for statistical analysis. Descriptive and inferential statistics were used. Descriptive statistics used in the study were frequency, percentage, mean and median. For inferential statistics tests, two sample t test, Paired t test, Pearson chi square test, fisher exact test, Kruskal Wallis, Wilcoxon rank sum test and Pearson's correlation coefficient were used. Two sample t tests were used to compare the means of clinical variable, physiological variable, child cooperation and pain perception between the two groups. Chi square test and fisher exact test was used to compare the means of demographic variable between the two groups. Pearson correlation coefficient was used to correlate the child's cooperation and pain perception. Wilcoxon and Kruskal Wallis tests were used to compare the median of demographic and clinical variable with child cooperation and pain perception. For all the tests, p value<0.05 was considered as significance level.

RESULT

The final sample comprises 46 subjects where, the mean with Standard deviation age of children was 7.6 ± 2.88 years in the control group and 7.2 ± 3.11 in the intervention group. Majority of children in both the groups were male. About 34.8% of children in both the groups were the second child of the family. In the control group 34.8% mothers had education up to graduation and above and in the intervention group 43.5% mothers had education up to higher secondary. Majority of children were from the rural community. 60.9% in the control group and 39.1% in the intervention group of children family monthly income was ₹ 5,000-15,000. Other clinical and bio-physiological variable are shown in the table 2,3 and 4 below.

As shown in table 5, the mean distress (range) score of FLACC behaviour scale was higher, 7±2 (3-10) in control group as compared to 4.52±2.15 (0-8) in the interventional group. Decreased mean distress score indicates increased child cooperation during the procedure. The mean score of Wong Baker FACES pain rating scale of children in the control group was slightly higher 7.04± 2.88, as compared to 6.95± 2.94 in the intervention group but the p value was not significant (0.919) between both the groups. The "r" value of Pearson's correlation was 0.31, which indicates that there was moderate positive correlation between mean distress score of FLACC behaviour scale and mean score of Wong Baker faces pain rating scale of children. So, if child's cooperation increases, pain perception decreases and vice-versa. There were no significant association of variables with child's cooperation and pain perception.

As shown in table 6, for continuous variables Pearson's correlation was calculated. Correlation "r" value between age and child's cooperation was -0.30 which indicate the weak negative correlation whereas Bio-physiological variables were not correlated significantly with child's cooperation and pain perception.

Table 2
Socio-demographic variables of children in control and intervention group (n = 46)

Socio-demographic variables	Control Group (n=23)	Intervention Group (n=23)	p value
	Mean ± SD		
Age	7.6 ± 2.88	7.2 ± 3.11	0.649α
	Frequency (%)		
Sex			
Male	17(73.9)	13 (56.5)	0.216*
Female	6 (26.1)	10 (43.5)	
Birth order			
First	7 (30.4)	11 (47.8)	0.511#
Second	8 (34.8)	8 (34.8)	
Third	5 (21.8)	2 (08.7)	
More than third	3 (13.0)	2 (08.7)	
Mother's education			
Graduation and above	8 (34.8)	5(21.7)	0.361#
Higher secondary	6 (26.1)	10 (43.5)	
Primary school	5 (21.7)	2 (08.7)	
Illiterate	4 (17.4)	6 (26.1)	
Area of residence			
Rural	7 (30.4)	10 (43.5)	0.359*
Urban	16 (69.6)	13 (56.5)	
Family monthly income			
Above 15,000	8 (34.8)	10 (43.5)	0.232#
5,000-15,000	14 (60.9)	9 (39.1)	
Below 5,000	1(4.3)	4 (17.4)	

*α Two sample t test, *Chi square test, #Fisher exact test, (p<0.05)*

Table 3
Clinical variables of children in control and intervention group (n=46)

Clinical Variables	Control Group (n=23)	Intervention Group (n=23)	p value*
	Frequency (%)		
Diagnosis			
ALL	16 (69.6)	11 (47.8)	0.435
AML	3 (13)	7 (30.4)	
HL	2 (8.7)	2 (8.7)	
NHL	2 (8.7)	3 (13.1)	
Procedure type			
Bone marrow biopsy	3 (13.1)	3 (13.1)	1.000
Bone marrow aspiration	20 (86.9)	20 (86.9)	

**Fisher exact test, (p<0.05)*
ALL: acute lymphocytic leukemia, AML: acute myelocytic leukemia, HL: hodgkin lymphoma, NHL: non-hodgkin lymphoma

Table 4
Bio physiological variables of children in control and intervention group (n=46)

Physiological variables	Control Group (n=23)	Intervention Group (n=23)	p value#
	Mean ± SD		
Heart rate			
Before the procedure	132±19.45	125.65±24.25	0.33
After the procedure	140±22.04	132.43±24.52	0.23
Blood pressure			
Before the procedure	(126.43±9.5)/(81.86±9.1)	(121.73±11.5)/(83±5.9)	0.13
After the procedure	(130.21±8)/(86.60±8.9)	(128.69±7.08/85.43±5.13)	0.49
Oxygen saturation			
Before the procedure	98.43±1.27	98.56±0.84	0.68
After the procedure	95.73±2.32	96.13±1.83	0.14

 # Two sample t test, (p<0.05)

Table 5
Child's cooperation and Pain perception of the control and intervention group (n=46)

Indicators	Control Group (n=23)	Intervention Group (n=23)	p value[a]	r value	p value[b]
	Mean ± SD (min-max)				
Child's Cooperation	7±2 (3-10) Severe discomfort/pain	4.52±2.15 (0-8) Moderate discomfort/ pain	0.0002	0.31	0.03[b]
Pain Perception	7.04± 2.88 (0-10) Hurts whole lot	6.95± 2.94 (2-10) Hurts even more	0.919		

[a] *Two sample t test, (p<0.05)*
[b] *Pearson's correlation coefficient, (p<0.05)*

Table 6
Association of child's cooperation and pain perception with selected variables (n=46)

Variables	r value	p value	r value	p value
Age	-0.30	0.04	-0.33	0.02
Heart rate	0.16	0.28	0.06	0.68
Blood pressure	0.25	0.09	0.16	0.27
Oxygen saturation	0.05	0.71	0.02	0.88

r: Pearson's correlation coefficient, (p<0.05)

DISCUSSION

Study findings confirm that recorded maternal voice improves the child's cooperation which is consistent with study done by Rajan (2017), who found that distress score decreases due to maternal voice. The study by Azarmnejad (2015) showed the significant effect of mother's voice on reducing the pain. The study done by Chirico (2017) showed that using recorded maternal voice appeared safe and effective to limit pain in preterm infants, are also consistent with the present study findings. Study on the effect of non-pharmacological intervention to decrease child distress and improve cooperation such as audio-visual distracting technique used by Bagnasco (2012) in a study which showed that audio-visual distraction effectively improved pain management and favoured child's cooperation during venepuncture. Present study finding shows no effect of recorded maternal voice on pain perception which is consistent with the study done by Haarika (2017) showed that recorded mother's voice is not effective in decreasing pain perception during venepuncture.

The present study finding shows a moderate positive correlation between child's cooperation and pain perception which is consistent with the systemic review which gather scientific evidence of distress associated pain in infants and children. The finding of the present study that age is negatively correlation with pain is consistent with the study done by Yuvali Karacan (2017) on patients with cancer which showed that pain and anxiety has a negative relationship with age. Association of other demographic and clinical variables are not found significant with child's cooperation and pain perception.

The findings of the present study that recorded maternal voice did not make any difference in the physiological variable like heart rate, blood pressure and oxygen saturation is consistent with the study done by Johnston (2007) which showed that maternal voice did not have any impact on heart rate and oxygen saturation. another study also reported no significant difference on any of the physiological parameter of children by maternal touch and talk during invasive procedure.[16] Even the clown therapy was effective in reducing child's distress but doctors found difficulty to

perform the procedure with clown, but in the present study researcher has not come across any difficulty reported from doctors and nurses to perform the procedure while administering intervention.[17]

CONCLUSION

The study concluded that recorded maternal voice can significantly increase the cooperation of children during the bone marrow examination along with local anaesthesia. As the cooperation of children increases, they perceived less pain during the procedure. Older children were more cooperative and perceived less pain as compared to younger ones. Nurses are at best position to implement this cost effective, non-pharmacological intervention for children undergoing bone marrow examination. Nurses in other paediatric settings can use this strategy in situations where children are separated from their parents like pre-anaesthesia rooms.

ACKNOWLEDGMENT

We would like to thank IRCH, AIIMS New Delhi hospital for giving permission to complete the project. A special thanks to the research nurses who help in randomization and administration of the intervention for the study. We would also like to express our gratitude to all the participants and their parents who participated and shared their experiences while visited the oncology OPD, AIIMS hospitals, for treatment. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

CONFLICT OF INTEREST

The research is free from conflict of interest.

BIBLIOGRAPHY

1. Afshan G, Bashir K. Cancer pain in children: a two-step strategy. PAIN & INTENSIVE CARE. 2014;18.
2. Steliarova-Foucher E, Colombet M, Ries LAG, Moreno F, Dolya A, Bray F, et al. International incidence of childhood cancer, 2001–10: a population-based registry study. Lancet Oncol [Internet]. 2017 [cited 2024 Jul 16];18:719–31. Available from: http://www.thelancet.com/article/S1470204517301869/fulltext
3. Asthana S, Labani S, Mehrana S, Bakhshi S. Incidence of childhood leukemia and lymphoma in India. Pediatric Hematology Oncology Journal. 2018;3:115–20.
4. Degen C, Christen S, Rovo A, Gratwohl A. Bone marrow examination: A prospective survey on factors associated with pain. Ann Hematol [Internet]. 2010 [cited 2024 Jul 16];89:619–24. Available from: https://link.springer.com/article/10.1007/s00277-010-0934-0
5. Yuvali Karacan Y, Demircioğlu B, Ali R. Pain, anxiety, and depression during bone marrow aspiration and biopsy. Agri. 2017;29:167–72.
6. Hjortholm N, Jaddini E, Hałaburda K, Snarski E. Strategies of pain reduction during the bone marrow biopsy. Ann Hematol [Internet]. 2013 [cited 2024 Jul 16];92:145–9. Available from: https://link.springer.com/article/10.1007/s00277-012-1641-9
7. Md GA, Fard G, Md M, Ar S. General Anesthesia for Lumbar Puncture and Bone Marrow Aspiration /Biopsy in Children with Cancer. Iran J Ped Hematol Oncol [Internet]. 2013 [cited 2024 Jul 16];3:54. Available from: /pmc/articles/PMC3915451/
8. Zeltzer LK, Altman A, Cohen D, LeBaron S, Munuksela EL, Schechter NL. Report of the Subcommittee on the Management of Pain Associated With Procedures in Children with Cancer. Pediatrics [Internet]. 1990 [cited 2024 Jul 16];86:826–31. Available from: /pediatrics/article/86/5/826/56552/Report-of-the-Subcommittee-on-the-Management-of
9. Zahid M. Methods of reducing pain during bone marrow biopsy: a narrative review. Ann Palliat Med [Internet]. 2015 [cited 2024 Jul 16];4. Available from: https://ecommons.aku.edu/pakistan_fhs_mc_mc/65
10. Gupta HV, Gupta VV, Kaur A, Singla R, Chitkara N, Bajaj K V., et al. Comparison between the Analgesic Effect of two Techniques on the Level of Pain Perception During venipuncture in Children up to 7 Years of Age: A Quasi-Experimental Study. J Clin Diagn Res [Internet]. 2014 [cited 2024 Jul 16];8:PC01. Available from: /pmc/articles/PMC4190764/

11. Rajan D, Lakshmanan G, Gupta SK, Sivasubramanian R, Saxena A, Juneja R. Effect of recorded maternal voice on child's cooperation during cardiac catheterization – A randomized controlled trial. Indian Pediatr [Internet]. 2017 [cited 2024 Jul 16];54:204–7. Available from: https://link.springer.com/article/10.1007/s13312-017-1031-4

12. Azarmnejad E, Sarhangi F, Javadi M, Rejeh N. The Effect of Mother's Voice on Arterial Blood Sampling Induced Pain in Neonates Hospitalized in Neonate Intensive Care Unit. Glob J Health Sci [Internet]. 2015 [cited 2024 Jul 16];7:198. Available from: /pmc/articles/PMC4803902/

13. Chirico G, Cabano R, Villa G, Bigogno A, Ardesi M, Dioni E. Randomised study showed that recorded maternal voices reduced pain in preterm infants undergoing heel lance procedures in a neonatal intensive care unit. Acta Paediatr [Internet]. 2017 [cited 2024 Jul 16];106:1564–8. Available from: https://onlinelibrary.wiley.com/doi/full/10.1111/apa.13944

14. Bagnasco A. Distraction techniques in children during venipuncture: An Italian experience. Article in Journal of Preventive Medicine and Hygiene [Internet]. 2012 [cited 2024 Jul 16]; Available from: https://www.researchgate.net/publication/229163015

15. Haarika V, Soundararajan P, Sundar S, Alingam R, Gunasekaran D, Pand K. The effectiveness of music and mother's voice on pain reduction during venepuncture in neonates-a randomized control trial. Int J Adv Res. 2017;5:2575–9.

16. Johnston CC, Filion F, Nuyt AM. Recorded maternal voice for preterm neonates undergoing heel lance. Advances in Neonatal Care [Internet]. 2007 [cited 2024 Jul 16];7:258–66. Available from: https://journals.lww.com/advancesinneonatalcare/fulltext/2007/10000/recorded_maternal_voice_for_preterm_neonates.13.aspx

17. Gorfinkle KS, Slater JA, Bagiella E, Tager FA, Labinsky EB. Child Behavioral Distress During Invasive Oncologic Procedures and Cardiac Catheterization With the Big Apple Circus Clown Care Unit • 55. Pediatric Research 1998 43:4 [Internet]. 1998 [cited 2024 Jul 16];43:12–12. Available from: https://www.nature.com/articles/pr1998203