

GENERAL INFORMATION

Title : **Effect of maternal voice on physiological and behavioral measures in premature infants : A Randomized Controlled Trial**

Protocol ID 18906

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Site of study :NICU Hospital Sultanah Bahiyah, Alor Setar

**LITERATURE REVIEW**

Premature infants remains in an isolette, an enclosed incubator where touching and sensory stimulation are restricted. Research has shown that ambient auditory stimuli from the surrounding NICU environment occur frequently, spike unpredictably, and can have deleterious consequences for the neonate (Standley 2000).

The human fetus can perceive and react to auditory information starting at approximately week 26 of life(Ruben, 1991).A study by (Graven, 2000) recommended that noise levels should not exceed 50 to 55 dB in the NICU. However, researchers have reported that NICU sounds average between 50 and 90 dB (Levy et al., 2003)

It is well known that sound levels in the NICU are a major source of environmental stress for premature infants(Peng et al., 2013) Studies have indicated that increased noise levels are associated with increased fatigue, stress behaviors, hyperalerting responses, startle, hypoxemia, agitation, crying, sleep interruptions, and intracranial pressure in neonates (Standley, 1991) (Caine, 1991)

The most common indicators of physiological stress and pain are similar and include changes in heart rate, respiratory rate, blood pressure, transcutaneous oxygen levels (tcPO<sub>2</sub>), oxygen saturation (O<sub>2</sub> Sat), intracranial pressure, vagal tone, skin blood flow, and palmar sweat (Peng et

voice supports the use of music in critical areas such as sucking and weight gain (Kemper and Hamilton, 2008), sleep (Arnon et al., 2006), and recovery from painful procedures (Tramo et al., 2011, Hartling et al., 2009). Vocal familiarity within the infant's sound environment may provide an essential domain of consistency, security, and comfort that even the most modern NICUs cannot replicate. Studies of mothers singing live, infant directed lullabies to newborns indicate stabilizing effects (Shenfield et al., 2003). Parents' voices have also been shown to enhance vocalization in premature infants. (Shenfield et al., 2003)

Studies have shown that preterm infants who were exposed to an audio recording of their mother's voice achieved full enteral feed quicker and showed meaningful changes in heart rate compared to age-matched controls receiving routine care (Krueger et al., 2010)

## OBJECTIVES AND PURPOSE

### General

- To determine the effect of maternal voice vs NICU environmental sounds on physiological and behavioral measures in premature infants.

### Specific

- To compare mean changes of HR, RR, SPO2 in infants exposed to mother's voice vs NICU environmental sound.
- To compare mean weight gain between premature infants exposed to mother's voice vs NICU environmental sound
- To compare mean neurobehavioral score between premature infants exposed to mother's voice vs NICU environmental sound



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### Study design

This study is a randomized control trial for premature infants from 27-35 weeks CGA who is admitted to NICU Hospital Sultanah Bahiyah, Alor Setar between June 2015 to November 2015.

### Sample size

Based on previous study by (Alipour et al., 2013), the sample size to achieve a power of 0.8, alpha level of 0.05, and the mean difference of 5 with standard deviation of 9.57 for physiological responses was 58 per group is needed. Therefore, total sample size of 140 is needed with 20% drop out.

### Inclusion Criteria

1. All premature infants with corrected gestational age 27-35 weeks
2. Achieved full feeding of at least 120cc/kg/day
3. Infant must be nursed in closed incubator (isolette)

### Exclusion Criteria

4. Premature baby who are on mechanical ventilation
5. Medically unstable infant: HIE, NEC, sepsis, on inotropic support
6. Infant with major congenital anomalies
7. Infant who is still on intravenous drip or parenteral nutrition

### Dropout criteria

- Infant who need to be ventilated during study period
- Infant who need to be kept nil by mouth during study period
- Infant who become medically unstable determined by treating clinician: HIE, NEC, sepsis, on inotropes etc

Study protocol:

All premature infants who fulfill the eligibility criteria of the study are identified. An appointment for a meeting with parents for consent will be arranged via phone or when parents visited the infant. The meeting will take place in NICU, Hospital Sultanah Bahiyah, Alor Setar. After consent is obtained, all infant's mother will be asked to sing appropriate lullaby of their choice due to multiracial population. The session will be recorded using a voice recorder (SONY ICD-UX543F) for 10 min in predetermine quiet room to minimize sound interference.

All subjects will be randomized into two groups that are Intervention and Control. All subjects are randomized into two groups by block randomization. Computer software is use for creation of randomization. Coding systems will be used instead of real name to identify each infant. All subject's data will be kept in a secured and separated cabinet locked in the departmental room of the investigator in Hospital Sultanah Bahiyah. An officer (Sister in charge of NICU) will be incharge of the list of subjects and all the equipments needed.

Intervention group will be receiving prerecorded maternal voice while control will have the same settings but without maternal voice recording.

All subject will be placed in own incubator. A neurobehavioral observation will be done using Behavioral Indicators of Infant Pain (BIIP) pre and post intervention (Holsti and Grunau, 2007). Infants belonging to the intervention group underwent daily sessions of exposure to maternal voice recorded in agreement with the American Academy of Pediatrics that recommends safe sound levels within the NICU 50-55dB. Sound level meter ( Mini Digital Decibel Audio Sound Pressure Meter MTR01DASP) will be used to monitor and maintain sound between level 50-55db throughout intervention. The voice recorder will be placed 10cm from infant ear.

Intervention group will be exposed to total of 14 times (daily) prerecorded maternal voice within 2 week-period. Each session will last for 30 min that is 10 min pre intervention, 10 min during intervention, 10 min post intervention. Heart rate, respiratory rate and SPO2(physiological parameter) will be centrally monitored and recorded every minutes in each session. Physiological parameters will be recorded every minute while weight gain will be monitored every alternate day for 2 weeks using a standard weighing machine.

on (BIIP) score will be measured 3 times per session (pre, during  
s will undergo hearing assessment prior to discharge from

NICU.

Clinical data to be entered into a standard proforma sheet include: Mothers demographic data, Gestational age, Heart Rate, Respiratory rate, SPO<sub>2</sub>, Weight gain, Behavioral Indicators of Infant Pain (BIIP) score **(Holsti and Grunau, 2007)**

### **Statistical analysis:**

All data will be entered and analyze using SPSS version 18. In descriptive analysis, Mean (SD) , Median (IQR) will be used to describe numerical data while number and percentage will be used for categorical data. Independent t test and Chi Square test will be used to compare the demographic numerical and categorical data accordingly. Repeated Measure ANOVA will be used to compare the difference in mean of the dependent variable between pre and post intervention group

### **ETHICAL ISSUES**

The study will be conducted in accordance with legal and regulatory requirements, as well as the general principles set forth in the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP).

### **DATA CONFIDENTIALITY**

The personal information of all study subjects will be kept and handled in a confidential manner, in accordance with applicable laws and / or regulations. Coding systems will be used instead of real name to identify each patient.

### **JUSTIFICATION FROM THIS STUDY**

Findings from this study could potentially add to the growing body of evidence highlighting the importance of involvement of parents particularly mother in developmental care of premature infants

NICU noise level is a major stressor for premature infants. Intervention as kangaroo care, swaddling and non nutritive sucking can be used for premature infants to significantly manage pain behaviors associated with acutely painful procedures. To date there is no published study in Malaysia looking at potential benefit of maternal voice in premature infant care. It is interesting to see if this maternal voice recording can be used to temporarily replaced mother’s who are not able to room in or visit their premature infants in NICU.

**GANTT CHART**

ACTIVITIES / TIME	Sept 2014- Mac 2015	June 2015 – Nov 2015	Nov 2015	June 2015- Dec 2015
ETHICS COMMITTEE				
DATA COLLECTION				
DATA ANALYSIS				
THESIS WRITING & SUBMISSION				

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- TRAMO, M. J., LENSE, M., VAN NESS, C., KAGAN, J., SETTLE, M. D. & CRONIN, J. H. 2011. Effects of Music on Physiological and Behavioral Indices of Acute Pain and Stress in Premature Infants Clinical Trial and Literature Review. *Music and Medicine*, 3, 72-83.
- YILDIZ, A. & ARIKAN, D. 2012. The effects of giving pacifiers to premature infants and making them listen to lullabies on their transition period for total oral feeding and sucking success. *Journal of clinical nursing*, 21, 644-656.

### Behavioural Indicators of Infant Pain (BIIP): Preterm and Full term

	<b>TIME</b>								
	<b>SITUATION</b> [e.g. Post-op; Procedure (e.g. suction, blood work, IV start)]								
<b>SCORE</b>	<b>STATE</b>								
0	Deep Sleep								
0	Active Sleep								
0	Drowsy								
0	Quiet Awake								
1	Active Awake								
2	Agitated/Crying								
	<b>FACE</b>								
1	Brow bulge								
1	Eye squeeze								
1	Naso-labial furrow								
1	Horizontal mouth stretch								
1	Taut tongue								
	<b>HAND</b>								
1	Finger splay								
1	Fisting								
	<b>TOTAL SCORE</b>								
<b>NOTES</b>									
Heart Rate (no change, increase, decrease)									
O <sub>2</sub> Saturation (no change, increase, decrease)									
<b>Environmental Support</b>									
<b>Analgesia</b>									
<b>Sedation Given</b>									

Adapted from (Holsti and Grunau, 2007)



**Table 3**

Behavioural Indicators of Infant Pain (Preterm and Fullterm) Definitions

Sleep/Wake States	Description
Deep Sleep	Eyes closed, regular breathing, no movements of extremities
Active Sleep	Eyes closed, twitches or startles of extremities, rapid eye movements, irregular breathing
Drowsy	Eyes open (but roving or not focused) or closed, irregular breathing, some body movements
Quiet Awake	Eyes open, focused, very few or no body movements
Active Awake	Eyes open, active extremity movements
Agitated/Crying	Upset, fussing, highly aroused, crying
<b>Face &amp; Hand Actions</b>	<b>Description</b>
Brow Bulge	Bulging, creasing and/or vertical furrows above and between brows occurring as a result of lowering and drawing together of the eyebrows.
Eye Squeeze	Squeezing and/or bulging of the eyelids
Naso-labial Furrow	Pulling upwards and deepening of the naso-labial furrow (a line or wrinkle which begins adjacent to the nostril wings and runs down and outwards beyond the lip corners).
Horizontal Mouth	A distinct horizontal stretch pull at the corners of the mouth sometimes accompanied by a taut upper lip.
Taut Tongue	Raised, cupped tongue with sharp tensed edges. The first occurrence of taut tongue is usually easy to see, often occurring with a wide open mouth. After this first occurrence, the mouth may close slightly. Taut tongue can be scored on the basis of the still visible tongue edges.
Finger Splay	Sudden opening of the hands with fingers extended and separated from each other
Fisting	Tight closing and flexing of the fingers to form a fist