Design and Clinical Evaluation of a Womb Sound Simulator Device for Reducing Stress in Preterm Infants in the Neonatal Intensive Care Unit (NICU)

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ABSTRACT

Preterm infants face significant physiological and developmental challenges due to the stressful environment of the Neonatal Intensive Care Unit (NICU), which starkly contrasts with the sensory-rich uterine environment. This abrupt transition can negatively impact neurodevelopmental outcomes. To address this, we propose the design of an innovative womb sound simulator. This device aims to recreate the auditory environment of the womb by using a multi-speaker system that generates directional sounds, including the maternal heartbeat, amniotic fluid noises, and live parental voice transmission via a SIM800L module. The primary objective is to reduce stress in preterm infants, thereby improving physiological stability and promoting better developmental care. Although the device has not yet been built, this paper presents its conceptual design, technical architecture, and a detailed protocol for its future clinical evaluation. The proposed study will be a randomized controlled trial (RCT) assessing physiological (heart rate, blood oxygen) and behavioral (NISS, PIPP-R scales) stress indicators. This technology holds the potential to bridge a critical gap in neonatal care by providing a non-invasive, developmentally supportive intervention.

***Keywords:* Preterm Infant, Womb Sound, Technological Development, Simulator Device, Auditory Stimulation, NICU, Stress Reduction**

1. INTRODUCTION

1.1. The Developmental Challenge in the NICU Environment

Care for preterm infants in the Neonatal Intensive Care Unit (NICU) presents a significant challenge: providing a stable, low-stress environment to improve the physiological conditions of these vulnerable patients. Preterm birth, defined as delivery before 37 weeks of gestation, is a major contributor to neonatal morbidity and mortality worldwide (1). Due to the underdevelopment of their neurological and respiratory systems, these infants are highly susceptible to environmental stressors, which can lead to growth impairments, prolonged NICU stays, and long-term neurological complications (2).

The NICU setting, while medically necessary, starkly contrasts with the protective intrauterine environment. It involves bright lighting, high levels of noise, frequent handling, and separation from parents—all of which increase stress and negatively affect physiological and neurobehavioral development (3). During fetal development, the auditory system is among the first to mature, accustoming the fetus to rhythmic, low-frequency intrauterine sounds like the maternal heartbeat and muffled voices. This consistent sensory input is critical for neurological organization (4). Therefore, environmental interventions aimed at replicating this auditory comfort are crucial.

1.2. Existing Auditory Interventions and Their Limitations

Studies confirm that reintroducing womb-like sounds in the NICU can positively influence vital signs, reduce stress, and improve sleep and feeding patterns (5, 6). Several devices have been developed to produce recorded or synthesized womb sounds. However, these solutions face significant limitations that constrain their efficacy:

- *Lack of Authenticity and Personalization: Existing devices often rely on generic sound loops and are not personalized. They lack the most crucial auditory anchor for an infant: the real, familiar voices of their own parents and their mother's unique heartbeat.*
- *Insufficient Technical Control: Many solutions lack precise control over acoustic parameters and may have low sound quality.*
- *Limited Clinical Evaluation: A significant number of these technologies have not undergone rigorous clinical evaluation, particularly in low- and middle-income healthcare settings where access is already limited.*

1.3. The Proposed Solution: A Personalized Womb Sound Simulator

This technological gap highlights the need for a standardized, evidence-based device that can serve as a valuable facilitator in neonatal care. To address this, the present study proposes the design and randomized clinical evaluation of a personalized womb sound simulator device for the NICU.

The core innovation of this device is its use of real sound recordings from each infant's own parents—including the maternal heartbeat and parental voices—which are combined with authentic intrauterine audio samples. These personalized recordings will be delivered through a clinically safe, easy-to-use system. The primary aim of the subsequent randomized controlled trial (RCT) is to evaluate the effectiveness of this personalized sound intervention in reducing physiological stress indicators (e.g., heart rate variability, oxygen saturation, and cortisol levels) and improving behavioral states like calmness and sleep duration. This research seeks to provide both a technological innovation and an evidence-based therapeutic strategy to enhance the quality of care for preterm infants.

.DEVICE DESIGN AND MECHANISM

a. **Auditory Simulation System**

The core of the WSS is its five-speaker sound delivery system, designed to produce a multi-dimensional soundscape:

- ***Ambient Fluid Sounds:*** *Three speakers are positioned on the sides and back of the enclosure to create an immersive, surrounding sound field that mimics amniotic fluid noises.*
- ***Maternal Heartbeat:*** *A dedicated speaker is located directly above the infant's head to simulate the sound of the mother's heartbeat, providing a primary rhythmic anchor.*

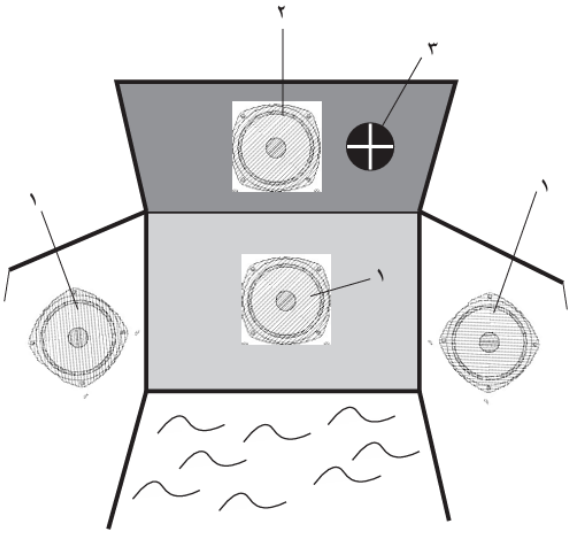

Fig.1. Schematic diagram of the device's overview and the placement of speakers.

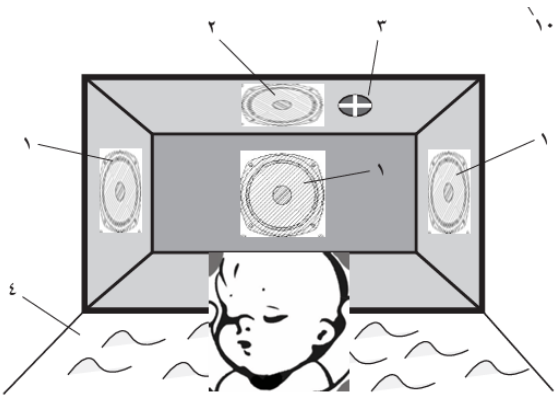

Fig.2. Schematic diagram of the device's overview and the placement of the infant's head.

b. Live Interaction Module

To foster parental bonding and provide personalized stimulation, a fifth speaker is integrated with a SIM800L module. This innovative feature allows parents to call the device and have their live voice transmitted directly to the infant, offering comfort and a familiar presence even when they cannot be physically there.

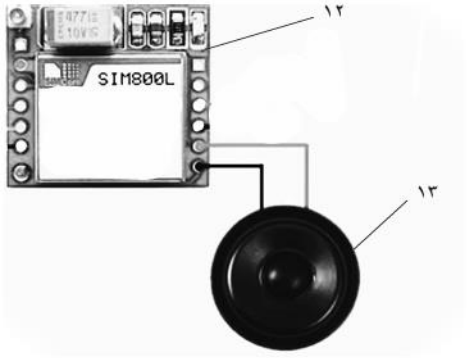

Fig.3. Schematic view of the module

c. Safety and Control System

Safety is paramount. The system includes:

- *Volume Control: An integrated limiter ensures the sound intensity is consistently maintained within the safe and therapeutic range of 50-60 decibels.*
- *Real-Time Monitoring: A sensor and display provide a real-time reading of the sound level, allowing for constant monitoring by caregivers.*
- *Sound Insulation: The enclosure itself is designed to dampen loud, external NICU noises, further protecting the infant from auditory stress (7).*

d. Principle of Operation

The WSS operates by creating a stable, continuous, and multi-layered auditory environment. When activated, the system plays a pre-recorded loop of a human heartbeat and low-frequency ambient sounds, while the live interaction module remains on standby for parental calls. This combination is intended to lower the infant's stress levels by providing a familiar sensory input, which in turn helps to stabilize physiological functions (heart rate, breathing) and promote deeper, more restorative sleep states.

2. METHODOLOGY FOR EVALUATION

a. **Study Design and Setting**

The study will employ a pre-test/post-test design, where each infant serves as their own control. The evaluation will take place in the NICU of a designated university hospital.

b. **Participants and Sample Size**

The study will recruit 30 clinically stable preterm infants with a gestational age of 32-36 weeks, following parental informed consent (1). The sample size was calculated to provide adequate statistical power (0.80) to detect a significant effect (8, 9).

c. **Data Collection and Performance Metrics**

A combination of physiological and behavioral data will be collected:

- ***Physiological Metrics:*** *Heart Rate (HR), Respiratory Rate (RR), and Blood Oxygen Saturation (SpO2) will be recorded continuously from the patient monitor.*
- ***Behavioral Metrics:*** *Infant stress and pain will be systematically assessed using the validated Neonatal Infant Stressor Scale (NISS) (10) and the Premature Infant Pain Profile-Revised (PIPP-R) (11).*

d. **Statistical Analysis**

Data will be analyzed using SPSS software. Paired t-tests or ANOVA with repeated measures will be used to compare the means of the outcome variables between the baseline and intervention phases. A p-value of less than 0.05 will be considered statistically significant.

3. EXPECTED RESULTS

It is expected that the use of the WSS will lead to statistically significant improvements in key indicators of well-being. The mean HR and RR are expected to decrease and stabilize, while SpO2 levels are expected to remain more consistent. Crucially, it is anticipated that scores on the NISS and PIPP-R scales will be significantly lower, indicating a reduction in perceived stress and pain (10, 11). Furthermore, qualitative observations are expected to show longer periods of quiet sleep, which aligns with research on the positive effects of music therapy (12) and white noise (13).

4. DISCUSSION

The expected results suggest that the WSS can offer a significant therapeutic benefit. The primary contribution of this device is its authentic replication of the womb's auditory environment, which distinguishes it from simpler solutions like white noise machines (13). By providing a familiar and constant sensory anchor, the WSS may help organize the preterm infant's developing nervous system and improve its capacity for self-regulation (5). The clinical implications are substantial, potentially leading to improved weight gain, shorter hospital stays, and enhanced parent-infant bonding.

5. CONCLUSION

The Womb Sound Simulator (WSS) is a novel device engineered to address the critical need for stress reduction in preterm infants. By employing a unique multi-speaker system and a live parental interaction module, the WSS is designed to provide a safe, standardized, and developmentally appropriate therapeutic intervention. The proposed clinical evaluation is expected to validate its efficacy. The WSS has the potential to become an integral component of developmental care, offering a new standard for supporting the most vulnerable patients in the NICU.

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