

# Music therapy as painkiller

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<b>Registration date</b> 23/03/2026	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/03/2026	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Neonates admitted to a Neonatal Intensive Care Unit (NICU) or a high-care (HC) ward experience a highly different environment compared with the womb. Although this environment is lifesaving, it involves a variety of stressors, such as painful procedures that may have long-lasting consequences after discharge. Mechanisms through which these long-term consequences occur are proposed to be altered hypothalamic-pituitary-adrenal (HPA) axis development, responsible for stress regulation in the body through cortisol production, and a direct effect on brain development. While pharmacological analgesia has been implemented, non-pharmacological options have also been suggested to reduce pain, among which is music therapy. Specifically in a NICU and HC setting, music therapy is a promising and novel intervention that may counteract or attenuate the altered stress response through creating a possible link to exposure to musical sounds in the womb (i.e., rhythmic heartbeat, maternal voice, or music listened to by the mother). Music therapy regards the use of live-performed musical interventions by a certified neonatal music therapist, and it is tailored to the needs of the individual infant and their parents. With our study, we aim to investigate the effects of music therapy during skin-breaking procedures in neonates admitted to a NICU or HC ward on the pain and stress response.

### Who can participate?

Infants born preterm (between 24 and 37 weeks of gestation) admitted to a NICU or HC ward will be considered eligible if they are clinically stable enough to receive music therapy (deemed by local neonatologists and nurses, according to our standard protocol). In the case of infants born before 30 weeks' gestation, music therapy is commenced after the first week of life. This study will start at the University Medical Center Groningen (UMCG) NICU and will most likely be broadened to a HC ward in the region to study uptake of music therapy as procedural support in a HC setting as well.

### What does the study involve?

The intervention will be a sedative live-performed music therapy session according to the Rhythm, Breath and Lullaby method. The intervention will commence before the painful procedure and will be continued after the painful procedure is finished, to cover the full procedure. Our primary outcome is the direct pain response measured before and after interventions.

What are the possible benefits and risks of participating?

Data for this study cannot be obtained in another population, as the intention is to study live music for procedural support in infants. As this intervention may be pain-relieving, stress-reducing and improve neurodevelopment, it is worthwhile to study. We believe that the burden and risks associated with participation in this pilot study are small to non-existent.

Where is the study run from?

University Medical Center Groningen (Netherlands)

When is the study starting and how long is it expected to run for?

April 2025 to April 2030

Who is funding the study?

University Medical Center Groningen (Netherlands)

Who is the main contact?

Dr Nienke H. van Dokkum, n.h.van.dokkum@umcg.nl

## Contact information

### Type(s)

Principal investigator, Scientific, Public

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## Additional identifiers

## Study information

### Scientific Title

Music therapy during skin-breaking procedures in infants admitted to a Neonatal Intensive Care Unit or High Care ward: a non-pharmacological intervention

### Acronym

SPARK

### Study objectives

The objectives of the study are to:

1. Determine the effects of music therapy during skin-breaking procedures on the pain response in infants admitted to a NICU or HC ward.
2. Determine the effects of music therapy during skin-breaking procedures on the autonomic

nervous system regulation in infants admitted to a NICU or HC ward.

3. Further clarify the mechanism of music therapy in regulating pain response and autonomic nervous system response by performing a micro-analysis of the music played in concordance with responses by infants.

4. To evaluate parental perspectives on music therapy during skin-breaking procedures.

5. To evaluate staff perspectives on music therapy during skin-breaking procedures.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 22/03/2026, University Medical Center Groningen Medical Ethics Review Committee (Hanzeplein 1, Groningen, 9713GZ, Netherlands; +31 (0)50 361 42 04; metc@umcg.nl), ref: 2024-125

### **Primary study design**

Interventional

### **Allocation**

Randomized controlled trial

### **Masking**

Open (masking not used)

### **Control**

Active

### **Assignment**

Sequential

### **Purpose**

Supportive care

### **Study type(s)**

### **Health condition(s) or problem(s) studied**

Admission to a neonatal intensive or high-care (HC) ward and need for repeated skin-breaking procedures

### **Interventions**

The three study arms are:

1. Care as usual (CAU)
2. Music therapy during the intervention
3. Music therapy after the intervention

The intervention in this study will be a sedative music therapy session according to the Rhythm, Breath and Lullaby method. This method employs the ocean disc or guitar and voice as instruments and is specifically designed for NICU music therapy by Loewy and colleagues. The music therapists is trained to observe the infant and individualize the therapy sessions aimed at specific goals, including, for example, relaxation or parent-infant bonding. This protocol is currently standard care in the UMCG NICU but at present not used for procedural support. The

UMCG NICU employs two board-certified music therapists with this additional specialization. The therapist will use the following protocol: First, the neonate's behavioural state will be matched and mirrored using music. If the infant is fussing or agitated, a moderate to active tempo and intensity will be used. Throughout playing, the tempo is slowed gradually and intensity reduced. The music is slowed and simplified. The music is then transitioned into triple meter and further slowed and simplified so that the infant is aided to achieve a calm state. The instrumental music is faded out using toning or humming of the melody. The melody is then sustained in long notes and triple meter and repeated with a cadence. The session is closed on one tone. For the intervention, a parent-preferred lullaby (Song of Kin) will be used, which is a familiar piece of music to the neonate.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

1. Pain response measured using the Premature Infant Pain Profile-Revised (PIPP-R) at before and after interventions

## **Key secondary outcome(s)**

1. Oxygen saturation measured using near-infrared spectroscopy before and after interventions
2. Heart rate variability measured using standard ECG monitoring before and after interventions
3. Brain activity measured using amplitude-integrated electroencephalography before and after interventions
4. Brain function measured using general movement optimality scores before and after interventions
5. Specific reactions to music therapy measured using an in-depth musical micro-analysis throughout interventions
6. Parental acceptance of music therapy measured using a semi-structured interview after study procedures have ended
7. Staff acceptance of music therapy measured using a semi-structured interview after study procedures have ended

## **Completion date**

09/04/2030

## **Eligibility**

### **Key inclusion criteria**

1. If the gestational age is between 33 and 42 weeks, expected length of stay >2 weeks
2. If the gestational age is <32 weeks, expected length of stay > 3 weeks (because one of our research projects has shown that starting music therapy after 7 days is more beneficial for these children than starting before 7 days of life)
3. Need for repeated skin-breaking procedures (at least three) within the study period
4. Written informed consent from parents

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

**Lower age limit**

0 days

**Upper age limit**

3 months

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

Inability of the parents to understand/speak Dutch

**Date of first enrolment**

09/04/2025

**Date of final enrolment**

09/04/2028

**Locations****Countries of recruitment**

Netherlands

**Sponsor information****Organisation**

University Medical Center Groningen

**ROR**

<https://ror.org/03cv38k47>

**Funder(s)****Funder type****Funder Name**

Universitair Medisch Centrum Groningen

**Alternative Name(s)**

University Medical Center Groningen, UMCG

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Netherlands

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not expected to be made available