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Music therapy as painkiller

Submission date 22/03/2026	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 23/03/2026	**Overall study status** Ongoing	
Last Edited 23/03/2026	**Condition category** Neonatal Diseases	

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?
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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