Musical intervention for extremely preterm infants during NICU stay: a feasibility pilot study

Published: 30-07-2019
Last updated: 09-04-2024

Our first aim is to study whether it is feasible to provide live-music therapy for extremely preterm infants. Our second aim is to evaluate possible effects of live-music-therapy, to serve as a basis for power calculations in a larger study. This...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	Interventional

Summary

ID

NL-OMON48523

Source
ToetsingOnline

Brief title
Live-music for preterm infants

Condition

- Neonatal and perinatal conditions

Synonym
Prematurity

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Extremely preterm, Live music

Outcome measures

Primary outcome

For the current protocol we define the concept of feasibility as follows:

(a) Drop-out of children is lower than 20%

(b) The sessions are not increasing stress for the child

(c) Participant rate of parents is >50%

(d) >50% of parents evaluate the intervention as positive

(e) >50% of caregivers evaluate the intervention as positive

A drop-out regards children that are not stable enough to participate in the sessions. This stability is determined by the treating physician and nurses.

Before, during and after each session, the music therapist will rate the COMFORT-neo score of a child. These scores will be used to determine whether the sessions are stressful for a child. During each session the heart rate, blood pressure, respiration rate and oxygen saturation will be registered. In the second week of therapy, General Movements (GMs) will be filmed before and in the 2 hours after a session. Before the study period, after 3 weeks and after 6 weeks, GMs will also be filmed, a stool sample will be collected and parents will fill in a State and Trait Anxiety Inventory (STAI) and Beck's Depression Inventory. At three months of age, all children will again be videotaped to study Fidgety Movements (FMs).

Secondary outcome

Not applicable.

Study description

Background summary

Auditory brain development starts very early in gestation. From approximately 26 weeks* gestation, fetuses or preterm infants will be able to react to auditory stimuli. Sounds a fetus hears within the womb include a mother*s heartbeat, respiration and the maternal voice. Fetuses can react to these stimuli and via an activity-dependent system of bone conduction, the inner ear is stimulated. From 30 weeks* gestation onwards, the child will be able to distinguish between different speeches and is able to process complex auditory sounds. Because of preterm birth, this process is interrupted. Preterm infants are subsequently admitted to the Neonatal Intensive Care Unit (NICU), where they face many challenges. Among these challenges are the stress of physical and sensorial influences as well as maternal separation. On the one hand, this means that infants are exposed to noise in the NICU, that they may not yet be able to process, which could be harmful and has been shown to alter respiratory and cardiac functions. On the other hand, deprivation of the sounds heard in utero could have consequences for auditory brain maturation and speech and language development. Music might have an impact on preterm infants by three mechanisms, a) reducing stress, b) improving parent-infant interaction and c) offering an environmental enrichment to stimulate (auditory) brain development. Through stress reduction, music might deliver structured patterns to the developing brain, which in turn could lead to neurodevelopmental improvements. Because extremely preterm infants have been excluded in many studies, the feasibility of live-music therapy and the effects of live-music therapy are unknown for this group. However, it might be crucial to provide live-music therapy as early as possible to facilitate a more optimal outcome. Therefore, with our study, we aim to investigate the feasibility of live-music therapy for extremely preterm infants admitted to the NICU, and their parents.

Study objective

Our first aim is to study whether it is feasible to provide live-music therapy for extremely preterm infants. Our second aim is to evaluate possible effects of live-music-therapy, to serve as a basis for power calculations in a larger study. This concerns a) the effects of live-music therapy on hemodynamics, b) the effects of live-music therapy on infant and parental stress levels and parent-child interaction and c) the effects of live-music therapy on short-term neurological outcome.

Study design

This is a feasibility study investigating the feasibility of live-music therapy for extremely preterm infants (N=10). After proved feasibility, we will

continue to study the effects of live-music therapy on an additional 40 infants and their parents (total N=50).

Intervention

A music therapist will provide the infants with three weeks of live-music, including two sessions per week. Each session of live-music (two times a week) will last maximal 30 minutes, in which 10 to 20 minutes of actual music should be provided. In the sessions, the music therapist will tailor the contents of the music therapy for each individual infant. This includes choosing the appropriate instrument, determining the infant*s state, and while playing music continuously monitor the child and his /her reactions (aimed at relaxation, by particularly following respiration and respiratory patterns) but also looking for signs of overstimulation (such as tension, crying movements, hiccups, yawning or frowning). The music therapist will collaborate with parents in constructing the programme for the sessions. Parents will be actively involved in the sessions, to stimulate their role as caregiver and empower them.

Study burden and risks

Data for this study cannot be obtained in another population, as the intention is to study the feasibility of live-music for extremely preterm infants. As this intervention may be stress-reducing and improving neurodevelopment, it is worthwhile to study. We believe that the burden and risks associated with the participation in this pilot study are small to non-existent. The possible overstimulation by the live-music will be closely monitored by a trained music therapist. Regarding outcomes, as DNA methylation will be locus-specific, information will be collected without insights into genomic variations or mutations, avoiding the risk to yield unwanted genetic information. *

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Extremely preterm children (gestational age <30 weeks and/or birth weight <1000 grams) admitted to the Neonatal Intensive Care of the UMCG.
- Written informed consent from parents.

Exclusion criteria

Inability of the parents to understand/speak Dutch

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-08-2019

Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	30-07-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-03-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ISRCTN	ISRCTN94562698
CCMO	NL68951.042.19