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Live music for preterm infants

Submission date
29/01/2019

Recruitment status
No longer recruiting

Registration date
31/01/2019

Overall study status
Completed

Last Edited
03/08/2021

Condition category
Neonatal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Preterm birth has many effects during childhood, such as delayed growth and developmental and behavioral problems. Being admitted to a Neonatal Intensive Care Unit and encountering many stressful circumstances may be a contributing factor. For example, this means that a child is deprived from the sounds heard in the womb, and instead exposed to possibly harmful sounds. In turn, this may have consequences for the development of the brain, speech and language. Music may contribute through three mechanisms (a) reducing stress, (b) improving parent-infant interaction and (c) creating an environment where brain development is stimulated. In many studies, extremely preterm infants were excluded. As such, the effects of live music therapy are unknown in this group of patients. Possibly, offering the intervention earlier may have a beneficial effect for their developmental outcome. The aim of this study is to assess the effects of live music therapy on extremely preterm infants.

Who can participate?
Infants born with a gestational age of less than 30 weeks and/or with a birthweight of less than 1000 grams, admitted to the Neonatal Intensive Care Unit of the University Medical Center Groningen

What does the study involve?
After consent, eligible infants are randomly allocated to one of the two groups, music therapy or care as usual. Infants in the music therapy group start with the intervention in the first three weeks. Infants in the care as usual group do not yet receive the intervention. After three weeks the groups cross-over. The intervention involves a music therapist providing the infants with three weeks of live music, including two sessions per week. Each session of live music (two times a week) lasts up to 30 minutes, in which 10 to 20 minutes of actual music should be provided. In the sessions, the music therapist tailors 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 breathing) but also looking for signs of overstimulation (such as tension, crying movements, hiccups, yawning or frowning). The music therapist collaborates with parents in constructing the programme for the sessions. Parents are actively involved in the sessions, to stimulate their role as caregiver and empower them.

What are the possible benefits and risks of participating?
The possible benefits of this intervention are reduced stress effect and improved neurodevelopment. The burden and risks associated with the participation in this study are small to non-existent. The possible overstimulation by the live-music will be closely monitored by a trained music therapist.

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?
September 2018 to September 2020 (updated 17/05/2019, previously to May 2019)

Who is funding the study?
University Medical Center Groningen (Netherlands)

Who is the main contact?
Hanneke van Dokkum

Contact information

Type(s)
Scientific

Contact name
Ms Hanneke van Dokkum

Contact details
Hanzeplein 1
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9713 GZ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
-

Study information

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

Study objectives

The trialists expect live-music therapy to be feasible in extremely preterm infants. In addition, they expect to find effects on hemodynamics, stress levels and short-term neurological outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/07/2019, Medical Ethical Committee of the University Medical Center Groningen, Postbus 30.001, 9700 RG Groningen, The Netherlands; +31 (0)50 361 4204; metc@umcg.nl), ref: 2019.093

Study design
Randomized non-blinded pilot feasibility study with a cross-over design

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Being born extremely preterm (i.e. <30 weeks gestation) or with very low birth weight (i.e. <1000 grams)

Interventions
After consent, eligible infants will be randomly assigned to one of the two arms, music therapy or care as usual. Assignment to treatment allocation will be done through a web portal. The randomisation schedule will be computer-generated, using the method of randomised blocks. This trial will thereby be protected from selection bias by using concealed randomization. Infants in the music therapy group will start with the intervention in the first three weeks. Infants in the care as usual group will not yet receive the intervention. After three weeks the groups will cross-over. The intervention entails a music therapist providing 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.

Intervention Type
Other

Primary outcome measure
Feasibility, defined as
1. Drop-out of children is lower than 20%
2. The sessions are not increasing stress for the child
3. Participant rate of parents is >50%
4. >50% of parents evaluate the intervention as positive
5. >50% of caregivers evaluate the intervention as positive
Feasibility will be measured after the study has included 40 infants, but during the study the trialists will closely monitor for overstimulation according to COMFORTneo scores by the music therapist.

Secondary outcome measures
1. Hemodynamic parameters (i.e. heart rate, respiratory rate, blood pressure and oxygen saturation) measured before, during and after each therapy session
2. Parental stress levels measured using the State and Trait Inventory (STAI) at baseline, after the three weeks of intervention and at discharge
3. Infant stress levels measured using COMFORTneo scores before and after each therapy session
4. Short-term neurological outcome measured using General Movements Assessment at baseline, before and after a therapy session in the second week of therapy, after three weeks of intervention and at three months corrected age

Overall study start date
01/09/2018

Completion date
01/09/2021

Eligibility

Key inclusion criteria
1. Born with a gestational age < 30 weeks and/or with a birth weight < 1000 grams
2. Admitted to Neonatal Intensive Care Unit of the University Medical Center Groningen
3. Written informed consent from both parents

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
Inability of parents to understand and/or speak Dutch

Date of first enrolment
01/09/2019

Date of final enrolment
01/09/2020

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
Hanzeplein 1
Groningen
Netherlands
9713 GZ

Sponsor information

Organisation
University Medical Center Groningen

Sponsor details
Hanzeplein 1
Groningen
Netherlands
9713 GZ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/09/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Hanneke van Dokkum. Data will be available from 01/05/2021 onwards for example for meta analyses regarding music therapy. Data will be coded and anonymised. This will regard data for the trial, it is not known what data exactly and for whom data will be available. However, any reasonable request will be taken under consideration by the research group.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/06/2021	22/07/2021	Yes	No
Results article		02/07/2021	03/08/2021	Yes	No