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Music combined with touch therapy to decrease pain response in preterm infants

Submission date
26/07/2016

Recruitment status
No longer recruiting

Registration date
29/07/2016

Overall study status
Completed

Last Edited
05/08/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
About 11% of all babies born worldwide are preterm (premature), meaning that they are born more than three weeks before their due date. In many cases, infants are admitted to a neonatal intensive care unit (NICU), as they need comprehensive medical care to ensure their survival. Many of these infants have to undergo painful procedures as part of their standard care in these units. Recent studies have shown that preterm infants are able to experience pain and are particularly susceptible to feeling pain because of their immature and vulnerable nervous systems. Undergoing repetitive and prolonged pain can have damaging short-term effects, such as excessive crying, choking, gagging, vomiting and long-term effects such as altered pain sensitivity, permanent nervous system defects and behavioral problems. Therefore, there is an urgent need to find safe effective treatments to relieve pain among these infants. Music combined touch therapy (MCT) is a type of treatment which combines listening to music and gentle touching of the skin. Previous studies have shown that it can be an effective way of alleviating pain in infants. The aim of this study is to investigate the effects of MCT in lowering pain experienced by premature infants during routine painful procedures in NICU.

Who can participate?
Infants born at least three weeks early who have been admitted to the NICU at Nanjing Children' s Hospital within 72 hours of birth

What does the study involve?
Practices are randomly allocated to one of two groups. Infants in the first group undergo their routine painful procedures as usual, without any extra treatment. Infants in the second group undergo their routine painful procedures with the addition of MCT. This involves having a CD player placed 15-20cm above their heads, which plays lullabies continuously from five minutes before the procedure starts until 30 minutes after it ends. The touch therapy involves the assistance gently placing their left hand on the infant's head with the fingertips on the eyebrow line and the palm on the infant's crown, and their right hand with the thumb on the infant's right shoulder and the rest of the hand on the infant's arm. At the start of the study, infants in both groups are examined for signs of pain and have samples of blood taken to measure levels of cortisol (a hormone released when stressed) and beta-endorphin (a chemical messenger that produces a numbing effect).

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved to those taking part in this study.

Where is the study run from?
Nanjing Children's Hospital Affiliated to Nanjing Medical University (China)

When is the study starting and how long is it expected to run for?
January 2011 to December 2012

Who is funding the study?
Nanjing Children's Hospital Affiliated to Nanjing Medical University (China)

Who is the main contact?
Dr Jie Qiu

Contact information

Type(s)
Public

Contact name
Dr Jie Qiu

Contact details
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210008

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effect of music combined with touch therapy on pain response and level of beta-endorphine and cortisol in late preterm infants

Study objectives
The combined music and touch intervention might decrease the pain response of preterm neonates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nanjing Children's Hospital Affiliated to Nanjing Medical University Ethics Committee, 31/05/2011, ref: #201601035-1.1

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cortisol and β-endorphin levels in pre-term infants

Interventions
After consent is obtained from parents, infants are randomly assigned to either the experimental or control group using a random numbers table. Participants in both groups undergo a range of painful procedures during their standard medical care in the NICU.

Control group: Infants receive daily painful procedures without intervention

Experimental group: Infants receive painful procedures as well as the combined music and touch intervention (CMT). A CD player (Philips AZ-1103) is used for the music intervention. Audio stimulation is provided by "Smart Baby Lullaby" compact discs. The music includes lullabies and nursery rhymes, which are musically simple songs with lower pitch and slower tempo. The disc player is placed approximately 15-20 cm above the infants' heads, allowing for continuous play of the music from 5 minutes before the experimental procedure until 30 minutes after the procedure. The touch intervention protocol (Gentle Human Touch, GHT), starts from the beginning of procedures until 10 min after the procedure. It involves the assistant gently placing her left hand on the infant's head with the fingertips resting immediately above the eyebrow line and the palm touching the infant's crown. The right hand is then placed with the right thumb on the infant's right shoulder (at midline position) with the rest of her hand and fingers on the infant's arm above the elbow. These procedures are repeated for every painful procedure during the two weeks data collection period.

Intervention Type
Behavioural

Primary outcome(s)
Pain is measured using the premature infants' pain profile (PIPP) at baseline and 2 weeks.

Key secondary outcome(s))
1. Cortisol levels are measured using blood testing at baseline and 2 weeks
2. Beta-endorphin levels are measured using blood testing at baseline and 2 weeks

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Admitted within 72 hours after birth
2. Gestational age is less than 37 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
62

Key exclusion criteria
1. Serious birth injuries
2. Serious malformations (especially in oral cavity or external ear deformity)
3. Significant parenchyma brain injury (IVH grade IV, or PVL)
4. Had received analgesics or sedatives within 72 h of the assessment
5. Failed hearing screening.

Date of first enrolment
01/06/2011

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
China

Study participating centre
Nanjing Children's Hospital Affiliated to Nanjing Medical University
72 Guangzhou Road
Nanjing
China
210008

Sponsor information

Organisation
Nanjing Children's Hospital Affiliated to Nanjing Medical University

ROR
https://ror.org/000xvke80

Funder(s)

Funder type
Government

Funder Name
Nanjing Health Bureau

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/01/2017	05/08/2019	Yes	No
Basic results		29/07/2016	01/08/2016	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes