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Harp music: Effects on heart rate variability, cortisol and activity

Submission date	Recruitment status	[_] Prospectively registered
06/08/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/08/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/05/2019	Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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27157

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NIH AT001901

Study information

Scientific Title

Harp music: Effects on heart rate variability, cortisol and activity

Study objectives
The null hypothesis is that harp music has no effect compared with usual care or a quiet room on any parameter of heart rate variability, salivary cortisol or activity of premature infants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by Wake Forest University School of Medicine (WFUSM) Institutional Review Board on 03/31/2005 (Protocol no. BG05-162)

Study design
Randomized controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Prematurity

Interventions
Harp music vs quiet room. The infants allocated to the intervention group had harp music for 45 minutes each day for 3 days.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Salivary cortisol was measured just prior to harp music/quiet/usual care observation period and just after each day
2. HRV was measured during the intervention each day
3. Activity was measured during and after the intervention each day
4. Weight, meausred at baseline (Monday) and 5 days (Friday)

Secondary outcome measures
Growth, measured as weight gain at 5 days (this trial is 5 days long).

Overall study start date
01/04/2005

Completion date
30/12/2006

Eligibility

Key inclusion criteria
Infants hospitalized at Brenner Children's Hospital Neonatal Intensive Care or Intermediate Care UnitsInfants were eligible if they satisfied the following criteria:
1. Born between 25 and 36 weeks gestational age
2. At least 34 weeks gestational age by the time of enrollment
3. Had been medically stable in the intermediate care nursery for at least three days
4. Had passed the neonatal hearing screen
5. Slept in a crib rather than an isolette
6. Took full oral feedings
7. Free of apnea and bradycardia spells
8. Expected to remain in the intermediate nursery for at least seven more days to achieve stable body temperature

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
90

Total final enrolment
8

Key exclusion criteria
1. Any medical condition known to adversely affect either:
1.1. Central nervous system (e.g. intraventricular hemorrhage of Grade II or higher)
1.2. Cardiac or adrenal function (e.g. major cardiac anomaly)
1.3. Movement (e.g. spasticity, hypotonia, or fractured clavicle)
2. Any ongoing need for stressful or invasive medical procedures or steroid medications

Date of first enrolment
01/04/2005

Date of final enrolment

30/12/2006

Locations

Countries of recruitment
United States of America

Study participating centre
Wake Forest University School of Medicine
Winston-Salem
United States of America
27157

Sponsor information

Organisation
National Institutes of Health, National Center for Complementary and Alternative Medicine (USA)

Sponsor details
6707 Democracy Blvd.
Suite 401
Bethesda
United States of America
20892

Sponsor type
Government

ROR
https://ror.org/00190t495

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health (ref: NCCAM AT001901)

Alternative Name(s)
Institutos Nacionales de la Salud, US National Institutes of Health, NIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2008	17/05/2019	Yes	No