

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)

Primary study design

Interventional

Study design

Randomized controlled trial.

Study type(s)**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(s)

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, measured at baseline (Monday) and 5 days (Friday)

Key secondary outcome(s)

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

Completion date

30/12/2006

Eligibility**Key inclusion criteria**

Infants hospitalized at Brenner Children's Hospital Neonatal Intensive Care or Intermediate Care Units. Infants 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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

ROR

<https://ror.org/00190t495>

Funder(s)

Funder type

Government

Funder Name

National Institutes of Health (ref: NCCAM AT001901)

Alternative Name(s)

US National Institutes of Health, Institutos Nacionales de la Salud, NIH, USNIH

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

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