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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
06/08/2007		☐ Protocol		
Registration date 29/08/2007	Overall study status Completed	Statistical analysis plan		
		[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

Dr Kathi Kemper

#### Contact details

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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)

#### Study design

Randomized controlled trial.

#### Primary study design

Interventional

#### 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, meausred 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 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** 

#### Healthy volunteers allowed

No

#### Age group

Neonate

#### Sex

All

#### Total final enrolment

R

#### 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