UNIVERSITY OF LIVERPOOL

Alder Hey Children's NHS
NHS Foundation Trust

CASCADE MUSIC
Music in Healthcare

Music:ED

iMpact of therapeUtic live muSic on pain and distress levels during Interventions within the paediatriC Emergency Department

Research Protocol
Version: V8.3
Date: 13/11/2018

Study Title:
Music:ED

iMpact of therapeUtic live muSic on pain and distress during Interventions within the paediatric Emergency Department.

Project Team
The core project team will consist of
Dr Charlotte Durand - Consultant in Paediatric Emergency Medicine, (PI)
Louise Roper CPsychol. - University of Liverpool Lead Applicant
Rachel Fillhart - Lead Musician, Director of Cascade Music
Martin Bickerton – Musician, Cascade Music
Dr Shrouk Messahel - Consultant in Paediatric Emergency Medicine
Elizabeth Lee - Research Nurse
Rachel Greenwood-Bibby - Research Nurse
The researchers have relevant methodological, clinical and academic expertise and will share particular facets of their expertise. All listed above have current GCP certification.

Introduction and Context

The Emergency Department (ED) can be stressful and traumatic, especially for children and young people, and the clinical environment can be a frightening, unfamiliar space, which adds to an already anxious experience.

Musicians from Cascade Music, who have an established track record of working with the Paediatric ED, will provide recruited participants in the experimental arm with high-quality calming, distracting music during selected procedures. A wide range of music will be used, ranging from nursery rhymes to classical to pop tunes, to engage with and comfort children, taking their attention away from their immediate pain or distress. Pain scores throughout the procedure will be self-assessed by patients (if old enough to use a self assessment tool i.e. 3 years and above) as well as observed by a Research Nurse. Qualitative data on distress and the experiences of patients, families and staff will also be collected via a questionnaire. Participants recruited to the control arm will complete the same measures but receive no live music.

This project is underpinned by three areas of need:

1. Despite there being a wide breadth of clinical studies that have used music within various healthcare settings, one area that has been almost completely unexplored is the Paediatric Emergency Department (PED). Alder Hey Children's Hospital (AHCH), as a world leader in research, is ideally situated to conduct this preliminary research**.**

2. By 2020 AHCH plans to be a world class, child-focused centre of research, innovation and education expertise to improve the health and wellbeing outcomes for children and young people. Supporting patients through stressful and invasive procedures is crucial. Inspired by the patients and families that we care for, this research fits well with the AHCH vision, demonstrating an innovative and evidence-informed approach to enhancing practice.

3. The University of Liverpool's impact intensive approach to research is a key strength. This study is designed to have a positive immediate impact on the children and young people participating and those undergoing interventional procedures in the future, helping to enhance patient experience of the ED.

Value of the study

There is a growing evidence-base for the use of music in healthcare settings, with music already demonstrated to reduce stress, distress and the perception of pain in some clinical contexts[1] [2]. Yet, there is a lack of studies examining the impact of live music in paediatric emergency contexts.

A literature review revealed that there is a lack of studies examining the impact of live music in paediatric emergency contexts.

Related studies either used recorded music in the place of live music, or, if live music was used, then it was within a non-emergency setting.

Prior related studies include:

'Interactive music as a treatment for pain and stress in children during venipuncture: a randomized prospective study.' [3]
This controlled study demonstrates that songs and music, performed by "professional" musicians, have a beneficial effect in reducing distress before, during, and after blood tests. This study shows, moreover, that the presence of musicians has a minor, but yet significant, effect on pain due to needle insertion.'
This study uses similar methods and looked for similar outcomes as Music:ED, but in a non-emergency setting

'Music to reduce pain and distress in the pediatric emergency department: a randomized clinical trial.' [4]
Health care providers reported that it was easier to perform the procedure for children in the music group (76% very easy) vs the standard care group (38% very easy) (P = .03). Health care providers were more satisfied with the intravenous placement in the music group (86% very satisfied) compared with the standard care group (48%) (P = .02). Music may have a positive impact on pain and distress for children undergoing intravenous placement. Benefits were also observed for the parents and health care providers.
This study uses similar methods and looked for similar outcomes as Music:Ed, but using recorded rather than live music, and in a non-emergency setting.

The Music:ED study will therefore use a controlled experimental design to investigate the impact of using therapeutic live music in the Alder Hey Paediatric Emergency Department to reduce pain and distress during interventional procedures.

The outcomes of the study will provide evidence for the use of live music in the PED to support and enhance patient experience. Distress is often particularly high within the emergency department. If a patient's experience whilst attending the Emergency Department can be less traumatic, this will be of benefit to all: patients, families and clinicians. A patient who is less distressed is more cooperative and may be easier and quicker to treat.

Methodology and Methods

Research Question
Does live music decrease the pain and distress of patients undergoing a procedure within the paediatric emergency department?

Aims of the Study

Our aims/objectives include:

1. To explore whether live music helps to decrease pain and distress in patients in the Paediatric Emergency Department
2. To explore whether procedures can be carried out with greater ease from a clinician's perspective and whether staff experience of the situation is impacted by the presence of live music.
3. Exploring the overall impact on the ED experience from the patients, families and clinicians' perspectives.

Methodological Approach

We have chosen a mixed method design to provide us with different forms of data and insights from multiple practitioner, parent and patient perspectives throughout the experience.

Quantitative data includes collecting information about the patient's pain levels and qualitative data will be collected from open response questionnaires to explore patient distress and the practitioner, parent and patient perspectives on the experience.

Methods

There will be an experimental (live music) and a control (no live music) group. Research Nurses will identify appropriate patients using a screening tool that will outline the inclusion/exclusion criteria. Participant Information Sheets (PIS) will be provided to patients and their families for their appropriate ages. They will be offered a copy of the results if they would like and will be told how the results will be reported when the study is completed.

After gaining written consent from the parent and written or verbal assent from the child, Wong-Baker pain scoring methods will be explained in advance of the procedure. Necessary data will be collected for the CRF.

The participant's involvement in the study will be limited to the length of time of their Emergency Department visit, so will be just one day and one procedure.

For the experimental (music) group, Cascade's musicians will spend eight weeks, twelve hours per week in the ED and will aim to recruit all eligible children during that period. As this is a pilot study recruitment targets need to remain flexible, but are estimated at 60-80 participants (per group).

The same number of participants will be recruited to the control (no live music) group as a comparison, on days that the musicians are not in the department. All patients in both groups will continue to receive standard care. Each child can only be in the study once and for one procedure. Patients will be free to withdraw from the study at any time.

Following the procedure and interviews, patients involved will be offered a sticker and a CD of calming music recorded by Cascade Music as a thank you for their participation. For ethical reasons, this will not be mentioned in advance.

Timeline:
December 2018:
Implementation of study including finalising ethical approval
Recruitment of Research Nurse,
Publicise study within Alder Hey Children's Hospital's Emergency Department.

January - March 2019:
Recruitment of participants to the study, both experimental (music) and control (non-music) groups.
Data collection from participants.

March - May 2019:
Complete data analysis
Write report
Explore dissemination options including publishing and conferences
Plan next funding application

Methods of data collection and analysis
Three sets of data will be collected:

1. Quantitative: Self-reported pain.
A validated observational tool will be used: Wong Baker Faces.
This is suitable for children age 3+. As children self-report, the Research Nurse will collect this data on a paper CRF. Wong Baker scores will be collected before, during and after the procedure. If mid-procedure collection of pain score is inappropriate, then participants can be asked about mid-procedure pain scores after the procedure.
A self-reported pain score will also be taken in advance, during the recruitment process, to provide a baseline measure.

2. Quantitative: Observed pain.
Data will be collected on observed pain levels using a validated observational tool: Faces, Legs, Activity, Cry and Consolability (FLACC) pain assessment tool.
This tool is suitable and validated for all ages of the recruited participants, from 6 months until 16 years. References regarding justification of this scale for these age ranges are below. [5] [6]
Scoring will take place before, during and after the procedure.
The Research Nurse will carry out this scoring, and when available, an independent observer from the Emergency Department staff will also. The Research Nurse will collect this data on the paper CRF.

Heart rate will also be monitored throughout, where a child is cooperative enough. HR will be noted approximately every two minutes before, during and after procedure, (cleaning marks the beginning of the procedure, final bandage/dressing marks the completion). The Research Nurse will note HR data on the CRF. There will be an option for the Research Nurse to record 'not available' for heart rate measurements either because child refuses or because of probe or monitor issues etc.

3. Qualitative: Distress and experiences of patients, families and clinicians.

Our outcome measures will include collecting qualitative information on patient's distress, and patients', families' and clinician's Emergency Department experience. All recruited patients will receive a paper questionnaire with open text response options.

Qualitative questions for Experimental AND Control Groups:

The following two questions will be asked of both the experimental (live music) AND control (no live music) groups. The questions will be asked of each of these two people: patient and parent/legal guardian.

'Please answer the following questions, in particular, in regard to distress levels/lack of distress':

- Qualitative question 1. What do you think helped you/your child during their procedure?

- Qualitative question 2. Did anything make the situation worse?

Qualitative questions for Experimental Group Only:

Within the experimental group only, the following three additional questions will be asked, via a paper questionnaire, of each of these three people: patient, parent/legal guardian and clinician. These questions directly link to the objectives of the study.

These questions are in particular regard to music, which is why they would not be appropriate to be asked of the control (no live music) group.

- Qualitative Question 1. How did you feel the music affected the child's distress before, during and after the procedure?

- Qualitative Question 2. Can you tell me about how the live music helped or hindered the procedure?

- Qualitative Question 3. Can you tell me about your experience of the ED (Emergency Department) today, in particular in regard to the music?

The qualitative questions will be included in a open ended questionnaire style sheet which the parent, child or practitioner if the parent wishes, can fill out between the end of the music intervention and when they are discharged from the ward. It will be collected by the RN and stored in a secure room in a locked filing cabinet.

Target population and sampling
This will be a single centre study.
Study participants for both the control and experimental groups of the study will be recruited from AHCH Emergency Department. The study population will consist of children between the age of 6 months and 16 years needing to undergo a painful procedure from a specified list. The Research Nurse will use a screening tool to assess eligibility within this age group.

Necessary data will be collected for the CRF by the Research Nurse:

CRF:
Patient's name
Patient's age
Patient's gender
Parent(s)/legal guardian in attendance during procedure (names)
Whether or not the patient has had this procedure before
How many times the child has visited the hospital in the last 12 months
Have they had an upsetting hospital experience in the past? Yes or no
Record a Wong-Baker pain score at this point (for children age 3+) as a baseline measure

Record whether patient has had analgesia in advance, or during hospital visit
Record use of local anaesthetics e.g EMLA/ametop, LAT gel, cold spray (ethyl chloride)
Record use of Entonox during the procedure
Record if other distraction methods were also used
(Play Specialist/books/bubbles/IPad/TV/ IPhone/ staff dancing and singing, etc)

Record whether the procedure was successful
Record the duration of the procedure (cleaning marks the beginning of the procedure, final bandage/dressing marks the completion)
Record how many attempts were required to carry out procedure
Record the role and grade of the Clinician carrying out the procedure

Record heart rate at 2-minute intervals if tolerated. Include option for the research nurse to record 'not available' for heart rate measurements either because child refuses or if probe or monitor issues etc

Is there an independent observer present? If so, who?

Inclusion criteria
Parent/Legal Guardian present and able to consent.

Age range: 6 months - 16 years. (see references at end notes 5&6 below)
Procedures: Capillary blood sampling, cannulation, venepuncture, suturing, wound cleaning and closure.
Families and children whose primary language is other than English will be included in the study if their English speaking skills are at a level that they can understand and complete the consent/assent process.

Exclusion criteria
Children with Special Educational Needs, children with global development delay, sensory impairments, neurological deficits or disorders, impairment to pain i.e. spina bifida.
Children in resuscitation or unconscious.
Non-English speaking.
Suspected ingestion of recreational drugs, antidepressants or alcohol
Concerns relating to NAI (non accidental injury)/safeguarding concerns
Life or limb critical injuries
Children too unwell to participate

Recruitment
Research Nurses will identify appropriate patients using a screening tool that will outline the inclusion/exclusion criteria. For inclusion in either group, a parent or legal guardian must be available to give consent, collected by the Research Nurse.
The Research Nurse will introduce the study to potential recruits, and supply and explain Participant Information Sheets. Posters will be displayed within Alder Hey's Emergency Department to promote the study and give some initial details.
The same number of participants will be recruited to the control (no live music) group as a comparison, on days that the musicians are not in the department. All patients in both groups will continue to receive standard care. Each child can only be in the study once and for one procedure. Patients will be free to withdraw from the study at any time**.**

Ethics and governance
Full ethics approval will be obtained and clear data protection measures will be put in place for sharing of data between the research team. Parental consent and children's assent will be obtained in all cases. Consent and assent will specifically address the use of quotations in papers, conferences and dissemination.
We do not expect that the study will raise significant issues and will be of minimal risk to the children (and their families). The main issues relate to the engagement of children within research and ensuring that they understand what they are assenting to and are able to indicate (at any point) if they wish to withdraw from the study.

Data Protection
Alder Hey Children's Hospital, as the study sponsor, will own the study data.

The researchers will comply with the requirements of the Data Protection Act.
Storage and anonymity: Research nurses will collect data from parents and children and enter them into the database. Data will be anonymised and will be stored electronically on Alder Hey Children's NHS Foundation Trust's secure server. This can be accessed when on trust premises. The data will NOT be shared with other organisations other than members of the study team which includes the University of Liverpool, or exported outside the EU. Consent forms will be kept separately from the data. Information about participants will not be disclosed to anyone. Any identifying information will be changed to maintain anonymity and the data will be stored securely. After storage (10 years), data will be deleted from the AHCFT secure server. Any paper based information such as consent forms will be destroyed.
The researchers will comply with the requirements of the Data Protection Act. This will be achieved through careful and conscientious management of the study including approaching the families, handling the data and through to dissemination of the findings. Only the Research Nurse, PI and treating clinician will access to the child's medical or other records. All data will be encrypted. All electronic files will be encrypted. Reports from and presentations from the study will not contain any quotes directly attributable to individuals and so will be anonymized. Any specific contextual information will be omitted to ensure that participants' identities are not disclosed. This will be made very clear in the information sheet and within the consent/assent forms.

Data Analysis
Quantitative data will be entered into SPSS. We will analyse the data using the chi-square test for trend, paired samples t-tests and Wilcoxon sign ranks tests as appropriate. Participants with missing data (either before procedure or after procedure) will be excluded from analysis. NVivo 10 Software will be used to assist in the organization and coding of qualitative data (e.g. free text open question responses). Qualitative thematic analysis will be interpretive and iterative. Our approach to synthesizing qualitative and quantitative data will draw on the constant comparative method.

Dissemination
Findings from the study will be disseminated to professionals and to children and their families. Dissemination potentially includes publication in journals and via presentation at conferences and at practice development workshops. This will be done locally through the associated universities and hospitals as well as potentially internationally. By working with colleagues in clinical practice on an on-going basis throughout the study, the researchers anticipate that the study will have a direct impact on practice.

Benefit to patients
Findings will be used to further our understanding of the potential benefits of using live music within the Paediatric Emergency Department, with an aim to improve patient experience.

Link to Alder Hey Research & Universities' Strategies

Alder Hey Children's Hospital's strategy is to build a healthier future for children and young
people. One of Alder Hey's main aims is to 'ensure all of our patients and their families have a positive experience whilst in our care'. This study very much follows this ethos, by exploring ways to make the hospital experience a less traumatic one.

A key strength of the University of Liverpool's research strategy is its impact intensive approach. The design of this study will explore ways of making immediate, effective improvements to the care of children and young people.

References:

[1] A. Y. R. Kühlmann(2018) Meta‐analysis evaluating music interventions for anxiety and pain in surgery. Available at 002 https://onlinelibrary.wiley.com/doi/abs/10.1/bjs.10853

[2] Kari Sand-Jecklin, EdD, MSN, RN, AHN-BC,Howard Emerson, BA, CMP (2010) The Impact of a Live Therapeutic Music Intervention on Patients' Experience of Pain, Anxiety, and Muscle Tension Holist Nurs Pract 2010;24(1):7–15

[3] J Dev Behav Pediatr. 2007 Oct;28(5):399-403.
Interactive music as a treatment for pain and stress in children during venipuncture: a randomized prospective study.
Caprilli S[1], Anastasi F, Grotto RP, Scollo Abeti M, Messeri A.

[4] Hartling L, Newton AS, Liang Y, Jou H, Hewson K, Klassen TP, Curtis S.
JAMA Pediatr. 2013 Sep;167(9):826-35. doi: 10.1001/jamapediatrics.2013.200.
Music to reduce pain and distress in the pediatric emergency department: a randomized clinical trial.

[5] *Pediatric Emergency Care. 28(12):1281–1296, DEC 2012*
DOI: 10.1097/PEC.0b013e3182767d66
The Use of the Faces, Legs, Activity, Cry and Consolability Scale to Assess Procedural Pain and Distress in Young Children
Franz E. Babl; Dianne Crellin; Joyce Cheng; Thomas P. Sullivan; Ronan O'Sullivan; Adrian Hutchinson

[6] *The FLACC behavioral scale for procedural pain assessment in children aged 5–16 years*
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First published: 08 July 2008
https://doi.org/10.1111/j.1460-9592.2008.02655.x