

Music Under Surgery In Children

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Surgical procedures are accompanied by high levels of distress and pain in the adult as well as the pediatric population. Music interventions have shown to reduce this anxiety and pain in adult populations. In this study, we will investigate the...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19989

Bron

Nationaal Trial Register

Verkorte titel

MUSIC

Aandoening

music intervention, preoperative anxiety, postoperative pain, parental anxiety.

Ondersteuning

Primaire sponsor: Sophia Kinderziekenhuis Rotterdam

Overige ondersteuning: Stichting Swart van Essen, WM de Hoop Stichting, Dokter Izak Wessel Stichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

distress intensity assessed with the COMFORT behavior scale at t=1,t=2, t=4,t=5, t=6, t=7

Toelichting onderzoek

Achtergrond van het onderzoek

This study will investigate the effects of a music intervention on distress, anxiety and pain in pediatric surgery. Surgical procedures are accompanied by high levels of distress and pain in the adult as well as the pediatric population. Studies in adult populations found that music interventions prior to and during surgery can alleviate anxiety and distress surrounding surgery and postoperative pain. In this study, we will investigate the hypothesis that music interventions prior to and during surgery will result in less anxiety and distress in infants undergoing surgical procedures.

The research will take place in children in the age of 0-3 years who will have surgery for inguinal hernia, undescended testicle or hypospadias.

This study will be performed as a single-blinded randomized controlled intervention study. Patients will be allocated to one of three study arms, resulting in two, one or no music interventions. Music interventions are administered by headphone. Subjects will listen to an appropriate music intervention, as reported in literature and recommended by music therapists.

The effect of the music intervention will be monitored during the first 24 hours after surgery. All patients will be recruited in The Netherlands.

Doel van het onderzoek

Surgical procedures are accompanied by high levels of distress and pain in the adult as well as the pediatric population. Music interventions have shown to reduce this anxiety and pain in adult populations. In this study, we will investigate the hypothesis that music interventions prior to and during surgery will result in less anxiety, distress and pain in infants undergoing surgical procedures.

Onderzoeksopzet

t=0 outpatient clinic

t=1 ward

t=2 holding area

t=3 start of surgery

t=4 end of surgery

t=5 30 minutes postoperatively

t=6 4 hours postoperatively

t=7 24 hours postoperatively

Onderzoeksproduct en/of interventie

Patient randomly allocated to one of three intervention groups:

1. music intervention prior to and during surgery
2. music intervention prior to surgery
3. control group, no music intervention, receives standard care.

Patients in group 1 and 2 receive music intervention by headphone for approximately 15 minutes prior to surgery, patients in group 3 receive standard care. During surgery, all patients receive headphones, but only patients in group 1 will have a music intervention.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age 0-3 years (inclusively 3 years), both male and female
- Scheduled for surgery for inguinal hernia (uni- or bilateral), undescended testicle (uni- or bilateral), hypospadias
- American Society of Anesthesiologists (ASA) physical status 1 and 2
- General anaesthesia with caudal block
- Parents good knowledge of the Dutch or English language
- Signed informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Age ≥ 4 years
- Hearing impairments
- Emergency surgery
- Premedication with midazolam
- Impaired communication with parents
- Difficulties in speaking and reading Dutch or English in parents
- Missing informed consent

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	27-08-2015
Aantal proefpersonen:	195
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	26-08-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5293

Register	ID
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NTR-old	NTR5402
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Ander register METC Erasmus MC Rotterdam : MEC 2015-264 NL53900.078.15

Resultaten