

# Effects of live-performed music therapy, kangaroo care and combination therapy on stress, comfort and bonding in parents of extremely preterm infants

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Neonatal and perinatal conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON56802

### Source

ToetsingOnline

### Brief title

The effect of live-music and kangaroo care on parental stress and bonding

### Condition

- Neonatal and perinatal conditions
- Family issues

### Synonym

parental bonding, Parental stress

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Bonding, Kangaroo Care, Music therapy, Stress

## Outcome measures

### Primary outcome

Primary endpoint: Difference in cortisol levels before and after all three interventions

### Secondary outcome

Secondary endpoints:

- (A) Difference in Oxytocin levels before and after all three interventions
- (B) Difference in STAI-6 outcomes before and after all three interventions
- (C) Difference in PBQ outcomes at inclusion and after 3 weeks
- (D) Difference in PSS-NICU outcomes at inclusion and after 3 weeks
- (E) Difference in 10-point numeric rating scale for stress before and after all three interventions
- (F) Difference between scores of mothers and fathers

## Study description

### Background summary

Preterm birth is a major public health concern, affecting approximately 10% of births worldwide. Preterm infants are at a significantly high risk of experiencing a wide range of complications and developmental problems. Parents of preterm infants also face a range of challenges, including parental stress, postnatal bonding difficulties and increased anxiety levels. Live-performed

music therapy (LPMT), kangaroo care (KC), and music therapy during kangaroo care (CT) are commonly used interventions to improve neonatal and parental wellbeing. However, limited research exists on the comparative effects of these interventions on postnatal bonding and anxiety in parents of preterm infants, and on the underlying hormonal mechanisms that may be involved, such as salivary cortisol (SC) and salivary oxytocin (OT) responses. Understanding the differences in these interventions on mothers and fathers can also be important, given the potential gender differences in the experience of parenting preterm infants.

## **Study objective**

The aim of this study is to investigate the effects of Kangaroo care (KC), live-performed music therapy (LPMT), and combination therapy (CT) on salivary cortisol (SC) and salivary oxytocin (OT) responses in parents of preterm infants, as well as on postnatal bonding and anxiety. The study aims to determine whether the effects of these interventions differ between mothers and fathers of preterm infants. The findings of this research can provide important insights into effective interventions to improve parental outcomes and bonding with preterm infants.

## **Study design**

The study will include 58 parent-infant triads. This cohort will consist of preterm infants with a gestational age of <30 weeks or a birthweight <1000g and their parents. Parent-infant dyads (either mother-infant dyads or father-infant dyads) will function as their own controls. We will measure stress responses and parental interactive behaviours by analysing salivary cortisol (SC) and salivary oxytocin (OT) levels. These levels will be measured before and after each intervention, which include LPMT, KC and CT. Short-term stress will be evaluated through a 10-point numeric rating scale for stress and Parental Stressor Scale: Neonatal Intensive Care Unit (PSS-NICU), whereas parent-infant bonding will be measured using a Postpartum Bonding Questionnaire (PBQ) at inclusion and 3 weeks later. To assess parental anxiety, we will use the State-Trait Anxiety Inventory - 6 (STAI-6), a shortened version of the STAI, before and after each therapy intervention. Both LPMT and KC are standard care interventions in the Neonatal Intensive Care Unit (NICU) of the Beatrix Children's Hospital.

## **Intervention**

Infants will receive live-performed music therapy by a licenced music therapist for three to four sessions per week. In the Beatrix Children's Hospital this is considered standard care. Each session of LPMT will last maximal 30 minutes, in which 10 to 20 minutes of actual music will be provided. In the sessions, the music therapist will tailor the contents of the music therapy for each

individual infant. The music therapist will collaborate with parents in constructing the programme for the sessions. Parents will be actively involved in the sessions, to stimulate their role as caregiver and empower them. Kangaroo Care (KC) is a method of caring for preterm infants that involves skin-to-skin contact between the parent and infant. KC is typically initiated as soon as possible after birth and can be provided for extended periods, depending on the infant's condition and the parent's availability. KC is also considered standard care and is provided at least once a day to preterm infants admitted to the Neonatal intensive care unit of the Beatrix Children's Hospital. For extremely preterm infants, KC is an essential part of care as it is beneficial for the infant's development and growth. During KC, the infant is placed on the parent's chest, with the infant's head facing the parent's breast or shoulder. The infant is then covered with a blanket to maintain warmth and comfort. LPMT and KC can also be provided simultaneously. The combination therapy of LPMT and KC involves the use of music therapy interventions while the infant is undergoing KC. During KC, the infant is placed skin-to-skin on the parent's chest, and the music therapist provides live music interventions tailored to the infant's needs. The music therapist may use techniques such as singing, playing instruments, and gentle vocalizations to promote relaxation and comfort in both the parent and infant.

### **Study burden and risks**

Data for this study cannot be obtained in another population, as the intention is to study the effects of live-music, kangaroo care and a combination of these therapies in parents of extremely preterm infants and its effects on stress, anxiety and bonding. All interventions are already part of standard care in our NICU environment, so there is no extra burden for the preterm born infants that are included in this study. As this intervention may be stress-reducing and improve bonding for parents as well, it is worthwhile to investigate this. Understanding the effects on parents is an important aspect of this study, as family-centered care is a crucial factor in our healthcare system. Although parents are required to complete questionnaires and provide salivary samples before and after therapy, participating in the study entails only a minimal and non-invasive burden. Parents of preterm infants will be provided with all necessary information and are free to make their own informed decision on whether or not to participate in this research.

## **Contacts**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Premature newborns (<37 weeks pregnancy)

### **Inclusion criteria**

- Mother and father of an infant with a gestational age below 30 weeks and/or birth weight below 1000 grams
- Parents must both be able to attend at least 1 live-performed music therapy session, 1 kangaroo-care session and 1 session where the therapies are combined
- Parents >18 years of age
- Written informed consent from parent(s)

### **Exclusion criteria**

- Inability of the parents to understand/speak Dutch
- Prior history of depression either one of the parents (A history of a diagnosis of depression in parents is a significant predictor of either maternal or paternal postpartum depression and may influence oxytocin levels)

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-01-2024

Enrollment: 116

Type: Anticipated

## Ethics review

Approved WMO

Date: 27-05-2024

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

**In other registers**

Register	ID
CCMO	NL85374.042.23