Impact of a pre-feeding oral stimulation program on first feed attempt in preterm infants: double-blind controlled clinical trial

Sep 10, 2020

PLOS One

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1 Works for me dx.doi.org/10.17504/protocols.io.bcp6ivre

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ABSTRACT

Objective: To evaluate the effect of an oral stimulation program in preterm on the performance in the first oral feeding, oral feeding skills and transition time from tube to total oral intake.

Study Designer: Double-blind randomized clinical trial including very preterm newborns. Congenital malformations, intracranial hemorrhage grade III or IV, bronchopulmonary dysplasia, and necrotizing enterocolitis were excluded. Intervention group (GI) received an oral stimulation program of tactile extra-, peri-, and intraoral tactile manipulation once a day for 15 minutes, during a 10-day period. Control group (GII) received sham procedure with same duration of time. Feeding ability was assessed by a speech-language pathologist blinded to group assignment. The classification of infants' oral performance was determined by Oral Feeding Skills (OFS). Neonates were monitored until hospital discharge.

Results: Seventy-four (37 in each group) were randomized. Mean gestational ages and birth weights were 30±1.4 and 30±1.5 weeks, and 1,452±330g and 1,457±353g for intervention and control groups, respectively. Mean proficiency (PRO), transfer rate (RT), and overall transfer (OT) were 41.5%±18.3 and 19.9%±11.6 (p<0.001), 2.3 mL/min and 1.1 mL/min (p<0.001), 57.2%±19.7 and 35.0%±15.7 (p<0.001) in intervention and control groups, respectively. Median transition time from tube to oral feeding was 4 and 8 days in intervention and control groups, respectively (p=0.003). Intake of breast milk was found to reduce transition time from tube feeds to exclusive oral feeding (p<0.001, HR 1.01, 95%CI 1.005-1.019), but the impact of the study intervention remained significant (p=0.007, HR 1.97, 95%CI 1.2-3.2).

Conclusion: Breast milk intake and an oral stimulation program proved beneficial in reducing transition time from tube feeding to oral feeding.

ClinicalTrials.gov number NCT03025815

EXTERNAL LINK

https://doi.org/10.1371/journal.pone.0237915

THIS PROTOCOL ACCOMPANIES THE FOLLOWING PUBLICATION

Pereira KdR, Levy DS, Procianoy RS, Silveira RC (2020) Impact of a pre-feeding oral stimulation program on first feed attempt in preterm infants: Double-blind controlled clinical trial. PLoS ONE 15(9): e0237915. doi: 10.1371/journal.pone.0237915

DOI

dx.doi.org/10.17504/protocols.io.bcp6ivre

PROTOCOL CITATION

Karine Da Rosa Pereira, Deborah Salle Levy, Renato S. Procianoy, Rita de Cássia Silveira 2020. Impact of a pre-feeding oral stimulation program on first feed attempt in preterm infants: double-blind controlled clinical trial. **protocols.io**

https://dx.doi.org/10.17504/protocols.io.bcp6ivre

MANUSCRIPT CITATION please remember to cite the following publication along with this protocol

Pereira KdR, Levy DS, Procianoy RS, Silveira RC (2020) Impact of a pre-feeding oral stimulation program on first feed attempt in preterm infants: Double-blind controlled clinical trial. PLoS ONE 15(9): e0237915. doi: 10.1371/journal.pone.0237915

EXTERNAL LINK

https://doi.org/10.1371/journal.pone.0237915

KEYWORDS

oral stimulation, preterm infants, feeding

CREATED

Feb 19, 2020

LAST MODIFIED

Sep 10, 2020

PROTOCOL INTEGER ID

33246

GUIDELINES

This double-blind randomized controlled trial was conducted according to Consolidated Standards of Reporting Trials (CONSORT 2010) guidelines.

BEFORE STARTING

The inclusion criteria of this study was as follows:
1) Preterm infants with gestational age ranging from 26 weeks to 32 weeks 6 days, as defined by reliable last menstrual period (LMP) or by obstetric ultrasound performed in the first trimester of pregnancy or, in the absence of best obstetric estimate of final gestational age, by neonatal physical examination;
2) Medically stable preterm infants;
3) Preterm infants on continuous positive airway pressure (CPAP).
The exclusion criteria of this study was as follows:
1) Preterm infants with confirmed intracranial hemorrhage grade III or IV, hydrocephalus, or cystic periventricular leukomalacia;
2) Syndromic preterm infants or those with complex congenital malformations;
3) Preterm infants with severe asphyxia;
4) Preterm infants with necrotizing enterocolitis.

PROCEDURES FOR SAMPLE SELECTION

1 Preterm infants were identified using medical record information. Following patient identification, parents or guardians were invited to participate in the study.

PROCEDURES FOR PATIENT RANDOMIZATION

2 The randomization process was performed in the Random Alloc Software environment, using a four-block design. First, the sample was stratified for randomization (26-27; 28-29; 30-31; 32). Neonates were, then, randomly allocated, by stratum, into the intervention or control group.

Citation: Karine Da Rosa Pereira, Deborah Salle Levy, Renato S. Procianoy, Rita de CÃÂ¡ssia Silveira (09/10/2020). Impact of a pre-feeding oral stimulation program on first feed attempt in preterm infants: double-blind controlled clinical trial. https://dx.doi.org/10.17504/protocols.io.bcp6ivre

INTERVENTION

3 The study intervention was started in the 31st week of postmenstrual age, according to clinical stability.

- Intervention group (GI) received an actual oral stimulation program, proposed by

> Fucile S, Gisel E, Lau C (2002). Oral stimulation accelerates the transition from tube to oral feeding in preterm infants.. The Journal of pediatrics.

whereby the first 12 minutes of stimulation consisted of stroking the cheeks in a circular motion and stroking the vestibular region of the lips, gums, and tongue with the fingertips in an anteroposterior direction. The last 3 minutes of stimulation consisted of nonnutritive sucking.

- Control group (GII) received a sham intervention program, which consisted of remaining beside the incubator, for the same time spent in the intervention group, placing the infant in the proper position, and administering gentle perioral touch, without, however, performing the oral stimulation maneuvers themselves. This sham intervention lasted 10 consecutive days.

MEASUREMENT

4 Assessment of OFS was performed once the neonate was clinically stable, at 33 weeks or older ofpostmenstrual age (regardless of weight). The assessment was performed during the first attempt at oral feeding, as prescribed by the attending physician.

All assessments of OFS were performed by the same speech language pathologist, blinded to group allocation.
Assessment of oral feeding was performed using a bottle with a slow flow nipple.
The specific assessment protocol proposed by

> Lau C, Smith EO (2011). A novel approach to assess oral feeding skills of preterm infants.. Neonatology. https://doi.org/10.1159/000321987

for this study population was used.

DATA ANALYSIS

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- All analyses were performed in the PASW Statistics® for Windows, Version 18.0 software environment (Chicago, IL: SPSS Inc. Released 2009).
- Categorical variables were expressed as absolute and relative frequencies. Symmetrically distributed continuous variables were described as means and standard deviations, while asymmetrical distributed categorical variables were described as medians and interquartile ranges.
- Fisher's exact test was used for comparison of categorical variables. Student's t test was used for comparisons of symmetrically distributed quantitative variables, while the Mann–Whitney test was used for asymmetrically distributed variables. Bivariate analysis ($p < 0.20$) was used to ascertain the factors involved.
- Multiple Poisson regression with robust variance was used to evaluate the independent association of the factors involved in level 4 (L4) status.
- Generalized estimating equations (GEE) were used for analysis of the volume intake in the first days of oral feeding between the groups during the transition period from tube to oral feeding. Bonferroni correction was applied for multiple comparisons.
- Log rank test was used for analysis of the time until transition to full oral feeding.
- Cox multivariable regression was used to control for breastfeeding rates.
- The significance level was set at 0.05.

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