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Official Title of the study: Effects of Oral Stimulation and Supplemental Nursing System on the Transition Time to Full Breast of Mother and Sucking Success in Preterm Infants: A Randomized Controlled Trial

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Aim: This study aimed to investigate the effect of oral stimulation and a supplemental nursing system on the time to full maternal breastfeeding and sucking success in preterm infants. The sample consisted of 70 preterm babies.

Research Design : This longitudinal, randomized controlled study was conducted at a 21-bed level III NICU in a specialized hospital in the central district of Izmir, Turkey, between February and June 2018.

Setting and Participants: Since there was no study that used similar scales, G*POWER 3.1.9.6 program was used to calculate the sample size. GPOWER is a free statistics program that calculates sample size, power, and effect size. Statistical power analysis was used to calculate the required sample size, which indicated 26 participants were needed in each group for 80% power ($1-\beta=0.80$) with a large effect size ($d=0.80$) and a confidence interval of 95% ($\alpha=0.05$) for an analysis using t-tests (Cohen, 1988, Faul et al., 2007). We included 70 preterm infants (35 experimental, 35 control) in the study, considering sample attrition.

The inclusion criteria for the preterm infants in this study were Turkish preterm infants with (1) a birth weight of 1,000 gr and above, (2) a gestational age between 30 and 34 weeks, (3) no congenital anomaly, (4) no severe asphyxia or chronic lung disease, (5) spontaneous breathing, and (6) grades III and IV intracranial hemorrhage and no periventricular leukomalacia.

Randomization: Stratified randomization methods were used while assigning babies to control and experimental groups.

Experimental Group: Oral Motor Stimulation and an Supplemental Nursing System were applied to preterm infants in the experimental group.

Control Group: The clinic's routine feeding protocol was applied to the babies in the control group.

Follow-Up: One month after discharge, we phoned the families of the babies and were informed about their sucking status and weight after discharge.

Data Analysis: Statistical analyses were performed using the Statistical Package for the Social Sciences software for Windows, version 22.0 (SPSS, Inc., Chicago, IL, USA). A p-value of <.05 was significant for all analyses. Descriptive statistics were expressed as percentages, means, and standard deviations. The descriptive characteristics of the experimental and control groups were compared using chi-square and independent t-tests. Independent t-tests were used to analyze differences between the experimental and control groups in terms of transition times to oral feeding and full breastfeeding and discharge as well as gestational age and body weights at the relevant times. Independent t-tests were also used to compare the control and experimental groups in terms of mean scores of the LATCH tool. The breastfeeding status of the experimental and control groups in the first month after discharge were compared using chi-square tests. A repeated measured ANOVA test was used to compare the vital signs before, during, and after nutrition of infants in the experimental and control groups.

Ethics: Ethical approval was received from the Health Science Ethics Committee of X University. The researcher informed parents about the aim of the study and obtained written consent forms from parents. Additionally, permission from the hospital where the study was conducted was obtained.