

Optimal Training Frequency for Oral Stimulation and Non-Nutritive Sucking in Preterm Infants: A Randomized Clinical Trial

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ABSTRACT

Background: Oral stimulation program and non-nutritive sucking (NNS) have been introduced as a training program to promote oral feeding skills in preterm infants. However, no studies are available on the effects of different frequencies of performing this program on infants' feeding skills. The current study sought to find the more effective training frequency for this program on oral feeding skills of preterm infants.

Methods: Thirty-two preterm infants were randomly allocated to two groups. Infants in Groups I and II respectively received one and two sessions of the oral stimulation program and NNS training per day for ten days. The outcome measures included transition time, dependency on tube feeding upon discharge, Preterm Oral Feeding Readiness Scale (POFRAS) score improvement, and weight gain during two weeks.

Results: No significant differences were observed in the transition time and infant weight gain during two weeks. Both groups significantly improved the mean of POFRAS scores during the intervention period (22.63 ± 4.08 to 27.69 ± 3.14 in Group I; and from 20.13 ± 5.89 to 28.88 ± 3.00 in Group II; $P < 0.001$ for both groups). The POFRAS score was significantly more improved in Group II ($P = 0.045$). The ratio of infants who had reached full oral feeding upon discharge to those who were still tube-fed was almost 1.3 to 1 in Group I versus 7 to 1 in Group II.

Conclusion: When the oral stimulation program and non-nutritive sucking are implemented twice a day, compared to only once, the probability of discharge of infants without a feeding tube may increase, and the level of their oral feeding readiness improves more, without having a detrimental effect on the weight gain of infants.

Keywords: Feeding, Infant, Oral feeding, Oral stimulation program and non-nutritive sucking, Preterm

Introduction

Oral stimulation program and non-nutritive sucking (NNS) have been introduced as a training program to promote oral feeding skills of preterm infants (1). This program, developed based on Beckman's principles, consists of 12 minutes of passive stroking of the cheeks, gums, lips, and tongue followed by 3 minutes of non-nutritive sucking training on a pacifier. Fucile, Gisell, and Lau showed that preterm infants

receiving this program once per day for ten consecutive days experienced a significantly shorter transition period from tube to oral feeding. Moreover, compared to the control infants, the rate of milk transfer and overall intake were significantly greater in these infants (1). Since then, other promising outcomes have been reported regarding oral feeding skills of preterm infants receiving this program once a

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day in Neonatal Intensive Care Units (NICUs), including the earlier achievement of full oral feeding (2), higher feeding efficiency (volume of milk consumed relative to the duration of the oral feeding session) (3), greater mean volume of oral intake (4), and shorter length of hospital stay (5). There are also some more recent studies that have administered the oral stimulation program and NNS more than once a day (6–8). For instance, Fucile *et al.* (8) showed that infants who had received this stimulation program twice a day had significantly better feeding proficiency, more advanced sucking stages, and greater suction and expression amplitude than infants who received usual care.

In addition to the oral stimulation program and non-nutritive sucking (NNS) and other similar protocols that focus on stimulating oral structures and training of NNS, some different approaches (8–10) have also been proposed for promoting oral feeding performance in premature infants. "Tactile/kinesthetic stimulation" (10) and "swallowing exercise" (11) are among these approaches, the former uses non-oral sensori-motor stimulation on the trunk and limbs and the latter focuses on the pharyngeal phase of swallowing. Therefore, mothers and nurses of premature infants probably have various options to choose from, both in terms of the type of intervention and the frequency of training that can alter the outcomes. In our experience, the number of sessions of the oral stimulation program and NNS training performed per day is the most repetitive question of the mothers, speech and language therapists (SLTs), and nurses who work with premature infants. To date, no studies have directly examined the effects of different frequencies of performing this program on the oral feeding outcomes in premature infants. Dose-dependent studies investigating training effects on the other skeletal musculature (12, 13) have shown that volume and frequency of the exercise have significant effects on the outcomes. However, there is a paucity of data on responses of oropharyngeal muscles to different frequencies of training. Therefore, the current study sought to find the more effective training frequency for the oral stimulation program and NNS training on oral feeding readiness of preterm infants. Since this program is the routine training program in our Neonatal Intensive Care Units (NICUs), we were especially interested in the effects of its different performing frequencies. If

once and twice a day performing this program has similar statistical and clinical impact, we may use other interventional programs during a day instead of repeating this program for the second time in a day. Furthermore, as some physicians and nurses prefer not to involve these infants in energy-consuming activities like sucking, we wanted to know if performing this program twice a day might negatively affect the infants' weight gain.

Methods

This double-blind clinical trial was conducted between May and November 2021 in the NICU at the Shahid Beheshti Hospital in Isfahan, Iran.

Ninety-four premature infants with 26–31 postmenstrual ages (PMA) were assessed for eligibility. Eligibility included infants: (1) with no congenital anomalies, craniofacial malformations, and chronic medical complications; (2) with physiological stability during the past 24 h; (3) with no ventilator or high-flow oxygen dependency; and (4) receiving all feedings by tube. The infants were excluded if serious medical complications (like intraventricular hemorrhage grades III and IV, bronchopulmonary dysplasia, necrotizing enterocolitis, seizure, and death) or unresolved physiological instability (for more than two days) occurred during the intervention period. Discharging or transferring to another hospital during the intervention period were also exclusion criteria. A total of thirty-seven infants who met the inclusion criteria were recruited and randomly assigned to the two groups using a blocked randomization method with a block size of 2 and 4. The random allocation sequence was generated by the second author, and the first author assigned infants to interventions (Figure 1). The sample size was calculated to ensure 80% power to determine the smallest detectable difference of the POFRAS scores to a 5% significance level. Infants in Groups I (N = 17) and II (N = 20) respectively received one and two sessions of the oral stimulation program and NNS training per day for ten days during two consecutive weeks (1). The examiner, parents, and data analyst were blinded to the number of stimulation sessions performed for each infant. Five infants were excluded based on the reasons described in Figure 1, and finally, 16 infants in each group were reported.

A speech therapist, the first author,

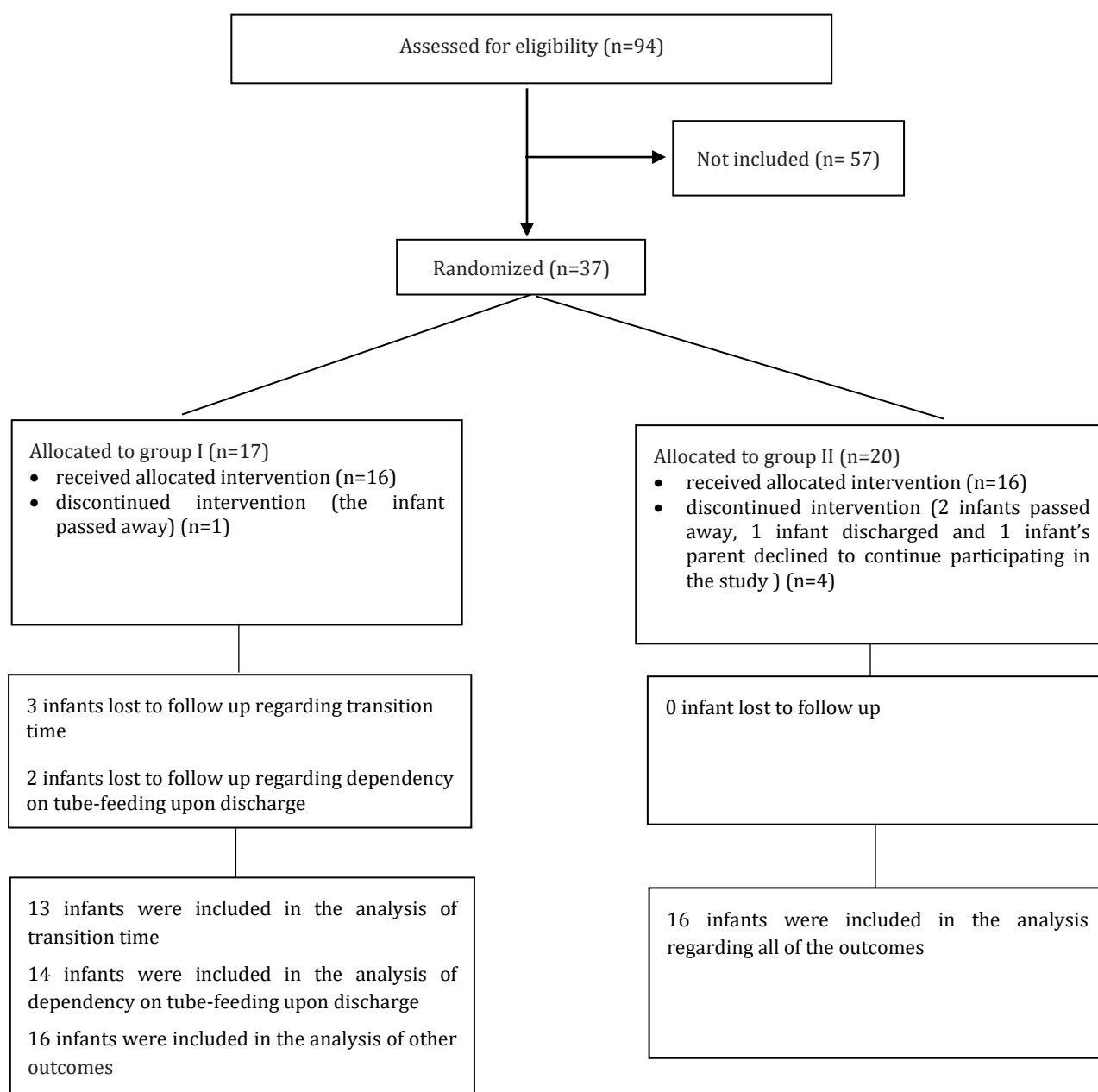


Figure 1. Participant CONSORT diagram

administered the oral stimulation program and non-nutritive sucking (NNS) 15–30 min before a tube feeding in the mornings (1, 14). After gently waking the infant up, the stimulation program was performed in a supine position precisely according to the detailed program provided by Fucile, Gisell, and Lau (1). The infants in Group I received one session of the stimulation program, and those in Group II received two sessions daily, separated by at least two hours. Each stimulation

session consisted of 12 minutes of passive stroking of the cheeks, gums, lips, and tongue and then 3 minutes of non-nutritive sucking training on the therapist's gloved little finger. To blind the mothers and nurses to group assignment, one session of sham stimulation was also provided daily for infants in Group I. In this session, the speech therapist gently stimulated the infants' arms without waking them up. Infants' physiological status during stimulation in both

groups was monitored by a nurse, blinded to the study purpose and methods. If medical instability signs like bradycardia, apnea, and decreased oxygen saturation occurred and did not resolve spontaneously, the stimulation was discontinued, and the infant was investigated repeatedly during the day for restarting the stimulation.

The outcome measures included transition time (the number of days from the start of oral feeding to full oral feeding), infant's dependency on tube feeding upon discharge, and infant weight gain during two weeks. Moreover, the infant's oral feeding readiness was assessed by a trained and experienced nurse on the first day (before starting the interventions) and also after completing the intervention on the 14th day. The nurse was unaware of the infant's group. The Preterm Oral Feeding Readiness Scale (POFRAS) (15) was used to measure oral feeding readiness. This scale scored the infants in five categories, including corrected gestational age; behavioral organization; oral posture; oral reflexes; and non-nutritive sucking. Its total score ranges from zero to 36 (higher scores indicate a higher infant's readiness for oral feeding) (15). The difference between POFRAS scores before and immediately after intervention was calculated as an outcome indicating the progress of the infant's readiness.

The intra-rater coefficient for the POFRAS score was reported as 0.693 by Ostadi et al. (16) in 26 infants with PMA of 27–31 weeks. To establish the inter-rater reliability of the POFRAS score, 21 infants with PMA of 26–32 weeks were assessed by two experienced nurses. The nurses assessed the infants consecutively but separately. They were blinded to each other's scores and did not communicate regarding the evaluated infants. These infants, like infants receiving the intervention in the main phase of the study, were physiologically stable and were not dependent on the ventilator or nCPAP. Pearson correlation showed a significant positive association between the POFRAS scores provided by two raters ($r = 0.70$; $p < 0.01$), indicating good reliability (17).

SPSS statistical software [version 19.0; SPSS Inc., IBM Corporation, Armonk, NY, USA] was used, and statistical significance was set at $P = 0.05$. The normality of the distribution of all variables was tested by the Shapiro–Wilk test. Independent samples t-tests were employed to compare baseline characteristics between groups. The mean of transition time and weight

gain during two weeks were compared between two groups by independent samples t-tests. Paired t-test was used to compare the mean of POFRAS scores before and after the intervention within each group. Chi-square test was applied to compare the frequency of infants without tube-feeding upon discharge between two groups. Based on the results of the Shapiro–Wilk test, a Mann–Whitney U test was performed between groups to compare the mean of POFRAS score progress immediately after the intervention.

Ethical approval

The study protocol was reviewed and approved by the medical research ethics committee of Isfahan University of Medical Sciences (IR.MUI.RESEARCH.REC.1399.508), and informed consent was provided by parents before randomization.

Results

As illustrated in Figure 1, a total of 32 infants were finally analyzed in two groups: Group I, who received the oral stimulation program once a day ($n = 16$; nine boys and seven girls), and Group II, who received this program twice a day ($n = 16$; ten boys and six girls). However, two infants in Group I passed away after the intervention period, and hence 14 infants were included in the analysis of dependency on tube-feeding upon discharge in this group. Also, one infant was discharged with tube feeding, and his parents did not inform us of the time of full oral feeding. As a result, the transition time in Group I was calculated in 13 infants. Other outcomes were analyzed for 16 infants in each group.

The Shapiro–Wilk tests showed all studied variables ($p > 0.05$) except the POFRAS scores progress ($p < 0.01$) are normally distributed. Independent samples t-tests demonstrated no significant differences between groups regarding the mean gestational age (GA), birth weight, PMA, and weight at the beginning of the intervention ($P > 0.05$) (Table 1). The mean of POFRAS scores was also not significantly different before intervention (22.63 ± 4.08 in Group I and 20.13 ± 5.89 in Group II; $P = 0.17$).

Table 2 shows the results of between-group comparisons on transition time, weight gain, and the POFRAS score progress immediately after the intervention. The mean of transition time was 24.54 ± 17.72 days in Group I vs. 22.69 ± 7.93 days in Group II, and this difference was not statistically significant ($p = 0.73$). Both groups

significantly improved the mean of POFRAS scores during the intervention period based on paired samples t-test analysis of before and after treatment scores (from 22.63 ± 4.08 to 27.69 ± 3.14 in Group I; and from 20.13 ± 5.89 to 28.88 ± 3.00 in Group II; $P < 0.001$ for both groups). The POFRAS score was, however, significantly more

improved in Group II (8.75 score in Group II vs. 5.06 score in Group I, $P = 0.045$) (Table 2). Fourteen (87.50%) of 16 infants who had received the oral stimulation program twice a day were discharged from the hospital without tube-feeding, in contrast to eight (57.14%) of 14 infants in Group I ($p = 0.061$).

Table 1. Baseline Demographic Characteristics of Preterm Infants by Group

Group	N	GA[wk]	Birth Weight[g]	PMA at the beginning of the intervention[wk]	Weight at the beginning of the intervention[g]
		Mean \pm SD	Mean \pm SD	Mean \pm SD	Mean \pm SD
I	16	29.06 ± 1.49	1175.00 ± 247.43	30.24 ± 1.35	1190.31 ± 207.54
II	16	28.67 ± 1.91	1148.44 ± 207.40	30.21 ± 1.16	1228.13 ± 178.31
P-Value		0.53	0.74	0.94	0.59
Total	32	28.87 ± 1.70	1161.72 ± 224.99	30.22 ± 1.24	1209.22 ± 191.29

Abbreviations: GA, gestational age; wk, weeks; g, grams; PMA, postmenstrual age. Independent T-tests were used to compare the values between groups.

Table 2. Between-group Comparisons of Clinical Outcomes

Variable	Group I Mean \pm SD (min-max) N=13	Group II Mean \pm SD (min-max) N=16	P-Value
Transition Time (day)	24.54 ± 17.72 (4-63) N=13	22.69 ± 7.93 (9-36) N=16	0.73
Weight gain	230.31 ± 89.77 (85-395) N=16	273.13 ± 150.31 (85-620) N=16	0.34
POFRAS score progress	5.06 ± 3.59 (0-13) N=16	8.75 ± 5.48 (3-20) N=16	0.045

Independent T-tests were used to compare transition time and weight gain between groups.

Mann-Whitney U test was performed to compare the mean of POFRAS score progress between groups.

Discussion

Among the proposed approaches to promote oral feeding skills in preterm infants, oral stimulation program and non-nutritive sucking (1) have had the most evidence of effectiveness. Several papers (5–8, 18) have described the results of administering this program one or more times a day. No studies, however, have compared the effects of different frequencies of performing this program on the infants' oral feeding skills. Considering the workload of the NICU staff, we wanted to know if administering this program twice a day necessarily has an advantage over performing it once. Moreover, we wanted to know if waking up, manipulating, stimulating, and having infants practice sucking twice a day may disturb the weight gain of preterm infants.

Our results showed that the infants receiving twice-daily oral stimulation experienced a 2-day shorter transition time than those receiving once-daily stimulation. Although this difference was

slight and not statistically significant, it may be clinically important, especially for mothers. Considering excluding three infants from Group I regarding this functional outcome, increasing the sample size could probably help to conclude more precisely. Fucile, Gisell, and Lau (1) indicated that the transition time in infants receiving once-daily oral stimulation program is seven days shorter than in infants receiving a sham stimulation program. Fucile et al. (18), when administering the oral stimulation program twice a day, observed a 9-day shorter transition time compared to the control group. Although these studies (1, 18) did not compare the frequency of the oral stimulation program, their results are almost in line with the present study and show that two repeats of this program during a day shorten the transition time more.

In our hospital, mothers were encouraged to breastfeed their infants exclusively after tube weaning. More than 87% of infants in Group II

were breastfed upon discharge compared to 57% of infants in Group I. In other words, the ratio of infants who had reached full oral feeding upon discharge to those who were still tube-fed was almost 1.3 to 1 in Group I and 7 to 1 in Group II. This difference was quite close to the significance level and clinically meaningful. Since the infants' ability to oral feed safely is a key factor determining discharge from NICU (19), the infants receiving two sessions of oral stimulation a day had a developmental advantage over those in Group I. Moreover, infants who were tube-fed for more extended periods and were deprived of pleasant oral stimulants during critical periods of development have been shown to be at higher risk for long-term altered oral sensitivity and additional feeding delays and difficulties (20).

One of the concerns of mothers and some staff was that increasing the frequency of implementation of the oral stimulation program during the day may be energy-consuming for the infants and interfere with their weight gain. The results, however, showed a very similar weight gain in both groups during 14 days of intervention. Therefore, the twice-daily implementation of the oral stimulation program seems not to have disadvantages for the weight gain of preterm infants.

Infants in both groups showed a significant increase in oral feeding readiness according to the POFRAS score after the intervention. Oral stimulation and NNS exercise seem to provide opportunities for infants to more efficiently use their oral structures and improve their level of oral feeding readiness (1). Infants receiving twice-daily oral stimulation program experienced significantly more progress in their level of oral feeding readiness than the infants in Group I. Therefore, oral feeding readiness seems to be more improved by increasing the training frequency of the oral stimulation program. The sucking practice part in this program is intended to teach a complex movement sequence to premature infants. Based on motor learning principles, when an intervention aims to establish a new movement sequence, repeated opportunities for practicing the sequence should be provided. In this situation, the infants can establish better relationships between movements and hence be more successful in retrieving the motor programs (21).

This study was the first to explore the optimal training frequency for a well-known stimulation program for promoting oral feeding skills in preterm infants. The strength of this study is that all staff and parents were blinded to the infant-

allocation group. The speech therapist who administered the treatment was also not aware of the POFRAS scores reported by the nurse. The most important limitation of this study was the limited sample size, especially after the exclusion of three infants from Group I. The possibility of this type of exclusion should be considered in the design of future similar studies, and the results of this study should be interpreted with caution. Longer recruitment periods or multi-center sampling may help to make a larger and more representative sample in future studies. Moreover, if the treatment had been continued until the start of infants' oral feeding, a more precise conclusion would have been reached about the differential effects of the treatment frequency. Also, if we had examined the oral feeding skills and nutritive sucking of infants during breastfeeding using tests such as Neonatal Oral-Motor Assessment Scale (NOMAS), we would probably have been able to observe more differences between the two groups.

Conclusion

Our findings indicated that when the oral stimulation program and non-nutritive sucking are implemented twice a day, compared to when they are executed only once, the probability of discharge of infants without a feeding tube may increase, and the level of their oral feeding readiness improves more, without having a detrimental effect on the weight gain of infants.

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Conflicts of interest

The authors declare no conflict of interest.

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