[Protocol for Clinical Trial]

The effects of direct swallowing training and oral sensorimotor stimulation in preterm infants

2015.07

NCT02508571

Table of Contents

[Clinical Trial Overview]

Clinical Trial Title	The effects of direct swallowing training and oral sensorimotor stimulation in preterm infants
Objective of the Clinical Trial	This study aims to evaluate whether the application of direct swallowing training (DST) and oral sensorimotor stimulation (OSMS) in preterm infants preparing for the transition from tube feeding to oral feeding shortens the time required for complete oral feeding and improves oral feeding skills. Additionally, the study will assess the long-term impact of oral feeding

	interventions in the neonatal intensive care unit (NICU) on developmental outcomes and dietary habits.
Phase of the Clinical Trial	Prospective, blind, controlled, randomized trial
Clinical Trial Institution	Seoul National University Hospital
Principal Investigator	Ee-Kyung Kim, Department of Pediatrics, Seoul National University College of Medicine
Study Design	single-center, prospective, open-label, controlled, randomized study
Study participants	-Gestational age at birth < 32+0 weeks -Eligible for respiratory support using heated humidified high-flow nasal cannula (HHHFNC) or equivalent, within 33+0 weeks -Infants who have been progressing with tube feeding at a volume of 120 ml/kg/day or more -Informed consent obtained from parents or legal guardians
Number of participants	189
Study methodology	In this study, preterm infants who are receiving adequate tube feeding and have been discontinued from continuous positive airway pressure (CPAP) for at least 48 hours will be divided into three groups: - Control Group -DST Group (Direct Swallowing Training) -DST + OSMS Group (Direct Swallowing Training + Oral Sensorimotor Stimulation) Each group will receive its respective intervention.
Study period	From IRB approval date in 2015 to December 30, 2025.
Outcomes	1. Time from initiation of oral feeding to full oral feeding 2. Oral feeding performance 3. Neonatal Oral Motor Assessment Scale (NOMAS) 4. Bayley Scales of Infant and Toddler Development, Third Edition: CA 18-24months 5. Korean Version of MacArthur-Bates Communicative Development Inventories (K M-B CDI): postnatal age 36 ± 2 months 6. Korean-Wechsler Preschool and Primary Scale of Intelligence (K-WPPSI)-Fourth Edition: 4:0~4:11 years 7. Korean Developmental Screening Test for Infants (K-DST) : postnatal age 48 ± 3 months 8. Strengths and Difficulties Questionnaire (SDQ) : postnatal age 48 ± 3

	months 9. Behavioral Pediatric Feeding Assessment Scale (BPFAS) : postnatal age 48 ± 3 months
Expected outcomes and potential impact	It is expected that the group receiving DST will show improved oral feeding abilities compared to the control group. Furthermore, the combination of OSMS with DST is anticipated to have a synergistic effect, further enhancing oral feeding skills. Additionally, it is expected that interventions during the neonatal period will have a lasting impact on long-term development and feeding behaviors.

1. Title of the clinical trial

The effects of direct swallowing training and oral sensorimotor stimulation in preterm infants

2. Name and Address of the Clinical Trial Institution

Institution Name: Seoul National University Children's Hospital
Address: 101 Daehak-ro, Jongno-gu, Seoul, 03080, Republic of Korea

3. Study period

From IRB approval date in 2015 to December 30, 2025.

4. Objectives of study

We will observe whether the application of direct swallowing training (DST) and oral sensorimotor stimulation (OSMS) to preterm infants, preparing for the transition from gavage feeding to oral feeding, shortens the period of transition to full oral feeding and improves oral feeding ability. Additionally, we will evaluate the long-term impacts of oral feeding interventions in the neonatal intensive care unit (NICU) on development, feeding behaviors, and other related factors.

5. Study Design

single-center, prospective, open-label, controlled, randomized study

6. Study participants

6.1 Participants

Preterm infants with a gestational age of less than 32+0 weeks, admitted to the NICU at Seoul National University Children's Hospital, who can be administered respiratory support with heated, humidified high-flow nasal cannula within 33+0 weeks and who have received gavage feeding of at least 120 ml/kg/d.

6.2 Target sample size and rationale for calculation

The primary objective of this study is to determine whether there is a difference in the time taken to reach full oral feeding, from the initiation of oral feeding, when DST and OSMS are applied to preterm infants preparing for the transition from gavage feeding to oral feeding.

To calculate the sample size required to achieve the research objective, the following assumptions are made:

Protocol_DST and OSMS_oral feeding performance

(1) Level of significance (α): 0.0167 (two-tailed test).
When comparing the control group with the DST group, the control group with the DST + OSMS group, and the DST group with the DST + OSMS group, there is an issue of multiple comparisons. To address this, Bonferroni correction is applied. The significance level used is 0.05/3 = 0.0167.

(2) Group ratio: Control group : DST group : DST + OSMS group = 1 : 1 : 1.

(3) Type II error (β): 0.20, maintaining a test power of 80%.

(4) Primary outcome: Days from start to full oral feeding (SOF-FOF).

(5) The hypothesis of the study is as follows:

[Hypothesis 1]
Null hypothesis: There is no difference in SOF-FOF days between the control group and the DST group.
Alternative hypothesis: There is a difference in SOF-FOF days between the control group and the DST group.

[Hypothesis 2]
Null hypothesis: There is no difference in SOF-FOF days between the control group and the DST + OSMS group.
Alternative hypothesis: There is a difference in SOF-FOF days between the control group and the DST + OSMS group.

[Hypothesis 3]
Null hypothesis: There is no difference in SOF-FOF days between the DST group and the DST + OSMS group.
Alternative hypothesis: There is a difference in SOF-FOF days between the DST group and the DST + OSMS group.

(6) Sample size calculation method: The PASS program (Power Analysis and Sample Size software; http://www.ncss.com) will be used.

Based on existing research data (16, 18), the average SOF-FOF days for each group were assumed as follows: Control group 20.8 days, DST group 14.6 days, and DST + OSMS group 10.0 days. The pooled standard deviation was calculated to be 7.19. With a significance level of 1.67% and a two-tailed test, the required sample size for 80% power is 56 participants per group, for a total of 168 participants.

Assuming a 10% dropout rate, the final sample size, accounting for dropouts, is 189 participants.

6.3 Recruiment method for study participants

The guardians of eligible participants will be approached to obtain their consent for participation in the study. Detailed information about the study will be provided to them, including its objectives, procedures, potential risks, and benefits. Informed consent will be obtained from the guardians before the preterm infants are enrolled in the study. All necessary ethical considerations and guidelines will be followed during the recruitment process, ensuring the confidentiality and protection of the participants' privacy.

6.4 Inclusion and Exclusion criteria for enrolment

6.4.1. Inclusion criteria

(1) Preterm infants with a gestational age of less than 32+0 weeks.

(2)Infants currently receiving sufficient tube feeding (at least 120 ml/kg/day).

(3) Infants who can be treated with heated, humidified high-flow nasal cannula (HFNC) within 33+0 weeks.

(4) Infants who only have feeding-related issues remaining, with no need for special medical treatment.

(5) Infants whose parents voluntarily sign the informed consent form for participation in the study.

6.4.2. Exclusion criteria

(1) Infants with major congenital malformations, such as those affecting the face, central nervous system, gastrointestinal system, or heart.

(2) Infants with gastrointestinal complications.

(3) Infants with chronic medical conditions, such as Grade 3 or higher intraventricular hemorrhage (according to the classification by Papile et al), periventricular leukomalacia, or those who have undergone surgical treatment for necrotizing enterocolitis.

7. Study procedures

7.1 Screening

Evaluation items: gestational age at birth, participant consent, assessment of inclusion/exclusion criteria

7.2 Randomization

In this study, eligible participants who meet all the inclusion criteria will be randomly assigned in a

1:1:1 ratio to the control group, the DST group, or the DST + OSMS group. However, randomization will be stratified by gestational age and sex.

The randomization will be done using a block randomization method with block sizes of 3 and 6, generated through SAS 9.2. The randomization process will be managed via the MRCC website (http://mrcc.snu.ac.kr) using web-based randomization.

The detailed randomization procedure is as follows:
- Study coordinators will be provided with an ID and password for randomization.
- The study coordinators will log in to the MRCC website (http://mrcc.snu.ac.kr) and access the randomization screen.
- The study coordinator will enter the participant's basic information, test results, inclusion/exclusion criteria, and other relevant data, and click the confirmation button.
- If the participant is eligible, a randomization number will appear on the screen.
- The randomization screen will be printed, and one copy will be kept for records.
- The study coordinator will use the assigned randomization number to prescribe the corresponding intervention.

7.3 Intervention protocol

7.3.1. Initiation

The intervention will begin at the point when the preterm infant, who is receiving sufficient feeding via gavage (≥ 120 ml/kg/d), has reached a postmenstrual age (PMA) of at least 28 weeks and has been at least 48 hours since the removal of nasal continuous positive airway pressure (CPAP) therapy.

7.3.2. Frequency of implementation and the duration of each intervention

- DST group: The intervention will be administered once a day, for 15 minutes each session.
- DST + OSMS group: Both interventions will be applied once a day. DST will be administered once a day for 15 minutes, and OSMS will be performed once a day for 15 minutes as well. The order of the interventions is not specified, so they can be done in any sequence.
- Both groups will receive their respective interventions 5 times a week.

7.3.3 Discontinuation of intervention

The intervention will be discontinued when the infant can feed orally without requiring special treatment (including apnea, bradycardia, and oxygen desaturation) for two consecutive days during all feedings.
- If the infant is disrupted by factors such as taking sedatives or undergoing ophthalmologic exams

within 30 minutes prior to the intervention, the intervention will not be applied that day.

- During the intervention, if any hemodynamic instability, apnea, bradycardia, or oxygen desaturation that does not resolve spontaneously occurs, the intervention will be stopped early. The intervention will only resume once the infant has stabilized and returned to a stable condition.

7.3.4. Detailed method for each intervention

Both the experimental group and the control group will continue the use of non-nutritive sucking through a rubber nipple and oral support during feeding, which are currently standard practices in the neonatal intensive care unit.

7.3.4.1. Direct swallowing training (DST)

The procedure will be carried out between feedings, lasting a total of 15 minutes.

Amount administered at one time: Formula milk (or distilled water if the caregiver refuses) is given at 1 ml. The administration starts with 0.05 ml using a syringe, gradually increasing by 0.05 ml increments while checking for the presence of a swallowing reflex. Once this threshold is determined, the procedure will continue using that dose. The maximum volume administered will not exceed 0.2 ml.

Administration site: The milk will be dropped onto the tongue at a level approximately where the soft palate and hard palate meet, specifically in the central-to-posterior region of the tongue.

Interval between administrations: The procedure will be performed at 30-second intervals for a total of 15 minutes.

7.3.4.2. Oral sensorimotor stimulation (OSMS)

The procedure will be carried out 15-30 minutes before the tube feeding, specifically during behavioral stages 3-5, and the total duration will be 15 minutes.

Composition		**stimulation**	**Objective**	**Duration**
Triggering sucking reflex	Cheek	1) Place the index finger on the philtrum (the area above the upper lip). 2) Gently press and apply pressure, moving towards the ear and then back to the corner of the mouth, tracing a "C" shape.	Enhance the range of motion and strength of the cheeks, and improve lip closure.	4 min.

	Curling and pulling the upper and lower lips	1) Place the index finger at the center of the upper lip. 2) Continue pressing and pull downward, rolling the lip. 3) Place the index finger at the center of the lower lip, press, and pull upward, rolling the lip.	Enhance lip strength, range of motion, and lip closure.	30 sec
Upper lip		1) Place your index finger on one side of the upper lip. 2) Gently press down. 3) Move your finger in a circular motion, starting from one end, passing through the center of the lips, and ending at the opposite side.	Improvement of lip range of motion and lip closure strength.	30 sec
Lower lip		1) Place your index finger on one corner of the lower lip. 2) Gently press down. 3) Move in a circular motion, starting from one corner, passing through the center of the lip, and continuing to the opposite corner.	Improvement of lip range of motion and lip closure strength.	30 sec
Inside of the cheek		1) Place your finger on the inside of the corner of the mouth. 2) Gently press and move towards the molars, then return to the corner of the mouth.	Improvement of the range of motion of the cheeks and lip closure.	1 min
Upper gums		1) Place your finger on the center of the upper gums and press firmly, slowly moving inward inside the mouth.	Range of tongue motion, swallowing stimulation, and	40 sec

	2) Slowly return to the center.	sucking improvement.	
Lower gums	1) Press your finger firmly on the center of the lower gum and slowly move it inward. 2) Slowly return to the center.	Range of tongue motion, swallowing stimulation, and sucking improvement.	40 sec
Side of the tongue	1) Place your finger between the side of the tongue and the gum near the molars. 2) Move your finger toward the center while pushing the tongue in the opposite direction. 3) After pushing the tongue, immediately return to the cheek and stretch it as much as possible.	Tongue range of motion and strength enhancement	30 sec
Dorsal surface of the tongue	1) Place the index finger in the center of the mouth. 2) Press against the hard palate for 3 seconds. 3) Place your finger on the center of the tongue and press down firmly. 4) Immediately return to the center of the hard palate after pressing the tongue.	Tongue range of motion and strength enhancement, swallowing stimulation, sucking improvement	40 sec
Induce sucking	1) Place your finger in the center of the palate and gently rub it to induce sucking.	Sucking improvement, velum activation	3 min
Pacifier	1) Place the pacifier in the mouth and gently move it in a rhythmic motion, up/down and front/back.	Sucking improvement, velum activation	3 min.

10.4.3.3 For blind study

For the blind study, all interventions are conducted with the screen in place. For the control group, the researcher spends time with the patient next to them while keeping the screen up at the same time as in the intervention group. The researcher inserts their hand into the incubator and spends 15 minutes without performing any interventions.

8. Study evaluation

8.1 Basic cllinical factors

- Gestational age, birth physical measurements, sex, singleton/twin, delivery type, Apgar score, umbilical cord blood gas findings, birth place, pregnancy complications, use of antenatal steroids, presence of pathological chorioamnionitis
- Public insurance status (general insurance vs. social assistance), marital status, parents' education level, parents' age, parents' occupation
- Neonatal respiratory distress syndrome, confirmed sepsis, patent ductus arteriosus (treatment status), abnormal findings on brain ultrasound, necrotizing enterocolitis requiring medical treatment, apnea of prematurity (treatment status), timing of discontinuation of apnea medication, feeding intolerance (treatment status), neonatal rickets, bronchopulmonary dysplasia, duration of mechanical ventilation (invasive, non-invasive, supplemental oxygen)
- Age (postnatal days, postmenstrual age) and physical measurements, feeding volume, and respiratory support methods at the following time points:
  * When the initial gavage feeding starts,
  * When the intervention begins,
  * When the feeding volume reaches 120 ml/kg/d,
  * When the first oral feeding begins,
  * When the oral feeding volume reaches 50% and 100% of 120 ml/kg/day,
  * When all feeding transitions to oral feeding, regardless of feeding-related side effects,
  * When full oral feeding is possible without any feeding-related side effects that require special treatment (end of intervention),
  * When full oral feeding is possible without any feeding-related side effects.
- The day of birth weight recovery, duration of TPN, duration of gavage feeding, type of milk, period until resolution of feeding-related apnea, bradycardia, and oxygen saturation decrease after reaching full oral feeding.
- Total hospitalization period, age (in postnatal days, postmenstrual age) and physical measurements at discharge.
- Results of developmental assessment tests for long-term developmental evaluation in eligible patients for clinical purposes:
  * Bayley Scales of Infant and Toddler Development, 3rd Edition (corrected age 18-24 months)

(Indications: GA < 32 weeks or BW < 1500g)

* Korean version of the McArthur-Bates Communicative Development Inventory (at 36±2 months) (Indications: GA < 32 weeks)

* Korean Wechsler Preschool and Primary Scale of Intelligence, 4th Edition (K-WPPSI-IV) (from 4 years to less than 5 years of age) (Indications: GA < 29 weeks or BW < 1000g)

8.2 Clinical observation factors

8.2.1. Vital signs: SpO2, blood pressure, heart rate, respiratory rate

8.2.2. Indicators for evaluating the patient's condition before feeding

(1) Behavioral organization states

State	Descriptor
1	Deep sleep
2	Light sleep
3	Drowsy or semi-dozing
4	Quiet alert
5	Active alert and aroused
6	Highly aroused, agitated, upset, and/or crying

2) Feeding readiness behaviors :

①Crying near scheduled feeding time
② Increased general activity level (involving increased heart rate)
③ Hand-to-mouth and sucking on hand
④ sucking pacifier

(If none of 1, 2, or 3 apply, provide a pacifier, and if sucking is present, check item 4.)

8.2.3. Indicators for evaluating oral feeding performance

Data will be collected through three evaluations:

1) The time point when oral feeding starts,
2) The time point when oral feeding volume reaches 50% of total feeding volume,
3) The time point when oral feeding volume reaches 100% of total feeding volume.

-Overall transfer (% volume taken/volume prescribed)
-Proficiency (% volume taken at 5 min/volume prescribed)

Protocol_DST and OSMS_oral feeding performance

-Rate of transfer (mL/min volume of milk consumed relative to the duration of the oral Feeding session)

-Volume loss (% volume of milk spilled from the lips as a percentage of the total milk transferred)

8.2.4. Neonatal Oral Motor Assessment Scale (NOMAS)

Evaluation time points:

1) Between 3-5 days after the start of oral feeding,

2) Within 3 days after the end of the intervention.

8.2.5. Korean Developmental Screening Test for Infants and Toddlers (K-DST), Strengths and Difficulties Questionnaire (SDQ), Behavioral Pediatric Feeding Assessment Scale (BPFAS)

Survey time point: 48 months of age ± 3 months

Survey method: The survey will be conducted by implementing a web-based questionnaire, which will be sent via email or smartphone and returned through the same method.

8.3 Outcome

8.3.1. Primary outcome: The period from the start of oral feeding to the time when full oral feeding is achieved without any feeding-related side effects requiring special treatment.

8.3.2. Secondary outcomes

- The period from the start of oral feeding to the first achievement of full oral feeding
- The period from the start of oral feeding to the achievement of full oral feeding without any feeding-related side effects
- Overall transfer, proficiency, rate of transfer, volume loss
- length of hospital stay
- NOMAS
- Bayley Scales of Infant and Toddler Development (Bayley-III)
- Korean version of the McArthur-Bates Communicative Development Inventory (K-MBCDI)
- Korean Wechsler Preschool and Primary Scale of Intelligence (K-WPPSI-IV)
- Korean Developmental Screening Test for Infants and Toddlers (K-DST)
- Strengths and Difficulties Questionnaire (SDQ)
- Behavioral Pediatric Feeding Assessment Scale (BPFAS)

8.4 Statistical analysis methods

8.4.1. Definition of Analysis Sets

- ITT Analysis Set (Intent-to-Treat): Includes data from all pediatric patients who received at least one session of oral rehabilitation therapy and had at least one assessment of the outcome variable.
- FAS Analysis Set (Full Analysis Set): Includes data from the ITT set, excluding patients who did not meet the eligibility criteria or failed to undergo the primary outcome assessment.
- PP Analysis Set (Per-Protocol): Includes data from the ITT set, specifically from patients who strictly adhered to the clinical trial protocol by completing direct swallowing training or both direct swallowing training and sensory-motor stimulation therapy, with outcome variables assessed.

This study will conduct ITT, FAS, and PP analyses, with FAS analysis being the primary approach.

* Subgroup Analysis: Subgroup analysis will be performed based on gestational age, birth weight, and bronchopulmonary dysplasia.

8.4.2 Statistical Analysis Methods

- Statistical Software: SPSS for Windows (version 19.0)
- Continuous Variables: Mann-Whitney U test, One-way ANOVA
- Categorical Variables: Chi-square test, Fisher's exact test
- Evaluation of the Effect of Interventions on Primary and Secondary Outcomes:
  - Two-way analysis of variance
  - Repeated measures analysis of variance
  - Post-hoc analysis, if necessary
- Univariate/Multivariate Analysis: Binary and multiple logistic regression analysis
- Unless otherwise specified, all statistical tests will be conducted at a two-sided significance level of 0.05.

9. Drop out

<Criteria for Clinical Trial Dropout>

- When the guardian requests discontinuation of the clinical trial or withdraws consent for participation.
- When the participant experiences respiratory deterioration during the trial period, requiring the use of a respiratory device beyond nasal positive pressure ventilation.
- When the participant experiences gastrointestinal deterioration during the trial period, necessitating fasting for more than 48 hours.
- When a serious adverse event occurs.

10. References

1) American Academy of Pediatrics Committee on Fetus and Newborn.Hospital discharge of the high-risk neonate.*Pediatrics* 2008;122:1119-26.

2) Bragdon DB. A basis for the nursing management of feeding the premature infant. *JOGN Nurs* 1983;12(3 Suppl):51s-7s.

3) Gryboski JD. Suck and swallow in the premature infant. *Pediatrics* 1969;43:96-102.

4) Krauss AN, Brown J, Waldman S, Gottlieb G, Auld PA. Pulmonary functionfollowing feeding in low-birth-weight infants. *Am J Dis Child* 1987;132:139-42.

5) Lau C, Sheena HR, Shulman RJ, Schanler RJ. Oral feeding in low birth weight infants. *J Pediatr* 1997;130:561-9.

6) Bingham PM. Deprivation and dysphagia in premature infants. *J Child Neurol* 2009;24:743-9.

7) Choi HW, Park HW, Kim HY, Lim GN, Koo SE, Lee BS, et al. Feeding desaturation and effects of orocutaneous stimulation in extremely low birth weight infants. *J Korean SocNeonatol* 2010;17:193-200.

8) Kim HY, Bang KS.Effects of an oral stimulation program on the transition from tube to bottle feeding in premature infants.*J Korean AcadFundamNurs* 2011;18:160-7.

9) Lau C, Sheena HR, Shulman RJ, Schanler RJ. Oral feeding in low birth weight infants. *J Pediatr* 1997;130:561-9.

10) Lamm NC, De Felice A, Cargan A. Effect of tactile stimulation on lingual motor function in pediatric lingual dysphagia. *Dysphagia* 2005;20:311-24

11) Dodrill P, McMahao S, Donovan T, Cleghorn G. Current management of transitional feeding issues in preterm neonates born in Queensland, Australia. *Early Hum Dev* 2008;84:637-43.

12) Fucile S, Gisel EG, Lau C. Oral stimulation accelerates the transition from tube to oral feeding in preterm infants. *J Pediatr* 2002;141:230-6.

13) Pinelli J, Symington AJ. Non-nutritive sucking for promoting physiologic stability and nutrition in preterm infants (review). *Cochrane Database Syst Rev* 2005;19:CD001071.

14) Fucile S, Gisel EG, Lau C. Effect of an oral stimulation program on sucking skill maturation of preterm infants. *Dev Med Child Neurol* 2005;47:158-62.

15) Boiron M, DaNobrega L, Roux S, Henrot A, Saliba E. Effects of oral stimulation and oral support on non-nutritive sucking and feeding performance in preterm infants. *Dev Med Child Neurol* 2007;49:439-44.

16) Fucile S, Gisel EG, Mcfarland DH, Lau C. Oral and non-oral sensorimotor interventions enhance oral feeding performance in preterm infants. *Dev Med Child Neurol* 2011;53:829-35.

17) Fucile S, Mcfarland DH, Gisel EG, Lau C. Oral and nonoral sensorimotor interventions facilitate suck-swallow-respiration functions and their coordination in preterm infants. *Early Hum Dev* 2012;88:345-50.

18) Lau C, Smith EO. Interventions to improve the oral feeding performance of preterm infants.*ActaPaediatrica* 2012;101:e269-74.

19) Bang KS, Park JS, Kim JY, Park JY, An HS, Yun BH. Literature review on nursing intervention for premature infants in Korea*. J Korean SocMatern Child Health* 2013;17:49-61.

20) Park HR. Effects of nonnutritive sucking on heart rate, lingual lipase activity, and behavioral state of low birth weight infants.*가톨릭대학교 논문집* 1994;47:1027-37..

21) Shin HS. Effects of nonnutritive sucking on behavioral state in preterm infants. *Child Health Nurs Res* 1998;4:305-13.

22) Park HR, Park SN. Effects of nonnutritive sucking on lingual lipase activity and body weight of low birth weight infants with bottle feeding. *Child Health Nurs Res* 2001;7:236-44.

23) Joung KH, Yoo IY, Kim HS, Kim S, Lee JH.Effects of non-nutritive sucking on the physiological and behavioral states of preterm infants during tube feeding*. J Korean AcadNurs* 2006;36:732-41.

24) Park JH, Park HR. Effects of nonnutritive sucking on heart rate, oxygen saturation and behavioral state in preterm infants. *Child Health Nurs Res* 2007;13:299-307

25) Kim JE. The effects of oral stimulation program on oral feeding of premature infants. Unpublished master's thesis, *Seoul National University, Seoul.*

26) Poore M, Barlow SM,Wang J, EstepM, Lee J. Respiratory treatment history predicts suck pattern stability in preterm infants. JNeonatal Nurs 2008;14(06):185–192

27) Poore M, Zimmerman E, Barlow SM, Wang J, Gu F. Patterned orocutaneous therapy improves sucking and oral feeding in preterm infants. Acta Paediatr 2008;97(07):920–927

28) Li XL, Liu Y, Liu M, Yang CY, Yang QZ. Early premature infant oral motor intervention improved oral feeding and prognosis by promoting neurodevelopment. Am J Perinatol 2019. doi: 10.1055/s-0039-1685448. [Epub ahead of print]

29) Partridge JC, Babcock DS, Steichen JJ, Han BK. Optimal timing for diagnostic cranial ultrasound in low-birth-weight infants: detection of intracranial hemorrhage and ventricular dilatation. *J Pediatr* 1983;102:281-7.