

Using A Wechat Mini-Program-Based Lactation Consultant Intervention To Increase The Consumption of Mother's Own Milk Feeding of Preterm Infants In The Neonatal Intensive Care Unit: A Study Protocol For A Cluster Randomized Controlled Trial

Jie Huo

Yangzhou Maternity and Child Health Care Hospital <https://orcid.org/0000-0003-4127-0296>

Xinping Wu

Yangzhou Maternity and Child Health Care Hospital

Chuanli Gu

Yangzhou Maternity and Child Health Care Hospital

Zhangbin Yu

Nanjing Maternity and Child Health Care Hospital

Jun Zhang

Nanjing Maternity and Child Health Care Hospital

Xiaohui Chen

Nanjing Maternity and Child Health Care Hospital

Jingai Zhu

Nanjing Maternity and Child Health Care Hospital

Feng Liu

Nanjing Maternity and Child Health Care Hospital

Beibei Liu

Nanjing Maternity and Child Health Care Hospital

Qianqian Li

Xuzhou Maternity and Child Health Care Hospital

Shuping Han (✉ shupinghan@njmu.edu.cn)

Nanjing Maternity and Child Health Care Hospital <https://orcid.org/0000-0003-2077-1673>

Study protocol

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Abstract

Background: The benefits of Mother's Own Milk (MOM) for preterm infants have been widely recognized. Many studies have shown that the rate of breastfeeding of premature infants remains very low. Although many studies use measures to promote breastfeeding, few high-quality cluster randomized controlled studies have evaluated the effectiveness of these measures. In today's information age, WeChat mini-programs have been used by various groups and have been widely used to promote health and self-management in China. Based on this background, we designed a group randomized controlled study based on WeChat mini-programs to promote MOM feeding of premature infants in the neonatal intensive care unit (NICU).

Methods/Design: This study will evaluate the effectiveness of WeChat mini-programs to increase the consumption of MOM feeding in twelve NICUs in Jiangsu Province—six “intervention” NICUs and six “control” NICUs. The study process is as follows: (1) design and preparation; (2) NICU recruitment and training; (3) interpretation and analysis of baseline data; (4) quality control implementation process; (5) data analysis feedback and publication of study reports. The primary outcome is the proportion of MOM feeding of premature infants during NICU hospitalization. The secondary outcomes are as follows: (1) time to starting MOM feeding (hours) and proportion of first-time MOM feeding (%); (2) duration of parenteral nutrition (days); (3) time to total gastrointestinal feeding (days); (4) hospitalization time and hospitalization cost; (5) incidence of complications [necrotizing enterocolitis (NEC), bronchopulmonary dysplasia (BPD), feeding intolerance, late-onset sepsis (LOS), retinopathy of prematurity (ROP)].

Discussion: This study is a first cluster randomized controlled trial on the intervention of using a WeChat mini-program-based lactation consultant for premature infants in the NICU in China. We hope this study can improve NICU premature infants receiving more MOM during hospitalization through the intervention of WeChat mini-programs.

Trial registration: ClinicalTrials NCT04383379. Registered on May 5, 2020.

Background

The benefits of breastfeeding for preterm infants have been widely recognized, especially Mother's Own Milk (MOM) feeding, because it can not only reduce the incidence of preterm infant complications, such as retinopathy of prematurity (ROP) [1], necrotizing enterocolitis (NEC) [2,3], infection [4,5], and bronchopulmonary dysplasia (BPD) [6] but also improve the development of the nervous system [7] and the health status in adulthood [8].

In recent years, with the prevalence of prenatal lactation consultation, breastfeeding education and guidance, mothers of preterm infants have greatly improved their understanding of breastfeeding worldwide. However, a large gap persists in different regions and neonatal intensive care units (NICUs) for MOM feeding of preterm infants. The causes may be due to closed management practices at most NICUs in China and the prohibition of parents in the NICU ward. For each NICU, the measures of feeding and

other factors are related because they can directly affect the volume of breast milk expression of preterm mothers and whether preterm infants can accept MOM feeding. The American Academy of Pediatrics (AAP) suggests that premature infants should be breastfed as early as possible, and many hospitals have developed strategies to promote breastfeeding. The US Centers for Disease Control and Prevention (CDC) has suggested that breastfeeding should be promoted by professional institutions. MOM is considered the golden nutrition standard of NICU premature infants [9]. A multicenter study reported [10] that, in China, only 23% of premature infants in the NICU receive MOM feeding during hospitalization, and only partial MOM feeding, rather than exclusive MOM feeding. In 2020, the goal for healthy people is that the early postpartum breastfeeding rate is 75% [11], but the growth of the breastfeeding rate is very low or even stagnant [12].

Although many studies have been conducted to promote exclusive breastfeeding interventions, few high-quality randomized controlled trials have been performed. Breastfeeding interventions have been demonstrated to be effective in improving the rate of exclusive breastfeeding, especially individualized interventions, which are related to the promotion of breastfeeding [13]. The success of breastfeeding is influenced by socio-economic, cultural and personal factors (maternal age, disease, delivery mode, premature status) and other factors, which mainly depend on breastfeeding education and support provided by medical professionals [14-16].

In recent years, the number of smartphone users is increasing, and some devices will be an important part of health promotion and self-management [17]. Presently, many breastfeeding applications have been used in the clinic to help new mothers understand breastfeeding and breastfeeding guidance after discharge [18]. In 2019, an application app named "Milk Man" in Australia, which can record breastfeeding information and provide support for fathers and expectant fathers to prepare for breastfeeding during the whole perinatal period, showed strong applicability and good effect with the game form of forum communication [19]. In today's information age, WeChat is widely used by people of different ages, cultural backgrounds and industries. There are 1.15 billion monthly active users (2019, 11, 3), and it is one of the most popular social platforms in China. More than 300 million WeChat mini-programs are used every month [20]. WeChat mini-programs are applications that can be used without downloading and installation and can meet the needs of different people and industries. In the era of WeChat mini-programs, users only need to scan or search to use them, making these programs convenient and efficient directly.

Based on this background, we designed a lactation consultant intervention based on WeChat mini-program to promote the MOM feeding of premature infants in NICU. To further improve the quality of the intervention, we planned a cluster randomized controlled trial. Using the WeChat mini-program as a lactation consultant, we can improve the lactation of premature mothers so that premature infants can receive MOM feeding as soon as possible and more during the hospitalization of NICU to improve the prognosis of premature infants. If this study is successfully implemented and proved effective, it can be promoted in other NICUs in China.

Methods/design

Study objectives

The primary objective of the study is to increase the proportion of MOM feeding of premature infants during hospitalization in the NICU using the “Ning BX breastfeeding” WeChat mini-program lactation consultation intervention.

The secondary objectives of this study will be the following: (1) to shorten the time for premature infants to receive mother's milk for the first time and increase the proportion of first-time MOM feeding; (2) to shorten the time of duration of parenteral nutrition and achieve the full enteral gastrointestinal feeding as soon as possible; (3) to shorten the hospitalization time and reduce the hospitalization cost; (4) to reduce the incidence of premature complications, such as necrotizing enterocolitis (NEC), bronchopulmonary dysplasia (BPD), late-onset sepsis (LOS), and retinopathy of prematurity (ROP).

Study Design

In this study, the cluster randomized controlled matching design was used. The hospital was chosen as a cluster. The supervision unit is used for quality control, coordination and technical support during the entire study process. In this study, we will recruit 12 NICUs. The two NICUs with a similar number of premature infants, the same scale of NICU and proportion of MOM feeding in the same range taken as a floor are then randomly divided into two groups—an intervention group 6 NICUs and a control group 6 NICUs. The intervention group will use the “Ning BX breastfeeding” WeChat mini-program and routine management, while the control group will only use routine management (Fig. 1 and 2).

Hypothesis

We hypothesize that, if the “Ning BX breastfeeding” WeChat mini-program is implemented successfully, the proportion of MOM feeding of premature infants during hospitalization of NICU will increase by at least 15%; the second hypothesis is that the length of hospitalization and medical expenses will be reduced, and the quality of life of the premature infants will be improved.

Eligibility and exclusion criteria

Inclusion criteria

- Preterm infants weighing less than 2,000 g and/or with a gestational age of fewer than 34 weeks.
- All preterm infants have the informed consent of their guardians.

Exclusion criteria:

- Pregnancy with serious diseases, infectious diseases or other medical contraindications for breastfeeding (such as galactosemia);
- No parental consent.

Randomization

Because the intervention could not be completely blinded in this study, with randomized groups for units and considering that the scale of the NICUs involved is different, the whole-group matching design was adopted. Twelve units are randomized into two groups (intervention groups and control groups) instead of patients to avoid confounding of patients in control groups. Two NICUs with a similar number of premature infants, the same scale of NICU and the proportion of MOM feeding roughly in the same range taken as a floor were randomly divided into six groups. Next, the names of 12 units are written on paper and placed in the same envelope. One third-party individual blinded to this project takes one envelope from each of the six groups, and the six envelopes chosen are assigned to the intervention group. The remaining six envelopes are assigned to the control group.

Sample size calculation

The proposed sample size is based on the primary outcome of the proportion of MOM feeding. According to the baseline data reported (unpublished data) by each unit in 2019, the average proportion of MOM feeding is 42.46%. We expect the proportion of MOM feeding of premature infants during NICU hospitalization will increase by at least 15% in the intervention group compared with that in the control group. We will achieve 90% power to detect a difference between the group means of at least 6, and the standard deviation of subjects is 30.00, assuming the intracluster correlation coefficient is 0.005[21,22]. We estimate that a total sample size of 1,620 (810 in the intervention group and an average of 135 each in group). Considering a 10% drop-out rate following enrolment in the study, we will enroll 900 premature infants for the intervention and control groups. To achieve this sample size, we will conduct a one-year study in 12 NICUs.

Intervention

In 2019, the “NingBX neonatal homogeneity platform” team developed a WeChat mini-program named “Ning BX breastfeeding”, which is used to solve the problems related to breastfeeding and lactation consultation of premature infants and mothers with NICU mother-infant separation. The “Ning BX breastfeeding” WeChat mini-programs has been in the trial phase at Nanjing Maternity and Child Health Care Hospital, with very promising results. The “Ning BX breastfeeding” WeChat mini-program is divided into the Doctor version and Patriarchal version. Through scanning the corresponding QR code, a mobile number can be entered and used to register and log in. A mobile number can only be registered once to protect the privacy of users and prevent information leakage. By binding the corresponding hospital and designating the doctor, information can be shared. The “Ning BX breastfeeding” WeChat mini-program is divided into four parts (Fig. 2): Mother's Daily, Baby Feeding, Growth Record and Growth Curve.

Part 1 Mother's Daily

Mother's daily is used to record lactation information, such as the number of times of pumping, volume of feeding by pumping, number of times of feeding and volume of feeding. The mother can record the

time, place, mode and volume of each pump in detail, and a curve will be constructed between the number and volume of pumps. By continuously uploading information from the mother, breastfeeding evaluation can be automatically generated, such as the first lactation time, the start time of lactation phase II and the start time of lactation, which are divided into three levels: good, commonly and bad. This part can record the whole process of mother's lactation, which is different from the traditional paper diary or by recall recording the information of pump milk. It can more timely and more accurately understand the lactation information and can timely provide professional guidance and intervention for mothers who have difficulty starting lactation.

Part 2 Baby Feeding

Baby feeding is used to record the daily feeding information of the premature infant discharged from the NICU after returning home. The mother can upload the time, volume, type (mother's own milk, amino yogurt, ordinary formula) and daily weight of the infant. It can evaluate whether the infant is fed adequately and whether the weight growth is within the normal range according to the amount and weight of the infant to guide the mother of premature infant on whether professional outpatient consultation is needed. Because this study is focused on premature infants during hospitalization, this section is not currently available.

Part 3 Growth Record

The growth record is used to interact with mothers of preterm infants admitted to the NICU. Doctors or nurses can upload photos of babies in the NICU for separated from mothers and infants so that mothers can be informed about the current situation by uploading photos of babies every day and to promote earlier lactation by mothers with the help of daily photos. Additionally, this part also has the function of communication. The mothers of premature infants can communicate with the binding doctor, ask about the current diagnosis and treatment of the baby and feeding situation, consult about difficulties and challenges encountered in the process of breastfeeding, and obtain responses from professional personnel. During the novel coronavirus (2019-nCoV) epidemic period, this function has played a great role and truly achieved "isolated viruses, not isolated love".

Part 4 Growth Curve

A growth curve is used to record the growth indicators of premature infants, such as weight, length, and head circumference, and carry out nutritional risk assessment and feeding guidance using the weight, length and head circumference. The mother can regularly upload the baby's weight, length and head circumference records, automatically generate the Fenton growth curve, and carry out nutrition risk assessment to determine whether the baby's growth and development are normal. Additionally, the growth curve can give feeding guidance or suggestions for the growth and development clinic according to the assessment results. Presently, this section is not available.

Pre intervention training

Before the study, the supervision unit shall be responsible for the training on the use of the “Ning BX breastfeeding” WeChat mini-program and development of a user guide. The intervention group unit needs to establish a “Ning BX breastfeeding” WeChat mini-program implementation team, comprising at least one neonatologist and one neonatal nurse. Each participant needs to be trained in the use of the “Ning BX breastfeeding” WeChat mini-program and master the ability to teach parents how to use it. Each intervention group unit shall formulate a corresponding implementation process based on the actual management situation of the unit. The supervision unit shall set up a “Ning BX breastfeeding” WeChat mini-program communication group to communicate difficulties and doubts encountered in the implementation process over time and provide help to some units with relatively difficult implementation.

Implement process quality control

The supervision unit is responsible for the quality control, technical support and experience transfer of the entire implementation process and is assigned by a dedicated person. The unit includes the following aspects: ☒ The supervision unit regularly assigns professionals to the site to provide guidance and propose problems and solutions; ☒ Each participating unit surveys the user experience with the mini-program initially, during and after use, if needed later; ☒ The “Ning BX breastfeeding” WeChat mini-program data will be exported every month for data quality control, feedback problems, and timely update; ☒ A face-to-face experience sharing and communication meeting between the doctor version user and patriarchal version user will be held to promote the best use of the WeChat mini-program.

Control group

The control group is given routine management according to the existing management measures and policies of the unit, such as traditional education and completing a breast milk paper diary. The control unit does not use the “Ning BX breastfeeding” WeChat mini-program.

Data collection

The data collection of this study was performed according to the online database “NingBX neonatal homogeneity platform” (<https://www.ningbx.com/>) developed by a collaboration group in 2019. The basic data required for this study, such as the birth time, gestational age, weight, diagnosis and treatment process, complications, outcome, and other information, are all from the online database. The data related to breastfeeding are also obtained from online databases, such as MOM at starting feed (hours), proportion of first-time MOM (%), duration of parenteral nutrition (days), time to total gastrointestinal feeding (days), the total volume of breastfeeding per day, and the total volume of breastfeeding during hospitalization. All the data in the online database are from professional personnel who are trained and qualified for entry will be the input. The database quality control personnel shall regularly control and feedback the data, and the database can modify and update the information in time, as well as export the

data in real time for data quality control and statistical analysis. Some contents of the database are as follows (supplementary file 1).

Data management

Nanjing Maternity and Child Health Care Hospital, as the supervision unit, formulates the database entry guide and provides a detailed definition of each variable in the database to ensure the consistency of data entry. The data entry personnel shall be doctors or postgraduates with a rich clinical experience in neonatology, and the chief physician of Neonatology or personnel with a higher professional title shall be data quality control personnel. The supervision unit is responsible for the selection, training and assessment of the input, as well as quality control personnel of the cooperation group. Only those who regularly participate in the training and pass the assessment can participate in the data entry work and become database entry personnel. Additionally, the supervision unit is responsible for regular training, mid-term assessment and year-end summary of data entry during the whole research period. The supervision unit will hold an online meeting for the quality controller and recorder every month to discuss the problems encountered in the recent input and quality control data, rectification plan, and experience sharing. The professional personnel in charge of the database management of the supervision unit will conduct unified quality control for all data, make a summary and feedback the opinions to all participating units in a timely manner. Statistical experts will analyse the data every three months, summarize the statistical results, and recheck and update the ambiguous results.

Data Association

The Doctor version and Patriarchal version data of the WeChat mini-program can be shared and stored in online database. The online database has a special data export function for the “Ning BX breastfeeding” WeChat mini-program. The three form a closed loop, which can realize the timely export and sharing of the data (Fig. 3).

Statistical Analysis

Statistical analysis will be performed by statisticians; continuous variables will be presented as the means and standard deviation, and categorical variables as numbers and proportions. Adjusted chi-squared analysis will be used to compare the primary outcome indicators of the intervention group and control group, and the cluster effect will be considered. The two-level stratified logistic regression model will be used to compare the main outcome indicators between the two groups. Evaluation of neonatal characteristics (such as gestational age, small for gestational age, gender, and 5-min Apgar score) and NICU characteristics (number of preterm infants admitted and rate of MOM feeding) was adjusted. All statistical tests will be two-tailed, and $P < 0.05$

will be considered significant.

Outcome and definitions

The primary outcome is the proportion of MOM feeding of premature infants during NICU hospitalization.

The secondary outcomes are as follows: \square MOM at starting feed hours \square and proportion of first time MOM(%); \square duration of parenteral nutrition (days); \square time to total gastrointestinal feeding (days); \square hospitalization time and hospitalization cost; \square incidence of complications \square such as NEC, BPD, LOS, and ROP.

Table 1 Outcome and definitions

Categories		Source of data	Implement process control	Definitions
Primary Outcomes	Proportion of MOM feeding of premature infants during NICU hospitalization[23]	Online database	Continuous data entry of each unit regular data export for statistics	Calculated to determine the relative amount of MOM and total milk \square human milk+formula, TM \square taken by each infant during NICU hospitalization $[mLsMOM/mLsTM]*100$
Secondary outcomes	Time (h) of first mother's own milk and proportion of mother's own milk (%)	Online database	Continuous data entry of each unit regular data export for statistics	Time after birth to the first MOM and proportion of the first MOM to the total milk
	Duration of parenteral nutrition (d)	Online database		Duration of total parenteral nutrition required for complete fasting in preterm infants
	Time to full enteral gastrointestinal feeding (d)	Online database	Full enteral gastrointestinal feeding is defined as no longer in need of parenteral nutrition or fluid	
	Hospitalization time and hospitalization cost	Online database	Hospitalization time refers to the time in NICU, and hospitalization cost refers to the total cost during hospital stay	
	Incidence of complications (NEC, BPD, LOS, and ROP)[24]	Online database	Incidence of common complications in preterm infants, such as necrotizing enterocolitis \square NEC \square , bronchopulmonary dysplasia (BPD), late-onset sepsis(LOS), and retinopathy of prematurity (ROP)	

Discussion

This is the first cluster randomized controlled trial in China in which a WeChat mini-program is used to improve MOM feeding during hospitalization of premature infants. The goal of this study is to increase NICU premature infants receiving MOM during hospitalization through the intervention of a WeChat mini-program. If the implementation of the program is successful, it can be promoted in other NICUs.

Breastfeeding for mothers of NICU preterm infants faces more challenges than that for mothers of full-term infants. Foreign studies have shown that the rate of MOM feeding of premature infants in the NICU is 76% [25]. However, a multicenter study in China has found that the rate of exclusive MOM feeding of premature infants during hospitalization is only 20% [26]. Such a large gap is not only related to the management policy of the NICU in China but also related to the anxiety and negative emotions of mothers and their families of premature infants and, more importantly, to the lack of effective lactation counseling interventions. WeChat mini-program can help mothers of preterm infants better participate in the medical process, enhance the emotional communication between mothers and infants, and help to prolong breastfeeding. Family members and society should be encouraged to provide more support to pregnant women to improve their confidence in breastfeeding. The purpose of this study was to evaluate the effect of WeChat mini-program lactation consultation on increasing the proportion of MOM feeding in premature infants in the NICU. We assume that the proportion of MOM feeding in the intervention group will be much higher than that in the control group, and this project can be carried out for a long time.

Our study has several limitations. First, the participating units of this study are distributed in all parts of Jiangsu Province. Although they can represent the situation of all regions, there may be some regional biases due to the different management modes of NICUs. Therefore, in the early stage of this study, we conducted the baseline data to avoid differences due to different NICU policies. Considering that this study is randomized to units, some patient potential confounding factors, such as gestational age, birth weight or treatment level, cannot be completely controlled. To reduce the possible deviation between the two groups, multilevel models will be used to compare the primary outcome indicators of the two groups, and these potential confounding factors will be adjusted in the analysis stage.

The significance of our study is to improve the MOM feeding of premature infants during NICU hospitalization using WeChat mini-program to carry out lactation consultation intervention and evaluate the effectiveness of WeChat mini-program, so that it can be promoted nationwide in the future and more premature infants can benefit.

Abbreviations

NICU :neonatal intensive care unit; MOM :Mother's Own Milk; PDSA :plan-do-study-act; NEC:necrotizing enterocolitis; BPD: bronchopulmonary dysplasia; LOS :late-onset sepsis; ROP :retinopathy of prematurity ; AAP :American Academy Pediatrics; CDC : Centers for Disease Control and Prevention.

Declarations

Trial status

The study began in June 2020, and patient registration started in June 2020. The internal pilot study will be completed by the end of June 2020. This research is in the main research stage. Officially registered and completed in March 2021. The whole project will be completed in May 2021. Protocol version number 1.2.

Ethical approval and consent to participate

Central ethics approval is obtained from The Medical Ethics Committee of Nanjing Maternity and Child Health Care Hospital (Reference No. [2020] KY-017). The ethical approval is applicable to all participating research centers.

All participants will obtain written informed consent from their parents or legal guardian (supplementary file 2).

Authors' contributions

SH and ZY planned the study. SH and XP designed the study. SH and JH provided ethical support and registered the study. JH, CG and XW wrote the study protocol and revised the manuscript. SH, BL, ZY and XC performed a critical revision of the manuscript. JZ, and QL provided the statistical analysis. All the authors read and approved the final version.

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Availability of data and materials

The baseline data and analyzed in the current study are available from the corresponding authors upon reasonable request.

Consent for publication

Not applicable.

Competing interest

All authors declare that there is no conflict of interest in this study.

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Author details

¹ Department of Neonatology, Yangzhou Maternity and Child Health Care Hospital, Yangzhou225002, China;² Department of Neonatology, Nanjing Maternity and Child Health Care Hospital, Nanjing Medical University, Nanjing 210004, China; Department of Neonatology, Xuzhou Maternity and Child Health Care Hospital, Xuzhou221009, China.

References

- [1] Manzoni P, Stolfi I, Pedicino R, et al. Human milk feeding prevents retinopathy of prematurity (ROP) in preterm VLBW neonates[J]. *Early Hum Dev*,2013,89 Suppl 1:S64-S68.
- [2] Alshaikh B, Kostecky L, Blachly N, et al. Effect of a Quality Improvement Project to Use Exclusive Mother's Own Milk on Rate of Necrotizing Enterocolitis in Preterm Infants[J]. *Breastfeed Med*,2015,10(7):355-361.
- [3] Sullivan S, Schanler R J, Kim J H, et al. An exclusively human milk-based diet is associated with a lower rate of necrotizing enterocolitis than a diet of human milk and bovine milk-based products[J]. *J Pediatr*,2010,156(4):562-567.
- [4] Meier P P. Human Milk and Clinical Outcomes in Preterm Infants[J]. *Nestle Nutr Inst Workshop Ser*,2019,90:163-174.
- [5] Duijts L, Jaddoe V W, Hofman A, et al. Prolonged and exclusive breastfeeding reduces the risk of infectious diseases in infancy[J]. *Pediatrics*,2010,126(1):e18-e25.
- [6] Kim L Y, Mcgrath-Morrow S A, Collaco J M. Impact of breast milk on respiratory outcomes in infants with bronchopulmonary dysplasia[J]. *Pediatr Pulmonol*,2019,54(3):313-318.

- [7] Corpeleijn W E, Kouwenhoven S M P, Paap M C, et al. Intake of Own Mother's Milk during the First Days of Life Is Associated with Decreased Morbidity and Mortality in Very Low Birth Weight Infants during the First 60 Days of Life[J]. *Neonatology*,2012,102(4):276-281.
- [8] Vohr B R, Poindexter B B, Dusick A M, et al. Beneficial effects of breast milk in the neonatal intensive care unit on the developmental outcome of extremely low birth weight infants at 18 months of age[J]. *Pediatrics*,2006,118(1):e115-e123.
- [9] Petersen R. A 2017 Update: Centers for Disease Control and Prevention's Contributions and Investments in Breastfeeding[J]. *Breastfeed Med*,2017,12(8):465-467.
- [10] Wang D H. [Multicenter study of the nutritional status of premature infants in neonatal intensive care unit in China: report of 974 cases][J]. *Zhonghua Er Ke Za Zhi*,2009,47(1):12-17.
- [11] US Department of Health and Human Services. Healthy People 2010, Volumes I and II. Washington, DC: US Dept of Health and Human Services, Public Health Service, Office of the Assistant Secretary for Health; 2000.[J].
- [12] Ryan A S, Wenjun Z, Acosta A. Breastfeeding continues to increase into the new millennium[J]. *Pediatrics*,2002,110(6):1103-1109.
- [13] Patnode C D, Henninger M L, Senger C A, et al. Primary Care Interventions to Support Breastfeeding: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force[J]. *JAMA*,2016,316(16):1694-1705.
- [14] Liu P, Qiao L, Xu F, et al. Factors associated with breastfeeding duration: a 30-month cohort study in northwest China[J]. *J Hum Lact*,2013,29(2):253-259.
- [15] Huang P, Ren J, Liu Y, et al. Factors affecting breastfeeding adherence among Chinese mothers: A multicenter study[J]. *Medicine (Baltimore)*,2017,96(38):e7619.
- [16] Sun K, Chen M, Yin Y, et al. Why Chinese mothers stop breastfeeding: Mothers' self-reported reasons for stopping during the first six months[J]. *J Child Health Care*,2017,21(3):353-363.
- [17] García-Gómez J M, de la Torre-Díez I, Vicente J, et al. Analysis of mobile health applications for a broad spectrum of consumers: a user experience approach[J]. *Health Informatics J*,2014,20(1):74-84.
- [18] Giglia R, Cox K, Zhao Y, et al. Exclusive breastfeeding increased by an internet intervention[J]. *Breastfeed Med*,2015,10(1):20-25.
- [19] White B, Giglia R C, White J A, et al. Gamifying Breastfeeding for Fathers: Process Evaluation of the Milk Man Mobile App[J]. *JMIR Pediatr Parent*,2019,2(1):e12157.

[20]Smith C. 110 amazing WeCaht statistics and facts (2020). 2020.

<https://expandedramblings.com/index.php/wechat-statistics/>

[21] Michalek, and Joel. "Chul Ahn, Moonseong Heo and Song Zhang. Sample Size Calculations for Clustered and Longitudinal Outcomes in Clinical Research. Boca Raton, CRC Press.

" Biometrics 74.1(2018):379-379..

[22] Campbell, Michael J. , and S. J. Walters . How to Design, Analyse and Report Cluster Randomised Trials in Medicine and Health Related Research (Campbell/How to Design, Analyse and Report Cluster Randomised Trials in Medicine and Health Related Research) || Statistics in Practice. John Wiley & Sons, Ltd, 2014.

[23]Bigger HR, Fogg LJ, Patel A, Johnson T, Engstrom JL, Meier PP. Quality indicators for human milk use in very low-birthweight infants: are we measuring what we should be measuring? J Perinatol. 2014 Apr;34(4):287-91. doi: 10.1038/jp.2014.5. Epub 2014 Feb 13. PMID: 24526005; PMCID: PMC3969767.

[24] Xiaomei Shao, Hongmao Ye, Xiaoshan Qiu. Practical neonatology [M]. Version 4. Beijing: People Health Press, 2011.

[25] Fernández Medina IM, Fernández-Sola C, López-Rodríguez MM, Hernández-Padilla JM, Jiménez Lasserrotte MDM, Granero-Molina J. Barriers to Providing Mother's Own Milk to Extremely Preterm Infants in the NICU. Adv Neonatal Care. 2019 Oct;19(5):349-360. doi: 10.1097/ANC.0000000000000652. PMID: 31651469.

[26] Zhou Q, Zhang L, Lee SK, Chen C, Hu XJ, Liu C, Cao Y. A Quality Improvement Initiative to Increase Mother's Own Milk Use in a Chinese Neonatal Intensive Care Unit. Breastfeed Med. 2020 Apr;15(4):261-267. doi: 10.1089/bfm.2019.0290. Epub 2020 Mar 4. PMID: 32129666.

Figures

TIMEPOINT	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		Close-out
	<i>Jun 2020</i>	<i>Jun 2020</i>	<i>Jun 2020</i>	<i>Jul 2020-Mar 2021</i>	<i>May 2021</i>
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
[Intervention group]			←————→		
[Control group]			←————→		
ASSESSMENTS:					
Baseline data	X				
Primary Outcomes Proportion of MOM feeding of premature infants during NICU hospitalization	X				X
Secondary outcomes Time (h) of first mother's own milk and proportion of mother's own milk (%), Duration of parenteral nutrition (d), Time to full enteral gastrointestinal feeding (d), Hospitalization time and hospitalization cost, Incidence of complications (NEC, BPD, LOS, and ROP)	X				X

Figure 1

Schedule of enrolment, interventions, and assessments

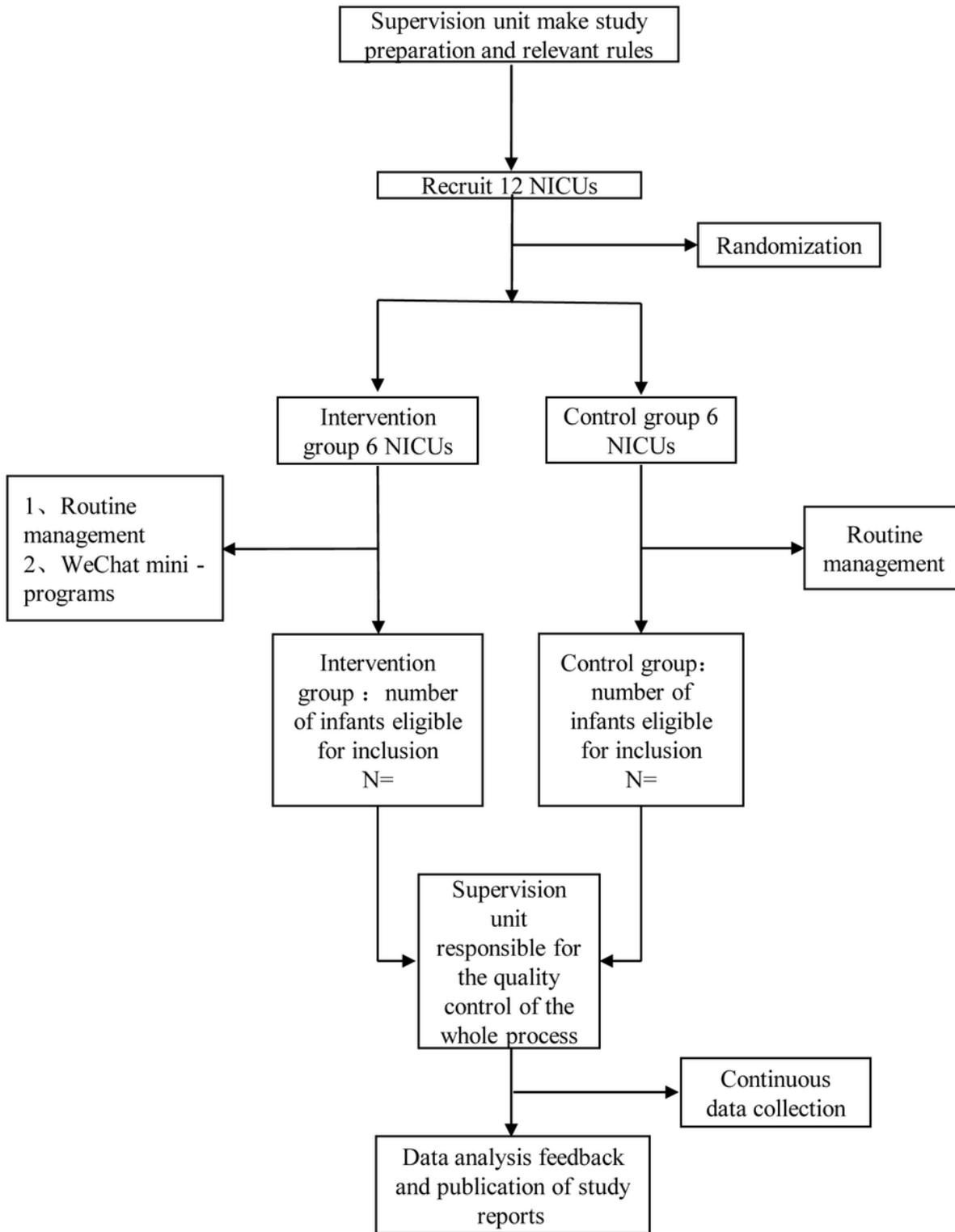


Figure 2

Study protocol flowchart of MOM feeding lactation consultant intervention via a WeChat mini –program

Step 1 Register and Log in

Parents and doctors scan the QR code below with wechat to complete registration and log in, and use mobile phone number to register.



Step 2 Binding hospital and doctor



Step 3 Introduction to the use and function of programs - Mother's daily



Step 4 Introduction to the use and function of programs - Growth daily record



Figure 3

Function and instruction of "Ning BX breastfeeding" WeChat mini-program

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [supplementaryfile1.pdf](#)
- [SPIRIT2013.docx](#)