

Application of e-health on neonatal intensive care unit discharged preterm infants and their parents: Protocol for systematic review and meta-analysis

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Abstract

Background: After preterm birth, parents often conformed with difficulties such as negative emotions, lack of care knowledge and skills, and insufficient professional support. As a remote health guidance method, e-health can provide a series of support for premature infants and their parents during the transition period from neonatal intensive care unit (NICU) to home care.

Objectives: To determine the efficacy of e-health interventions in discharged preterm infants as well as their parents, and to describe the process outcomes and elements of these e-health interventions to inform the effective design of future interventions.

Methods: The systematic review of the randomized and non-randomized controlled trials on the follow-up effect of e-health on preterm infants and their parents discharged from NICU between the inception to May 2023 will be electronically searched in the following nine databases: Web of Science, CINAHL Complete (EBSCO), PubMed, Embase, the Cochrane Library, Ovid MEDLINE, China National Knowledge Infrastructure, WANFANG DATA, and SinoMed. Quality will be appraised, respectively, via the revised tool to assess risk of bias (RoB 2) and the tool for risk of bias in non-randomized studies of interventions (ROBINS-I). The main outcome indicators of preterm infants are breastfeeding rate, readmission rate, neuro-behavioral development, and premature infant's body mass. The outcome indicators for parents of premature infants are anxiety, depression scale, and parenting competency scale. The RevMan 5.4 software provided by the Cochrane Collaboration will be used for statistical analysis of the data.

Conclusion: The results of this study may provide future development opportunities for e-health follow-up prevention in preterm infants and may support evidence-based decision-making for e-health interventions of post-discharge developmental support in preterm infants.

PROSPERO registration number: CRD42023410334.

Keywords

E-health, preterm infants, systematic review, meta-analysis, parental caregiving, home care, NICU discharge

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Introduction

According to the definition of the World Health Organization (WHO), preterm birth refers to live infants born at a gestational age of <37 completed weeks or 259 days of gestation.¹ Preterm birth affects an estimated 10.6% of live births globally, equating to 15 million live

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preterm newborn infants. The incidence of premature birth in China is 6.9%, which is lower than the global average. However, due to the large denominator population, premature babies account for 7.8% of the total number of premature babies in the world, ranking second in the world, second only to India (23.4%).² Additionally, a Chinese national study showed an annual increase in preterm births of 1.3% from 2012 to 2018, which means the number of preterm babies is rising.³ Prematurity is now the second leading cause of death in children under 5 years and the single most important direct cause of death in the critical first month of life.⁴

A large multinational cohort study found that the survival rate of very preterm infants in the neonatal intensive care unit (NICU) exceeds 75% and in developed countries even more than 90%.⁵ Even though, the mortality rate of preterm newborn infants is 3.8 times higher than full-term infants.⁶ Surviving premature babies are at greater risk of a range of short-term and long-term morbidity than full-term babies, such as bronchopulmonary dysplasia,⁷ necrotizing enterocolitis,⁸ sepsis,⁹ cerebral palsy,¹⁰ feeding difficulties,¹¹ vision and hearing problems,¹² developmental delays,^{13,14} etc. For preterm babies who survive, the additional burden of prematurity-related disability may affect families and health systems. Families with premature babies often experience considerable psychological and financial difficulties.¹⁵

Perinatal care in the NICU improves the survival outcomes of preterm infants. However, for parents of preterm infants, leaving a baby with severe illnesses and an unpredictable health status in the NICU for several weeks or months, can be a complex physical and emotional experience.^{16,17} When preterm infants are discharged from the NICU, parents encounter more complicated home-care problems.¹⁸ Ma et al.¹⁹ reported that parents may be troubled by insufficient knowledge, heavy caregiving burden, low care ability, and lack of professional support. The complex health conditions and care needs of preterm infants will put parents under negative emotion, leading to more intense depression and anxiety, which will last for about 14 months to 2 years post-discharge.^{20,21} Parents' mental health, ability to cope with the consequences of preterm birth, and the home environment have a significant effect on infant development, therefore both parents and preterm infants require continuous home care support after discharge.²²

Even though the staff in the NICU strive to provide consistent information to parents, verbally and in written form (e.g. brochures, books, and posters), there is still a lack of support for caregiver mental health, authoritative resources, and follow-up. A European cohort study showed that 14.2% of parents felt that they did not receive adequate post-hospital care, and this proportion was higher among preterm infants with health or developmental problems, such as cerebral palsy (34.4%) and epilepsy (36.9%).²³ Many parents

report feeling stress and often actively seek alternative ways to find information. When faced with all kinds of confusion in infant care and disease care, most parents consider seeking help from empirical elders or friends, relevant books, internet resources, medical staff, etc.¹⁹ However, the reliability and quality of information available to parents of preterm infants is lacking,²⁴ and they were still overwhelmed by caring for their preterm infant.

E-health refers to upgrading and optimizing health service processes and access to medical information through the Internet and related technologies.²⁵ E-health can provide follow-up guidance for parents of premature infants through various forms regardless of time and space constraints, and it is also cost-effective, especially during the COVID-19.²⁶ It has a positive effect on enhancing the parents' ability to provide care for premature infants, alleviating anxiety and depression, and promoting the physical and neurological development of premature infants.^{27,28}

E-health can be efficiently applied to the medical environment in the NICU, as well as telemedicine and remote intervention. Within the NICU, families of hospitalized premature infants were allowed to operate a videoconferencing module for virtual visits from their home to the NICU and a website to access information on the issues confronting them.²⁹ Weber et al.³⁰ applied FamilyLink's video access program to allow family members to remotely view their babies. This simple intervention improved rates of intention to breastfeed and provide expressed milk at discharge, and increased perceived parental involvement in the infant's care.³⁰

The transition to home from the NICU can be difficult for families of infants with medical complexity. E-health applications, such as video chat with providers for live assessment of physical examination findings, online resources, online parent forums, and communication with providers online or via mobile text, were suggested to facilitate this transition.^{31,32} Garfield et al.³³ designed a smartphone application called NICU-2-Home, in order to make the transition from hospital to home easier for parents with prematurely born infants. Holm sends preterm infants with stable clinical conditions to their parents for feeding at home, and the NICU provides support through telemedicine services. The results show that remote home care may be an appropriate mode of care for premature infants outside the hospital environment.³⁴ A randomized controlled study, where video conference and web application were offered to a small group of parents whose premature infants were discharged from hospital, showed that the families were satisfied with both the web application and video conferencing. Most parents thought e-health could decrease the need for home visits.³⁵ Online follow-up could promote the growth and neurobehavioral development of premature infants, and reduce the readmission rate of premature infants.³⁶

The research of e-health in the field of preterm infants is still in its infancy. Despite some evidence showing the

benefits of e-health interventions for preterm infants and their parents, the evidence on the effectiveness of e-health-based home care guidance after discharge for preterm infants and their parents has not yet been established.²⁷ A few programs and smartphone applications have been developed for telemedicine and remote intervention, but the results of these have not been systematically reviewed.³⁷ Therefore, this review was aimed at providing a first overview of e-health interventions targeted at preterm infants and their parents by systematically identifying and synthesizing the research findings, including the effectiveness in health promotion of premature infants and in preventing or reducing mental health issues in their parents.

The objectives of this study were two-fold. The primary objective is to determine the efficacy of e-health interventions in discharged preterm infants as well as their parents. The secondary objective was to describe the process outcomes and elements of these e-health interventions to inform the effective design of future interventions.

Methods

This systematic review was already registered with the International Prospective Register of Systematic Reviews

(PROSPERO) on 22 March 2023, and the registration ID was CRD42023410334. A review plan was developed by the research team in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 (see Supplemental Appendix 1).³⁸

Eligibility criteria

Inclusion and exclusion criteria will be defined according to the PICOTS framework,³⁹ as shown in Table 1. Randomized and non-randomized controlled trials will be included. The intervention group in the three-arm randomized controlled trial involving e-health will also be included. Secondary studies, observational designs (e.g. longitudinal surveys and cross-sectional studies), qualitative studies, and protocols of experimental studies may be excluded. Only studies written in English or Chinese will be included. Gray literature (such as preprints, academic theses, working reports, non-peer review conference abstracts, etc.) will be excluded, and only peer-reviewed papers in the form of original research reports will be included.

Patient population. Preterm infants discharged from the NICU and their parents. Preterm birth is born before 37

Table 1. PICOTS framework with inclusion and exclusion criteria.

PICOTS	Inclusion	Exclusion
Patient population	- Preterm infants discharged from the NICU and their parents.	- Other newborns admitted to the NICU. - Participants were not specified
Intervention	- Routine health education, discharge instructions, and e-health intervention; - Any form of e-health services (e.g. such as mobile apps, phone calls, web-based platforms, video consultation, WeChat, etc.) after discharge that are conducted by professional therapists and caregivers.	- E-health interventions targeted at nurses and healthcare professionals. - Only the development and description of mobile applications, programs, or web platforms without application. - Intervention by text message and email only.
Comparator	- Routine health education, discharge instructions, and routine follow-up at discharge.	- No exclusion criteria applied
Outcome	- Preterm: (1) breastfeeding, (2) readmission, (3) neuropsychological development, (4) physical development; - Parents of preterm infants: (1) stress, anxiety, depression, and other psychological outcomes, (2) parenting sense of competence.	- Qualitative results.
Timing	- Intervention timing at and after discharge of preterm infants.	- Intervention conducted only during NICU.
Setting	- Both in NICU and home or only at home.	- Only in NICU.

NICU: neonatal intensive care unit.

completed weeks of gestation age, or <259 days since the first day of the last menstrual period.¹

Intervention. E-health combines information and communication technology and modern medical care. It integrates all kinds of health resources effectively, links doctors and patients, medical institutions and policymakers, and makes the process of health care toward electronic information.⁴⁰ This review will include all studies evaluating the effectiveness of e-health for parents of preterm infants to improve the developmental outcomes of preterm infants and the mental health of parents. The intervention group received routine health education, discharge instructions, and any form of e-health services (e.g. such as mobile apps, phone calls, web-based platforms, video consultation, WeChat, etc.) at discharge conducted by professional therapists and caregivers. Given the broad definition of e-health, we will refer to the practice-based conceptual model for e-health developed by Shaw et al.,⁴¹ and divide e-health interventions into three domains in order to find out the effects of various e-health interventions more accurately. (1) Health in our hands: using e-health technologies to monitor, track, and inform health, (2) Interacting for health: using technology to communicate among health stakeholders, and (3) Data enabling health: the collection, management and use of health data sources. Studies will be excluded if the e-health interventions are targeted at nurses and healthcare professionals, or use only texting or emailing for intervention. Development and description of mobile applications, programs, or web platforms will also be excluded.

Comparison. The control group received only routine health education, discharge instructions, and routine follow-up at discharge.

Outcome. The main outcome indicators of preterm infants discharged from NICU will be (1) breastfeeding (i.e. sucking breast milk on the breast and on the bottle),³⁴ (2) readmission, (3) neuropsychological development (i.e. mental, psychomotor, and social-emotional development), and (4) physical development (i.e. body length, weight, and head circumference). The outcome indicators of parents of preterm infants will be (1) stress, anxiety, depression, and other psychological outcomes (i.e. symptoms, severity, or clinical diagnoses of psychological status when parenting infants), (2) parenting sense of competence (i.e. parenting self-efficacy, parenting confidence, etc.). The additional outcomes will be (1) attitudes toward breastfeeding, (2) breastfeeding self-efficacy, (3) perceived social support for parenting, and (4) parent–child relationship (i.e. interacting with infants).

Timing. Studies with intervention timing at and after discharge of preterm infants will be included. Studies will be

excluded if the intervention lasts only during their NICU stay.

Setting. Studies both in NICU and houses of premature babies or only conducted at home will be included. Studies conducted in settings where professional therapists were face-to-face accompanied and offered assistance will be excluded.

Data sources

To identify relevant published articles, the following nine databases will be searched: Web of Science, CINAHL Complete (EBSCO), PubMed, Embase, the Cochrane Library, Ovid MEDLINE, China National Knowledge Infrastructure, WANFANG DATA, and SinoMed. Reference lists of published relevant reviews and included studies will be manually searched to supplement additional records. The target papers will be published between the inception of the databases to May 2023.

Search strategy

Keywords derived from the medical subject heading terms and entry terms will be used in the search strategy. A search will be conducted using the following combinations of terms and truncated words were used: (a) premature infant, preterm infant, “neonatal, prematurity”, low birth weight infant, parents, parent*, father*, mother*, maternal*, and paternal*; (b) e-health, telemedicine, tele*, mobile, smartphone, APP, mHealth, internet plus, web, online, computer, computerized, digital, intelligent device, virtual reality, and WeChat; (c) NICU discharge, *discharge*, and *home*. The specific retrieval strategies of each database are shown in Supplemental Appendix 2.

Study selection

Two researchers will independently screen each of the potential titles, abstracts, and/or full-text to determine whether they are eligible for inclusion. Studies will be initially excluded based on their title and abstract. The full text will be reviewed by two researchers to assess eligibility. Any disagreement and uncertainty will be resolved by consensus among the third reviewer. A PRISMA flow diagram that summarizes the selection of studies will be shown in Figure 1.

Data management and extraction

Two reviewers will independently extract key information (e.g. author, year of publication, country, study type, participant characteristics, sample size, intervention/control group treatment, collection time, follow-up time, outcome metrics, etc.) for the selected papers, and conflicting

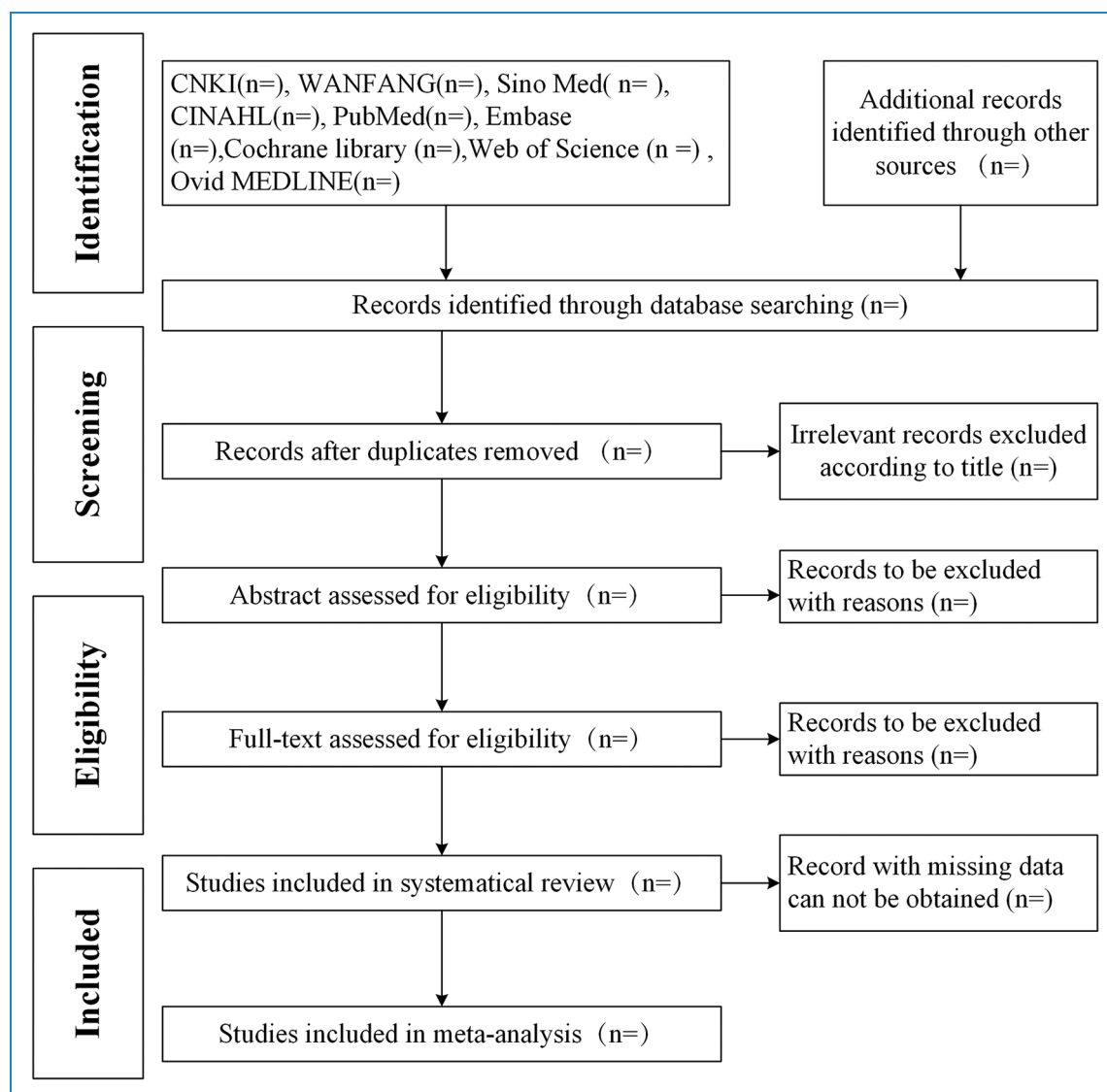


Figure 1. Flow diagram outlines the selection process for the papers to be included in this review.

sections will be discussed or the other author's opinion will be sought until consensus is reached. The exact interpretation of key extracted information is shown in Table 2. The collected raw data and information will be managed using Microsoft Excel and EndNote software.

Quality appraisal

According to *the Cochrane Handbook for Systematic Reviews of Interventions*,⁴² the quality of randomized and non-randomized controlled trials will be appraised respectively via the revised tool to assess risk of bias (RoB 2) and the tool for risk of bias in non-randomized studies of interventions (ROBINS-I). Two independent reviewers will rate the studies, and discrepancies will be discussed until a consensus is reached. The risk of bias

assessment results of each study will be recorded in a summary table. Low-quality studies will be excluded from the meta-analysis.⁴³

Outcome assessment

The primary outcomes of preterm infants were the breastfeeding rate, neuropsychological development, and physical development; the primary outcomes of parents included psychological states such as anxiety, depression, and stress, as well as feelings of parenting competence. The additional outcomes were: attitudes toward breastfeeding, breastfeeding self-efficacy, perceived social support for parenting, parent-child relationships, etc. The GRADE framework will be used to assess the quality of evidence for each outcome.⁴⁴ Evidence

Table 2. Extracted data information.

Data heading	Description
Title	The title of the selected study
Author	The last name of the first author
Year	Year of publication
Journal	The journal where selected papers published
Country	The country where the selected study had been conducted
Study design	Type of study design (RCT/quasi-experimental study)
Sample size	Number of participants in the intervention and control group
Setting	The place where our participants or Study implementors conduct intervention (e.g. in the NICU or at home)
Participant characteristic	Gestational age and birth weight of preterm infants
Intervention/control group	Characteristics of intervention group sociodemographic information of preterm families such as parents' age, gestational age, sex of preterm infants, number of fetuses, etc.
Type of e-health intervention	Name of the e-health intervention (application/platform...) was used
E-health domain	Purpose and capabilities of e-health intervention (application/platform...)
Comparator	Type of usual care or actions that the control group received
Outcome	Indicators that collected before and after e-health intervention according to the study questions
Data collection time	Baseline and follow-up time spots

RCT: randomized controlled trial; NICU: neonatal intensive care unit.

quality will be rated as high, moderate, low, or very low based on a rigorous assessment of the risk of bias, directness of evidence, precision of effect estimates, heterogeneity, and risk of publication bias.

Data synthesis and analysis

The RevMan 5.4 software provided by the Cochrane Collaboration will be used for statistical analysis of the data.⁴² Data for quantitative integration are mean, standard deviation, number of cases, sample size, and if the data to be integrated were not published, YXY will seek from the authors via email. Continuous variables are expressed by weighted mean difference, standardized mean difference (SMD), and 95% confidence interval (CI). The SMD will be used to combine one outcome that is measured in a variety of ways (e.g. some studies measure neurobehavioral development in preterm infants, but they use different measurement scales).⁴² Categorical variables are expressed using relative risk and 95% CI. The CI bounds for

continuous and categorical variables were set to 0 and 1, respectively, and if the CI crossed the bounds, the difference was not statistically significant. Two-tailed $P < 0.05$ was considered statistically significant.

Managing missing data. If there is missing data in the results of the included studies, to avoid inappropriate interpretation of the study results, the corresponding article authors will be contacted to reduce the possible risk of bias in the meta-analysis. We will handle missing data according to the *Cochrane Handbook for Systematic Reviews of Interventions*.⁴²

Examining heterogeneity. In this review, the Q test and I^2 test will be used to detect heterogeneity. When there is a high homogeneity of effect ($P \geq 0.1$, $I^2 < 50\%$), Meta-analysis will be performed using a fixed-effects model. We will perform a meta-analysis using a random effects model when heterogeneity effects are significant ($P < 0.1$, $I^2 \geq 50\%$).⁴⁵

Subgroup analysis and sensitivity analysis. Differences in eligibility criteria, methodology, interventions, cultural differences, baseline, and outcome indicators will be considered if the combined outcome heterogeneity effect is high, and the reasons for heterogeneity will be further considered by subgroup analysis and sensitivity analysis. Sensitivity analysis will be performed by the “leave one out method,” excluding individual studies one by one to see if the combined effect results and heterogeneity have changed.⁴² We will exclude studies with large effects on heterogeneity and will adopt narrative analysis for outcomes with large heterogeneity and where the source of heterogeneity cannot be identified.

Assessment of publication bias. Funnel plots will be made to assess publication bias, when no <10 studies are included in the meta-analysis.⁴⁶ For continuous variables, Egger’s test will be used to analyze the symmetry of the funnel plot.^{46,47} For categorical variables with small consistency, the Harbord test will be used when heterogeneity is small, and the AS-Thompson test will be used when heterogeneity is large.

Discussion

Premature infants still need high-quality care after discharge.¹² Parents of preterm infants are under great psychological pressure due to various factors such as concerns about the illness and prognosis of their preterm babies, changes in parental roles, economic pressure, and lack of knowledge.^{16,23,24} The accompanying anxiety and depression will affect their own physical and mental health and cannot build confidence in caring for premature infants.¹⁷ It also affects the subsequent development of premature infants. Therefore, parents of preterm infants also need post-discharge family support.²²

Currently, post-discharge follow-up for preterm infants in China has not been implemented due to the time, place, and lack of manpower.²⁶ The COVID-19 pandemic has been associated with increased psychological distress and economic stressors among families with premature babies.⁴⁸ E-health-based follow-up can be a new model of follow-up that reduces the difficulty of implementation, saves time and cost of follow-up, and is more convenient to use in practice during the COVID-19 pandemic.⁴⁹

However, there are still many uncertainties in the follow-up intervention studies of e-health. Horizontal comparisons of different e-health interventions are lacking. Differences in outcomes between active parental counseling and passive uptake of e-health interventions have not been explored. The information push services provided by different studies use self-generated information, the accuracy and operability of which is questionable. The follow-up period of most studies was <12 months and the analysis of intervention effect between different follow-up periods is lacking.

This protocol describes the methodology for a systematic review and meta-analysis that will provide a qualitative and narrative synthesis of current evidence on the benefits, risks, and costs of e-health follow-up interventions for post-discharge follow-up and telemedicine education for families of preterm infants. More detailed results will be reported in a future review manuscript published in accordance with PRISMA guidelines,⁵⁰ with deviations and changes from the protocol of this study reported in a section entitled “Differences between Protocols and Reviews.”

Limitations

There are some expected limitations. First, inconsistencies in the methods of included e-health interventions, interventions, follow-up duration, and study design may contribute to heterogeneity in outcomes. Second, the inability to identify all potentially relevant papers due to the wide variety of e-health-related search terms and all kinds of online tools or platforms. Third, we exclude papers written in languages other than Chinese and English, gray literature, and papers that have not been peer-reviewed.

Conclusion

The results of this review may highlight future opportunities for the development of preventive e-health follow-up practices and may support evidence-based decision-making related to e-health interventions in the area of preterm infants.

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