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# Development of a post discharge telecare program for premature infants in Covid 19 era: Protocol for a mixed methods study

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## Abstract:

**BACKGROUND:** Post-discharge care of premature infants is an important goal that can provide a safe transition for these infants from the hospital to the home setting, especially who has undergone significant changes during Covid19. Most premature infants experience complications because of routine hospital care termination after discharge because of limitations and barriers that Covid can create for the infant and the parents. It is necessary to develop a program that provides ongoing care for these infants. Telecare is one feasible option that can be used to implement this program. The study aims to develop a post-discharge telecare program for premature infants in the Covid era in Iran.

**MATERIAL AND METHODS:** This is an exploratory mixed-methods study that will be conducted by Qualitative-quantitative methods in three consecutive phases at Isfahan University of Medical Sciences in January 2022. In the first phase, a qualitative study will be conducted to identify and determine the needs and strategies in the Covid 19 era to promote premature infant care after discharge. The data will be collected through deep semi-structured interviews. Participants (parents, physicians, and nurses) will be selected by purposive sampling methods, and the conventional content analysis method will be used for data analysis. In the second phase, the identified infants' and parents' needs as an initial draft of the program will be prioritized and confirmed by the modified Delphi method and a panel of experts. The final program will be developed in this phase. In the quantitative third phase, the confirmed program will be implemented as a semi-experimental study that uses a telecare strategy. Finally, we will evaluate the effectiveness of this telecare program.

**RESULT:** A program that uses qualitative and quantitative methods can provide evidence for promoting premature infant health after hospital discharge in Covid 19 era.

**CONCLUSION:** We anticipate that this program will promote knowledge and empower health team members, especially nurses, to provide ongoing telecare for premature infants.

## Keywords:

Discharge planning, follow-up studies, infant, Iran, nursing care, premature, telemedicine

## Introduction

Today, the care of premature infants is one of the main issues for improving mother and infant health worldwide. It is one of the international health development goals of care systems in both advanced and developing countries. According to a World Health Organization report, 1.5 million

infants are born prematurely each year, which is approximately more than one in ten births worldwide. The incidence of premature birth is estimated to be an average of 7% to 16% in different cities, or ~5000 live births per day, and 12% have low birth weight.<sup>[1,2]</sup> Despite the increase in infant life expectancy attributed to advances in modern medicine and equipment, chronic complications of prematurity continue after hospital discharge

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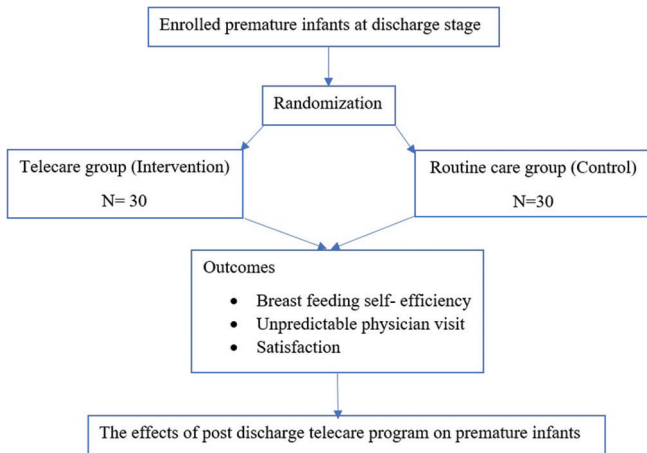


Figure 1: Mixed methods study design in different phases

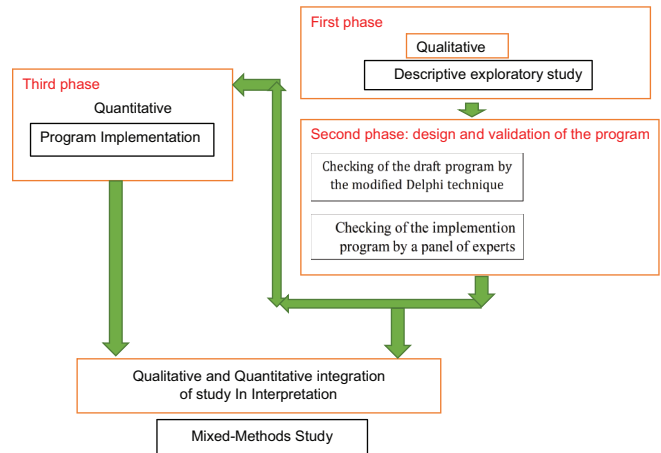


Figure 2: Study design flowchart

and include respiratory instabilities, risk of hypoglycemia, hypothermia, developmental disorders, poor sucking, ineffective breastfeeding patterns, all of which can increase the risk of readmission. This is particularly true when the parents, as primary caregivers, cannot manage preterm infant care during these vital periods.<sup>[3,4]</sup>

Premature birth is an unexpected stressful situation for parents who are left with numerous questions about the future, including questions about infant survival and health. In addition, parents are faced with a lack of skills and competency to provide preterm infant care after hospital discharge, so providing adequate support for parents is a challenging issue<sup>[5,6]</sup> They need a program that is developed according to their particular needs and perspectives, particularly during outbreaks of infectious diseases, such as the Covid-19 pandemic.<sup>[5,6-9]</sup>

Telecare is an option that can help parents manage their concerns, recognize their problems, provide the possibility for education about preterm infant care, and manage the preterm infant’s health. It provides a fast, economical, and feasible solution for post-discharge continuing care. Telecare can introduce safe, supportive care for parents, particularly for those who reside in remote areas, by establishing a connection to a reliable source who can respond to their concerns.<sup>[10,11]</sup>

Despite the importance of discharge of providing continuing care for premature infants, there are a limited number of studies that address the development of these programs for post-discharge care and parental support worldwide. Most quantitative studies do not consider parents’ and practical experts’ views through dynamic, interactive, and multifaceted plans. The politics compiled based on the opinion of newborn specialists in the Ministry of Health.<sup>[12-14]</sup>

Consideration of infants’ needs from parents’ perspective guarantee infants’ health. This issue is

dominant in the Covid pandemic because of face-to-face hospital visiting restrictions, so investigation of the capability of telecare follow-up to cover stakeholders’ needs after discharge is essential.<sup>[15-17]</sup> Thus, we intend to develop an exploratory mixed-method study that assesses the ability of telecare to reinforce healthcare services for premature infants discharged to the home setting.

## Material and Methods

The current study is a sequential exploratory mixed methods study that includes qualitative and quantitative steps, and it will be based on the paradigm of pragmatism.

### Study design and setting

This sequential exploratory mixed methods study (QUAL-quant) will be developed according to the Ewles and Sminett model and will be implemented from 2022–2023 in three phases at Neonatal intensive care units (NICU) units of hospitals affiliated with Isfahan University of Medical Sciences. It is essential to have a thorough understanding of the care needs, especially in the Covid era; It must be weighted the qualitative part, and then, two parts of the qualitative and quantitative data will be integrated into the interpretation stage [Figures 1 and 2].<sup>[18,19]</sup>

The first phase of this study is investigating the need to provide the initial draft of the post-discharge telecare program for premature infants. In the second phase, the program will be validated according to the classic Delphi technique and by a panel of experts. In the third phase, which is the quantitative part, the evaluation of the program’s effectiveness will be assessed by variables that include the average number of visits to medical centers and offices, breastfeeding self-efficacy, and satisfaction [Table 1].

**Table 1: The process of the research**

Phase	Purpose	Method
1	Identification of post discharge premature infants needs	Qualitative & Literature review
2	Prioritize discovered needs	Modified Delphi technique
3	Investigation of details of telecare program & Production of educational contents	Expert panel
4	Implementation & Evaluation of final program	Quantitative (RCT)

## Phase I

### Stage 1: Literature review

A narrative review will be conducted by searching library resources (articles, reference books, and theses) and electronic databases (MEDLINE, EMBASE, ProQuest, ISC, ISI Web of Science, Science Direct, and Scopus) using the following keywords: premature infants, caring, Hospital discharge, telecare, and parent's needs, and by derivations of mesh in titles and abstracts of original articles and review articles from 2015 to 2021. Persian literature will be searched using Iranmedex, SID, ISC, and magiran databases using the exact keywords and for articles published from 2010 to 2020. Papers with the following criteria will be excluded: duplicate studies, letters to the editor, posters, and conference papers. This phase will be conducted to identify models, areas, and dimensions of post-discharge premature infant care needs, and the results will be used as the basis for the qualitative phase.

### Stage 2: Qualitative study - Investigating the needs and strategies of the program

The qualitative study will be conducted through in-depth interviews to explain the needs and strategies of the program. The setting of this research phase is the centers that provide.

Premature infants care services in Tehran and Isfahan, two cities in Iran. All of the interviews will be conducted in a private setting and selected according to participant preference. The qualitative data will be analyzed according to the content analysis method with the intent to extract the proposed needs and strategies of the program.

### Study participants and sampling

The participants of the qualitative research phase will include premature infants' parents and health providers (nurses, neonatologists, physiotherapists, developmental care experts, ophthalmologists, and audiologists). The participants will be selected by the purposive and snowball sampling methods and by taking into consideration the maximum variation in sex, age, and education in the different centers that are affiliated with Tehran University of Medical Sciences and Isfahan University of Medical Sciences, which have NICU,

neonatal clinics, and home visit agencies. The number of participants will not be previously determined, and interviews will be conducted until data saturation.

The research objectives will be described for all of the participants, and informed written consent will be obtained for study participation. Interviews will be continued until data repetition and data saturation.

### Inclusion and exclusion criteria

The main target participants include parents of discharged or soon-to-be-discharged premature infants who enrolled in this study. Regarding study participation, the health service providers must have at least six months of work experience in the NICU. Other inclusion criteria are: signing a written consent form and fluency in the Persian language to participate in this research. Participants can withdraw at any stage of this research.

### Data collection tool and technique

In the qualitative phase, the data will be collected using in-depth semi-structured interviews by taking field notes with observation. Study participants will receive explanations about the study's aims, and, informed consent will be obtained before recording their voices. The setting and the length of the interviews will be specified based on participant preference.

### Interview questions

The interview questions will be designed according to parents and health providers.

The researcher will start with general questions such as talking about your experiences with your infant's care at home or explaining your experiences with premature infants' problems after discharge. How is the care of premature infants after discharge currently? Then, the probing questions will be asked to clarify the participants' viewpoints. The interview setting will be Neonatal Intensive care units in hospitals affiliated with the Isfahan University of Medical Science. The interview time will be based on the participants' willingness for at least 20 min. At the end of each interview, the researcher will summarize his/her understanding of the participant's responses to the interview questions. Participants will have the opportunity to revise their responses in case of any misunderstanding.

## Statistical analysis

The researcher will import interviews word-by-word in Word Office, and data analysis will be performed by using the Graneheim and Lundman method of conventional content analysis.<sup>[20]</sup>

For better management of data analysis, the researcher will use MAXQDA software. To verify the trustworthiness of the research findings, Guba and Lincoln's criteria of credibility, dependability, transferability, and confirmability will be used.<sup>[21]</sup>

## Phase II: Validation of the Program

In this phase, the draft program will be thoroughly checked by using the modified Delphi technique and a panel of experts.

### Stage 1: Modified Delphi technique

In this phase, the program will be developed based on the results of the first phase and evaluated by the modified Delphi method to develop the final version of the program. In the first Delphi, the researcher will provide the checklist from the items obtained in the first phase and email this checklist to ten experts (nurses and physicians) who are faculty members of Tehran and Isfahan Universities of Medical Sciences. Each item will be rated according to a Likert scale for impact, significance, variability, acceptability, and availability.

In addition, in each relevant dimension, an open question will be placed in writing other cases or solutions that the experts have in mind. After one week, the comments will be collected from the expert panel, and the necessary corrections will be made.

In the second round, the researcher will email a revised checklist for the same experts to confirm. The results of this stage will be used to develop an intervention program that will be finalized by the panel of experts.

### Stage 2: Panel of experts

In this stage, the experts will use the literature review to assess the objectives, extracted strategies, and the operational program. The panel members will consist of experts who are faculty members of the Medicine, Nursing, and Medical Information Colleges of Isfahan University of Medical Sciences. The expert panel will evaluate the implementation program in terms of feasibility, cost-effectiveness, time, effectiveness, efficiency, acceptability, and consistency with organizational policies and values. A final decision will be made by the panel of experts.

## Phase III: Implementation of the Intervention Program (Quantitative Study)

In this phase, the quantitative study will be conducted as a semi-experimental study.

### Study participants and sampling

The research setting will be NICU in a hospital affiliated with Tehran or Isfahan University of Medical Sciences. The target population of the study will consist of premature infants who are about to be discharged from the hospital according to the physician's recommendations. According to similar clinical trial studies and probable attrition rate, we intend to choose 30 premature infants for this phase.<sup>[13-17]</sup>

### Inclusion and exclusion criteria

This phase of the study will include parents of premature infants who are in the process of being discharged according to physician recommendations. All premature infants who are stable and can be taken care of at home will be eligible for this study. Infants with congenital abnormalities or complex situations that need face-to-face visitations will not be enrolled. Other exclusion criteria are parent withdrawal of consent for study participation, emergency readmission, or physician recommendation of surgery for the infant.

### Data collection tool and technique

The sampling process will be performed in the control group before implementation and sampling of the intervention group. The study variables include frequency of clinic visits and physicians' offices, breastfeeding self-efficacy in mothers, and parental satisfaction. The breastfeeding self-efficacy scale-short form, which is a 14-item Likert scale, will be provided and used to measure the mothers' ability to breastfeed. The validity of this questionnaire has been reviewed and confirmed, and it has a Cronbach's alpha of 0.87 readability.<sup>[22,23]</sup> The responses range from a score of "1," or "I completely disagree," to a score of "5," or "I agree." The minimum and maximum scores are 14 and 70, respectively. The highest score indicates the highest level of self-efficacy in breastfeeding.

A self-made questionnaire will be used to determine parental satisfaction. The validity and reliability will be evaluated by several expert nursing faculty professors.

### Intervention

In this phase, the telecare will be implemented based on multimedia and web communication software, which will be finalized by a panel of experts in the previous phase according to Isfahan University of Medical Sciences facilities in the intervention group. Telecare can comprise native social software, video consultation,

and telephone follow-up. The researcher will act as the coordinating agent, data collector, and referrer of information, and will be the intermediary between the families and the research team.

The researcher, after receiving permission, will identify premature infants who are in the discharge process according to the physician's recommendation and begin sampling. The samples will be informed about the project verbally and in writing. The purpose of the study, the right to withdraw consent, and data confidentiality will be explained by the researcher. Two informed consents will be obtained. The first will be related to study participation, and the second will guarantee confidentiality because of the telecare program.

Before implementation, in the preparedness stage, the demographic checklist will be completed, and a research guide notebook will be provided for families to familiarize themselves with the telecare program. Security of data exchanges during telecare will be under the supervision of the Isfahan University of Medical Sciences internet.

A summary of the infant's treatment records will be reviewed to identify particular problems during treatment and care. The virtual educational content will be provided based on an assessment and prioritization of the mother's needs to enable mothers to increase their knowledge according to their prioritized problems. During the study, all routine medical clinic visits and developmental checkups will be continued as usually scheduled.

After the preparation stage, the first telecare communication will be implemented during the first 24 h of the infant's discharge from the hospital, and it will continue, according to the determined time, which has been finalized by the panel of experts.

The second telecare communication will be set according to the parent's initial reflections.

Any medical questions will be communicated to the study physician and, according to his assessment, in an emergency, the infant will immediately be referred to the nearest medical center.

After completion of the telecare program, the physician will confirm its termination. The questions will be completed again after the termination stage to evaluate the telecare program.

At the end of the study, the virtual educational contents will be shared for the benefit of the control group.

### Statistical analysis

Data will be analyzed with SPSS version 19, in addition

to descriptive and inferential statistical methods. The Kolmogorov-Smirnov test will be used to evaluate data normality. To compare quantitative baseline characteristics in the control and intervention groups, we will use the independent t-test. The Mann-Whitney test will be used to compare qualitative baseline characteristics, and the Chi-square test will be used to compare nominal qualitative variables. At the end of the study, the results obtained from the qualitative and quantitative parts of the study will be integrated during the interpretation stage of the mixed-methods study.

### Ethical consideration

The Ethics Committee of Isfahan University of Medical Sciences in Isfahan, Iran (IR.MUI.NUREMA.REC.1400.055) has approved this study. Informed consent will be obtained from the participants at all phases of the research.

### Discussion

The development and implementation of a telecare program for premature infants after their discharge is one of the challenges needed to improve premature infants' health.<sup>[24]</sup> A telecare program can be a supportive program that can prevent possible complications in the premature infant after discharge. This would be a unique experience introduced through a telecare service in Iran, which can create specific conditions for health policymakers.

In developing this study, through analyzing the experiences of the infants' parents and the service providers, there will be an attempt to provide specific programs according to their actual needs in the covid 19 era.

Research findings also can reveal that programs based on need assessments are more successful. Attempts to implement telecare interventions to improve the knowledge and competency of premature infants' parents may be associated with a reduction in unnecessary clinic and hospital visits and a desire for earlier hospital discharge<sup>[25]</sup>; however, there is insufficient evidence in this regard.

The present program will be developed according to the socio-cultural and religious contexts of Iran and will provide robust information about the needs and strategies of telecare promotion programs for premature infants. As such, this program appears to be suitable for countries with similar characteristics, such as South Asian countries. Nonetheless, many of the obtained strategies may apply to other societies, including Western countries. Efforts will be made to develop strategies that can be used in medical centers, especially in countries with socio-cultural structures similar to Iran.

### Limitation and recommendation

The lack of direct access to the target community due to the risk of contracting Covid-19 will be one of the study's limitations, compensating through virtual communication and telephone interviews.

The present conducted study recommends conducting telecare as a complementary element of ordinary follow-up at the primary stage until the provision of the foundation of telecare in the health system.

Furthermore, barriers to telecare services, and the capacity of our society to accept telecare culture are required to investigate.

### Conclusion

We hope that the developed program will have the capacity for integration into the instructions of the telecare service center, which would be a step forward in improving the health of premature infants and enable telecare services to be included in health system policies in Iran and other countries that focus on face-to-face care.

### Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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### Conflicts of interest

There are no conflicts of interest.

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