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# Development of an exclusive breastfeeding intervention based on the theory of planned behavior for mothers with preterm infants: Study protocol for a mixed methods study

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## Abstract:

**BACKGROUND:** Despite the significance and benefits of exclusive breastfeeding, its rate among infants, especially preterm infants, is not optimal. Based on evidence, the mother's attitude toward breastfeeding, the subjective norm, and the mother's perceived behavioral control play a role in initiation and continuation of breastfeeding; so the interventions that consider these factors may be useful for breastfeeding premature infants. The aim of this study is to design and develop an exclusive breastfeeding intervention based on the theory of planned behavior for mothers with preterm infants.

**MATERIALS AND METHODS:** This exploratory, sequential, mixed methods study will be conducted in three phases. In the first phase, a qualitative study will be conducted based on the theory of planned behavior, to describe the exclusive breastfeeding beliefs of the mothers with preterm infants, the barriers to breastfeeding, and to explain the ways to overcome them. Moreover, the items of the Predictors Of Exclusive Breastfeeding Questionnaire are prepared based on the theory of planned behavior. In the second phase, the intervention plan is designed based on the literature review and the findings of the qualitative study, and it is approved by a panel of experts. Additionally, the psychometric properties of the questionnaire are evaluated and confirmed qualitatively and quantitatively. In the third phase, the developed intervention is implemented and evaluated.

**CONCLUSION:** Implementation of supportive educational interventions based on scientific theories can be a step toward improving the rate of onset and continuation of breastfeeding in mothers with preterm infants. Development of interventions based on evidence, identified beliefs, and perceived barriers of the mothers with preterm infants can provide the foundation for more effective interventions according to cultural, social, and religious contexts.

## Keywords:

Breastfeeding, exclusive breastfeeding, premature infants, preterm infants, the planned behavior theory

## Introduction

As the leading cause of death in children under five years of age, preterm birth threatens the lives of 15 million infants worldwide each year. The prevalence of preterm birth varies from 5% to 18% and

continues to increase as a health problem around the world. Nutritional support with an emphasis on exclusive breastfeeding is one of the strategies used by the World Health Organization (WHO) for improving the outcomes of preterm births.<sup>[1]</sup>

The short-term and long-term benefits of exclusive breastfeeding for children

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are as follows: reduced length of stay in the hospital, increased mother–infant attachment, increased weight, lower body mass index (BMI), stability of metabolic parameters in infants with metabolic disorders, healthier eating habits, prevention of obesity and cardiovascular disease in children, and better cognitive and behavioral development in children.<sup>[2,3]</sup>

Benefits for mothers include reduction of postpartum hemorrhage and the anemia caused by it, Occurrence of lactational amenorrhea, creation of a distance between later pregnancies and reduction of subsequent preterm births, lower levels of fats and blood sugar, and reduced risk of diabetes, hypertension, hyperlipidemia, metabolic syndrome, stroke, cardiovascular disease, rheumatoid arthritis, breast cancer, ovarian cancer, and endometrial cancer.<sup>[4,5]</sup>

It has been estimated that increased exclusive breastfeeding can prevent the annual death of 823,000 infants under the age of five and 20,000 deaths of women caused by breast cancer worldwide. However, in low- and middle-income countries (LMICs), only 37% of newborns under six months are exclusively breastfed, and this rate is even lower in high-income countries.<sup>[6]</sup>

Moreover, despite the known benefits of breastfeeding, the rate of exclusive breastfeeding in preterm infants has been reported to be lower than that in term infants, indicating the need for effective intervention.<sup>[7]</sup>

In Iran, the prevalence of preterm delivery and exclusive breastfeeding is reported to be 10% and 53%, respectively. Given the lower probability of exclusive breastfeeding in preterm infants, it can be predicted that many preterm infants born in Iran are deprived of the benefits of exclusive breastfeeding.<sup>[8,9]</sup> In a study conducted in Iran, a follow-up of preterm infants after discharge from a high-risk neonatal clinic showed that the rate of exclusive breastfeeding was 17%.<sup>[10]</sup>

With regard to the factors associated with the continuation of exclusive breastfeeding among preterm infants, a Chinese study reported that continuous exclusive breastfeeding of late preterm infants is positively related to breastfeeding self-efficacy and social support.<sup>[11]</sup> According to another study, the support provided to Greek mothers with preterm infants after discharge from the neonatal intensive care unit was related to the mothers' intention to breastfeed.<sup>[12]</sup> A survey of Iranian mothers showed that 61.9% of them did not have a positive attitude toward breastfeeding.<sup>[13]</sup> In the United Kingdom, subjective norms and attitudes of mothers toward formula predicted the intention of these mothers to breastfeeding. In this study, the intention

to behave and the experience of formula feeding also predicted breastfeeding in the sixth week.<sup>[14]</sup>

According to these studies, the design of the interventions based on the theory of planned behavior can be effective on exclusive breastfeeding of infants. Based on this theory, human behavior is directed by one's beliefs about the possible consequences of behavior (behavioral beliefs), the normative expectations of others (normative beliefs), and the factors which facilitate or prevent behavior (control beliefs).<sup>[15]</sup>

Behavioral, normative, and control beliefs shape attitudes toward behavior, perceived social pressure or subjective norms, and perceived behavioral control, respectively. Positive attitude and supportive subjective norms motivate the person to conduct a behavior, and the behavioral intention is formed if the perceived control over one's behavior is strong.<sup>[16]</sup>

An Iranian study showed that after the implementation of the intervention based on the theory of planned behavior among pregnant women, the mean scores of attitudes, subjective norms, perceived behavioral control, and the intention and exclusive behavior of breastfeeding increased significantly in the experimental group compared to the control group.<sup>[17]</sup> Another study in Iran showed that the structures of the theory of planned behavior are a suitable framework to promote exclusive breastfeeding among pregnant women.<sup>[18]</sup>

According to other studies, a breastfeeding support intervention based on the planned behavior theory appears to be an effective program to delay cessation of exclusive breastfeeding and therefore to increase breastfeeding duration and exclusivity in populations such as primipara women, drug-dependent mothers, mothers after cesarean section, and term infants.<sup>[19-22]</sup>

So test the effectiveness of a breastfeeding support intervention based on the planned behavior theory in other populations such as preterm infants could be useful to promote breastfeeding. The purpose of this study is to design and develop an exclusive breastfeeding intervention based on the theory of planned behavior for mothers with preterm infants.

## Materials and Methods

### Study design and setting

This exploratory sequential mixed methods study will be conducted in three phases. In the first phase, using a qualitative study, the beliefs of mothers with preterm infants regarding exclusive breastfeeding are identified and described based on the theory of planned behavior.

Then, facilitating factors as well as perceived barriers and ways to overcome them will be extracted in the field of exclusive breastfeeding. Moreover, considering the results of the study, the initial items of the predictors of exclusive breastfeeding questionnaire are prepared based on the theory of planned behavior. In the second phase of the study, the intervention plan is designed and approved. Additionally, the psychometric properties of the questionnaire will be evaluated qualitatively and quantitatively. This questionnaire will be used for the evaluation of the theoretical structures before and after the intervention in the study groups. In the third phase, an intervention will be implemented and evaluated based on the theory of planned behavior.

### Phase 1: Qualitative study

In this phase, a qualitative study will be conducted based on the theory of planned behavior to describe the exclusive breastfeeding beliefs of the mothers with preterm infants, the barriers to breastfeeding, and to explain the ways to overcome them. Then, the items of the questionnaire will be prepared.

#### *Study participants and sampling*

Participants of the qualitative study will be 18- to 40-year-old mothers who have referred to comprehensive health centers in Isfahan, Iran, for periodic child care. Purposive sampling method will be performed and continued until data saturation is reached.

#### *Inclusion and exclusion criteria*

Inclusion criteria will be mothers having a preterm singleton infant born before completing its 37<sup>th</sup> week, having no psychiatric problems and addiction, and no contraindications to breastfeeding in the mother and infant. Exclusion criterion will be the unwillingness of the mothers to continue their cooperation at any time. In selecting mothers, we will try to consider the maximum variation in terms of parity, age, and feeding method of the infant.

#### *Data collection tool and technique*

Data will be collected through in-depth semi-structured interviews based on the theory of planned behavior to discover the beliefs, motivating factors, and perceived barriers to exclusive breastfeeding and the ways of overcoming them. Before the interviews, the participants will be explained about the purpose of the study, the written and informed consent of participants will be obtained, and the time and place of the interview will be determined considering the participants' opinions.

### Data analysis

The data will be analyzed using conventional content analysis based on the Landman and Granheim method.

### Phase 2: Intervention design/questionnaire approval

#### *Design and approval of the intervention*

In the first step of this phase, using the results of the qualitative phase and literature review, an intervention will be designed based on the theory of planned behavior about exclusive breastfeeding of mothers with preterm infants. The content of this intervention will be reviewed and approved by a panel of experts in reproductive health, neonatal health, and health education.

#### *Questionnaire approval*

In the second step, after extracting the predictive items of exclusive breastfeeding based on the theory of planned behavior from the qualitative study, the psychometric properties of the questionnaire will be evaluated. Face and content validities will be qualitatively evaluated using the opinions of reproductive health, neonatal health, and health education experts. Moreover, the content validity ratio and the content validity index of the questionnaire will be calculated based on the opinions of these experts. To determine the external reliability, the questionnaire will be completed in two stages with an interval of a fortnight by a number of mothers with preterm infants who are eligible for the third phase of the study. The internal reliability of the questionnaire will be determined by calculating Cronbach's alpha coefficient for the entire questionnaire and for each of the dimensions of the questionnaire, and the external reliability of the questionnaire will be obtained by calculating the Pearson correlation coefficient.

### Phase 3: Quantitative study

In this phase, the designed intervention will be implemented and evaluated through a two-group, four-stage field trial. The purpose of this phase is to determine the effect of exclusive breastfeeding intervention based on the theory of planned behavior on breastfeeding intention (exclusive breastfeeding, combined breastfeeding including breast milk and formula, using formula exclusively to feed the infant) on mothers with preterm infants. The setting of research in this study is the neonatal intensive care units and internal wards of the two major referral hospitals in Isfahan, Iran, where the highest number of preterm infants of Isfahan and its suburbs are admitted.

#### *Study participants and sampling*

The population of this study will be mothers with preterm infants (34 to 36 weeks and 6 days) whose neonates are hospitalized in intensive care and internal wards of these two hospitals. Of these, 72 mothers who fulfill the inclusion criteria will be selected and registered using convenience sampling method.

Then, using random allocation they are placed in two groups of intervention and control. For this purpose,

they will select one of the 72 cards on which the name of the control or intervention group is written.

Demographic characteristics of the participants will be recorded, written and informed consent will be obtained from all of them, and they will be assured of the confidentiality of their information.

### *Inclusion and exclusion criteria*

Inclusion criteria will be mothers' willingness to participate in the study, literacy, Iranian nationality, no psychiatric disorders and addiction in the mother, and no contraindications to breastfeeding in the mother and infant according to the contents of the medical record of the mother and infant, being singleton, gestational age of 34–36 weeks and 6 days at the time of birth, and stable condition of the infant to start breastfeeding. Exclusion criteria will include infant death, maternal depression or postpartum psychosis, the reluctance of the mother to continue cooperation, and cessation of breastfeeding for maternal or neonatal reasons.

### *Implementation of the intervention*

An intervention will be performed on participants of the intervention group based on the manipulation of the structures of the theory of planned behavior and the results of the qualitative study. Monthly telephone calls will also be considered for the subjects of this group to investigate breastfeeding status and related issues (based on the structures of the theory of planned behavior) for up to four months. Additionally, through a social network channel, the participants of the intervention group will be able to communicate with the researchers to talk about the issues related to the intervention. The control group will receive routine hospital care. The exclusive breastfeeding predictor questionnaire based on the theory of planned behavior will be used for both intervention and control groups, and the intention of the mothers behind breastfeeding will be measured by completing the questionnaire in four stages, including before and immediately after the intervention, and when the infant is two and four months old. IBM SPSS Statistics version 19 will be used for statistical analysis.

### **Ethical consideration**

This study, with the ethics code of IR.MUI.NUREMA.REC.1400.012, has been approved by the ethics committee of Isfahan University of Medical Sciences. Written and informed consent will be obtained from all of the participants, and they will be assured of the confidentiality of their information.

## **Discussion**

Despite the significance of exclusive breastfeeding of up to six months for all infants, especially preterm infants,

findings show that the risk of not starting breastfeeding and discontinuing exclusive breastfeeding before six months is a prevalent and challenging problem for late preterm infants.<sup>[23]</sup>

Therefore, further research seems necessary to empower mothers with preterm infants in exclusive breastfeeding and increase the rate of exclusive breastfeeding to an optimum level in late preterm infants. An investigation of Iranian women's experiences in the field of breastfeeding empowerment has shown that breastfeeding-related knowledge and skills, the ability to overcome barriers to breastfeeding, and understanding family support provide the foundation for a woman to be able to breastfeed.<sup>[24]</sup>

The capacities of planned behavior theory have been used to conduct behavioral change interventions in several areas.<sup>[16]</sup> Moreover, literature review shows how previous studies have investigated the factors influencing the intention of exclusive breastfeeding behavior.<sup>[25,26]</sup> Accordingly, it seems that using the theory of planned behavior can prepare the ground for the onset and continuation of exclusive breastfeeding for these infants through creating positive behavioral beliefs about the intention of exclusive breastfeeding behavior, correcting misconceptions in this area, and empowering women with preterm infants.

Together with the efforts made in the development of mother-friendly hospitals, the implementation of supportive educational interventions based on scientific theories can be a step toward improving the rate of initiation and continuation of breastfeeding in mothers with preterm infants. Development of interventions based on theories, identified beliefs, and perceived barriers of mothers with preterm infants can provide the ground for more effective interventions according to cultural, social, and religious contexts.

### **Limitation and recommendation**

One of the limitations of the present study is that as only healthy singleton preterm infants will be included in this study, it is impossible to generalize the results to mothers with preterm infants resulting from multiple pregnancies or sick infants.

Thus, Implementation of the intervention in other populations such as mothers with early preterm infants, sick preterm infants or preterm infants resulting from multiple pregnancies is recommended.

## **Conclusion**

Development of interventions based on Behavioral theories, identified beliefs regarding exclusive

breastfeeding, and perceived barriers to breastfeeding in mothers with preterm infants can provide the ground for more effective interventions according to cultural, social, and religious contexts.

### 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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