



## The Effect of the Health Promotion Monitoring Program Applied to Mothers Based on Meleis' Transition Theory: A Randomized Controlled Study Protocol

### Meleis'in Geçiş Teorisine Dayalı Annelere Uygulanan Sağlığı Geliştirme Eğitim Programının Etkisi: Randomize Kontrollü Bir Çalışma Protokolü

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#### ÖZET

**Amaç:** Bu çalışmanın amacı, Meleis'in Geçiş Kuramı'na dayalı olarak gebelere bireysel seanslar şeklinde uygulanan dört modülden oluşan Sağlığın Geliştirilmesi İzleme Programı'nın maternal bağlanma, ebeveyn öz-yeterliği ve bebeğin gelişimi üzerindeki etkisini değerlendirmektir. **Yöntem:** Bu çalışma, son test düzenli paralel grup (deney-kontrol) ve randomize kontrollü deneyel bir araştırma tasarımdır. Araştırmanın evrenini Konya ilinde bir Aile Sağlığı Merkezine kayıtlı 36 ve 40 haftalık gebeler oluşturdu. Randomize kontrollü deneme katılımcısı akışı, CONSORT'a göredir. Katılımcılar, tabakalı randomizasyon yöntemi ile deney ve kontrol gruplarına atanmıştır. Çalışmada permütasyon yöntemi kullanılarak tabakalar arası denge sağlanmıştır. Rutin bakıma ek olarak, 36-40. gebelik haftaları ile doğumdan sonraki 1. ve 2. aylar arasında Sağlığı Geliştirme Programı uygulandı. Sonuç ölçütleri maternal bağlanma, ebeveyn öz-yeterliği ve bebek gelişimi idi. Veriler gebelikte, doğum sonrası 2. ve 6. aylarda toplanmıştır. **Tartışma:** Bu çalışma, teoriye dayalı, yenilikçi bir programı anne ve bebek sonuçlarıyla değerlendirmek için sıkı çalışma tasarımlını kullanan türünün iyi bir örneği olacaktır. Çalışmanın sonunda annelerde bebek sağlığını geliştirmeye yönelik uygun davranışlar geliştirilebilir. Annelerin bağlanma ve ebeveyn öz-yeterlik düzeyleri bebeklerin gelişimini iyileştirebilir. Böylece anneler anneliğe sağlıklı bir geçiş yapmış olacaklardır.

**Anahtar Sözcükler:** Geçiş kuramı, maternal bağlanma, ebeveyn öz-yeterliği, bebek gelişimi, hemşirelik.

#### ABSTRACT

**Objectives:** The aim of this study was to evaluate the effect of the Health Promotion Monitoring Program consisting of four modules applied to pregnant women in the form of individual sessions based on Meleis' Transition Theory on maternal-fetal attachment, parental self-efficacy, and infant development. **Methods:** This study is a prospective and randomized controlled experimental research design with a post-test regular parallel group (experimental-control). Pregnant women at 36 and 40 gestational weeks who were registered in a Family Health Center in Konya, Turkey constituted the population of the study. The randomized controlled trial participant flow is relative to the CONSORT. The participants were assigned to the experimental and control groups by stratified randomization method. In the study, the balance between the layers was achieved by using permutation method. In addition to routine care, a Health Promotion Program was performed between 36-40 weeks of gestation and 1 and 2 months after delivery. Outcome measures were maternal infant attachment, parental self-efficacy and infant development. Data were collected during pregnancy, postpartum 2nd and 6th months. **Discussion:** This study will be the first one of its kind to use hard work design to evaluate a theory-based, innovative program with maternal and infant outcomes. At the end of the study, appropriate behaviours for the improvement of infant health may be developed in mothers. Mothers' attachment and parental self-efficacy levels may improve the development of infants. Thus, mothers will have a healthy transition to motherhood.

**Keywords:** Transition theory, maternal attachment, parental self-efficacy, infant development, nursing.

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## INTRODUCTION

One of the important milestones in women's lives is maternity. Maternity is also the beginning of a process in which very significant responsibilities are assumed (Meleis, 2010; Öztürk and Erci, 2016). The development of maternal identity is the woman's process of learning maternal behaviours. This process begins with the recognition of pregnancy, develops during pregnancy, and continues after delivery (Meighan, 2013). Although taking the maternal role and the inclusion of a new individual in the family bring happiness, it is a difficult period since it requires a change in which new roles are acquired and responsibilities are taken (Ozkan and Polat, 2011). Mothers learn how to meet both their needs and the needs of their new-born infants during this period (Kavlak, 2007). If the mother lacks information on infant care, growth, and development, understanding infant behaviours and diseases, anxiety and withdrawal from the maternal role may be observed. The skills to cope with potential problems and to solve problems should be increased with appropriate nursing interventions, and thus, the mother's quality of life should be improved (Taskin and Kukul, 2012).

## Theoretical Framework of the Study

This study will be guided by based on Meleis' transition theory. This study will be guided by John Bowlby's attachment theory and Bandura's self-efficacy theory, based on Meleis' transition theory. The transition theory is a suitable tool for nurses to understand the transition to parenting, which is a type of developmental transition. Furthermore, it has the potential to help professionals determine appropriate strategies and practices to provide parents with adequate assistance and support. This is important because an important function of nursing is to help people manage their life transitions, as it was indicated by Meleis. However, longitudinal intervention designs are recommended in time to explore transition experiences completely. Many conditions in the transition experience affect the child's development, health, and well-being, and parenting is the key to the health and well-being of the child (Barimani et al., 2017).

Attachment starts in the prenatal period and continues in the postnatal period. Prenatal and postnatal maternal-fetal attachment are interrelated (Klossner, 2006; Maas et al., 2015; Mutlu et al., 2015; Müller, 1996; Rossen et al., 2017; Yilmaz, 2013). It is recommended to evaluate maternal-fetal attachment during pregnancy to determine risks that may arise in terms of maternal and infant health after delivery (Petri et al., 2018). Abasi et al. (2013) indicated that the intervention program to promote attachment they applied to pregnant women could positively affect maternal mental health, fetus health, and, ultimately, child health (Abasi et al., 2013). In a study, it was found that the education of mothers on attachment strengthened the attachment between the mother and fetus and had positive effects on the mental health of infants after delivery (Akbarzadeh et al., 2016). In another study, it was indicated that the education program during pregnancy had a positive effect on the postnatal period, increased mothers' self-confidence, and improved the functional status, and thus, it was necessary to improve postnatal maternal and infant health (Bagherinia et al., 2017). Maternal-fetal attachment is also a factor associated with postnatal parental self-efficacy (Delavari et al., 2018).

Bandura (1997) considered self-efficacy as a cognitive process that evaluates the ability to perform a given task (Bandura, 1997). Attachment is important for maternal health as well

as for infant health. It was determined that the infant care education provided to mothers by nurses in the postnatal period improved the mother's self-confidence and positively affected the attachment (Cinar and Ozturk, 2014). According to the meta-analysis result obtained by Branjerdporn et al., studies involving nursing interventions were recommended to evaluate the relationship between maternal-fetal attachment and development (Branjerdporn et al., 2017). Parental self-efficacy is an important component of a smooth transition to maternity (Leahy Warren, 2005; Ngai et al., 2010; Sanders and Woolley, 2005). In a study, it was found that the applied nursing intervention significantly increased parental self-efficacy (Kaya and Şahin, 2018).

Sustainable Development Goals include "developmental support of children in early childhood, health, learning and psychosocial welfare, gender equality rates" (2030 Sustainable Development Goals, 2019). Emergency action plans supporting nutrition, health, sensitive care, safety, and development should be prepared for children (Black et al., 2017). The first 6 years of children are important for development. A developmental delay that is recognized late in this period will negatively affect the rest of the child's life. Therefore, the chance of treatment of developmental delays with an early diagnosis should be increased (Akdağ, 2015). It is first necessary to evaluate mothers' levels of knowledge about child development and supportive practices to keep the development of infants at a good level (Zellman et al., 2014).

### Aim of the study

The aim of this study was to evaluate the effect of the Health Promotion Monitoring Program consisting of four modules applied to pregnant women in the form of individual sessions based on Meleis' Transition Theory on maternal-fetal attachment, parental self-efficacy, and infant development.

### Objectives

- ❖ To determine the development level of infants of experimental group mothers (posttest-1, posttest-2).
- ❖ To determine the maternal attachment level of the experimental group (baseline, posttest-1, posttest-2).
- ❖ To determine the self-efficacy level of the experimental group (posttest-1, posttest-2).

### Hypotheses of the study

**H0:** Maternal attachment levels, levels of parental self-efficacy perception, and infant development of the mothers in the HPMP-applied experimental group were not different from those of the mothers in the control group.

### METHODS

This study is a prospective and randomized controlled experimental research design with a pre-test post-test regular parallel group (experimental control). The study was carried out in a Family Health Centre (FHC) in Konya, Turkey.

### **Determination of the Study Population and the Size of the Study Group**

Pregnant women at 36 and 40 gestational weeks who were registered in a family health center in Konya, Turkey, constituted the population of the study. Pregnant women who met the inclusion criteria and agreed to participate in the study constituted the sample of the study. *Calculation of the sample number:* In the study by Sercekus and Baskale (2016) in which maternal attachment levels of mothers were examined, the mean maternal attachment scores of the experimental group and the control group were found to be  $100.1 \pm 4.9$  and  $98.5 \pm 5.3$ , respectively (Sercekus and Baskale, 2016). Based on these values, it was determined that there should be a total of 52 individuals, at least 26 individuals in the experimental and control groups, in the sample calculation made with a 5% alpha error and 80% power by envisaging the change in big/large effect size of the mothers in the experimental group in our study (effect size of 0.80, a change of up to 80% in standard deviation) (G\*Power 3.1.9.2). Considering that there could be losses during data collection, it was decided to include 64 individuals in each study group with a 20% surplus.

### **Study Group, Inclusion and Exclusion Criteria**

Women who were at least primary school graduates and older than 18 years of age and had no chronic disease were included in the study. Pregnant women who had multiple pregnancies, were at risk of preterm delivery and did not speak Turkish were excluded from the study. Mothers who did not participate in at least one education and/or measurement, wanted to leave the study, and developed mental or physical illnesses such as postpartum depression during the follow-up, and women whose infants had congenital and/or metabolic disease that was not diagnosed before and during delivery but was detected during the postpartum follow-up were planned to be excluded from the study.

### **Ethical Aspect of the Study**

The relevant permissions were obtained from the authors for the scales to be used before starting the study. Ethics committee approval and permission of the institution were obtained. The participants were informed about the study, and their informed consent was obtained in writing.

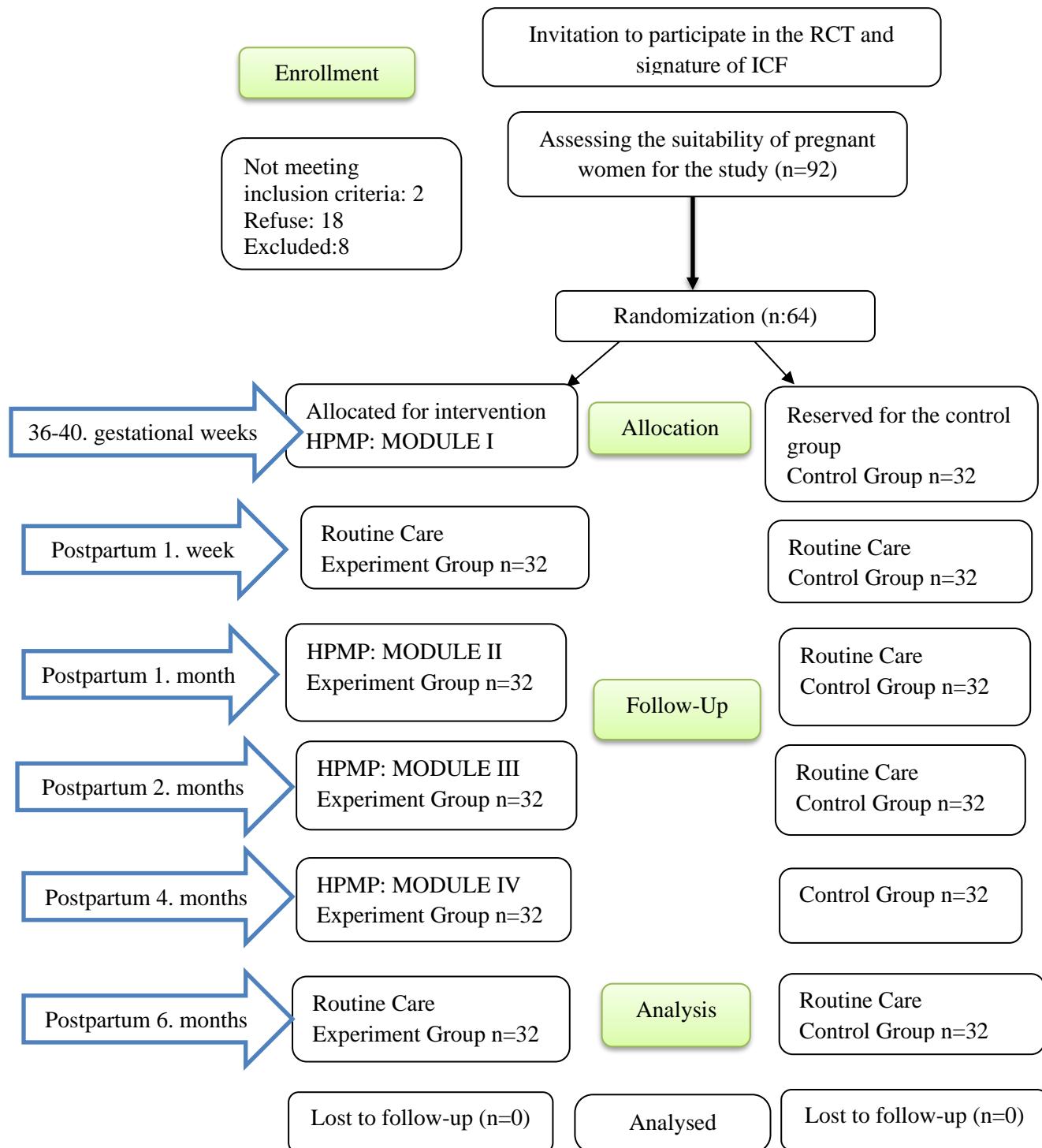
### **Validity and Reliability**

All data were carefully checked immediately after collection, and no problem was found. The data entered in SPSS were cross-checked for verification. The statistical assumptions for certain tests were tested before data analysis. Randomization indicates that there is no systematic bias regarding the qualifications in the groups and that any difference between the groups can be deduced from the intervention. The control group also distributes the effects of foreign variables and increases the internal validity of the study. Furthermore, basic data in both the control and experimental groups were tested for initial equivalence between the groups (Polit and Beck, 2006). The differences were statistically controlled to further increase the internal validity of the study.

## **Randomization**

Ninety-two pregnant women between 24 and 36 gestational weeks who were registered in a Family Health Center constituted the study group of the research. Since the FHC records revealed that 2 of pregnant women had multiple pregnancies, they were excluded from the study group. In the study, 90 pregnant women were randomly assigned to the experimental and control groups in order to reduce selection bias and to control the variables that might have an effect on dependent variables. Assignment to the experimental and control groups was performed by an independent statistician to prevent bias and ensure confidentiality. Thus, selection bias was taken under control by randomized assignment and concealment of randomization. A total of 26 pregnant women were not included in the study group since 6 pregnant women moved from the FHC region, 2 pregnant women were at risk of preterm delivery, and 18 pregnant women refused to participate in the study. Sixty-four healthy pregnant women, who met the inclusion criteria and accepted to participate in the study, constituted the study group of the research. Before the assignment, pregnant women in the study group were provided with general information about the study, and their consent was obtained for participation in the study. 32 pregnant women were randomly assigned to the intervention group and 32 pregnant women to the control group.

In this study, a stratified randomization method was used (Figure 1). The use of the stratified randomization method is desired in randomized controlled trials. The number of subjects in randomized controlled trials is desired to be equal or balanced and also similar in terms of prognostic factors (Kahan et al., 2015).



**Figure 1: Flow Chart of RCT experiment and control group, CONSORT (2017)**

Source: <http://www.consort-statement.org/consort-2017>

HPMP: Health Promotion Monitoring Program

In the study, two strata consisting of educational level (primary, secondary, and high school, university) and the number of children (primiparous and multiparous) were formed to ensure homogeneity in each group. Thus, imbalances that might arise in the groups were limited by the stratified randomization method. The proposed stratified random sampling method in this study is intended to minimize confounding bias. In the study, the permutation method was used to ensure balance between the strata. The block sets in the permutation method were generated for each combination of prognostic factors (education and the number of children). Eight quadruple blocks were formed by the permuted blocked randomization method. After the formed blocks, the experimental and control groups were randomly assigned to the strata using the random numbers table generated in the computer environment ([www.random.org](http://www.random.org)). The chosen letter would be the experimental or control group was determined by the coin toss method at the beginning of the study. Consequently, letter "A" was included in the experimental group, and letter "B" was included in the control group. The randomization of the study is as follows.

### **Blinding**

Researcher and participant blinding could not be performed in this study. The scales were applied to the experimental and control groups by nurses and midwives working in the FHC to avoid bias in the data collection process. Furthermore, all data obtained were coded as "A" and "B" and transferred to the computer by getting support from another academician. The data were coded in groups to avoid bias in the evaluation of the data, and data analysis was performed by an independent statistician. After the analysis and interpretation of the data in the statistical process were finished, the codes of the experimental and control groups in the study were revealed. Thus, the statistician was blinded in the evaluation stage of the study.

### **Data Collection Tools**

The Family Information Form and Monitoring Form were used to collect socio-demographic data. In data collection, the Prenatal Attachment Scale, Maternal Attachment Scale, Denver II Developmental Screening Test, and Parental Self-Efficacy Scale were used to measure the dependent variables.

***Family information form and monitoring form:*** The Family Information Form consists of 18 questions to determine the socio-demographic and obstetric characteristics of pregnant women. The form includes pregnant women's age, educational status, gestational week, employment status, number of children, family type, health insurance, monthly income assessment, and husband's age, educational status, employment status, and duration of marriage. With respect to obstetric characteristics, it includes 21 questions examining maternity preparation education, a person who is considered as a role model for maternity, the history of previous pregnancy and previous important life events, the presence of social support, the desire for an infant, and satisfaction with the gender of the infant. The monitoring form contains information such as the date of birth and sex of infants, postpartum maternal and infant health problems, if any, application of an intervention program by the mother, and diet of the infant (breast milk, formula, mixed).

**Denver II developmental screening test:** The Denver II Developmental Screening Test form is the international developmental screening test that is used to evaluate and monitor the development of children aged from 2 months to 6 years. The test consisting of 134 items and four parts: gross motor, fine motor, language, and personal-social fields. Turkish standardization of the test form was performed by Prof. Dr. Kalbiye Yalaz and Prof. Dr. Shirley Epir and began to be used in Turkish children (Yalaz et al., 2009).

**Prenatal attachment inventory:** This scale, which was developed by Muller in 1990, is used to determine the prenatal attachment levels of the mother to the infant during pregnancy and to explain her feelings, thoughts, and situations. Turkish validity and reliability studies of the scale were performed by Yilmaz and Beji (2013). It is a 21-item scale. Each item is of a four-point Likert type scored between 1-4. The lowest and highest scores obtained from the scale are 21 and 84, respectively. The level of attachment increases as the scale score increases. Cronbach's alpha reliability coefficient of the scale was found to be 0.84. The scale was found to be valid and reliable in pregnant women who were 18 years and older, completed 20 weeks of gestation, had no communication difficulties, had a healthy fetus and had no complaints of gestational diabetes, eclampsia and preeclampsia and chronic disease (Yilmaz and Beji, 2013).

**Maternal attachment scale:** The Maternal Attachment Scale (MAS) was developed by Müller in 1994 to measure the love and attachment of the mother to her infant. Its validity and reliability studies in Turkey were performed by Kavlak and Şirin (2009). It is a 4-point Likert-type scale and consists of 26 items, and each item ranges from "always" to "never." A total overall score is obtained from all items. The lowest and highest scores obtained from the scale are 26 and 104, respectively. A high score obtained from the scale indicates high maternal attachment. In the internal consistency analysis of the scale, Cronbach's alpha ( $\alpha$ ) value was found to be 0.77 in mothers having 1-month-old infants and 0.82 in mothers having 4-month-old infants (Kavlak and Sirin, 2009).

**Parental self-efficacy scale:** The Parental Self-Efficacy Scale (PSES) was developed by Kılıçarslan and İşmen Gazioğlu in 2008. It is a 5-point Likert-type scale consisting of 18 items, which was developed to determine the personal beliefs of new parents about their competence in their roles. Parents are asked to respond to the items on the scale in the form of "Totally Agree," "Agree," "Undecided," "Disagree," and "Strongly Disagree." The scale is scored on a scale of 1 to 5. In reverse statements, points are converted to the opposite system, i.e. from 5 to 1. In the internal consistency analysis of the scale, Cronbach's alpha ( $\alpha$ ) value was found to be 0.852 (Kılıçarslan et al., 2008).

## Data Collection

Data collection was started at 36 weeks of gestation and completed in the 6<sup>th</sup> month after delivery. The data collection process took place between October 3, 2018, and August 12, 2019.

**Pre-tests:** Pregnant women were informed about the study at the FHC, their written informed consent was obtained, and pre-tests were performed. The application took approximately 10

minutes. Within the scope of pre-tests, the Family Information Form and Prenatal Attachment Scale were applied to the mothers.

**Intermediate measurements:** Intermediate measurements were performed for mothers and infants in the 2<sup>nd</sup> month after delivery. While the Monitoring Form, Maternal Attachment Scale, and Parental Self-Efficacy Scale were applied to mothers by nurses working at the FHC, the Denver II Developmental Screening Test was applied to infants by the researcher.

**Post-tests:** Post-tests were performed on mothers and infants in the 6<sup>th</sup> month after delivery. While the Monitoring Form, Maternal Attachment Scale, and Parental Self-Efficacy Scale were applied to mothers by nurses working at the FHC, the Denver II Developmental Screening Test was applied to infants by the researcher. The research period is in Table 1.

**Table 1. Study period**

Timepoint	Enrolment	Allocation		Post-allocation			Closeout	
	-t <sub>1</sub> (at nurse appointment)	t <sub>1</sub> (1st week)	t <sub>2</sub> (4th week)	t <sub>3</sub> (8th weeks)	t <sub>4</sub> (12th week)	t <sub>5</sub> (20th week)	t <sub>6</sub> (28th week)	t <sub>7</sub>
<b>Enrolment</b>	x							
<b>Eligibility Screen</b>								
Informed consent	x							
The pretest	x							
Allocation								
Randomization	x							
<b>Interventions</b>								
(Sgip)								
Modül 1		x						
Modül 2				x				
Modül 3					x			
Modül 4		x	x	x	x	x	x	
<b>Assessments</b>								
Sociodemographic characteristics	x							
Clinical indicators of transition process (maternal attachment)	x			x			x	
Parental self-efficacy				x			x	
Infant development				x			x	
Infant growth	x		x	x			x	

### Health Promotion Monitoring Program (HPMP) and Application

The application process of the study was conducted by the researcher between October 2018 and August 2019. In this process, the Health Promotion Monitoring Program (HPMP) (individualized education and telephone reminders and telephone counselling in case of need of mothers) was conducted.

According to Meleis, the primary purpose of nursing is to help people who are in the transition process to achieve healthy outcomes, and accordingly, nursing is the science and art that facilitates the health and well-being of the community in transitions (Meleis 2010). An

HPMP was prepared to support the factors that facilitate women's transition to maternity and to eliminate inhibitory factors. In line with the goal of "To Ensure Healthy Lives and Promote Well-being for All at All Ages" (<http://www.tr.undp.org>, 2019) included in the main goal of the "Health and Well-being" main article among the 2030 Sustainable Development Goals, the care and development needs of mothers and infants were determined based on Meleis' "Transition Theory." We prepared the "Health Promotion Monitoring Program" based on Meleis' transition theory in order to meet these needs and also to ensure that the mother in transition could achieve healthy outcomes (Meleis, 2010). The HPMP has 3 main objectives. These objectives are to maximize infant development, increase maternal-fetal attachment and increase parental self-efficacy in the experimental group. The training content of the HPMP was collected under four main headings, including nutrition in the first part, infant development in the second part, infant health in the third part, and security in the fourth part. The HPMP consists of 4 modules and phone counselling.

### **Experimental group**

In addition to routine care provided by nurses and midwives at the FHC, the HPMP was applied to pregnant women in the experimental group by the researcher for 7 months starting from the 36 and 40 weeks of gestation until the 6<sup>th</sup> month after delivery. In line with the booklet prepared, the Health Promotion Monitoring Program was conducted in the form of three training sessions and a telephone reminder and telephone counselling. Various training tools were used in this training. Three different PowerPoint presentations were made in the training sessions. A3 size illustrated printed training material was used.

**HPMP module I:** The first training session of the health promotion monitoring program was applied to pregnant women at 36 and 40 weeks of gestation by the researcher, and the training booklet was given. Within the scope of the training, for the objectives of strengthening maternal-fetal attachment, increasing parental self-efficacy, and supporting infant development, pregnant women were provided with training on breastfeeding, supporting infant development, protecting infant health, common problems in the postpartum period, and ensuring infant safety. Each training lasted for approximately 120-150 minutes, and two rest breaks were provided during the training. The questions of pregnant women were answered, and feedback was received.

**HPMP module II:** At the end of the 1<sup>st</sup> month after delivery, the researcher provided mothers with training on supporting the development of the infant between 1-2 months. The breastfeeding technique of the mother was checked by making her breastfeed her infant, the questions of the mother, if any, were answered, and feedback was obtained about breastfeeding. The screenings and immunization conducted for the protection of infant health were checked. Information about common problems experienced by the infant was obtained, and the solutions of the mother were discussed. Feedback about infant safety was obtained from the mother. Information about the infant's sleeping position, bed and room was obtained from the mother. Training and reminders were made for the issues needed by the mother. The training lasted for approximately 30 minutes.

**HPMP module III:** At the end of the 2<sup>nd</sup> month after delivery, the researcher provided mothers with training on supporting the development of the infant between 2-6 months. Mothers' questions, if any, about breastfeeding were answered, and feedback was obtained. Information about common problems experienced by the infant was obtained, and the solutions of the mother were discussed. Feedback about infant safety was obtained from the mother. Training and reminders were made for the issues needed by the mother.

**HPMP module IV (telephone reminders in the postpartum 4<sup>th</sup> month):** The mothers were phoned by the researcher in the postpartum 4th month, the reminder interviews were conducted for breastfeeding, supporting infant development, protecting infant health, common problems, and ensuring infant safety, which strengthened the training content, and mother's questions, if any, were answered.

**Telephone counselling:** In the process from the postpartum period to the 6th month of the infant, mothers asked their questions about themselves and their infants to the researcher via telephone if they needed them. The researcher answered the questions.

### **Control group**

The participants in the control group were provided with standard care by midwives and nurses working at the FHC starting from 36 and 40 weeks of gestation until the infant was 6 months old. Standard care included counselling, physical examination, new-born screening tests, breastfeeding training, and immunization appropriate to month.

### **Variables of the Study**

The Prenatal attachment scale score, Maternal attachment scale score, Parental self-efficacy scale score, and Denver II Developmental Screening Test result were the dependent variables of the study. The Health Promotion Monitoring Program was the independent variable of the study. The mother's age, educational status, employment status, perceived income status, number of living children, sex of the infant, and the infant's height, weight, and head circumference were the control variables of the study. The Denver II developmental screening test result, the level of maternal-fetal attachment, and the level of parental self-efficacy were the outcomes of the study.

### **Outcomes**

**Primary outcome:** The primary outcome is the level of development of infants. The level of development of infants is assessed with the Denver II development screening test. Infant development is considered to be developmental delay or normal development.

#### **Secondary outcomes:**

**Maternal attachment level:** Maternal attachment is one of the most important elements for the healthy growth and development of the infant. Maternal attachment, evaluated by a Likert scale, with 1 being the worst possible score and 4 the best possible score. A high score on the scale indicates that the level of attachment is high.

**Parental self-efficacy:** Parental self-efficacy is an important component of a smooth transition to maternity. Maternal attachment, evaluated by a Likert scale, with 1 being the worst possible score and 5 the best possible score. A high score on the scale indicates that the level of attachment is high.

### Data Analysis

Support was received from an expert statistician in the statistical analysis of the study. Statistical analysis would be performed using the SPSS 22 program. The statistical methods would be decided by evaluating the suitability of the data for normal distribution. The results obtained would be tested at a significance level of  $p<0.05$ . All pregnant women in the experimental group participated in the interventions, and all pregnant women in the experimental/control group participated in all measurements. Therefore, MoTT was not applied in presenting the results of the study. Moreover, no ITT analysis was needed for control purposes.

### Limitations of the study

The failure to perform researcher and participant blinding, failure to conduct group training, and the implementation of the Denver II developmental screening test by the researcher were the limitations of the study.

## DISCUSSION

This study will be the first of its kind to use hard work design to evaluate a theory-based, innovative program with maternal and infant outcomes. The health of both mother and infant is affected by maternal attachment and parental self-efficacy. At the end of the study, appropriate behaviours for the improvement of infant health may develop in mothers. Mothers' attachment and parental self-efficacy levels may increase the development of infants. Thus, mothers will have a healthy transition. At the same time, the importance of using theory in nursing therapeutic will be emphasized.

Many studies have been carried out on the problems experienced in transition to motherhood (Abasi et al., 2013; Barimani et al., 2017; Maas et al., 2015; Sanders and Woolley, 2005). More studies are needed to support healthy transition to motherhood. In the study, the effectiveness of the Health Promotion Monitoring Program will be evaluated. In line with the Sustainable Development Goals, we prepared the Health Promotion Monitoring Program based on Meleis' transition theory. Our study is innovative in many aspects. Many studies aimed at strengthening maternal-fetal attachment and parental self-efficacy were found in the literature. However, nursing intervention to support infant development is the first. The ultimate goal is to evaluate the impact of the Health Promotion Monitoring Program on maternal infant attachment, parental self-efficacy and infant development. The completion of these aims will facilitate the transition to motherhood by supporting women with standardized programs starting from pregnancy and in the postpartum period. Some of the most important indicators of transition to motherhood are maternal attachment level, parental self-efficacy level and healthy development of infants. It is the first study that discussed attachment, self-efficacy, and infant development together. In accordance with the purpose of protecting and promoting

health, which is the basic philosophy of nursing, addressing the mother and the infant from pregnancy brings our role as an educator and consultant to the forefront. We performed an intervention on pregnant women so that they could protect their infants' health before and after delivery and could support infant development at the best level. The researchers' experiences in pediatrics/neonatal clinic, the special training they received for developmental evaluation, and their studies in the field of social pediatrics and neonates were some of our advantages. With respect to our limitations, the failure to perform researcher and participant blinding, failure to conduct group training recommended by Meleis, and the fact that the study was carried out until the sixth month after delivery were our disadvantages. However, pregnant women excluded by us and the fact that infants were deprived of the program were not in line with the principle of equality in health.

## **CONCLUSION**

Meleis; stated that nursing is helping people get healthy results while making transitions. According to her, nursing is a science and art that facilitates the health and well-being of society in transitions. In this study, transition to motherhood will be easier. At the same time, the importance of using theory in nursing therapeutic will be emphasized.

## **Trial status**

Registration completed. Recruitment started in October 2018 and completed in August 2019. The targeted 64 people were enrolled in the study. There were no mothers/pregnant women who were excluded from the research. The data were sent to the statistical expert for analysis.

## **Availability of data and materials**

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

## **Author Contributions**

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE [<http://www.icmje.org/recommendations/>]):

- Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- Drafting the article or revising it critically for important intellectual content.

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