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Study protocol

The Effect of Baby-led Weaning and Traditional Complementary Feeding Trainings on **Baby Development: Study Protocol**

Bebek Liderliğinde Beslenme ve Geleneksel Tamamlayıcı Beslenme Eğitiminin Bebek Gelişimine Etkisi: Protokol Calışması

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Abstract

Aim: In this study, it was aimed to evaluate the risks of self-feeding, transition to early solids and home meals, choking, anemia and obesity in 6-and 12-month-old infants who were introduced to complementary feeding with the trainings of traditional complementary feeding (TCF) and baby-led weaning (BLW) methods.

Material and Method: This study is an experimental and randomized controlled study conducted to examine the effect of the trainings of the TCF and BLW methods on the transition to complementary feeding. The population of the study consisted of 73 infants aged 4 and 5 months who 62 were assigned to intervention groups by stratified randomization method. The study was conducted according to the CONSORT-2010 checklist. Five complementary feeding modular trainings with 8 sessions, appropriate for the age of the baby in months, were carried out in both intervention groups. In both groups, the trainings were maintained until the baby was 4 months to 12 months old. The outcomes consisted of height, weight gain, LAZ (Length for age z-score), WAZ (Weight for age z-score), and WLZ (Weight for length z-score) scores at 12 months, iron intake, hemoglobin, hematocrit, and ferritin levels, micronutrients, choking risk, growth retardation, transition time to solid foods, family meals and self-feeding, behaviors of transition to complementary feeding and developmental assessment parameters.

Practice Implications: This study, the trainings given are expected to give an idea about the extent to which they affect the infant's body weight, growth and development, iron and micronutrient intake, obesity, choking and growth retardation risks...

Keywords: Weaning, complementary feeding, pediatric obesit, anemia, iron deficiency, growth and development

Özet

Amaç: Bu çalışmada, Geleneksel tamamlayıcı beslenme (TCF) ve bebek liderliğinde beslenme (BLW) yöntemleri ile verilen tamamlayıcı beslenme eğitimlerinin 6 ve 12 aylık bebeklerde kendi kendine beslenme, erken katı gıdalara ve ev yemeğine geçiş, boğulma, anemi ve obezite risklerinin değerlendirilmesi amaçlandı.

Gereç ve Yöntem: Bu çalışma, TCF ve BLW yöntemlerine ilişkin eğitimlerin tamamlayıcı beslenmeye geçiş üzerindeki etkisini incelemek amacıyla yapılmış deneysel ve randomize kontrollü bir çalışmadır. Araştırmanın evrenini, tabakalı randomizasyon yöntemiyle müdahale gruplarına atanan 4 ve 5 aylık 73 bebekten 62'si oluşturmuştur. Çalışma CONSORT-2010 kontrol listesine göre yürütüldü. Her iki müdahale grubunda da bebeğin ay cinsinden yaşına uygun sekiz seanslık beş tamamlayıcı beslenme modüler eğitimi gerçekleştirildi. Her iki grupta da eğitimler bebek 4 aylıktan 12 aylık oluncaya kadar devam edildi. Sonuçlar boy, kilo alımı, 12 ayda (yaşa göre boy) LAZ, (yaşa göre ağırlık) WAZ ve (boya göre ağırlık) WLZ skorları, demir alımı, hemoglobin, hematokrit ve ferritin seviyeleri, mikro besinler, boğulma riski, büyüme geriliği, katı gıdalara geçiş süresi, aile yemekleri ve kendi kendine beslenme, tamamlayıcı beslenmeye geçiş davranışları ve gelişimsel değerlendirme parametrelerini içermektedir.

Uygulamaya Yönelik Öneriler: Bu çalışmanın, verilen eğitimlerin bebeğin vücut ağırlığını, büyüme ve gelişimini, demir ve mikro besin alımını, obezite, boğulma ve büyüme geriliği risklerini ne ölçüde etkilediği konusunda fikir vermesi beklenmektedir.

Anahtar Kelimeler: Bebek rehberliğinde sütten kesme, geleneksel tamamlayıcı beslenme, obezite riski, demir eksikliği, anemi riski, büyümede gerileme.

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1. Introduction

After the year of 2002, the age for the transition time to complementary feeding was updated by the World Health Organization (WHO) as 6 months of age and older. Currently, nutrition in the first 6 months of life consists mainly of only breast milk. Infants aged 6-24 months are introduced to complementary feeding in addition to breast milk. Inability to meet all of the nutrients taken from breast milk makes it necessary for the infants to begin complementary feeding when they are 6 months old. The development of infants' digestive system, the renal functions reaching the level to remove wastes, and infants' acquisition of motor skills such as chewing and swallowing, holding and grasping support the transition to complementary feeding after 6 months of age.

On the other hand, the fact that neuromotor development occurs at the same age as the time of transition to complementary feeding indicates whether advice on how to present complementary foods should be changed. Traditionally, complementary feeding is based on the gradual introduction of foods with different consistencies and textures over months (Daniels et al., 2015; Williams Erickson et al., 2018). This means that solid foods are given in the form of liquid, puree, lumpy, finely chopped consistency and finger food, respectively. However, a 6-7-month-old infant has the motor development to chew, sit without support, and take food or objects to his/her mouth (Alvisi et al., 2015; Daniels et al., 2015; Williams Erickson et al., 2018).

Considering the development of infants by months, it is concluded in this study that there is no need to give infants the foods in a puree consistency in the transition time to complementary feeding, and that it is possible for the infants to begin solid and finger foods earlier. The way that solid foods are given to the infants may prevent the occurrence of psychosocial problems experienced or to be experienced in the transition to complementary feeding (Cameron et al., 2015; Daniels et al., 2015; Dogan et al., 2018; Morison et al., 2016; Pearce ve Langley-Evans, 2022; Williams Erickson et al., 2018)

This study has the characteristics of a study that can be evaluated both quantitatively and qualitatively. It is considered that this study can make the parents who want to provide infant feeding with the traditional method adopt appropriate complementary feeding steps and it can give parents who want to provide infant feeding with the the baby-led weaning advice about the basics of the approach. With the evidence-based result, this study is considered to guide not only parents but also health professionals and politicians.

Baby-Led Weaning method

The Baby-Led Weaning (BLW) method is defined as an alternative approach to feeding that encourages baby and mother to feed and allows baby to enjoy feeding time, unlike traditional complementary feeding (Kurtuncu et al., 2018; WHO, 2009). BLW is a baby-friendly feeding method in which babies feed themselves with the pieces of foods, preferably from home meals instead of spoon foods prepared in the form of puree by the parents during the transition to complementary feeding. The foods in the BLW method consist of pieces that are large enough for babies to hold and that do not lead to difficulty for them while eating on their own (Brown & Lee, 2011; Rapley, 2011).

In the BLW method, the period from birth to six months is considered as the preparation stage for infant feeding. The period after the sixth month is considered as the stage of starting self-feeding with the BLW method. At the preparatory stage, the infant is fed only with breast milk. However, the infant is given the opportunity to recognize food by being present at family meal times and is encouraged to explore food with his/her hands. In the initiation phase, in addition to breast milk, the transition to starter foods and family foods is performed. At feeding times, foods are primarily presented as finger foods that the infant can hold by hand. Then, the transition between foods is performed according to the infant's preference (Cameron et al., 2015; Kurtuncu et al., 2018; Moore et al., 2014; WHO, 2009).



Health professionals and parents mention the disadvantages of choking, iron deficiency and insufficient energy intake in the complementary feeding with the BLW method, in which infant feeding is supported rather than maternal control. Due to the lack of sufficient evidence about the advantages and limitations of feeding with the BLW method, it is concluded that more evidence-based studies should be conducted (Addesi et al., 2021; Brown & Lee, 2011; Cameron et al., 2012; Cameron et al., 2015; Kurtuncu et al., 2018; Moore et al., 2014; WHO, 2009).

In spite of its potential disadvantages reported, complementary feeding with the BLW method is becoming preferable thanks to its advantages such as low obesity risk, better food quality, positive attitudes of families on eating behavior and being a method that supports infant development (Addesi et al., 2021; Brown & Lee, 2011; Cameron et al., 2012; Cameron et al., 2015; Kurtuncu et al., 2018).

Potential advantages of the BLW method

The common advantages of the BLW feeding include a lower risk of obesity thanks to better energy self-regulation, better diet quality, enjoyable feeding time for parent and baby and more developed motor skills.

Lower risk of obesity

Babies are fed with breast milk in the first six months taking into account the baby's hunger cues, in time periods adjusted according to physiological needs. When the baby is full, he stops feeding and the sucking action maintains for the mother-baby bond. In fact, baby-led feeding starts from the moment the baby is born for breastfed babies.

The consistency of the food, when and how much they will consume is determined by the parents of infants who are introduced to complementary feeding with the traditional spoon feeding. At the same time, since the foods are prepared in the form of puree or baby cereals with the traditional method, feeding is provided without the need for babies to chew. This suppresses the infants' capacity to adjust the amount eaten according to their physiological needs and their ability to self-feeding (Addesi et al., 2021; Brown & Lee, 2015; Cameron et al., 2013; Cameron et al., 2015; Köksal et al., 2015; Williams Erickson et al., 2018). In the BLW method, the baby can end the feeding when he is full by using the capacity to adjust the amount eaten according to his physiological needs. Therefore, infants can be fed by providing their own self-regulation in feeding. With the BLW feeding method, food intake of infants according to their satiety and the increase in their self-regulation of energy skills reduce the risk of obesity in infants (Addesi et al., 2021; Cameron et al., 2012; Cameron et al., 2015; Taylor et al., 2021; Williams Erickson et al., 2018).

Only randomized controlled trials can reveal whether there is a beneficial relationship between infant self-feeding and body weight. Therefore, although there is a need for randomized controlled studies evaluating obesity risk, this study is considered to help reveal the obesity risk in terms of complementary feeding methods.

Better diet quality

One of the five basic principles in complementary feeding is to provide nutrients of appropriate quality regardless of the feeding method. Quality complementary foods are the foods that are prepared in the right consistency and soft, are easy to digest, can be easily found locally, have cultural nutritional content, are diverse and can be easily prepared at home (Devecioğlu ve Gökçay, 2012; Fewtrell et al., 2011; Kurtuncu et al., 2018; Pekcan, 2018; Yazıcı, 2019). The amount of food to be used in complementary feeding is prepared at a level to meet the daily energy amount of the infant and in an amount suitable for the infant's stomach capacity. Considering the small stomach capacity of infants, it is of great importance to prepare the right and appropriate quality foods rather than feed the infant with foods in large quantities (Addesi et al., 2021; Fewtrell et al., 2011; Kurtuncu et al., 2018; Pekcan, 2018; Yazıcı, 2019).



It is assumed that infants fed with the BLW method may have higher quality nutritional intake thanks to their energy self-regulation skills. When the studies were examined, Brown & Lee (2011), Cameron et al. (2013), Taylor et al. (2017) and Townsend & Pitchford (2012) reported in their studies that adequate energy intake was provided and normal growth and development maintained in infants fed with the BLW method. It is seen that babies fed with the BLW method gain motor skills earlier and their energy self-regulation skills develop more (Alvisi et al., 2015; Brown & Lee, 2011; Cameron et al., 2013; Taylor et al., 2017; Townsend & Pitchford, 2012; Wright et al., 2011). The basic principle in complementary nutrition is to ensure that health professionals and parents adopt appropriate complementary feeding principles and perform complementary feeding steps through trainings and evidence-based studies.

More highly developed motor skills

In order to develop their motor skills, infants need to perceive their environment, be motivated for action and provide perception-motivation harmony. Developmental skills that increase physiologically from birth can be further developed through repetitive actions by modeling and imitating. In particular, the infant's feeding skills increase thanks to the motor skills gained over time. (Addesi et al., 2021; Dogan et al., 2018; Fewtrell et al., 2011; Kurtuncu et al., 2018; Pekcan, 2018; Yazıcı, 2019). In traditional feeding, giving mashed foods may prevent the development of chewing skills of infants. The preparation of foods as finger foods provides infants with an increase in motor skills such as holding, catching and taking to the mouth, as well as increasing chewing skills (Kurtuncu et al., 2018; Pekcan, 2018; Yazıcı, 2019). Therefore, infants' ability to learn to self-feed depends not only on the innate development of fine, gross and verbal motor skills, but also on the opportunity to develop these skills with repeated practice. Infants' feeding skills can be further enhanced by encouraging parents to feed their infants on their own. The more parents know about the advantages and disadvantages of selffeeding in infants, the more they can encourage their infants to self-feed (Addesi et al., 2021; Brown & Lee, 2015; Cameron et al., 2012; Cameron et al., 2015; Köksal et al., 2015; Williams Erickson et al., 2018). It is thought that the trainings to be given for complementary feeding will increase the gross and fine motor skills more especially in infants fed with the BLW method.

Enjoyable feeding time for parent and baby

Parental approaches play an important role in feeding. Responsive feeding is a form of feeding that encourages the baby, without forcing, slowly and patiently. It is thought that forcing the infant and providing more parental control during feeding negatively affect the self-regulation ability of the infant in self-feeding. Parents wanting the baby to eat more and gain more weight can negatively affect responsive feeding. In addition, less parental control in feeding ensures less negative feeding behaviors and more responsive feeding at feeding times. This makes feeding times more enjoyable for both parents and infants. (Brown & Lee, 2011; Kurtuncu et al., 2018; Rapley, 2011). Balanced parental role at feeding times and providing enjoyable feeding can be achieved with feeding trainings to be given to parents.

Potential disadvantages of BLW

When studies are examined, it is seen that concerns such as iron deficiency, retardation in growth and risk of choking are reported by health professionals and parents. However, more evidence-based studies are needed.

Iron deficiency

Although iron deficiency is common in our country, it still appears as a feeding problem in all around the world. Fruits and vegetables, which are called starter foods in the transition to complementary feeding, are generally foods with low iron content. For this reason, iron-rich foods such as red meat and



cereal products should be prepared in accordance with the diet and be offered to infants. Especially red meat and cereal products can be given in the form of finger food that the infant can hold and grasp. Thus, iron intake can be supported more in infants. When the studies are examined, there are very few studies that adequately examine the iron intake in infants fed with both the traditional complementary feeding and the BLW methods (Addesi et al., 2021; Brown & Lee, 2011; Cameron et al., 2012; Cameron et al., 2015; Kurtuncu et al., 2018; Moore et al., 2014). No study has been found in which complementary feeding trainings are given for complementary feeding methods and in which iron intake is examined. Since the trainings given in this study are for the preparation of foods in appropriate content, consistency and amount, it is considered that iron intake can be supported more in infants.

Choking risk

An infant introduced to complementary feeding has the ability to chew. Choking can easily occur in infants who have just learned to eat, as they try to bite, chew, and swallow food, though. On the other hand, spoon feeding can be difficult and dangerous in terms of choking risk, as the food goes towards the back of the mouth. Eating by hand is quite common in many cultures. Foods prepared in the form of finger food can be given to children with solid pieces of food that they can hold and chew. Few studies have examined the risk of choking during the complementary feeding period. Cameron et al. (2015) and Daniels et al. (2015) reported the risk of choking in their studies, but more evidence is needed.

Reterdation in growth

Some health professionals are concerned about the fact that nutrient and energy intake of infants will be less since the motor skills of self-fed babies are not fully developed, and their this will cause a retardation in growth and development of infants. Although the number of studies is not sufficient, Dogan et al. (2018) examined the effect of feeding with BLW and TCF method on growth in infants and reported that there was no difference in height growth and weight gain between the groups, and that there was no risk of growth retardation in infants fed with BLW method. Townsend & Pitchfort (2012) reported in their study that the prevalence of being underweight was 4.8% in babies fed with the BLW method, and nought in babies fed with the TCF method. Although the studies are limited, it is seen that both feeding methods have different results in terms of the risk of retardation in growth.

1.1. Objective of the study

The main objective of this study is to examine the growth and development, iron intake, anemia risk and obesity risk in 6-12-month-old infants introduced to solid foods with complementary feeding trainings of TCF and BLW methods. Secondary objective of the study is to provide evidence for the basic questions to be answered in the transition to complementary feeding as follows:

- 1. What is the effect of feeding with the BLW method on growth and development?
- 2. Is there a risk of low iron intake and anemia with both methods?
- 3. Is there a risk of choking in infants when fed with the BLW method?
- 4. Is there a risk of obesity in infants when fed with the BLW method?
- 5. Is the infant's energy and nutrient intake adequate with both methods?
- 6. Do the complementary feeding methods have an effect on the baby's feeding behavior?

2. Materials and Methods

2.1. Study design

This research is a prospective, triple-blinded, randomized controlled experimental and analytical study with the highest level of research evidence. In order to conduct the study, permission numbered 2019/173-16/10 from the Clinical Research Ethics Committee and written institutional permissions from the Zonguldak Provincial Health Directorate were obtained. The individuals in the sample were informed about the study and their consent was obtained with a voluntary consent form.



2.2. Sample of the study

The population of the study consisted of 73 infants aged 4, 5 and 6 months. In the calculation of the sample, power analysis was performed with an effect width of 0.30 and a margin of error of 5%. Accordingly, the total number of individuals was determined as 62 (31 infants in each group) at a power level of 90% for two repeated measurements. Blocked and stratified randomization methods were used for the selection of the experimental groups. The international standard CONSORT 2010 diagram was used for the flow of the study. A diagram of the CONSORT 2010 flow chart was given in Figure 1.

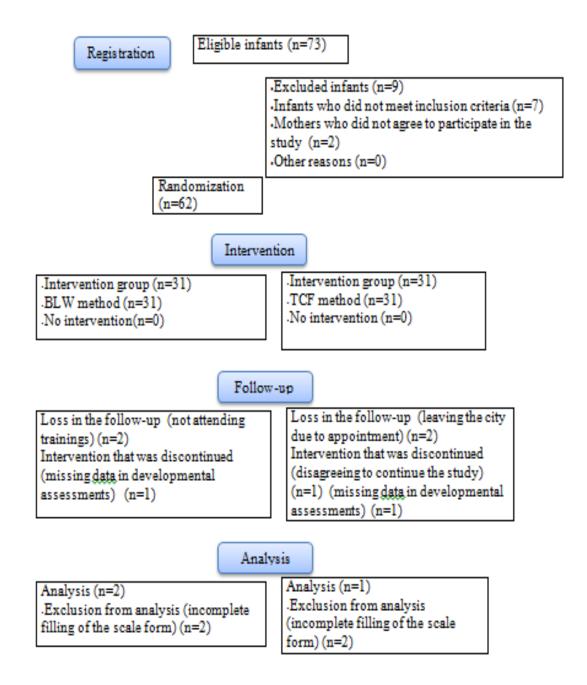


Figure 1. Consort 2010 Flow Chart



2.3. Inclusion criteria

Inclusion criteria in the study were evaluated separately for mothers and infants. Inclusion criteria for mothers were as follows:

- The arrival of mothers at the centre where the research would be conducted for routine baby follow-up and vaccination follow-up
- Volunteering of mothers to participate in the research
- Having no communication problems
- Being at least 19 years old
- Having no physical or mental disability

Inclusion criteria for infants were as follows:

- Being at least 4 months old and maximum 6 months old during the study
- Not having been introduced complementary feeding yet
- Being fed only with breast milk
- Not being born before 38 weeks of gestation
- Not having a congenital anomaly
- Having no digestive and neurological system disease that might affect feeding

2.4. Exclusion criteria

Regardless of the age of the baby in months, all infants and their families who began complementary feeding and did not meet the inclusion criteria were excluded from the study.

2.5. Selection of experimental groups and randomization

Face-to-face interviews were conducted with the mothers of the babies who were routinely followed up in the family health center at the time of the study. In these interviews, mothers were informed about the identity of the researchers, the purpose of the study and how it would be conducted. Before randomization, a literature review was performed on the variables affecting infant feeding. When the literature was examined, studies showing the effects of mothers' education level and previous complementary food experiences on the transition to complementary feeding formed the basis of randomization (Cameron et al., 2015; Daniels et al., 2015; Morison et al., 2018; Taylor et al., 2021; William Erickson et al., 2018). Blocked and stratified randomization methods were used in randomization. In the stratified sampling method, the education level of the mothers and the number of infants were taken as the basis for stratification. On the other hand, blocked randomization method was used for stratified sample selection. Experimental groups with two individuals in each block were formed homogeneously according to the education level of the mothers and the number of children.

Randomization was performed by an independent statistician, and none of the individuals assigned to the groups were known to the researchers.

2.6. Bias of the research

It was aimed to prevent bias at all stages of the research. In order to avoid bias in selection, all individuals who were followed in a single center and met the inclusion criteria were examined. Randomization was used to prevent conscious or unconscious bias. While the researcher who made the intervention was not involved in the evaluation of the post-intervention outcomes, the researcher who performed the developmental assessments did not have information about which intervention was applied to the groups, which groups the infants belonged to and what the intervention was. Both researchers worked independently during the intervention and evaluation phases of the study. In addition, the statistical evaluator who analyzed the studies conducted the analysis of the study without knowing which group was the treatment group. On the other hand, the volunteers in the study did not have information about the intervention groups. In this way, triple blinding method, the most reliable



method to avoid bias, was used in this study. With the usage of randomization and triple blinding method, there was no bias at any stages of this study.

2.7. Study groups

All participants were assigned to two intervention groups by randomization method. The first intervention group consisted of babies fed with the TCF method, and the second intervention group consisted of babies fed with the BLW method. Both groups were followed in accordance with the routine healthy infant follow-up protocol of the Ministry of Health of the Republic of Turkey.

2.7.1. Traditional Complementary Feeding (TCF) groups

In addition to the routine follow-up protocol, the participants, in accordance with their age, were included in feeding trainings with the TCF method from 6 months to 12 months of age. Traditionally, solid foods are recommended for infants after they are 9 months old. For this reason, this group was informed about the importance of feeding with solid food after the baby was 9 months old.

2.7.2. Baby-Led Weaning (BLW)

In addition to the routine follow-up protocol, the participants, in accordance with their age, were included in feeding trainings with the BLW method from 6 months to 12 months of age. Detailed information about the trainings can be found in the trainings section.

2.8. Complementary feeding trainings

Complementary feeding trainings were planned according to the age of the infant in months. Guide booklets were prepared for each training module and given to parents before the trainings. When the baby was 4-5 months old, Module 1 trainings were held online via Zoom. The content of Module 1 training consisted of general information about the importance of breast milk and complementary feeding.

When the baby was six months old, Module 1 and Module 2/A (TCF) and 2/B (BLW) trainings were held online via Zoom. The basic content of these modules included the complementary feeding characteristics pecular to 6-8 months old infants. Although the Module 2/B guide training booklet wqs the same as the 2/A guide education booklet in terms of content, the only difference was the information on the feeding approach with the BLW.

When the baby was nine months old, Module 3/A (TCF) and 3/B (BLW) trainings were provided to both groups and a guide training booklet was given to participants. The basic content of these modules consisted of the complementary feeding characteristics pecular to 9-12 months old infants. Although the Module 3/B guide training booklet was the same as the 3/A guide education booklet in terms of content, the only difference was the information about the feeding approach with the BLW.

Participant/participants who could not attend any session in each training module were included in the next training session. Thus, the participation of every mother was ensured in all training modules. The trainings by months were given in Table 1.



Table 1. Complementary feeding trainings by months

Baby age (month)	Training	Guide Used in Training	Number of trainings	Guide Training Booklet				
4, 5 and 6 months	Module 1	Successful complementary feeding guide for mothers	4 times in total in groups of 15	Module1 guide booklet				
6-8 months	Module 2/A	Guide for 6-8 month-old babies (TCF)	3 times in total in groups of 10	2/A guide booklet				
	Module 2/B	Guide for 6-8 month-old babies (BLW)	3 times in total in groups of 10	2/B guide booklet				
9-12 months	Module 3/A	Guide for 9-12 month-old nabies (TCF)	3 times in total in groups of 10	3/A guide booklet				
	Module 3/B	Guide for 9-12 month-old nabies (BLW)	3 times in total in groups of 10	3/B guide booklet				
		NXXX Is Inviting You To A Scheduled Zoom Meeting.						
		Topic: NXXX's Personal Meeting Room						
Zoom Training	g Links,	Join Zoom Meeting						
ID and Training Access Codes		Https://Us04web.Zoom.Us/J/5147794535?Pwd=U3Nsd0FrRUVia0wrU1FaeWRKd0doQT09						
		Meeting ID: 514 779 4535						
		Passcode: N.XXXX						

2.9. Outcome measures

Developmental assessments of infants were the basis of outcome measures. The main outcome measure of the study was the Z-score for height and weight, which was calculated according to age (Z-score is calculated using body weight and length). Secondary outcome measures were the assessment of iron and micronutrient intake, complementary feeding behavior, risk of choking, retardation in growth, and risk of obesity.

2.10. Assessment of baby development

Initial laboratory tests were started when the infant was six months old. These tests were carried out by the assistant researcher at the Zonguldak Obstetrics and Pediatrics Hospital Pediatrics Polyclinic. Developmental evaluation of infants was performed and data were collected with developmental evaluation follow-up forms. This form evaluates the physical, motor, cognitive, game, language and psychosocial development of infants. At the end of the sixth month after the transition to complementary food, the infants' behavior of transition to complementary feeding was evaluated with the "Behaviors of Transition to Complementary Feeding Scale (BTCF-S)" developed in the first phase of the study.

When the infants was 7, 8, 9-10 and 11-12 months old, developmental evaluations including the developmental characteristics of the infant were performed online. The last test laboratory tests were performed when the baby was 12 months old. At the end of the month, post-tests were performed to evaluate the infants' behavior of transition to complementary feeding using the "BTCF-S". The developmental evaluations were presented by months in Table 2.



Table 2. Stages of the research, training and months of developmental evaluations

	4-5	6 months	7 months	8 months	9-10	11-12
Dandaminatian	months				months	months
Randomization	X					
Anthropometry						
Weight		X				X
Length		X				X
Blood collection						
Iron in	ntake	X				X
Hemoglobin		X				X
Ferritin		X				X
Vitamin B12		X				X
Other		X				X
Feeding time resu	ılts					
Retching		X	X	X	X	X
Choking risk		X	X	X	X	X
Other		X	X	X	X	X
Developmental		X	X	X	X	X
assessment						
Scale evaluation		X				X
Complementary f	eeding training	gs				
Module 1	X	X				
Module 2/A ve 2/H	3	X	X			
Module 3/A ve 3/E	3				X	

2.11. Data collection tools

Introductory Information Form for Mothers and Babies, Transition to Complementary Feeding Behaviors Scale and Laboratory Findings Evaluation Form were used to collect data.

- **2.11.1. Introductory Information Form for Mothers and Babies:** The form prepared by the researchers consisted of the sociodemographic characteristics of the infants and parents, the mothers' experience of complementary food intake and breastfeeding.
- **2.11.2. Behavior of Transition to Complementary Feeding Scale (BTCF-S):** The scale developed by the researchers to evaluate the behavior of transition to complementary feeding in infants aged 6-24 months consisted of 28 items, five sub-dimensions and was in a five-point Likert-type. The answers in the scale were scored as never = 1; rarely = 2; sometimes = 3; often = 4, and always = 5 points. In the scale. There were some items scored in reverse (2, 5, 9-13, 18-26) and the scoring for those answers were as never = 5; rarely = 4; sometimes = 3; often = 2 and always = 1.
- **2.11.3. Laboratory Findings Evaluation Form:** The form consisted of 11 assessment parameters and two assessment times (at the 6th and 12th months).

2.12. Data collection

The mothers included in the study were informed about the purpose of the study, the confidentiality of the answers, where and how the data would be stored through face-to-face interviews. Interviews were held in the institution's meeting room (decorated with a table and a chair, bright and spacious, quiet and calm) after the infant follow-up. Due to the Covid-19 pandemic, the data was collected online.



2.13. Data analysis

In the evaluation of data obtained in the study, SPSS 22.0 Statistics package program was used for statistical analysis. While frequency, percentage, mean and standard deviation were used for descriptive statistical methods, Kolmogorov - Smirnov distribution test was used to examine the normal distribution. Independent samples t test was used for comparison of quantitative data between two groups. In case of more than two groups, the One way Anova test was used for comparisons between the groups and the Tukey test was used to determine the group that caused the difference. Mann-Whitney U test and Kruskal-Wallis H test, which were nonparametric tests, were used in the evaluation of data that did not show normal distribution. Cronbach alpha test statistics were performed for the reliability analysis of the scales in the sample group. Statistical significance was evaluated at the p < 0.05 level.

3. Discussion

The transition to complementary feeding with the BLW method has been increasing gradually (Kurtuncu et al., 2018; Brown & Lee, 2011; Rapley, 2011). However, the lack of sufficient evidence-based studies in the literature raises concerns about feeding with the BLW method (Addesi et al., 2021; Brown & Lee, 2011; Cameron et al., 2012; Cameron et al., 2015; Daniels et al., 2018; Kurtuncu et al., 2018; Moore et al., 2014). As the study is a randomized study, it is thought that it will provide more evidence to the literature.

The study provides basic information about the transition to complementary feeding in infants who are 6 months old. In this study, it is predicted that in both feeding methods, parents' concerns such as possible choking risk and retardation in growth will decrease inasmuch as they will find answers to their questions about complementary feeding. In this way, in addition to supporting the growth and development of babies, it is thought that the negative feeding behaviors experienced during the transition to complementary feeding will be less and responsive feeding will be supported more. It is predicted that the energy self-regulation skills of the self-feeding babies will be supported, especially in the feeding approach with the BLW method, and this will also contribute to the prevention of childhood obesity.

3.1. Limitations of the research

This research was conducted only at the institution where the study was conducted. The same study can be conducted with a larger sample. Since continuous participation in the training modules of the study was required, it caused data loss in the research.

4. Conclusion and Recommendations

This study is a guide for pediatric nurses on complementary feeding methods to support the growth and development of infants. With this study, nurses can guide infants and mothers who switch to complementary feeding to eliminate or reduce possible risks such as growth retardation, obesity risk, choking risk and anemia risk. This study can lead academic nurses in experimental studies.



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Conflict of Interest

No conflict of interest has been declared by the authors.

Ethical Statement

The consent forms were obtained from the university's Ethics Committee (Approval number: 12.02.2019/506) and from the gynecology and pediatrics hospital and two Family Health Centers.

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Study concept and design: M.K and N.A. Analysis and interpretation of data: N.A. Drafting of the manuscript: M.K, P.M.T and N.A. Critical revision of the manuscript for important intellectual content: M.K. Interpretation of Statistical analysis: M.K, P.M.T and N.A. Obtained funding: M.K and N.A. Study supervision: M.K.



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