Research Proposal: A Baby-Led Approach to Weaning: The Impact on Food Allergies

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Abstract

Background Little is known about the effect of baby-led weaning (BLW) on food allergy development. As this method of weaning is based on the infant self-feeding from the family meal, several allergens may be introduced at one time. It is unknown how this may impact food allergy incidence in infants.

Objective To determine if BLW can help prevent the development of food allergies at one year of age compared to caregivers who wean their infants by introducing a single new food every three or more days.

Methods Two hundred and forty participants in Milwaukee County will be recruited over a five-year span for a six-month intervention period. Term infants who are three to four months of age at the time of the questionnaire who have not been introduced to complementary foods will be included in the study. The infant's caregiver will decide what complementary feeding method they plan to use, spoon-feeding or baby-led weaning. Those in the BLW group will receive education to address concerns about choking, iron, and energy intake. Caregivers will record foods introduced and reactions in a food log. Food logs will be analyzed to determine incidence of food allergy development when the infant is nine and 12 months old. Statistical analysis will include comparisons between groups using analysis of chi-square, ANOVA, independent t-test, and logistical regression.

Results Anticipated results indicate the incidence of food allergies will not be significantly lower in the BLW group compared to the spoon-fed group (P=0.06).

Conclusion The proposed study will provide insight on future research regarding BLW and food allergies and propose changes to the protocol to help determine the best and safest infant weaning method.

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Chapter 1: Introduction to the Study

The term baby-led weaning (BLW) was created in 2001 by Gill Rapley (2018) and has become increasingly popular over the past 20 years. The word "weaning" refers to the phase where infants transition, once they are developmentally ready, from being fed exclusively human milk or formula to eating solid foods (Satter, n.d.). While there is no single definition of baby-led weaning, the term describes an approach used to introduce complementary foods at six months of age by allowing the infant to self-feed rather than being spoon-fed with purees or cereals by the caregiver, the traditional approach of introducing complementary food. With traditional weaning, food introduced starts with smooth purees and gradually advances textures to mashed foods, chopped foods, and then finger foods later in infancy (Daniels et al., 2015). With a baby-led weaning approach, finger foods, preferably the same food the family is eating at mealtimes, are offered to the infant rather than purees. Throughout this paper, the term "caregiver" will refer to the guardian of the infant.

The United States Department of Agriculture's (USDA*) Dietary Guidelines for Americans 2020-2025* is the first edition of the Dietary Guidelines since 1985 to include dietary recommendations for infants and toddlers (Sulaski Wyckoff, 2020). This edition recommends introducing complementary foods to infants when they are six months old, despite infants showing signs of developmental readiness before this time. These signs include being able to control their neck and head, sitting up with or without support, bringing objects to their mouth, moving food from the front to the back of the mouth to swallow, and swallowing food without pushing it out of the mouth (Dietary Guidelines for Americans, 2020).

In addition to achieving new developmental milestones, infants' nutritional needs change. Around six months of age, an infant's nutrient requirements begin to exceed what is provided from human milk or infant formula alone. At this time, additional sources of nutrition are needed to meet

those higher nutrient requirements (WHO, 2021). Weaning is an important developmental milestone in a baby's life as it not only provides a substantial change for the baby but it is also associated with the development of food preferences and eating behaviors (Cameron et al., 2013; Fu et al., 2018; Townsend & Pitchford, 2012).

Background

The baby-led weaning method of complementary feeding has brought up many questions and concerns from caregivers and the health-care community. Will the infant be at higher risk of choking? Will their energy needs be sufficiently met? Could this method cause nutrient deficiencies? Researchers have sought answers to these questions.

Studies have shown that after education on how to safely introduce finger foods, infants fed using the BLW method were not at any higher risk of choking compared to infants fed purees by a caregiver (Fangupo et al., 2016). In addition, a 2013 study conducted by Cameron et al. concluded that infants fed using BLW may be at an increased risk for iron deficiency, though education was impactful on the iron status of these infants. When caregivers received education on high-iron foods appropriate for BLW, there was no significant difference in the amount of iron offered to those who followed conventional weaning and those who followed BLW guidelines (Cameron et al., 2015). Similar findings were shown when looking at zinc intake (Daniels et al., 2018).

In response to the question of whether or not the increased difficulty of eating finger foods leads to a decrease in energy intake for infants being fed using the BLM method, there have been conflicting studies. Cameron et al. (2015) found that providing the caregiver with education on how to provide high calorie food lead to higher energy intake in infants fed utilizing BLW. Additionally, Taylor et al. (2017) found no significant difference in the BMI scores of toddlers 24 months old between the BLW

group and the traditional spoon-fed group. In contrast, other research showed the BMI of toddlers (20-78 months) in the BLW group was lower than the BMI of toddlers in the spoon-fed group, and there were more overweight children in the spoon-fed group, indicating that those in the BLW group had less energy intake (Townsend & Pitchford, 2012).

In addition to concerns about adequate energy and nutrient intake with BLW, questions arise related to this method and the incidence of food allergies. Recent research shows that early introduction to peanuts is an effective strategy to prevent peanut allergy in infants (Du Toit et al., 2015). This has not been studied specifically when introducing multiple allergens at once. The *Dietary Guidelines* give no instruction on how to go about introducing complementary foods. The Centers for Disease Control and Prevention advise caregivers who use the traditional spoon-feeding approach to introduce one new single-ingredient food every three to five days to allow time to assess for food allergy signs (When, What, and How to Introduce Solid Foods, 2021). Because baby-led weaning is focused on providing food from family meals, multiple allergens are introduced at one time; for this reason, the question arises: do infants fed using the BLW method develop less food allergies due to early exposure? Further research is needed to show the impact of BLW on the development of food allergies.

Problem Statement

Current research related to baby-led weaning focuses on iron, zinc, energy intake, choking, and picky eating. Research is lacking on food allergy development or prevalence of food allergies in infants introduced to foods by way of baby-led weaning compared to babies weaned by traditional spoon-feeding.

Purpose of the Study

This non-randomized control trial study will seek to determine if BLW can help prevent the development of food allergies at one year of age compared to caregivers who wean their infants by introducing a single new food every three or more days.

Research Question and Hypotheses

Does BLW reduce the incidence of food allergies?

H_O: There is no difference in the incidence of developing food allergies between infants whose caregivers employ BLW and infants who are weaned using traditional practices.

H_a: Baby-led weaning, in comparison to traditional spoon-feeding, is associated with lower incidence of food allergies in infants at 12 months of age.

Nature of the Study

Subjects will include infants who are three to four months old at time of completion of the questionnaire and who reside in Milwaukee County. Participants will be categorized based on caregiver weaning preference into two groups: those fed using a self-feeding method (BLW group) and those spoon-fed by the caregiver consistent with the traditional method commonly used (control group). Infants in the BLW group will receive a variety of foods from family meals while infants in the spoon-fed group will receive a single new food no sooner than every three days.

A chi-square test of independence will be used to analyze the differences between group participants to determine if significant differences exist in regard to the caregiver's education level, ethnicity, and employment status as well as the infants' sex, weight for length, and primary nutrition source. Additionally, one-way ANOVA and independent *t*-test will be used to compare the differences in incidence of food allergies in infants weaned using a BLW approach versus those utilizing a spoon-fed approach.

Definitions

- **Baby-led weaning** – A technique used to support the infant through weaning off human milk or infant formula by promoting infant self-feeding with pieces large enough for the infant to grab (Fangupo et al., 2016).
- **Caregiver** - The legal guardian of the infant.
- **Developmental readiness for weaning** - The ability of an infant to control their neck and head, sit up with or without support, bring objects to their mouth, move food from the front to the back of the mouth to swallow, and swallow food without pushing it out of the mouth (Dietary Guidelines for Americans, 2020).
- **Food allergy** – An adverse immune-mediated response caused by exposure to a protein in a food that re-occurs on repeated exposures to that food (Turnbull et al.,2014).
- **Food intolerance** – A non-allergic reaction to food that does not involve the immune system (Turnbull et al.,2014).
- **Iron deficiency** – A state in which there is inadequate iron intake to maintain normal iron blood levels (Baker et al., 2010).
- **Weaning** – The phase where infants transition from being fed exclusively human milk or infant formula to eating solids, once they are developmentally ready (Satter, n.d.).

Assumptions

- All participants will have similar backgrounds.
- The inclusion criterion for this study is appropriate.
- Caregivers will document in food logs honestly.
- Caregivers will adhere to their chosen group/feeding model throughout the duration of the study.

Limitations

- This study will not be randomized. Caregivers self-select the weaning method; therefore, confounding bias could exist.
- This study will only be able to show an association between food allergy development and weaning method, not causality.
- This study will be limited as it is based on self-reported data with, potentially, missing data in the food log entry.
- This study will be limited by the drop-out rate of the participants and overall compliance with the protocol.
- This study will be limited as there is lack of additional research on the subject.

Delimitations

- This study will exclude premature babies because developmental readiness and milestones may occur at different ages.
- This study will not be randomized to encourage adherence to the protocol.
- This study will provide education on methods of weaning and resources with information about food allergies.
- Caregivers of participants must provide written informed consent prior to the data collection.
- Caregivers who have introduced solids prior to the study will be excluded.

Significance

This study will be valuable because there has been minimal research on the incidence of food allergy in infants who are weaned with the baby-led weaning method, rather than the traditional spoon-feeding approach to introduction of complementary food. From current research discussed later in this paper, we know that introduction of allergens before 12 months may reduce the incidence of food

allergies. As the BLW method introduces several allergens at once, different than the traditional weaning method of providing one new allergen every three to five days, this raises the question of how this will affect prevalence of allergies. Results supporting the hypothesis that baby-led weaning reduces the incidence of food allergy will support the practice of introducing infants to finger foods from the family meals at time of weaning.

Summary

This research will determine if the approach to weaning (BLW or traditional spoon-fed) affects the incidence of food allergy in infants. Chapter 2 (Literature Review) will investigate current information and research on baby-led weaning as it relates to introduction of potential allergens and, therefore, possible reduction in food allergy development. Chapter 3 (Methodology) will include the methodology specific to this research. Chapter 4 (Anticipated Results) will outline the expected results of this study. Chapter 5 (Discussion) will discuss the results and determine potential significance for clinical practice.

Chapter 2: Review of Literature

Baby-led weaning has been increasing in popularity over the past couple decades along with research on this method of complementary feeding. Since BLW is focused on providing food from family meals, multiple potential allergens are introduced at the same time. As we know from research by Du Toit et al. (2015), early introduction to peanuts lead to decreased peanut allergies of the participants. Despite more research being conducted, the impact that BLW has on both incidence and prevalence of food allergies has not been studied. Further research is needed on this topic as no research to date has focused on the incidence of food allergies in infants of caregivers that utilize baby-led weaning.

Literature Research Strategy

Review of the literature utilized databases including PubMed, EBSCO Host, Science Direct, Google scholar, and the American Academy of Pediatrics. Additional research articles were found from other articles' references sections. Abstracts were examined before deciding which articles to use based on the content and relevance to the aim of this study.

Keywords used to search for relevant articles included: "baby-led weaning", "baby-led feeding", "complementary feeding", "infant feeding", "food allergy development", "food allergies in infants", "infant feeding".

Existing Research on the History of Infant Feeding

The term "baby-led weaning" was coined in 2001, though this was not a new method of weaning; it has been practiced over many generations before having a name assigned to it (Rapley, 2018). In the early Twentieth century, infant feeding recommendations were rapidly changing and sometimes contradictory.

Commercial baby foods were not developed until the 1920s. Prior to that time, there were contradictory recommendations on when caregivers should introduce solid foods to their infants. During World War I, the importance of fruits and vegetables for proper growth and nutrition was recognized. By the 1920s, dietitians were introducing people to the idea of vitamins and the importance of these vitamins for children as well as adults (Bentley, 2014). In the 1920s, infantile scurvy was found to be preventable by feeding infants fruit juice (Fomon, 2001). In 1928, Cartolla C. Greer advocated giving one teaspoon of orange juice to infants at three weeks old because it contains vitamins and minerals. The author also recommended offering cereals at five to six months; cooked and strained vegetable pulp at six months; toast at seven months; and egg yolk at 12 months (Greer, 1928). In the late 1920s, pediatricians recommended introducing fruits and vegetables to infants between the ages of four and six months due to the importance of vitamins and minerals (Bentley, 2014).

Very little data is available on the history of the introduction of solids in developing countries. Cereals and starchy roots and tubers were used as complementary foods, usually prepared in water to produce a thin mixture (Gibson et al., 1998). As strainers were not available in these areas, it can be assumed that foods provided to infants were crushed or fed in small pieces. In areas that did not have cutlery to spoon-feed an infant, finger foods were likely used in place of cereals and purees.

As BLW is becoming increasingly popular, it is important to understand the risks and benefits associated with this approach. Despite years of research on the baby-led weaning approach as well as use of similar approaches across the world, there are still unknowns about the impact this method can have on children later in life.

Risks

Several concerns have been raised regarding use of the baby-led approach to the introduction of solid foods as offering finger foods to infants is new to many caregivers and providers. Choking, reduced

energy intake, and iron and zinc deficiency are all concerns. Since babies at this age typically do not have many teeth, they are regulating their own intake and since solid food is harder to eat, the infant may end up eating less. Additionally, iron-fortified infant cereals are not used with this method as they require spoon-feeding (Cameron et al., 2012).

Inadequate energy intake or growth faltering. Baby-led weaning allows the infant to set the pace of their meals and allows them to eat as much as they want and decide when to stop. Since this method is less controlled by the caregivers and solids are more challenging to eat than purees, there is concern that infants fed using this method will not have adequate energy intake and will have inadequate weight gain.

A study protocol was developed for a modified version of baby-led weaning called Baby-Led Introduction to SolidS (BLISS); BLISS was modified by educating caregivers to address concerns about iron-rich foods, energy intake, and choking risk. The purpose of this protocol was to provide a method and design for a study to assess the efficacy of a modified version of BLW to address concerns for iron status, choking, and inadequate growth (Daniels et al., 2015).

In a BLISS study conducted by Cameron et al. (2015), part of the caregivers' education for the BLISS group involved instruction on how to provide high calorie foods in order to prevent inadequate energy intake in infants fed using BLW. This study showed that infants in both the BLW group and the BLISS group were offered more than the recommended number of calories. It should be noted that only the amount offered was calculated, not the amount eaten, so it is unclear if the groups had differences in actual calorie intake (Cameron, et al., 2015).

Taylor et al. (2017) conducted a randomized trial to examine the effect of baby-led weaning on lowering obesity risk compared to traditional spoon feeding. The study recruited women in late

pregnancy in order to follow their infant from birth to two years of age. Caregivers were assigned to one of two groups: a control group that was directed to use the traditional spoon-fed method and a BLISS group. Members of both groups received access to routine midwifery and well-child care. The members of the BLISS group received eight additional contacts; they were contacted several times from the infant's birth to five months of age by a lactation consultant to provide education and support to prolong exclusive breastfeeding or formula feeding until six months of age. At five and a half, seven, and nine months of age, families were provided support to use responsive feeding practices by paying attention to cues of hunger and satiety; to provide high-calorie, high-iron foods at each meal; to avoid foods that may be a choking risk; and to offer foods that were easy to pick up. Length and weight were obtained several times throughout the study using a blind approach from the researchers measuring the anthropometrics. Main findings included no significant difference in weight-for-length (for those under 24 months old) or BMI (for those over 24 months old) z-scores between groups at 12 and 24 months. Through caregiver report, those following the BLISS approach had infants that were less responsive to hunger and satiety cues and significantly less picky about food. This could cause concern that the BLISS technique may actually contribute to a higher BMI later in life if the decreased responsiveness to satiety continues.

Choking. Alongside the concern of inadequate weight gain is choking risk. Baby-led weaning is characterized by the infant self-feeding foods that are large enough to grab, so a big concern of introducing these solid finger-foods to infants is the risk of choking (Cameron et al., 2012; Cameron et al., 2013). Concerns about choking exist for these reasons: (1) infants are experiencing new textures for the first time, (2) infants have few or no teeth with gumming foods resulting in large pieces, (3) infants have developing, but immature tongue motions, and (4) infants have small airways.

Fangupo et al. (2016) conducted a randomized controlled trial over 12 months to determine the impact of baby-led weaning on choking and gagging risk in infants. Caregivers were randomized into a modified baby-led weaning group (BLISS) or control group of traditional spoon-feeding for a 6-month intervention with additional follow-up at 24 months of age. This version of BLW was modified by providing education on how to reduce choking risk. Caregivers received questionnaires five times periodically when their infant was six through 12 months. Caregivers were asked about their infant's energy intake, eating behavior, fine and gross motor skills, and caregivers' acceptance of the feeding method. No statistically significant difference on choking frequency was found between the two groups at any age. This study found that the BLW approach did not pose an increased risk of choking compared to the caregiver-led feeding when caregivers were provided with education on how to minimize choking (Fangupo et al., 2016).

Cameron et al. (2015) also followed the BLISS protocol mentioned previously, though they compared the BLISS group with an unmodified, uninstructed BLW group. The BLISS group received education on choking prevention. These researchers found no significant difference in choking occurrences between groups (Cameron et al., 2015).

Neither of these studies were based on in-person observation; both were based on what caregivers defined as choking. Misclassifications of choking versus gagging could have occurred, even though the authors made efforts to define both for the caregivers. Despite this potential confusion, these findings could provide reassurance to caregivers that their baby may not be at increased risk of choking if caregivers choose to utilize BLW. Knowing that receiving education could prevent choking may ease the mind of caregivers and encourage more to use this method, though there are still other concerns that need to be addressed, such as nutrient deficiencies.

Iron deficiency. One concern healthcare providers have with caregivers utilizing baby-led weaning is inadequate iron intake (Cameron et al., 2012). Since most infants' iron stores are depleted at around six months of age, iron-rich foods are important to provide at the start of complementary feeding (Baker et al., 2010). Foods commonly offered to infants that provide iron are iron-fortified cereals, pureed meats, or pureed legumes. These foods are not often utilized in baby-led weaning as these need to be spoon-fed, thus the concern about iron adequacy in the meals of a child who is fed by BLW.

Cameron et al. (2015) conducted a study utilizing the BLISS protocol educating caregivers on the following: (1) safety when starting complementary foods, (2) when, what, and how to offer first foods, (3) how to tell if an infant is full and, (4) high iron and high calorie foods (including recipes). Compared to an unmodified BLW group, they found that there was no statistically significant difference in the amount of iron offered between the groups, though the BLISS group received more red meat which could indicate increased iron status since the iron in meat is more bioavailable. This study showed that education on infant feeding prior to starting solids would be beneficial by allowing caregivers to be more aware of the risks and rewards of BLW and potentially decreasing the possibility for iron-deficiency (Cameron et al., 2015).

A study based on a questionnaire by Cameron et al. (2013) was conducted with caregivers who had infants between the ages of six and 12 months asking how and when they introduced complementary foods to their infant, mainly focusing on the start of complementary food introduction when the infants were six to seven months old. Participants were divided into one of four groups based on their answers to the survey questions: (1) adherent BLW (the infant mostly or entirely fed themselves), (2) self-identified BLW (caregivers reported following BLW but were using spoon-feeding at least half the time), (3) parent-led feeding (the traditional method of spoon-feeding), and (4)

unclassified method (the caregiver reported they were not following BLW but reported the infant mostly or entirely fed themselves). Results showed that babies in the adherent BLW group were most likely to offer fruits and vegetables as their first food. One (5.9% of this group) child was offered iron-fortified cereals. Those in the self-identified BLW group offered baby rice cereal 57.1% of the time, and those in the caregiver-led feeding group offered rice cereal 53.6% of the time. No meat was offered during this time period for any of the groups. These findings indicate that without education about high-iron food sources, infants fed using this method may be at increased risk for iron deficiency (Cameron et al., 2013). No studies to date have tested the biochemical markers of iron status for infants fed using BLW compared to infants fed using traditional spoon feeding.

Inadequate zinc intake. Since iron and zinc are found in a lot of similar foods, zinc deficiency is also a concern when it comes to BLW. Human milk provides adequate amounts of zinc for infants until around six months of age when their nutrient needs increase. Zinc deficiency can cause growth failure, loss of appetite, decreased immunity, and delayed wound healing (Zinc, n.d.). The first foods introduced with baby-led weaning are typically foods low in zinc, such as fruits and vegetables, which are easy to hold and self-feed. Meat, a food that is high in bioavailable zinc, is not typically offered as first foods due to concern for choking (Cameron et al., 2012). Daniels et al. (2018) conducted a study following the BLISS pilot study protocol by Daniels et al. (2015) to determine zinc intake by feeding infants using the BLISS method compared to traditional spoon feeding. The BLISS group received education and frequent follow-up from time of birth to nine months of age. Caregivers of the BLISS group were asked to offer one food from the following groups at each meal: (1) a food high in iron, (2) a high-calorie food, and (3) an easy to eat food. Blood samples were collected at 12 months of age to assess zinc levels and phytate levels since phytates inhibit zinc absorption. The majority of infants in both groups received adequate zinc at seven and 12 months. Nine percent of the control group compared to 5% of the BLISS group had zinc intakes below the estimated average requirement (EAR) at seven months and 1% had zinc intake

below the EAR for both groups at 12 months. Differences in plasma zinc concentrations were not statistically significant between the groups. A large portion of infants in both groups had low zinc concentrations: 63% in the control group and 57% in the BLISS group. Inflammation was not of concern in zinc levels as caregivers were instructed to wait 14 days for the lab draw if their infant was sick. Given the results of this research, the authors concluded that following a modified version of BLW led to similar intakes of zinc and zinc plasma levels compared to those fed using traditional spoon-feeding. It was noted, however, that the sources of zinc among the groups were different; the BLISS group consumed more breads and cereals compared to the control group who received more vegetables as their predominant source of zinc. At 12 months, there were no significant differences of the sources of zinc between the groups as most of their zinc came from dairy. Given that there were similar intakes of zinc in both groups, a modified BLW approach was effective in helping those infants meet the EAR (Daniels et al., 2018).

Benefits

Though there are concerns about safety and nutrient adequacy with baby-led weaning, there are also ways that this method of feeding could potentially benefit children later in life. Could these infants be less picky due to being offered a wider variety of foods? Could this method help prevent obesity down the road by promoting self-regulation of intake? Could a pattern for family meals be established early, which benefits children in many ways, such as nutritionally, socially, and academically (Satter, 2008)? These are some of the questions researchers have been trying to answer.

Decreased food fussiness.

One benefit thought to come from baby-led weaning is decreased pickiness because infants are being introduced to a wide variety of tastes and textures in the first year of life. Fu et al. (2018) conducted a study to determine whether feeding infants using BLW affects picky eating, weight, serious choking episodes, and early feeding characteristics. This study recruited 876

families through advertisements online and by word of mouth. The participants answered a survey with questions on how and when they introduced complementary foods to their infants. This study showed a dose-response relationship to food fussiness with BLW in infants up to 36 months of age. Food fussiness was significantly lower in infants following BLW, intermediate for those following partial BLW, and highest for those who were traditionally spoon-fed (Fu et al., 2018).

Improved BMI z-scores. In addition to decreased food fussiness, some professionals think allowing an infant to control how much they eat will improve their BMI z-scores. As discussed in the section above regarding inadequate energy intake and growth faltering, Taylor et al. (2017) found no difference in BMI z-scores between the modified BLW group (BLISS) and the spoon-fed group. Townsend & Pitchford (2012) conducted a case-controlled study on the impact of BLW on food preferences and BMI later in childhood compared to traditional spoon feeding. One-hundred fifty-five caregivers of 20 to 78-month-old children were recruited either through BLW websites (and placed in the BLW group) or through a toddler laboratory database (and placed in the spoon-fed group). Participants completed a questionnaire asking about what infant feeding method they utilized, their child's preference for 151 foods, exposure (frequency of consumption of foods), picky eating, and their child's height and weight. Due to a significant age difference between the groups (the infants in the BLW group were significantly younger than those in the spoon-fed group), food preference and exposure were analyzed using a case-controlled method to account for the effect of age on food preferences. Of the eight categories presented in the exposure section of the questionnaire (carbohydrates, dairy, fruit, meats, protein, savory snacks, sweet foods, and vegetables), children of the BLW group preferred carbohydrate foods compared to sweet foods preferred by the children in the spoon-fed group. These findings indicate that weaning style could influence food preferences later in life. BMI was also significantly different between the groups. Those in the BLW group had BMI percentiles closer to the 50th percentile for their age compared to the spoon-fed group whose BMIs were higher. Though there were more overweight (z-

score more than +2) children in the spoon-fed group (12.6%) compared to the BLW group (1%), there were more underweight (z-score less than -2) children in the BLW group (3%) compared to the spoon-fed group (0%) (Townsend & Pitchford, 2012). Though the difference of underweight children was small between the two groups compared to the difference of overweight children, this indicates that more children in the spoon-fed group are overfed and more children in the BLW group have inadequate energy intake.

Food Allergies

What is a food allergy? A food allergy is an adverse reaction caused by an immune response that occurs repeatedly on exposure to a specific antigen in food. On first introduction to the food, the immune system produces antibodies called immunoglobulin E (IgE), which are specific to that allergen. On subsequent exposures, antigens in the offending food bind to the IgE antibodies and trigger the release of histamine (Raymond & Morrow, 2021). Histamine causes a reaction, such as hives and wheezing, which lets the affected individual know that they have encountered something harmful (The Children's Hospital of Philadelphia, 2014). Those who have other medical reactions, such as eczema and asthma, are at a higher risk of developing a food allergy (*What is a food allergy?,* n.d.). According to McAleer & Irvine (2013), eczema can be associated with mutations of a gene in the body, called filaggrin, that is responsible for a major structural protein in the skin; given the weakened skin barrier, children with eczema are at a higher risk of developing food allergies. Asthma and food allergies often coincide, but the physiology of how they influence each other is not yet understood (Foong et. al., 2017). Mild symptoms of a food allergy include itchy or runny nose, sneezing, itchy mouth, mild hives, itchy skin, mild nausea, and stomach pain. Severe symptoms of a food allergy can affect several parts of the body including lungs (shortness of breath, wheezing, coughing), heart (pale skin, dizziness, weak pulse), throat (tightness, difficulty breathing or swallowing), mouth (swollen tongue or lips), skin (hives throughout the

body, widespread redness), stomach (vomiting, diarrhea), and the brain (confusion, anxiety) (Food Allergy & Anaphylaxis Emergency Care Plan, n.d.).

Once an individual begins to experience symptoms after eating a meal, a medical professional can attempt to isolate the offending food. Diagnosis can be completed through a thorough medical history, physical exam, and an oral food challenge if needed (Sampson et al., 2014). An oral food challenge is the gold standard for diagnosing food allergies which involves ingesting a small amount of the suspected allergen with healthcare staff in a medical setting in case of severe allergic reaction (Calvani et al., 2019). A diet history following an allergic reaction should include determining foods that may have caused the reaction, the form of the ingested food (raw, cooked, baked), how much of the allergen was ingested, timeline of the reaction, type of reaction(s), and other potential influencers such as ingestion of medications or exercise (Sampson et al., 2014).

Along with obtaining a history, assessing the reaction, and potentially completing an oral food challenge, there are other tests that can be used in addition to these methods. Skin prick tests and blood serum tests can be used to help diagnose a food allergy, though these results alone should not be considered diagnostic of a food allergy due to their poor accuracy (Sampson et al., 2014).

History of food allergies. Food allergies often develop in the first one to two years of life (Wood, 2003) and affect approximately 3-8% of children globally. Prevalence of food allergies is rising, though the exact prevalence is unknown (Longo et al., 2013). Vast discrepancies between (1) the incidence of self-reported and medically-diagnosed food allergies, (2) differing forms of the food consumed (cooked versus raw) verses complete avoidance, and (3) allergic sensitization make it difficult to know how many children are affected by a true IgE-mediated food allergy. More than 170 foods from around the world have been reported to be allergenic (Sampson et al., 2014). Food allergies that are especially common are known as the top nine allergens. The top nine allergens include: peanuts, tree nuts, milk, soy, wheat,

egg, fish, shellfish, and sesame (Common Allergens, 2021). Worldwide, the two most common food allergies are milk and egg. The third most common food allergy depends on the country: peanuts in the United States and Switzerland, wheat in Germany and Japan, tree nuts in Spain, and Sesame seeds in Israel (Fiocchi et al., 2010). Milk, the most common food allergy in childhood, makes up about one-fifth of all food allergies in children (Savage et al., 2016). Longo et al. (2013) noted that food allergies may resolve over time, with greatest resolution in those with cow's milk, egg, and wheat allergies. Peanut, tree nut, fish, and shellfish are more persistent allergies; a small percent will acquire tolerance with some recurring over time (Longo et al., 2013).

Du Toit et al. (2015) conducted important research to determine if early introduction to peanuts was an effective strategy to prevent peanut allergy development. The primary purpose was to assess the number of participants with a peanut allergy at 60 months of age after an oral food challenge. The Learning Early About Peanut Allergy (LEAP) trial was a randomized controlled trial conducted in the UK. Infants four to 11 months of age who had severe eczema and/or egg allergy were recruited. Participants were divided into two groups depending on the results of a skin-prick allergy test to assess for a reaction to peanut protein. Those who had a positive skin-prick test were randomly assigned to a consumption or avoidance group; similarly, those who had a negative skin-prick test were also randomly assigned to a consumption or avoidance group. Participants were fed at least six grams of peanut protein weekly until they reached 60 months of age. Adherence was assessed using food frequency questionnaires and clinical assessments were completed four times throughout the study. Those who were very unlikely to have a peanut allergy by 60 months of age were given five grams of peanut protein in a single dose. For all other patients, a double-blind placebo-controlled food challenge was conducted using 9.4 g of peanut protein administered in increments. Of the 530 participants in the group that initially had negative results on the skin-prick test, 13.7% infants in the avoidance group developed a peanut allergy by 60 months of age compared to only 1.9% in the consumption group. Of the 98 infants in the group that

initially had positive results on the skin-prick test, 35.3% developed a peanut allergy in the avoidance group compared to 10.6% in the consumption group. This research showed that early introduction to peanuts significantly reduced the development of peanut allergy for those at high risk of developing the allergy. This could indicate that early introduction of many foods may decrease the prevalence of food allergies (Du Toit et al., 2015).

Another study on food allergy development conducted by Natsume et al. (2017) investigated the impact of early stepwise introduction of eggs in infants with controlled eczema on egg allergy development. This was a randomized, double-blind, placebo-controlled trial that started when the infant was six months old through 12 months of age. Infants four to five months of age with eczema were recruited. Researchers aggressively treated the participants' eczema and before the trial began and maintained control without flair-ups throughout the intervention. The infants were split into an egg or placebo group and given trial powder that they were instructed to consume daily for six months. Those in the intervention group received a powder consisting of egg and squash; those in the placebo group received a powder consisting of only squash, both of which color and volume matched. Each group received two doses to be taken at three-month intervals. The first dose given from six to nine months contained 50 mg of heated egg powder and the dose given from nine to 12 months contained 250 mg of heated egg powder. Adverse events were recorded in an event diary which was checked by a physician at every visit. An oral food challenge (OFC) of seven grams of heated egg powder was given to both groups at 12 months old. Those that showed an immediate allergic reaction were diagnosed as having a hen's egg allergy. Eight percent of participants in the intervention group and 38% in the placebo group had confirmed hen's egg allergy at 12 months confirmed by OFC. This research found that hen's egg introduced to infants with atopic dermatitis in a step-wise approach had reduced development of egg allergy, even for those who had IgE sensitization to hen's egg prior to intervention. This provides

additional evidence that early introduction to solids could be protective against food allergy development (Natsume et al., 2017).

Research Methodology

There have been a number of studies conducted on baby-led weaning in regard to the safety of the infant (Cameron et al., 2015; Daniels et al., 2018; Fangupo et al., 2016; Taylor et al., 2017; Townsend & Pitchford, 2012), though research on food allergy incidence in infants fed with this method is lacking. Given the lack of research on this subject, the proposed study utilizes design components similar to several studies discussed throughout this paper (Cameron et al., 2015; Daniels et al., 2015; Daniels et al., 2018; Fu et al., 2018; Taylor et al., 2017; Cameron, Taylor, & Heath, 2013; Townsend & Pitchford, 2012). The following section will discuss articles with similar methodology that was adopted in this research.

The baby-led weaning method of complementary feeding is based on the that idea infants will be provided food from family meals, introducing several allergens at one time. The LEAP study by Du Toit et al. (2015) and the PETIT trial by Natsume et al. (2017) showed decreased peanut and egg allergy development, respectively, with early introduction of these foods. Given those results, as BLW will expose infants to several allergens at once, it may decrease the risk of developing a food allergy. The purpose of this study is to analyze how often infants of caregivers utilizing BLW develop food allergies compared to infants fed by traditional spoon-feeding during which a single new food is added every three or more days.

Several studies have been conducted utilizing the BLISS method, a modified version of BLW that entails educating caregivers on how to avoid the common concerns that are associated with BLW: choking, iron and zinc deficiencies, and inadequate energy intake (Cameron et al., 2015; Daniels et al., 2015; Daniels et al., 2018; Fu et al., 2018). This study will use the same approach of educating the BLW group to provide caregivers with comfort that this method is safe in order to increase adherence to their

chosen group. Advice and support will be available from the research staff on request throughout the study, similar to the study by Cameron et al. (2015).

To conduct this research, caregivers of term infants three to four months of age that are exclusively taking human milk or infant formula will be recruited through online forums, social media groups for caregivers of infants, in pediatrician offices, and in daycares in Milwaukee County, similar to the design study of Fu et al. (2018), who recruited participants on Facebook and online forums, and Taylor et al. (2017), who recruited participants at maternity units in hospitals. Similar to the study conducted by Daniels et al. (2018), premature infants (any infant born before 37 weeks 0 days gestation) will be excluded from this study as timing of introducing complementary foods depends on the gestational age at birth and when they show signs of developmental readiness. This study will also exclude infants with medical conditions that may delay introduction of complementary foods, similar to Fu et al. (2018). Also consistent with Fu et al. (2018), along with Cameron, Taylor, & Heath (2013) and Townsend & Pitchford (2012), caregivers who have interest in participating will fill out a questionnaire online asking questions on what their child currently eats and if they already introduced complementary foods, along with other baseline information on demographics.

All studies reviewed in this article have been randomized. This study will not be randomized as caregivers may not feel confident utilizing baby-led weaning or their infant might go to a daycare that has workers who are uncomfortable or unwilling to utilize BLW. Allowing the caregiver to choose the weaning method will increase adherence to their chosen group.

Summary

Benefits and risks of baby-led weaning as an approach to introduction of complementary foods have been explored by Cameron et al. (2013 & 2015), Daniels et al. (2018), and Townsend and Pitchford

(2012). Literature already in existence could be used to proactively inform and reassure caregivers about potential safety concerns of BLW prior to complementary food introduction.

Research shows that it may be beneficial for infants fed utilizing the BLW method to receive education on how to provide high-iron foods such as meat, meat alternatives, or iron-fortified foods in a safe manner (Cameron et al., 2015). Similar results were found regarding zinc (Daniels et al., 2018). Additionally, education on how to prevent choking in infants fed using BLW was also found to be effective (Cameron et al., 2015; Fangupo et al., 2016).

Caregivers utilizing BLW may have infants who are underweight (Townsend & Pitchford, 2012), but guidance on how to provide higher calorie foods could improve their weight status (Cameron et al., 2015). As research has indicated, BLW could promote healthy food preferences in early childhood which could protect against obesity later in life (Townsend & Pitchford, 2012). This is significant as the prevalence of obesity continues to increase across the globe (Fryar et al., 2021).

Despite several years of research, there are still unknowns about the impact this method can have on children later in life. For this reason, additional research is needed as baby-led weaning continues to become more popular so health care providers can accurately answer caregivers' questions and can educate them on safe feeding practices as well as what to look out for and expect if choosing this method.

Chapter 3: Methodology

Baby-led weaning is a method of weaning off human milk or infant formula that has historically been used around the world before being assigned a name in 2001. It is becoming increasingly popular and is being studied more often, though research on food allergies in infants weaned using BLW is lacking. The purpose of this research is to investigate if BLW leads to less food allergies than traditional spoon-feeding. This chapter will review the research design of this non-randomized, controlled trial. Inclusion and exclusion criteria will be discussed as well as why these criteria were chosen. The protocol will review the process of data collection and statistical tests that will be used to assess and analyze the data. Threats that may affect the validity of the study will also be discussed as well as the ethical procedures taken to protect the participants.

Research Question

This study will aim to answer the following question: Does BLW decrease the incidence of developing a food allergy?

Hypothesis

Baby-led weaning, in comparison to traditional spoon-feeding, is associated with lower incidence of food allergies in infants at 12 months of age.

Table 1

Description of Variables

Variable Type	Variable name	Potential Responses	Level of measurement	Confounding variables
Independent	Traditional spoon feeding	Yes or No	Nominal	Lack of documentation when introducing new foods. Protocol interference (not waiting 3 days to introduce a new food). Infants fed solids by a non-consented adult. Education level of caregiver/guardian.
Independent	BLW	Yes or No	Nominal	Lack of documentation when introducing new food. Infants fed solids by a non-consented adult. Education level of caregiver/guardian.
Dependent	Incidence of food allergies	Yes or No	Nominal	

Study Design

The proposed study is a five year non-randomized, controlled trial with a six month intervention period for each participant in order to investigate if infants weaned with the BLW method develop fewer food allergies than infants weaned with the traditional spoon-feeding method. The participants cannot be blinded due to the dietary intervention portion of this trial; statisticians and investigators will be blinded to limit bias. This non-randomized study design is appropriate as some caregivers may not want to use or feel confident utilizing BLW or their infant might go to a daycare that has workers that are uncomfortable or unwilling to utilize BLW.

Setting and Sample

Sample size

A sample size of 240 participants (120 from each group) will be obtained to maintain a 5% margin of error. The sample size was calculated through G*Power sample size calculator and adjusted accounting for 10% attrition to compensate for anticipated dropout.

Population and Recruitment

The study will be conducted in Milwaukee County with recruitment through online forums, social media groups for caregivers of infants, fliers at pediatrician offices, and in daycares in Milwaukee County, from January 2025 to January 2030. Recruitment will stop once 120 participants have been consented for each group. Websites will have a link and fliers distributed will have a scannable QR code to reach a website with a SurveyMonkey questionnaire (see appendix E). Caregivers with term infants aged three to four months old who are receiving exclusively formula or human milk will be recruited. The questionnaire will ask caregivers the following about their infant: age, dietary intake (formula, human milk, complementary foods), gestational age, height and weight of infant at their last pediatrician appointment (and date these measures were taken), and food allergies. Information on caregiver age, education level, and ethnicity will also be obtained in the questionnaire. Infants who have already been introduced to complementary foods will be excluded along with infants greater than four months old to give researchers the time to consent and do education. This study will also exclude premature babies because developmental readiness and milestones may occur at different ages. Infants with intolerances will be included in this data as they are likely to grow out of them. Infants with known allergies, like milk or soy, will also be included but those existing food allergies will not be counted as developed during the time of food introduction. An incentive of a $20 grocery store gift card will be offered to participants; gift cards will be distributed when the infant is one year old unless the participant drops out of the study.

Data Collection Process

When the infant turns 5.5 months, the researcher will obtain informed consent from the participating caregiver of each infant (see appendix B). After meeting study criteria and providing consent, each caregiver will select whether they want to be in the intervention group (utilizing BLW) or the control group (utilizing traditional spoon feeding that introduces one new food at a time every three or more days). Caregivers participating will be instructed to only provide human milk or formula until their infant is six months old. When the infant is 5.5 months old, caregivers will receive resources at an at-home visit with instructions on the diet they are assigned to, how to safely implement BLW (if in that group), how to log when a new food is introduced, and resources on signs of food allergies. Food logs (see appendix G) will be collected at 12 months. The log will have boxes to date when a food is introduced the first and second time to allow them to quickly reference if a food has been introduced twice. If those in the BLW group are given combination foods (e.g., a casserole, packaged food), the ingredients or brand will be documented in blanks provided on the food log. The log will also ask to specify the form of the ingested food (raw, cooked, baked). At baseline, data on what the infant currently eats will be confirmed from the survey as well as any current food allergies or intolerances.

The following baseline data will be collected in the questionnaire: age, weight, height, formula/human milk intake, food intake, known allergies/intolerances, and family history of food allergy. Infants with intolerances will be included in this data as they are likely to outgrow the intolerance. In addition, food allergies and intolerances have different etiology, presentation, and treatment protocols. Infants with known allergies, like milk or soy, will also be included but those allergies will be discounted when assessing for the development of new allergies when starting complementary feeding. A research assistant will call each caregiver a week after first introducing complementary foods and when the infant is nine and 12 months old to get data on current food allergy

status (see appendix F) and answer any questions as well as remind caregivers of the protocol. Data collected at each call will include self-reported weight and length/height, food allergy status.

Instrumentation

All participants will complete a questionnaire (see appendix E) prior to consent to ensure caregivers have not started solids yet, asking what the infant eats (human milk vs formula), and if there are any existing food allergies or intolerances. Participants will also complete consent forms and be provided with a food log to document what foods the infant is introduced to. If those in the BLW group are given combo foods (e.g., a casserole, packaged food), the ingredients or brand will be documented. The log will also ask to specify the form of the ingested food (raw, cooked, or baked). Education materials will also be provided (see appendix C). Those in the BLW group will be educated on how to prevent choking, how to offer high iron and calorie-dense foods, and how to introduce all nine top allergens by the time the infant is 12 months old. Those in the spoon-fed group will be instructed to provide one new food every three or more days and to introduce all nine top allergens by the time the infant is 12 months old. Both groups will receive education on how to recognize an allergic reaction (see appendix D). Additionally, if the infant has a reaction the first time a food is introduced, they will be instructed to introduce that food the second time in the food allergy clinic at Children's Wisconsin.

Data Analysis Plan

When the infant is 12 months of age, food logs will be analyzed to determine incidence of food allergy as well as look at the number of foods introduced to compare between the two groups. Statistical analysis will include comparisons between groups using analysis of chi-square, ANOVA, independent t-test, and logistical regression.

Descriptive Statistics

Data collected regarding infant demographics will include the sex, weight, height, and if the infant is taking formula or human milk. Data collected about the caregivers will include their age, education level, working status, and race. A chi-square test of independence will be utilized to test for differences between the spoon-fed group and the BLW group where the variables are not a continuous measure (caregivers' education, ethnicity, working status, infant's sex, weight for length, and breastfeeding status). This information will be useful to see if there are significant differences among the groups and if this may have had an impact on incidence of food allergies.

Inferential Statistics

Intervention and control group results (incidence of allergy) will be compared to determine if there is an association between BLW and food allergy in infants and children. Similar to the Natsume et al. (2017) PETIT trial, the two-tailed independent t-test and one-way ANOVA will be conducted to show the differences in food allergy development in those fed via the BLW method or spoon-fed method. Logistical regression will be run to examine differences in food allergy development for infants weaned using a BLW or spoon-fed approach while controlling for timing of introduction to solids. Data gathered when the infant is 12 months old will provide the information needed to obtain p-values that will determine if the hypothesis will be rejected or accepted. A p-value less than 0.05 will show a statistically significant change that will reject the null hypothesis. Table 2 provides an overview of the variables.

Table 2

Research Question and Variables

Research question	**Independent variable**	**Potential responses**	**Level of measure**	**Dependent variable**	**Potential response**	**Level of measure**	**Test of significance**
Does BLW decrease the incidence of food allergy development?	Complementary feeding method	Yes or No	Nominal	Food allergy	Yes or No	Nominal	Independent T-test One-way ANOVA

Threats to Validity

There will be a few threats to validity to be mindful of when completing this research. Expectation bias by researchers will be a threat to validity since this is not a randomized study. Unreliability of measures will be a threat if there is inadequate documentation on the food log. This will weaken the relationship between the variables. Attrition bias will be a threat due to differences between the groups in the number and way participants are lost from the study; this could be a reason for any observed effect and not the intervention itself. There may be low statistical powder if caregivers are not using the food log or drop out. Data prior to inadequate documentation or dropout will be used. Selection bias will be a threat as there will be differences between baseline characteristics of the groups since they are allowed to choose which method of weaning they want to use.

Ethical Procedures

IRB approval will be obtained prior to the start of this research (see appendix A). Subjects will not be put at risk or harm throughout the study; however, possible allergic reactions may cause discomfort. Consent (see appendix B) will also be obtained prior to starting the study which will explain the protocol, risks, freedom to withdraw, and confidentiality. The participants' identity will be protected by assigning them a nine-digit number used in place of their names for all data to be tracked with. Data will be stored in a password protected external hard drive. Caregivers in the BLW group will be given education on how to prevent choking, as well as high iron, and calorie-dense foods.

Summary

The proposed study will give insight on the connections between food allergy development and different infant weaning methods. Over the course of six months, participants will follow the BLW method or traditional spoon feeding while completing a food log throughout the introduction of new foods. Descriptive statistics will be used to describe the population and to analyze the data to determine if differences among the groups have had an impact on incidence of food allergies. Inferential statistics

will determine the association between weaning method and incidence of food allergies. Chapters four and five will review the anticipated results of this study and include a discussion on the topic.

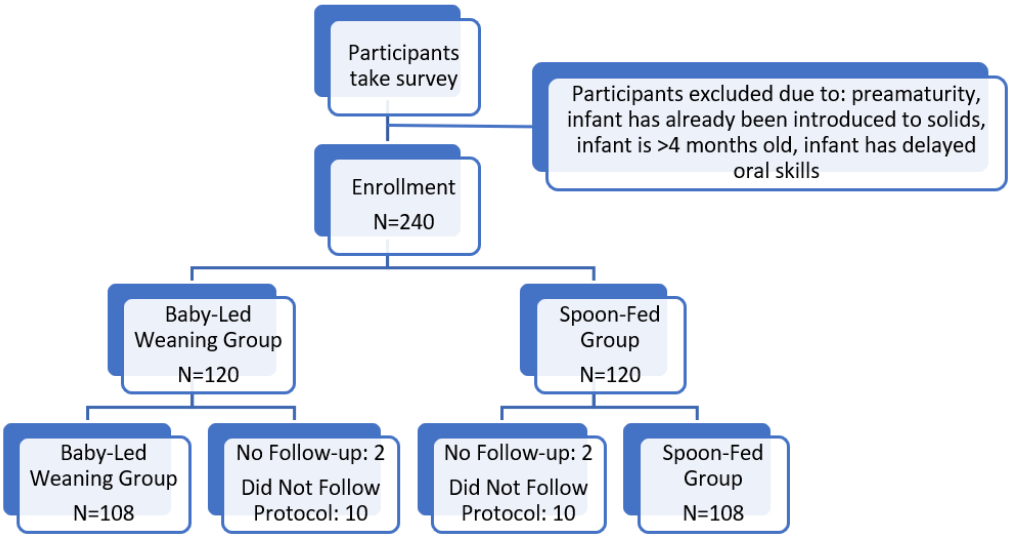
Chapter 4: Anticipated Results

Study Population

A total of 240 participants will be recruited to participate in this study. Recruiting will stop when 120 eligible participants choose to utilize the baby-led method of weaning and 120 participants choose to spoon-feed their infant. Participants will be excluded if their infants are outside of the study age range (greater than four months old at time of survey), were born prematurely (<37 weeks gestation), have delayed oral feeding skills, or if they have already been introduced to solids foods. The baby-led weaning (BLW) group will receive education on how to prevent choking while providing infants' finger foods, education on high iron and high calorie foods, and they will be instructed to introduce all nine top allergens by the time the infant is 12 months old. Regarding addition of allergenic foods to the diet, the only instruction the spoon-fed group will receive is to introduce one new food every three or more days and to introduce the top nine food allergens by the time their infant is 12 months old. It is projected that 24 participants will drop out or be excluded for non-adherence due to an estimated 10% attrition rate. Participants will be excluded from final analysis if caregivers cannot be reached during follow-up or they do not follow the study protocol. Figure 1 shows how many participants are anticipated to complete the trial.

Figure 1

Flowchart Illustration for the Study Participants



Characteristics of Study Population

A questionnaire prior to consent will be used collect information on primary nutrition source (formula or human milk), existing food allergies, and infant and caregiver demographics. This data will be useful to compare the characteristics of the two groups.

It is anticipated that out of 216 total participants at the final analysis, 62% of all infants participating in the study will be primarily breastfed (63% in the BLW group vs. 61% in the spoon-fed group). At screening, the mean age of the caregiver respondents will be 27.5 years (26.7 years in the BLW group and 28.4 years in the spoon-fed group), the median will be 28 years with a range of 18 to 37 years. Most of the infants will be described by their parents as being white (61.1% in the BLW group compared to 58.3% in the spoon-fed group), followed by black (16.7% in the BLW group compared to 15.7% in the spoon-fed group). Of the adult respondents, 48.1% are estimated to have a college degree

or higher (50.9% in the BLW group vs. 45.4% in the spoon-fed group) and all will have completed high school.

Additional information on anticipated characteristics of both groups, including both caregivers and infants, are presented in Table 3. It is anticipated that there will be no significant differences in baseline characteristics between the groups.

Table 3

Demographic Characteristics of Caregivers and their Infants

	Total (n = 216)	Spoon-Fed (n = 108)	Baby-Led Weaning (n = 108)	*p*-value*
Infant sex, n (%)				
Female	106 (49.1%)	53 (49.1%)	53 (49.1%)	1.0
Infants with current food allergies, n (%)	16 (7.4%)	9 (8.3%)	7 (7.4%)	0.789
Infant primary nutrition source, n (%)				0.779
Human milk	134 (62%)	66 (61%)	68 (63%)	
Infant formula	82 (38%)	42 (39%)	40 (37%)	
Infant weight-for-length percentile, mean (SD)	50.5 (6.6)	50 (6.2)	51 (6.9)	0.264
Caregiver respondent age (years), mean (SD)	27.5 (4.3)	28 (4.5)	27.1 (4.1)	0.126
Caregiver highest education, n (%)				0.994
Some high school	0 (0%)	0 (0%)	0 (0%)	
High school	52 (24.1%)	30 (27.8%)	28 (25.9%)	
Some college	60 (27.8%)	27 (25%)	25 (23.2%)	
Bachelor's degree	75 (34.7%)	37 (34.3%)	38 (35.2%)	
Graduate degree	20 (9.3%)	9 (8.3%)	11 (10.2%)	
Doctorate	9 (4.2%)	5 (4.6%)	6 (5.6%)	
Caregiver race, n (%)				0.819
Asian	27 (12.5%)	13 (12%)	14 (13%)	
Black	35 (16.2%)	17 (15.7%)	18 (16.7%)	
Hispanic	12 (5.6%)	8 (7.4%)	4 (3.7%)	
White	129 (59.7%)	63 (58.3%)	66 (61.1%)	
other	13 (6%)	7 (6.5%)	6 (5.6%)	
Caregiver employment status, n (%)				0.797
Full time	105 (48.6%)	53 (49.1%)	52 (48.2%)	
Part time	68 (31.5%)	32 (29.6%)	36 (33.3%)	
Unemployed/Stay at home	43 (19.9%)	23 (21.3%)	20 (18.5%)	

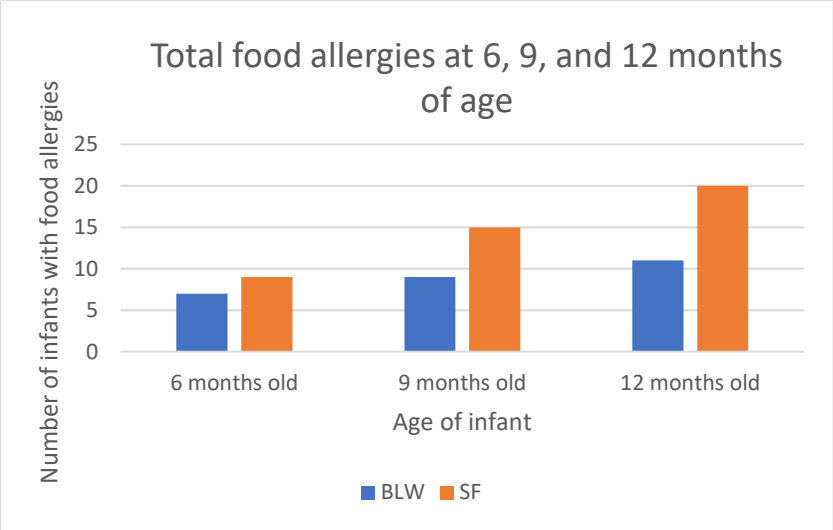
*$p<0.05$ indicates statistical significance

Food Allergy Development

Dietary compliance with the protocol will be determined based on the food log that each caregiver will fill out daily until the infant is 12 months of age. Compliance will be determined for the spoon-fed group by looking at each day's intake ensuring a new food wasn't introduced sooner than every three days and for both groups ensuring that all top nine allergens are introduced by the time the infant turns 12 months old. At nine months of age, data will be collected on food allergy development since introducing solids, weight, length, how many of the top nine food allergens were introduced, and how many foods have been introduced. This data will be collected again at 12 months. Table 4 shows anticipated results for the two-tailed independent t-test to show the differences in food allergy development in those fed via the BLW or spoon-fed method. Table 5 shows the anticipated results for the inferential statistics for the one-way ANOVA results to examine differences in food allergy development for infants weaned using a BLW or spoon-fed approach. As shown in table 4, it is anticipated that there will be no significant difference between the BLW group and the spoon-fed group when the infants are 12 months old, though the p-value for food allergy development from six to 12 months in the spoon-fed group is much stronger than the p-value of that in the BLW group. These results indicate that both groups had a statistically significant increase in food allergies from baseline to 12 months old, though when comparing the end results of both, data was not significantly different. Table 5 also indicated the test statistics is less than the critical value of 3.885 and the p-value is greater than 0.05 therefore it accepts the null hypothesis.

Figure 2

Food Allergies Developed



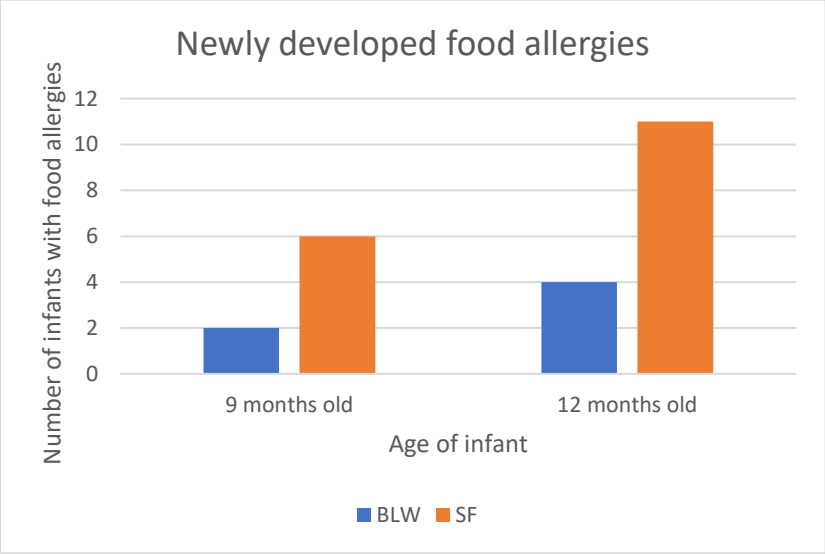


Table 4

Number of New Food Allergies at Baseline (6 Months), 9 Month, and 12 Months of Age

BLW				Spoon-fed				
Baseline	9 months old	12 months old	Change from Baseline to 12 months (p-value)	Baseline	9 months old	12 months old	Change from Baseline to 12 months (p-value)	Change between groups at 12 months of age (p-value)
0	2	4	0.04	0	6	11	0.0007	0.06

Table 5

ANOVA Inferential Statistics

Source of Variation	*Sum of Squares*	*df*	*Mean Square*	*F*	*P-value*	*F crit*
Between Groups	0.22685185	1	0.227	3.535	0.061	3.885
Within Groups	13.7314815	214	0.064			
Total	13.9583333	215				

Logistic regression was also completed accounting for the covariate of timing of introduction of foods between the groups. On average, the BLW group had introduced 60 foods while the spoon-fed group had introduced 45 foods by 12 months old. Results indicate that the number of foods introduced does not significantly impact food allergy incidence at 12 months old, $X^2(1) = 3.24$, $p = 0.07$.

Summary

Anticipated results throughout the course of the six-month intervention period were shown in tables 1-3. Anticipated changes between the BLW and spoon-fed groups were also discussed throughout

the chapter and found that there is no significant difference between food allergy incidence when utilizing a BLW method compared to a traditional spoon-feeding method. Chapter five will discuss the anticipated results and how they relate to current literature as well as discuss the strengths and weaknesses of the proposed study. Ideas for future research will also be discussed in chapter five.

Chapter 5: Discussion

There are currently no studies to date on the topic of food allergy incidence in infants fed utilizing baby-led weaning (BLW) compared to traditional feeding methods. Results from studies conducted by Du Toit et al. (2015) and Natsume et al. (2017) found that early introduction to allergens is protective against developing peanut and egg allergies. This chapter will discuss the anticipated results of the proposed study and compare those results from previous research. It will also discuss the strengths and limitations of the proposed study and suggest future research.

Interpretation of Results

This five-year long study that each participant will be enrolled in for a six-month intervention will evaluate the effect of infant weaning method on the incidence of food allergy development. It is expected that there will be significant decreases in food allergy development in the BLW group though it is anticipated that results will show no significant difference. The expected outcome includes significant decreases in food allergy development when utilizing a baby-led method of weaning when compared to the traditional spoon-feeding method.

Before conducting a logistic regression analysis, the association between the dichotomous independent variable (feeding method) and the dependent variable of the study (newly developed food allergies at nine months and 12 months) were examined. Some infants had existing food allergies through breastmilk at six months old. This proposed study examines the incidence of newly developed food allergies starting at the point of introduction of complementary foods; therefore, at baseline (six months) this study will count all infants as having zero food allergies, even if they had existing food allergies to breastmilk or formula.

Characterization of the Study Population

Infants participating in this study are expected to have no significant differences between the control and intervention group for sex, primary nutrition source, weight-for-length percentile, or food allergies at the start of the study. Similarly, caregivers of both groups are expected to be similar and indicate no significant differences in demographics. Similar characteristics between the participants and caregivers of two groups will be important as differences could make an impact on end results, indicating an inaccurate conclusion.

Education

It has been observed that caregivers may be discouraged from utilizing the baby-led method of weaning for their infant due to fear of choking, among other concerns (Cameron et al., 2012). Through utilizing the educational resources adapted from Cameron et al. (2015), caregivers will be educated on how to prevent choking, iron deficiency, and growth faltering. Using standardized education materials will help provide caregivers in the BLW group with equal information on how to be successful throughout the intervention period.

Comparison to Prior Studies

There is no research to date studying the impact of BLW on food allergies. There is, however, research on early introduction of some common food allergens in infants while controlling for complete avoidance of that food allergen in the control group. Research by Du Toit et al. (2015) and Natsume et al. (2017) concluded that early introduction of peanuts and eggs, respectively, lead to reduced allergy incidence. As early introduction has shown reduced food allergy development and there is no current research on BLW's impact on food allergies, this study will provide important information for caregivers and providers on the best method to wean off human milk or infant formula.

Strengths and Limitations

The main strength of this proposed study is the simplicity of the protocol and collection of data by researchers blinded to intervention status. Allowing the caregiver to choose the feeding method they wanted to utilize provided comfort to the caregiver which encouraged adherence. If the caregiver is assigned to the BLW group, they may not be comfortable feeding their infant finger foods for fear of choking, despite education on how to prevent choking. If the infant gags, the caregiver might confuse this with choking and break adherence to the protocol by spoon feeding the infant purees for fear of choking again. The follow-up on adherence of the caregivers throughout the six-month intervention provides confidence that the results are not a consequence of poor adherence.

This also brings about a limitation of this study. As this study will not be randomized and it is based on self-reported data, confounding bias could exist. Lack of documentation when introducing new foods or not waiting at least three days to introduce a new food for those in the spoon-fed group can interfere with the results. Additionally, this study will only be able to show an association between food allergy incidence and weaning method, not causality due to its non-randomization. Another limitation of this study is that the only education provided is to the primary caregiver. It is the caregiver's responsibility to educate anyone else that feeds their infant; this could include daycare workers, babysitters, grandparents, and other family members. These secondary caregivers may not be comfortable feeding the infant finger foods, as required by the BLW group protocol, or may not know the infant is a part of a study with protocols on feeding. Another limitation of this proposed study is not controlling the main source of the infants' nutrition. Research has shown that breastfeeding is protective against atopic dermatitis during infancy, and exclusive breastfeeding has a stronger protective effect than partial breastfeeding (Chiu et al., 2016). As those with atopic dermatitis are at higher risk of food allergy, breastmilk may have a positive preventative impact on food allergy development in infants. For this reason, it would be beneficial to have further research examine the

impact of BLW on food allergies while controlling for an exclusively breastfed and exclusively formula-fed group.

In this proposed study, it was anticipated that all adult respondents will be at least high school graduates, as those that aren't high school graduates may be less likely to want to be included in a study. As this is a generalization that may not be true, research may indicate that this population may want to be involved in a study which may change other demographics of the adult respondents and dropout rate.

Suggestions for Future Research

To expand on the proposed study, changes could be made that may produce more significant results. For one, more participants could be included in the study to potentially produce more significant data. Additionally, the study could only include infants fed breast milk as breast milk could impact food allergy development. Further, the maternal diet could be controlled to include a less allergenic diet or anti-inflammatory diet. This study could also be performed retrospectively, similar to research by Cameron et al. (2013), asking the parents how they fed their infant at time of weaning and dividing them into groups: (1) adherent BLW (the infant entirely fed themselves), (2) partially BLW (caregivers reportedly following BLW but were using spoon-feeding at least half the time), or (3) parent-led feeding; food allergy development could then be assessed based off each group.

There is existing evidence of breastmilk lowering risk of food allergies, but there are inconsistencies among articles based on duration of breastfeeding and age at which the participant was assessed. Additionally, research on the impact of exclusive breastfeeding on food allergy development remains inconsistent as human milk oligosaccharides vary from person to person (Han et al., 2020). As mentioned above, future research could focus on duration of exclusive breastfeeding while introducing solids since breastmilk may have an impact on food allergy development.

Additionally, as those with eczema are at higher risk of developing a food allergy due to an already weakened skin barrier, additional research could be done on infants utilizing a protocol similar to Natsume et al. (2017) by recruiting infants with eczema that has been treated prior to the start of the study and dividing them into a BLW and spoon-fed group, noting that these participants may need to be introduced to the top nine food allergens in smaller amounts as they are already at higher risk.

Furthermore, this study may have shown different results if it went further into early childhood, similar to Du Toit et al. (2015), as food allergies often develop in the first one to two years of life (Wood, 2003). Currently, no literature to date has included premature infants in research utilizing the BLW method; therefore, it would be interesting to see how this method may impact premature infants as this has yet to be addressed.

Conclusion

This is the first proposed research looking at the relationship between infant weaning method and incidence of food allergy at 12 months by utilizing the traditional spoon-fed method (one new food every three or more days) and a baby-led method of weaning that introduces several allergens at once. Continuing research on the impact of baby-led weaning on food allergy development will help create additional recommendations for caregivers to follow while weaning their infant off formula or human milk.

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Appendix A: IRB form

Office use only: IRB Approval #: _____

Mount Mary University

Institutional Review Board (IRB)

For the protection of Human Subjects

Application for IRB Review

DATA COLLECTION CANNOT BEGIN

UNTIL THE IRB HAS APPROVED THIS PROJECT

I. Required Documentation - No action will be taken without these attachments.

Are the following attached to the IRB application?

Informed Consent Document	☒ Yes	Informed Consent Documents should include an explanation of procedures, risk, safeguards, freedom to withdraw, confidentiality, offer to answer inquiries, third party referral for concerns, signature, and date. See Appendix. A and use the **MMU Informed Consent Template** to avoid delays in the process.
Questionnaire/Survey Instrument(s)	☒ Yes	If a survey is being administered in any written format (e.g., Survey Monkey, Qualtrics), a copy of that survey must accompany this application. If a survey is being conducted verbally, a copy of the introductory comments and survey questions being asked must be attached to this application. If survey includes focus group questions, a complete list of the question must be attached. For research using a published/purchased instrument, a photocopy of the instrument will suffice.
Verification of Human Subjects Training	☐ Yes	Copy of transcript, certificate, or other evidence that ALL members of the research team have completed the required training.
Copy of cooperating institution's IRB approval.	☐ Yes	Not required if there is no cooperating institution.

II. Investigator(s):

Name: Chandler Burgess Phone:

Affiliation with Mount Mary University (e.g., faculty, student, etc.): student
Email: burgessc@mtmary.edu

Signature: _Chandler Burgess_____ Date: 9/23/2022

Name: Phone:
Affiliation with Mount Mary University:
Email:

Signature: _____ Date:

If student, list Research Advisor and complete the application. Research Advisor must provide requested information and verify.		
Research Advisor's Name: Janine Bamberger Email: bambergj@mtmary.edu	Department: Dietetics Phone: 414-930-3264	
Research Advisor: Have you completed Human Subject's Training?	☒ Yes	☐ No
Research advisor's signature indicates responsibility for student compliance with all IRB requirements.		
Signature: _____ Research Advisor	Date:	

III. Project Description – Required by all applicants

Instructions: Briefly describe the proposed project including the sample and methodology (e.g., human subjects, data collection, data analysis and instruments).

1) Objectives (purpose of project):

This non-randomized control trial study will seek to determine if baby led weaning can help prevent the development of food allergies at one year of age compared to caregivers who wean their infants by introducing a single new food every three or more days.

2) Relevance to practice/body of knowledge:

The LEAP study showed that early introduction to peanuts significantly reduced the development of peanut allergy for those at high risk (Du Toit et al., 2015). This could indicate that early introduction of many foods may decrease the prevalence of food allergies. There have been a number of studies conducted on baby-led weaning (BLW) in regards to the safety of the infant, though research on food allergy incidence in infants fed with this method is lacking. Further research within this area will help create dietary recommendations on best ways to introduce foods to prevent food allergies in infants.

3) Describe the research design (e.g., subject/participant selection and assignment, design, intervention, data analysis):

The proposed study is a non-randomized trial with an intervention period of six months. Caregivers with term infants aged three to four months old who are receiving exclusively formula or human milk will be recruited. Caregivers will be able to choose how they want to introduce complementary foods (via BLW or traditional spoon feeding). Those in the BLW group will receive education on how to prevent choking, iron/zinc deficiency, and inadequate energy intake. The spoon-fed group will be instructed to introduce one new food every three or more days. Both groups will be instructed to introduce the top nine food allergens and will be taught how to identify an allergic reaction. They will also be told to wait until the infant is six months old to introduce complementary foods. Both groups will receive a food log to document the first and second time they introduce a new food and any reaction that may occur. Caregivers will be instructed to bring their infant to a hospital when introducing a food a second time when they had a reaction to it the first time. Data will be analyzed when the infant reaches 12 months old.

Individuals will be recruited through online forums, social media groups for caregivers of infants, in pediatrician offices, and in daycares in Milwaukee County. Those who choose to complete the survey will be screened based on their answers. Those eligible will be offered the opportunity to take part in the study. Financial incentives in the form of a grocery store give card of twenty dollars will be distributed when the infant is one year old unless the participant drops out of the study. Recruitment will continue until meeting the minimum of the sample size. This means that individuals may be in different phases of the clinical trial at any given time in the study. The study aims to recruit 120 individuals in each group.

Data will be collected at three separate points during this intervention: baseline, when the infant is 9 months old, and when the infant is 12 months old. Demographic data will be collected including sex, weight, height, and if the infant is taking formula or human milk. Data collected about the caregivers will include their age, education level, working status, and race.

A chi-square test of independence will be used to analyze the differences between group participants to determine if significant differences exist in regard to caregiver education level, ethnicity, and employment status as well as the infants' sex, weight for length, and primary nutrition source. Two-tailed independent t-test and one-way ANOVA will be conducted to show the differences in food allergy development in those fed via the BLW or spoon-fed method. Logistic regression will be run to examine differences in food allergy development for infants weaned using a BLW or spoon-fed approach while controlling for timing of introduction to solids

4) What measurement/data collection tools are being used?

A questionnaire and food log will be used to collect the data on demographics, baseline data, and food allergies developed

IV. Additional Project Information – Required by all applicants

1) What human subjects training has the researcher completed (e.g., course work, online certification)?
CITI training

2) What process is used for obtaining informed consent (attach the informed consent application)? See Appendix for consent application.
The caregivers of the infants will be given an informed consent for signature prior to the patient's participation in the study.

3) Does the research include special populations?

Minors under 18 years of age?	☒ Yes	☐ No
Persons legally incompetent?	☐ Yes	☒ No
Prisoners?	☐ Yes	☒ No
Pregnant women, if affected by research?	☐ Yes	☒ No
Persons institutionalized?	☐ Yes	☒ No
Persons mentally incapacitated?	☐ Yes	☒ No

4) If **YES**, describe additional precautions included in the research procedures.
This study includes infants. All infants' identity will be protected by assigning them a nine-digit number used in place of their names for all data to be tracked with. Data will be stored in a password protected external hard drive. There is no direct risk to the infants.

5) Does the research involve any of the following procedures?

False or misleading information to subjects?	☐ Yes	☒ No
Withholds information such that their informed consent might be questioned?	☐ Yes	☒ No
Uses procedures designed to modify the thinking, attitudes, feelings, or other aspects of the behavior of the subjects?	☐ Yes	☒ No

6) If **YES**, describe the rationale for using procedures, how the human subjects will be protected and what debriefing procedures are used.

7) Does the research involve measurement in any of the following areas?

Sexual behaviors?	☐ Yes	☒ No
Drug use?	☐ Yes	☒ No
Illegal conduct?	☐ Yes	☒ No
Use of alcohol?	☐ Yes	☒ No

8) If **YES**, describe additional precautions included in the research procedures.

9) Are any portions of the research being conducted online?

Survey posted on a website?	☒ Yes	☐ No	If yes, assure anonymity
URL for survey includes information that could identify participants?	☐ Yes	☒ No	If yes, assure anonymity
Invitation to participate sent by email?	☐ Yes	☒ No	If yes, assure anonymity
Items use drop-down box?	☐ Yes	☒ No	If yes, assure that items allow choice of "no response"

10) If **YES**, describe additional procedures.
The survey will ask for the phone number of the caregiver respondent in order to get in touch with the respondent to get consent and complete the study. Contact information will be stored in a password protected external hard drive.

11) Describe the methods used to ensure confidentiality of data obtained.

The participants' identity will be protected by assigning them a nine-digit number used in place of their names for all data to be tracked with. Data will be stored in a password protected external hard drive.

Risks and Benefits
1) Describe risks to the subjects and the precautions that will be taken to minimize them. (Risk includes any potential or actual physical risk of discomfort, harassment, invasion of privacy, risk of physical activity, risk to dignity and self-respect, and psychological, emotional, or behavioral risk.)

Adult respondents will get to choose which feeding method they want to utilize and feel comfortable doing. Caregivers utilizing the BLW group will be given education on preventing iron deficiency, choking, and preventing inadequate energy intake. Studies have shown that after education on how to safely introduce finger foods, infants fed using the BLW method were not at any higher risk of choking compared to infants fed purees by a caregiver (Fangupo et al., 2016). When caregivers received education on high-iron foods appropriate for BLW, there was no significant difference in the amount of iron offered between those who followed conventional weaning and those who followed BLW guidelines (Cameron et al., 2015). Additionally, Taylor et al. (2017) found no difference in BMI z-scores between the BLW group, which was provided instruction on how to provide high calorie foods, and the spoon-fed group.

With the introduction of new foods comes risk for allergy. Symptoms will be recorded in a food log at first and second introduction. If the infant has symptoms at first introduction, they are instructed to introduce it the second time in the food allergy clinic at Children's Wisconsin in order to easily seek medical attention if warranted.

2) Describe the benefits to subjects and/or society. (These will be balanced against risk.)

The proposed research study will look at the potential correlation between BLW and food allergy development. With known research that early introduction helps prevent food allergies, but limited research conducted comparing spoon-feeding versus BLW, further research within this area will help create dietary recommendations for parents on how to introduce solids in the safest way.

V. Is the proposed project "research" as defined by Institutional Review Board requirements? - Required by all applicants

- Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- A human subject is defined as a living individual about whom an investigator obtains either 1) data through intervention or interaction with the individual; or 2) identifiable private information.

Does the research involve human subjects or official records about human subjects?

If NO STOP here and SUBMIT application.

If the results will be available in the library, presented at a professional conference (includes any presentation to group(s) outside of the classroom), or published, please check the Yes box:

☐ Yes
☒ No

If the YES box is CHECKED, proceed to SECTION VI.

If the NO box is CHECKED, STOP here, and SUBMIT application.

Appendix B: Consent form

Mount Mary UNIVERSITY

Research Participant Information and Consent Form

Mount Mary University

Title of Study: A baby-led approach to weaning: The impact on IgE-mediated food allergies

Invitation to Participate and Purpose of the Research You are invited to participate in a research study that seeks to evaluate the impacts of following a baby-led weaning (BLW) method of introducing solids on food allergies. The study will seek to determine if the intervention results in decreased food allergy development. There will be two groups, one group will receive the intervention (BLW) and the other will not receive the intervention (the traditional method of spoon feeding). Participants will be asked to fill out food logs to record every first and second time a new food is introduced. Individuals in the intervention group will receive dietary education to prevent choking, inadequate iron intake, and inadequate energy intake. The individuals in the control group will be instructed to introduce one new food no sooner than every three days. Both groups will be instructed to introduce the top nine food allergies by the time the infant is 12 months old. Data will be kept anonymous and be analyzed by researchers. Participants must be 18 years of age or older.

Benefits and Risks: This research is designed to benefit the dietetics profession by analyzing the impact of baby-led weaning on food allergy development. Participants may benefit from being in this study by developing less food allergies. Although some participants may not benefit personally from being in this research study, findings generated by this research may add new knowledge to the dietetics field in general. There will be $20 grocery store card provided as compensation. There are no additional potential risks associated with participating in this study. Please address any questions or issues of concern to the researchers using the contact information provided above.

Confidentiality: All information obtained will be kept confidential by the researchers who will be the only people with access to the data. Information obtained will be stored electronically and will be password protected. Per the U.S. Office of Human Research Protections (code §46.115), all data will be destroyed three years after the end of data collection. Paper files will be shredded, and electronic files will be deleted. Individual participants will not be identified in any report or publication about this study.

Contact Information If you have questions about this research study, your rights as a research subject, or would like to know the outcome of the research, please contact Janine Bamberger, 414-930-3264, bambergj@mtmary.edu and Chandler Burgess, 414-266-8660, burgessc@mtmary.edu. If you have any questions regarding your rights or privacy as a participant in this study, please contact Dr. Tammy Scheidegger, Mount Mary University Institutional Review Board Chair, 2900 North Menomonee River Parkway, Milwaukee, Wisconsin, 53222-4597, telephone (414) 930-3434 or email schediet@mtmary.edu.

Consent By signing below, you are indicating that you have read this consent form, have been given the opportunity to ask questions, and have agreed to voluntarily participate. You may withdraw from participation at any time, or refuse to answer any question herein, without penalty or loss of benefits to which other participants are entitled.

You may request a copy of this page for your records. Thank you for your participation.

Signature of participant_____ Date _____

Other Possible Elements Needed

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant. For research involving more than minimal risk, a statement describing any compensation for injuries and contact information. (Minimal risk is a risk of harm to the participant that is no greater than the risk encountered in normal, day-to-day activities or during routine physical or psychological examinations.) If the participant is a patient or client receiving medical, psychological, counseling, or other treatment services, there should be a statement that withdrawal from the study will not jeopardize or otherwise affect any treatment or services the participant is

currently receiving or may receive in the future. Participants also should be told whether their data will be destroyed should they withdraw from the study. If a survey instrument or interview questions are used and some questions deal with sensitive issues, the participants should be told they may refuse to answer individual questions.

Appendix C: BLW education materials:

Aim of recommendation	Summary of recommendations provided by the research team to the caregivers	Recommendation guided by
Increase the intake of high-iron foods	1) Encouraged to offer a high-iron food at each meal.	Registered Dietitian
	2) Provided with ideas for increasing the iron content of foods (e.g., including iron-fortified infant rice cereal in baking).	
	3) Provided with recipes and food ideas for iron-containing foods (including red meat which is high in total iron, heme iron, and the "meat/fish/poultry" factor that enhances non-heme iron absorption).	
Reduce the risk of growth faltering as a result of low energy from self-feeding	1) Encouraged to offer a variety of foods, including at least one high-energy food at each meal.	Pediatric health professionals
	2) Provided with food ideas and recipes that were high in energy and could be easily self-fed by the infant.	
	3) Encouraged to practice responsive feeding, ensuring that: the feeding environment is pleasant with few distractions (e.g., no television), caregivers pay attention to the infant's hunger and satiety cues, and that caregivers respond to the infant promptly and supportively.	
	4) Encouraged to offer 'easy' foods and more frequent milk feeds when their child was ill and during recovery.	
Reduce the risk of choking	1) Advised to test foods before they are offered to the infant to make sure they are soft enough to mash with the tongue on the roof of the mouth.	Pediatric speech-language therapist
	2) Provided with a list of specific foods to avoid (e.g., raw apple).	
	3) Advised to also avoid: foods that form a crumb in the mouth, hard foods, small foods, and circular (coin) shaped foods.	

Aim of recommendation	Summary of recommendations provided by the research team to the caregivers	Recommendation guided by
	4) Educated on safety around eating including how to differentiate between gagging and choking, and what to do if choking occurs.	

Note. Adapted from "Development and pilot testing of Baby-Led introduction to SOLIDS - a version of Baby-Led Weaning modified to address concerns about iron deficiency, growth faltering and choking," by Cameron, S. L., Taylor, R. W., and Heath, A.-L. M., 2015, *BMC Pediatrics*, 15(99). (https://doi.org/10.1186/s12887-015-0422-8). Copyright http://creativecommons.org/licenses/by/4.0/. Changes were made to header to apply to the caregivers of the study as not all are parents, and who the recommendation will be guided by.

Foods classified as iron containing foods	**Foods classified as high-energy foods**
Beef	All foods except *most* fruit and vegetables, plain rice crackers, or clear soups were classified as high-energy foods.
Chicken	Fruits classified as high energy: Avocado and banana
Fish	Vegetables classified as high-energy: Pumpkin, potato and kumara (sweet potato).
Ham	Foods classified as high-choking-risk foods
Lamb	Raw vegetables (e.g., carrot, celery, salad leaves)
Bacon	Raw apple
Liver (including pâté)	Rice crackers, potato crisps, corn chips
Luncheon sausage or other sausage	Whole nuts
Pork	Dried fruit (e.g., raisins, cranberries)
Salami	Cherries, grapes, berries, cherry tomatoes
"Saveloys" or "cheerios" (processed meat sausages)	Peas, corn
Iron-fortified infant rice cereal	Lollies (i.e., sweets or candy)
Baked beans	"Saveloys", hotdogs (processed meat sausages)
Lentils	Other hard food (i.e., foods that could not be squashed against the roof of the mouth with the tongue)
Hummus	
Chickpeas (other than hummus)	

Note. Adapted from "Development and pilot testing of Baby-Led introduction to SOLIDS - a version of Baby-Led Weaning modified to address concerns about iron deficiency, growth faltering and choking," by Cameron, S. L., Taylor, R. W., and Heath, A.-L. M., 2015, *BMC Pediatrics*, 15(99). (https://doi.org/10.1186/s12887-015-0422-8). Copyright http://creativecommons.org/licenses/by/4.0/. Change was made to formatting of table to fit on 1 page.

Appendix D: How to identify an allergic reaction

FOOD FACTS

U.S. FOOD & DRUG ADMINISTRATION

Food Allergies: *What You Need to Know*

Although new treatments are being developed, there is no cure for food allergies. Medical diagnosis to find out which foods cause an individual to have an allergic reaction and strictly avoiding those foods are important ways to prevent serious adverse health effects.

What Are the *Major Food Allergens?*

While many different foods can cause allergic reactions, the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) identifies the eight most common allergenic foods. These major food allergens make up 90 percent of food allergic reactions in the United States:

1. **Milk**
2. **Eggs**
3. **Fish** (e.g., bass, flounder, cod)
4. **Crustacean shellfish** (e.g., crab, lobster, shrimp)
5. **Tree nuts** (e.g., almonds, walnuts, pecans)
6. **Peanuts**
7. **Wheat**
8. **Soybeans**

Millions of Americans have food allergies and may experience adverse reactions to products that have food allergens. Most reactions cause mild symptoms, but some are severe and may even be life-threatening.

Allergen Labeling

The FDA enforces FALCPA in the labeling of foods the agency regulates, which include all foods except poultry, most meats, certain egg products, and most alcoholic beverages (all of which are regulated by other Federal agencies). FALCPA requires that food labels clearly identify the food source names of any ingredients that are one of the eight major food allergens or contain protein derived from a major food allergen.

Proper labeling of foods helps allergic consumers identify foods or ingredients that they should avoid.

How Major Food Allergens Are Listed

FALCPA requires that food labels identify the food source names of all major food allergens used to make the food. This requirement is met if the common or usual name of an ingredient (e.g., buttermilk) that is a major food allergen already identifies that allergen's food source name (i.e., milk). Otherwise, the allergen's food source name must be declared at least once on the food label in **one of two ways:**

1. In parentheses following the name of the ingredient in the ingredient list.
   Examples: "lecithin (soy)," "flour (wheat)," and "whey (milk)"

— OR —

2. Immediately after or next to the list of ingredients in a "Contains" statement.
   Example: "Contains soy, wheat, and milk..."

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Know the Symptoms of Food Allergies

If you are allergic to a food you have eaten, you may experience a variety of symptoms. These symptoms are not always present or the same for every person or reaction and can vary depending on a number of actors, including the amount of food allergen eaten.

If you are allergic to a food that you have eaten, symptoms may appear from within a few minutes to a few hours.

Symptoms of food allergies (allergic reactions), can include:

- Hives
- Flushed skin or rash
- Tingling or itchy sensation in the mouth
- Face, tongue, or lip swelling
- Vomiting and/or diarrhea
- Abdominal cramps
- Coughing or wheezing
- Dizziness and/or lightheadedness
- Swelling of the throat and vocal cords
- Difficulty breathing
- Loss of consciousness

Food Allergies Can Be Life-Threatening

While most symptoms from food allergies are mild and limited to skin or digestive discomfort, some may progress to a severe, life-threatening allergic reaction called **anaphylaxis**.

This can lead to:

- constricted airways in the lungs
- severe lowering of blood pressure and shock ("**anaphylactic shock**")
- suffocation by swelling of the throat and larynx

If you have a known food allergy and start having symptoms of an allergic reaction:

- Stop eating the food immediately
- Evaluate the need for emergency treatment (such as epinephrine)
- Seek medical attention

Symptoms of anaphylaxis may start out as relatively mild but, if not treated promptly, symptoms can become life-threatening in a short amount of time.

Recognizing early symptoms of anaphylaxis and prompt injection of the drug epinephrine and other medical care or intervention can help prevent life-threatening consequences.

It is important to understand that a mild allergic reaction does not always mean the allergy is mild. Any allergic reaction has potential to lead to anaphylaxis. Allergic individuals are taught to always monitor symptoms and seek medical care if needed when symptoms occur.

What to Do If Symptoms Occur

The appearance of symptoms after eating certain foods may be a sign of a food allergy. The food(s) that caused these symptoms should be avoided, and the affected person should contact a health care provider for appropriate testing and evaluation.

If you or a loved one has food allergies, use these 4 tips to help reduce your risk of getting sick:

1. Always read food labels.
2. Avoid foods that you are allergic to.

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FOOD FACTS

3. Learn to recognize the early symptoms of an allergic reaction, in case of accidental ingestion.
4. Know what to do in case an allergic reaction occurs. Plan to have ready access to the appropriate treatment measures and medical care.

Reporting Adverse Reactions and Labeling Concerns

If you or a family member has had an allergic reaction after eating an FDA-regulated food or food product with unclear labeling or a possible allergen, discuss this with your health care provider. Keep any food packages because they may contain important information. You may want to contact the manufacturer. Also, report the suspected reaction or labeling concerns to the FDA in one of these ways:

- Consumers and manufacturers can submit reports detailing product reactions or other complaints to an FDA Consumer Complaint Coordinator for the state where the food was purchased. A list of FDA Consumer Complaint Coordinators is available at https://www.fda.gov/safety/report-problem-fda/consumer-complaint-coordinators#section-nav.
- Call FDA at 1-888-SAFEFOOD, or
- Submit a report using FDA's MedWatch Online reporting form for consumers, which can be found here: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm.

Reports submitted to FDA should include as much information as possible:

- Who is reporting the incident and who was affected? Please provide names, addresses, and phone numbers.
- The name and address of the place where the product was purchased.
- A clear description of the reaction, including:
  - o Date the reaction occurred.
  - o All symptoms experienced.
  - o How long after you ate or drank the product that the reaction occurred.
  - o Medications used to treat symptoms.
  - o Whether the reaction required further medical care, and if so, what kind. Please provide contact information for the doctor or hospital.
- A complete description of the product, including:
  - o Date of purchase.
  - o Any codes or identifying marks on the label or container, such as lot number, expiration date, and UPC code.
  - o Photos of the product, label, ingredient statement, and lot code.

Consumer reports of adverse events help FDA identify problem products and better protect all consumers.

For more information on food allergies, visit
https://www.fda.gov/food/food-labeling-nutrition/food-allergies

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Appendix E: Questionnaire

Caregiver phone number (to contact if eligible):Click here to enter text.

Caregiver age: Click here to enter text.

Caregiver highest education level (please select): ☐Some high school ☐High school degree ☐Some college ☐Bachelor's degree ☐Graduate degree ☐Doctorate ☐Prefer not to respond

Caregiver employment status (Please select): ☐Full time, ☐Part time, ☐Unemployed ☐Prefer not to respond

Was the baby born preterm (born before 37 weeks gestation) or term (born 37 weeks or later)? Please select: ☐Preterm ☐Term

Baby's birth date: Click here to enter text.

Baby's weight and height at last pediatrician appointment: Click here to enter text.

Date these measures were taken: Click here to enter text.

Infant race (Please select): ☐White ☐Black ☐Asian ☐Hispanic ☐Other ☐Prefer not to respond

Infant gender (Please select): ☐Male ☐Female ☐Prefer not to respond

Is your baby fed human milk or baby formula? Click here to enter text.

Have you introduced solids/purees to the baby? Please Select: ☐YES ☐ NO

Does your baby have any existing food allergies or intolerances? ☐YES ☐ NO

If YES, please list the food(s) and reaction(s):Click or tap here to enter text.

Appendix F: During-study interview questions

1. Have you tried to introduce any new foods this week?
2. How many times a day is [baby's name] eating solids?
3. What amount of [baby's name] did he/she feed him/herself? None, some, half, most, or all.
4. What amount of [baby's name] total food was he/she spoon-fed? None, some, half, most, or all.
5. Did [baby's name] develop any adverse reactions to any foods this week?
6. If yes to question 5, what were the reactions?
7. If yes to question 5, were you able to identify the food that caused the reaction?
8. If yes to question 7, what was the food that caused the reaction?
9. If yes to question 7, have you introduced that food/allergen twice?
10. How much did [baby's name] weigh at their last pediatrician well-child appointment? What was their length? What was the date of these measures?

Appendix G: Food Log

Log each new food given on the line. Date the box the first and second time the food has been introduced. Make note of the form of the food and of any allergic symptoms.

Date 1st time given	Date 2nd time given	Food	Form of food (cooked/baked or raw)	Symptoms

Date 1st time given	Date 2nd time given	Food	Form of food (cooked/baked or raw)	Symptoms