Educational Interventions for Women and Their Support Persons on Breastfeeding Outcomes

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EDUCATIONAL INTERVENTIONS FOR WOMEN AND THEIR SUPPORT PERSONS ON BREASTFEEDING OUTCOMES

BY

ALEXANDRA CORDELL

A dissertation partial fulfillment of the requirement for the degree

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This dissertation is approved as a creditable and independent investigation by a candidate for the Doctor of Philosophy degree and is acceptable for meeting the dissertation requirements for this degree. Acceptance of this does not imply that the conclusions reached by the candidate are necessarily the conclusions of the major department.

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Date
DEDICATIONS

I would like to dedicate this dissertation to my family. To my parents who have been nothing but encouraging to me throughout this entire process. You have been instrumental in my success and I thank you for the continued support and love throughout this all. To my husband, Lee, thank you for granting me grace during this very busy time in our lives.

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ABSTRACT

EDUCATIONAL INTERVENTIONS FOR WOMEN AND SUPPORT PERSONS ON BREASTFEEDING OUTCOMES

ALEXANDRA CORDELL

2020

Breastmilk is the ideal food source for infants providing health immediate and lifelong health benefits for the woman and infant. Current recommendations from the American Academy of Pediatrics state that infants should be breastfed exclusively for the first six months of life and continued breastfeeding in combination with solid foods through one year of age. Despite these recommendations, the United States continues to have suboptimal breastfeeding rates for any and exclusive breastfeeding in the first year. This topic has been extensively studied with many interventions developed and implemented; however, many have lacked effectiveness. Gaps in the science related to effective breastfeeding interventions persist. This dissertation addresses the current state of the science concerning breastfeeding in three phases. First, a thorough review of the literature is presented in an integrative review of breastfeeding interventions targeted at improving breastfeeding outcomes from 6-weeks to 6-months in Chapter 2. Using the strengths of previous interventions, this review of existing breastfeeding interventions provided recommendations to guide the development of an innovative breastfeeding intervention. Detailed development of a theory-based intervention is described in Chapter 3. A pilot trial of the developed breastfeeding intervention is described in Chapter 4. Together the findings of this dissertation: (a) provide recommendations for future breastfeeding intervention development and implementation, (b) present an in-depth guide to the
development and implementation of an innovative breastfeeding intervention, and (c) demonstrate the feasibility of a fully-powered trial to evaluate the effectiveness of this educational intervention for women and their support persons on breastfeeding outcomes.
Chapter 1: Introduction

Current recommendations state that infants be breastfed exclusively through 6 months with breastfeeding continuing until the infant turns 1 year (Eidelman et al., 2012). Current exclusive breastfeeding rates are not at ideal levels. Striving to improve breastfeeding rates in the United States is important because of the health benefits and protective factors for both postpartum women and infant.

Breastfeeding benefits for the infant include protection against allergic diseases, respiratory tract infections, otitis media, gastrointestinal tract infections, necrotizing enterocolitis, inflammatory bowel disease, asthma and type II Diabetes Mellitus. Risk of obesity and Sudden Infant Death Syndrome (SIDS) also decrease with breastfeeding (NICHD, 2018). By not addressing this, there are both medical and fiscal consequences. Bartick and Reinhold identified that if 90% of mothers in the United States exclusively breastfed for six months $13 billion would be saved every year (2010).

This topic has been studied at length; however, gaps in breastfeeding definitions, breastfeeding measurements, and effective breastfeeding interventions continue to exist. Behavior change and environmental factors such as social support need to be understood and examined.

Background

A common issue identified in breastfeeding research is the inconsistency of breastfeeding definitions. The two most common definitions used are from the World Health Organization (WHO) (2010) and Labbok and Krasovec (1990). While these two are the mostly commonly utilized in breastfeeding literature, researchers often will use a combination of the two, or utilize their own definitions. Inconsistent breastfeeding
definitions provide an additional barrier to the advancement of breastfeeding research as it can be very unclear what definitions are used in each individual study. Discrepancies also arise when considering the introduction of solid foods. Some researchers will capture solid food introduction, while others focus only on the liquids provided to the infant.

Discrepancies within the agreement on breastfeeding definitions makes breastfeeding measurement inconsistent. These measurement inconsistencies make it challenging to compare breastfeeding literature as exclusive breastfeeding may mean many different things to different researchers and comparing instruments used to capture breastfeeding outcomes at any time period are often developed by the researcher themselves or adapted from existing instruments. In some situations, the definition used did not match the measurement. For example, if the researcher used the WHO definition which considers solid food intake, researchers would not capture solid food intake in their measurement of breastfeeding outcomes.

A wide array of breastfeeding interventions exist, however the United States continues to have suboptimal rates of exclusive or any breastfeeding. In depth examinations of these breastfeeding interventions identifies the need for efficacious interventions. Utilizing the body of literature to develop and implement innovative breastfeeding interventions must be a priority to provide women the educational, supportive, and positive experiences they deserve to be successful in their breastfeeding journeys.

Within the context of the state of science related to behavior change in breastfeeding, this dissertation contains three manuscripts that are briefly described in the following paragraphs. The first manuscript is an integrative review, the second
manuscript is a breastfeeding intervention protocol, and the third is a report of original data-based research.

**Manuscript 1**

The first manuscript presented in this dissertation is an integrative review that was conducted using Whittemore and Knafl’s method (2005). The aim of this integrative review was to examine the effects of interventions during prenatal, immediate postpartum hospitalization, and the first 6-months to provide lactation education and support breastfeeding duration and exclusivity from 6-weeks to 6-months of life. This integrative review examined the literature from January of 2008 to January of 2020. Inclusion criteria included: (a) RCT or CCT studies, (b) pregnant and/or nursing mothers who receive breastfeeding interventions, (c) education or support interventions promoting breastfeeding, (d) measurement of breastfeeding duration or exclusivity in the infant’s first 6-weeks to 6-months of life, and (e) English language. Based on the recommendations of the Joanna Briggs Institute, studies were excluded based on sample sizes under 10 per group (2014).

Based on this review of 21 studies, recommendations were made to guide the development and implementation of future breastfeeding interventions. This manuscript was submitted to the Journal of Human Lactation, which passed and submitted to the Western Journal of Nursing Research in APA style 7th Ed. and is currently with reviewers. The findings of this review were utilized to design a breastfeeding intervention based on the strengths and limitations of interventions in the existing literature.

**Manuscript 2**

Manuscript 2 presented in this dissertation is a protocol paper of a breastfeeding
intervention that was developed based on the integrative review findings. The breastfeeding intervention was developed to leverage efficacious characteristics of existing interventions. It included: (a) multiple intervention delivery methods, (b) 7 intervention contacts, (c) included the mother and support person, and (d) utilized both education and social support components. This manuscript has been targeted to be submitted to the journal Maternal & Child Nutrition following dissertation defense.

**Manuscript 3**

A report of original research is the final manuscript presented in this dissertation. Thirty mother and support person dyads agreed to participate in an evaluation of the breastfeeding intervention developed by the first author and International Board-Certified Lactation Consultants (IBCLCs) from a local healthcare organization. With minimal attrition, 28 dyads competed the study that started in their third trimester and concluded when the infant was 10-weeks old, with final data collection occurring at 12-weeks. This pilot study had a primary aim of evaluating the feasibility of a fully powered study and the overall acceptability of the intervention. An attention-control group leveraged SIDS reduction materials from the National Institutes of Health (NIH) Safe to Sleep® Campaign.

**Chapter 5**

The final chapter of this dissertation presents a synthesis of dissertation. This conclusion also describes my overall Ph.D. journey, lessons learned throughout this process, contributions to science, and directions for future research and practice. A submission plan for each manuscript is also outlined in this chapter.
Appendices

The appendices of this dissertation include materials that were not published in the separate manuscripts but were all integral to the dissertation research.
Chapter 2: Manuscript 1

Interventions to Improve Breastfeeding Duration and Exclusivity: A Systematic Review

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In the United States breastfeeding duration and exclusivity rates are not at ideal levels, therefore there is a need to examine existing interventions. The purpose of this systematic review was to examine the effects of education and support interventions during the third trimester, immediate postpartum, and the first six months of life on breastfeeding duration and exclusivity from six weeks to six months. Inclusion criteria were (a) randomized controlled trials or controlled clinical trials, (b) pregnant and/or postpartum women, (c) lactation education and support interventions, (d) measurement of breastfeeding outcomes from six weeks to six months, and (e) published between 2008-2020. Twenty articles (21 studies) were reviewed. Thirteen studies employed innovative interventions that resulted in statistically significant differences in breastfeeding outcomes between groups. Interventions with statistically significant results were primarily combinations of education and social support and all were provided during the postpartum period. Interventions that targeted both the woman and a support person were more likely to be effective. A limited number of studies targeted the adolescent population and minorities. Common study weaknesses included limited use of a theoretical model, incomplete description of the intervention, and inconsistent outcome definitions and measurements. Based on these results recommendations for future research were derived.

*Keywords:* breastfeeding, education, social support, lactation, systematic review
Interventions to Improve Breastfeeding Duration and Exclusivity: A Systematic Review

Breastfeeding promotion, protection, and support are global health priorities since 1990, when the Innocenti Declaration was signed by 30 countries (United Nations International Emergency Fund [UNICEF], 1990). The Innocenti Declaration required governments to establish national breastfeeding policies and set national targets, making way for the Baby-Friendly Hospital Initiative (BFHI), Healthy People breastfeeding goals, and Surgeon General’s Call to Action to Support Breastfeeding. The American Academy of Pediatrics (AAP) recommends exclusive breastfeeding through the first six months, and after the introduction of solid foods at six months, continued breastfeeding for one year or longer (2019). In 2018, 24.9% of all infants were exclusively breastfed at six months of age (Centers for Disease Control and Prevention [CDC], 2019). In order to achieve substantial improvements in exclusive breastfeeding rates, it is of utmost importance to identify efficacious intervention strategies.

Systematic reviews have included examinations of social support (McFadden et al., 2017), counseling (McFadden et al., 2019) and behavioral change (Davie et al., 2019) interventions. Kim et al., (2018) reviewed intervention studies and determined that the most effective interventions were the Baby Friendly Hospital Initiative in combination with breastfeeding education and social support that occurs from the prenatal to postpartum period. Breastfeeding self-efficacy interventions have been examined in
reviews completed by Brockway et al. (2017) and Bai et al., (2019). Bai et al., completed a review that examined self-efficacy theory, theory of planned behavior, and social cognitive theory use in breastfeeding interventions and identified that application of one or more theories in the development of interventions was associated with positive breastfeeding outcomes (2019). Mahesh et al. found in a review that interventions that incorporated fathers were effective (2018). Lumbiganon et al., examined interventions that focused on the prenatal time period and identified that prenatal education alone does not improve breastfeeding outcomes at six months (2016). Despite the various reviews of research on breastfeeding interventions there are still gaps in the knowledge of what characteristics of interventions are efficacious. No reviews were identified that examined the effectiveness of interventions with support persons identified by the woman, not necessarily only the father as the father may not be where women find their support. The reviews of education and support reported a limited number of outcome measures. For example, Kim et al., (2018) limited to a single outcome of exclusive breastfeeding at six months and (McFadden et al., 2017) limited outcomes to any and exclusive breastfeeding at six weeks and six months.

Due to the limitations of these systematic reviews there is a critical need to synthesize the evidence on breastfeeding interventions targeted on the individual level that focus on education, support, or a combination of the two and span the prenatal to postpartum periods. It is necessary to examine experimental studies to determine what methodology and characteristics of breastfeeding interventions are advantageous to replicate in future studies. In addition, identification of gaps in what has been tested can guide researchers to design and test innovative interventions.
Purpose

The purpose of this literature review was to: (a) examine the effects of social support and education interventions during prenatal, immediate postpartum, and the first six months on breastfeeding duration and exclusivity from six weeks to six months of life and (b) recommend future directions for breastfeeding intervention research.

Methods

Design

Whittemore and Knafl (2005) guided review methods in combination with Joanna Briggs Institute (Tufanaru et al., 2017) and PRISMA (Liberati et al., 2009). Increasing analytic rigor, the Whittemore and Knafl method incorporates explicit and systematic processes that include (1) problem identification, (2) literature search, (3) data evaluation/reduction, 4) data comparison/synthesis, and 5) presentation.

Search Methods

One author (AC), assisted by a medical librarian, searched CINAHL, MEDLINE®, and Cochrane Central Register of Controlled Trials using the keywords pregnancy, prenatal care, perinatal care, intrapartum care, obstetric care, maternal-child care, postnatal care, postpartum care, breastfeeding promotion, intervention, education, support, and health services and their combinations. The search was limited to research articles published in peer-reviewed journals between January 2008 and June 2020. A hand search was conducted in the Journal of Obstetric, Gynecologic, and Neonatal Nursing and Journal of Human Lactation for October of 2018 to January of 2020 to account for articles that had not yet been indexed. A secondary search was
conducted by reviewing reference lists of the articles that were retrieved in full-text and ancestry searching of articles included in the sample (see Figure 1).

**Inclusion criteria.** Studies were eligible if they met the following criteria: (a) RCT or CCT studies, (b) pregnant and/or nursing women who receive breastfeeding interventions, (c) education or support interventions promoting breastfeeding, (d) measurement of breastfeeding duration or exclusivity in the infant’s first six weeks to six months of life, and (e) English language. Articles were excluded based on sample sizes under 10 per group, per the recommendations of the Joanna Briggs Institute (Tufanaru et al., 2017).

**Outcome measures.** The primary outcomes of this study were breastfeeding duration categorized as *any* or *exclusive*. *Any* breastfeeding included an infant that was being fed breastmilk as well as other foods and liquids. The authors coded *any* breastfeeding for studies that used WHO (2019) definitions of *partial* or *predominant* and Labbok and Krasovec (1990) categories of *partial* or *token* breastfeeding were coded as *any* breastfeeding. *Exclusive* breastfeeding was defined as infant’s being fed breastmilk as their only source of food and coded to included categories of *exclusive* from both WHO (2019) and Labbok and Krasovec (1990) criteria. Data was extracted for *any* or *exclusive* breastfeeding at six weeks to six months.

**Sample**

The search yielded a total of 308 citations. Following a review of titles and abstracts by the first author, 54 articles were retrieved in full text. Two authors (AC & CE) reviewed the full texts of potentially relevant papers to determine if they met the inclusion criteria. Of these, 32 were excluded for the following reasons: three for small
sample sizes (fewer than 10 per group), 17 for study design, 10 for breastfeeding outcomes measured, and four for intervention type. A total of 20 articles (21 studies) met the inclusion criteria and were included in the present review (see Figure 1).

**Quality Appraisal**

One author (CE) independently appraised the quality of each study included in this study by assessing the risk for bias using the Joanna Briggs Institute Checklist for Randomized Controlled Trials (Tufanaru et al., 2017). This checklist consists of 13-items. One author (AC) determined the ease of which a researcher could replicate the intervention with the Intervention Content Checklist developed by Conn (2015).

**Analysis**

The twenty-one studies were abstracted, and information was displayed in narrative tables. Studies were initially evaluated regarding sample characteristics, country of origin, purpose, sample size, outcomes, and study findings in an evidence table (see Table 1). Authors categorized intervention type as either education, support, or education and support. Next, the studies were compared regarding the intervention target population, the number of intervention contacts, intervention type, intervention delivery method, and intervention delivery time period in a synthesis table (see Table 2). Studies with statistically significant results were evaluated for effect size. If the author provided an effect size that was used. If no effect sizes were provided, one author (AC) calculated odds ratios using RStudio (2020). See Table 3.

**Results**

**Characteristics of Included Studies**
A total of 20 articles (21 studies), published between 2010 and 2018, were included in this review. See Table 1. Authors were based in 11 countries, although a disproportionate number of articles were from the United States (30%), China (15%) and Australia (15%), which may be due to a language bias since the search only included articles published in English. All studies were RCTs. Four of the studies employed cluster randomization. Two of the studies utilized attention control groups (Sikander et al., 2015; Wambach et al., 2011). Most of the studies used usual care as their control group. Three of the studies were conducted in Baby-Friendly designated facilities, and three were conducted at facilities that were working toward Baby-Friendly designation. Fifteen studies did not mention the Baby-Friendly designation of the institution. Sample sizes ranged from 86 (Pollard, 2011) to 2,724 (Jolly et al., 2012). Fifteen of the studies were adequately powered, five were underpowered, and one did not state the required sample size for full power (see Table 1).

Participant Characteristics

Seventeen studies focused breastfeeding interventions for pregnant/postpartum women and four directed interventions towards pregnant/postpartum women and their support person (Abbass-Dick et al., 2015; Daniele et al., 2018; Kronborg et al., 2012; Maycock et al., 2013). Inclusion criteria included: (a) having no serious medical complications \((n = 21)\), (b) living with a male partner \((n = 1);\) Abbass-Dick et al., 2015\), (c) being a primiparous woman \((n = 5);\) Khresheh Suhaimat et al., 2011; Pollard, 2011; Tahir & Al-Sadat, 2013; Wen et al., 2011; Wong et al., 2014\), and (d) having a singleton \((n = 8);\) Abbass-Dick et al., 2015; Bonuck et al., 2014; Gross et al., 2016; McDonald et al., 2010; Pollard, 2011; Tahir & Al-Sadat, 2013; Wong et al., 2014\). Specific age criteria
included: (a) 18+ years of age \( (n = 8; \) Abbass-Dick et al., 2015; Bonuck et al., 2014; Fu et al., 2014; Gross et al., 2016; McDonald et al., 2010; Pollard, 2011; Tahir & Al-Sadat, 2013; Wong et al., 2014), (b) between 15-18 years of age \( (n = 1; \) Wambach et al., 2011), and (c) 16+ years of age \( (n = 1; \) Wen et al., 2011). Two studies recruited from Women, Infants, and Children (WIC) locations (Efrat et al., 2015; Reeder et al., 2014). Two studies recruited women of a specific racial or ethnic background; Efrat et al. (2015) and Gross et al. (2016) recruited only women who identified as Hispanic.

**Methodologically Quality**

The studies included in this review had Joanna Briggs Institute Checklist for Randomized Controlled Trials scores ranging from 7 to 13 out of a possible 13 (Tufanaru et al., 2017). Of the studies included in this review, none met all components of the Intervention Content Checklist (Conn, 2015). All the articles provided the number of doses, timing of the intervention, target recipients, and modes of delivery; however, dose strength was frequently missing in the intervention description. Only four of the articles referenced a conceptual or theoretical framework. One of the studies included in this review had a published protocol paper that provided detailed information about the intervention (Wen et al., 2007).

**Intervention Characteristics and Effectiveness**

Intervention characteristics are available in Table 2.

**Theoretical or conceptual framework.** Of the 21 studies included in this review, only four specifically referenced a guiding theoretical or conceptual framework (Gross et al., 2016; Gu et al., 2016; Pollard, 2011; Wambach et al., 2011). Statistically significant results were found when using the Theory of Planned Behavior \( (n = 2; \) Gu et al., 2016;
Wambach et al., 2011) and a combination of Social Cognitive Theory and Social Learning Theory \( (n = 1; \) Gross et al., 2016). Pollard (2011) used Bandura's Social Cognitive Theory as a guiding framework and found statistically significant differences at six months. While others may have utilized a guiding framework, these studies did not explicitly describe such in the published articles.

**Interventionists.** The studies included in this review utilized individuals with many different qualifications to deliver interventions. Five did not clearly describe interventionists (Abbass-Dick et al., 2015; Daniele et al., 2018; Gu et al., 2016; Khresheh et al., 2011; Pollard, 2011). Three utilized peers either trained \( (n = 1; \) Jolly et al., 2012) or untrained \( (n = 2; \) Reeder et al., 2014; Sikander et al., 2015) to deliver interventions. Efrat et al. (2015) had undergraduate students who had taken a semester-long lactation course as interventionists while Ochola et al. (2012) recruited women and trained them with a breast-feeding counselor class. Registered nurses (RNs) were the interventionists in two studies (Wen et al., 2011; Wong et al., 2014). Certified Nurse Midwives (CNMs) were the interventionists in two studies (Kronborg et al., 2012; McDonald et al., 2010). Physicians and CNMs delivered interventions in two studies (Bonuck et al., 2014). International Board-Certified Lactation Consultants® (IBCLC®) delivered interventions in one study (Wambach et al., 2011) and one study leveraged certified lactation counselors (Tahir & Al-Sadat, 2013). One study leveraged a combination of CNMs and certified lactation consultants (Fu et al., 2014). Gross et al. (2016) leveraged certified lactation counselors and registered dieticians (RDs). One study also had a male facilitator with undisclosed profession as the interventionist working with fathers (Maycock et al., 2013).
**Targeted populations.** Four studies targeted women and a support person for the intervention (Abbass-Dick et al., 2015; Daniele et al., 2018; Kronborg et al., 2012; Maycock et al., 2013). The remaining 17 studies targeted women alone. Of the four that targeted women and their support persons, three showed statistically significant differences between groups (Abbass-Dick et al., 2015; Daniele et al., 2018; Maycock et al., 2013). Of the 17 studies that targeted women alone, eight showed statistically significant differences between groups (see Table 2).

**Intervention type.** Intervention types were categorized into three types (see Table 2): *educational* (*n* = 12), *support* (*n* = 3), and *educational and support* (*n* = 6). Among the 12 educational interventions, seven had statistically significant results (Abbass-Dick et al., 2015; Bonuck et al., 2014; Gu et al., 2016; Maycock et al., 2013; Pollard et al., 2011; Wambach et al., 2011; Wen et al., 2011). Of the three support interventions, one had statistically significant results (Reeder et al., 2014). Four of the six interventions that combined educational and support had statistically significant differences (Daniele et al., 2018; Gross et al., 2016; Ochola et al., 2012; Sikander et al., 2015).

**Mode of delivery.** The interventions used various modes of delivery, including face-to-face, online, telephone, and combinations (see Table 2). One study leveraged face-to-face and online delivery methods, three studies utilized telephone only, seven used face-to-face only, and ten employed face-to-face and telephone delivery methods. Of the nine studies that showed statistically significant differences between groups, one used telephone only (Reeder et al., 2014), one used face-to-face and online (Abbass-Dick et al., 2015), five used face-to-face only (Bonuck et al., 2014 BINGO; Gross et al., 2016;
Ochola et al., 2012; Sikander et al., 2015; Wen et al., 2011), and six utilized face-to-face and telephone methods (Bonuck et al., 2014 PAIRINGS; Daniele et al., 2018; Gu et al., 2016; Maycock et al., 2013; Pollard et al., 2011; Wambach et al., 2011). Face-to-face and telephone methods had statistically significant differences between groups 40% of the time this combination was used.

**Time periods and number of contacts.** Of five studies with intervention components during the prenatal, immediate postpartum hospitalization, and first six months of life, three had significant differences between groups (Maycock et al., 2013; Ochola et al., 2012; Wambach et al., 2011). Six of eight studies that had intervention components during the prenatal and postpartum periods found statistically significant differences between groups (Bonuck et al., 2014 (both), Daniele et al., 2018; Gross et al., 2016; Reeder et al., 2014; Sikander et al., 2015). Three of seven studies with components in the immediate postpartum hospitalization and postpartum periods had statistically significant results (Gu et al., 2016; Pollard et al., 2011; Wen et al., 2011). The one study with only postpartum components also found significant differences between groups (Abbass-Dick et al., 2015). The number of contacts in this review varied greatly across the 21 studies from one contact (Wong et al., 2014) to 26 contacts (Gu et al., 2016). The nine studies with statistically significant differences between groups had a similar number of contacts: a median of seven with a minimum of three and a maximum of 26. The length and characteristics of these contacts varied widely making it difficult to compare the dose strength.

**Measurement of Outcomes**
Most studies used self-report with a variety of conceptual definitions of breastfeeding outcomes. In most cases the researchers contacted the women and asked them to recall their breastfeeding behaviors over a period of time. The time periods of recall ranged from 24-hours, to 1-week, to since birth. One study included use of a daily log to encourage shorter intervals between breastfeeding outcome recording (Pollard, 2011). Many of the studies utilized WHO (2019) breastfeeding definitions ($n = 8$) or Labbok and Krasovec ($n = 4$; 1990), and one used a combination of WHO (2019) and Labbok and Krasovec (1990). One study used a definition from Labbock and Coffin (1997). Two studies did not clearly define their outcome measures. Three studies used researcher defined measures of breastfeeding outcomes including a single study defined breastfeeding duration as the total number of days the infant was breastfed or provided breast milk (Wambach et al., 2011). In summary, there was an inconsistency among the conceptual and operational definitions of breastfeeding outcomes.

**Effectiveness of Interventions**

As mentioned, of the studies included in this review, only thirteen studies found statistically significant differences between groups (See Table 3).

**Breastfeeding exclusivity at six weeks to two months.** Of the six studies that measured breastfeeding exclusivity at six weeks, only one found a statistically significant difference between the control group and the intervention group at six weeks. Gu et al. (2016) found that 90 of 157 (57%) participants in the intervention and 38 of 128 (30%) participants in the control group were breastfeeding exclusively at six weeks.

**Breastfeeding exclusivity at twelve weeks to four months.** Eleven studies included in this review measured breastfeeding exclusivity at 12 weeks. Three found
statistically significant differences between the intervention and control groups (Bonuck et al., 2014; Daniele et al., 2018). In the BINGO trial 2.7% participants in the control group were breastfeeding exclusively compared to 11%, 4.4% and 10.6% for the lactation consultants, electronically prompted, and lactation consultant and electronically prompted groups respectively (Bonuck et al., 2014). In the PAIRINGS trial 6.2% of the control group were breastfeeding exclusively at 12 weeks compared to 16% of the intervention group. Forty-three percent of women in the intervention group were breastfeeding exclusively at 12 weeks, while 32% of women in the control group were breastfeeding exclusively at 12 weeks (Daniele et al., 2018).

**Breastfeeding exclusivity at six months.** Five of seventeen (29%) studies found statistically significant results for this outcome measure (Gross et al., 2016; Gu et al., 2016; Ochola et al., 2012; Pollard, 2011: Sikander et al., 2015). Using a 24-hour recall, Gross and associates (2016) found that 73 of 221 (33%) participants in the intervention group and 55 of 235 (23%) participants in the control group were breastfeeding exclusively at 24 weeks. Gu and associates (2016) found that 66 of 157 (42%) participants in the intervention and 13 of 128 (10%) participants in the control group were breastfeeding exclusively at 24 weeks. Pollard found that 71% of the intervention group were exclusively breastfeeding at 24-weeks compared to 23% in the attention control group (2011). In a three-arm study by Ochola et al. (2012), 47% of participants in the facility-based group, 61% in the home-based group, and 37% in the control group were breastfeeding exclusively at 24 weeks. In a study conducted by Sikander et al. (2015), 125 of 210 (60%) participants in the intervention group and 60 of 211 (28%) participants in the control group were exclusively breastfeeding at six months, with an
OR = 3.7, 95% Cis [2.4643 – 5.5583], p < 0.01. Three of the five studies that found statistically significant results had interventions that combined education and social support (Gross et al., 2016; Ochola et al., 2012; Sikander et al., 2015). All five of these studies included contacts during more than one period: (a) prenatal and postpartum (Gross et al., 2016; Sikander et al., 2015), (b) immediate postpartum and postpartum (Gu et al., 2016; Pollard et al., 2011), and (c) prenatal, immediate postpartum, and postpartum (Ochola et al., 2012).

**Any breastfeeding at six weeks to two months.** Of five studies, only one (Maycock et al., 2013) found statistically significant results. Maycock et al. (2013) found 304 of 372 (82%) participants in the intervention group and 247 of 328 (75%) participants in the control group were doing any breastfeeding at six weeks. The study found an odds ratio of 1.45, 95% CI [1.00 – 2.12], p = 0.04).

**Any breastfeeding at twelve weeks to four months.** Two of the nine studies measuring this outcome (11%) found statistically significant results (Abbass-Dick et al., 2015; Reeder et al., 2014). Abbass-Dick et al. (2015) found that 100 out of 104 (96%) women in the intervention group were breastfeeding, compared to 92 out of 105 (88%) in the control group, with an odds ratio of 3.53, 95% CI [1.1120 – 11.226]. Reeder et al. (2014) identified that peer counseling increased any breastfeeding at twelve weeks and reported a risk ratio of 1.22, 95% CI [1.10-1.34].

**Any breastfeeding at six months.** Two of thirteen studies measuring this outcome found statistically significant results for this outcome measure (Wambach et al., 2011; Wen et al., 2011). The study conducted by Wambach and associates (2011) identified that the intervention group had increased duration of any breastfeeding for the
intervention group to a median of 177 days (approximately six months), compared to a median of 61 days in the control group (roughly two months). The study also reported that there was a higher number of participants in the control group who had experienced a cesarean section. Wen et al., found that home visits in the prenatal and postpartum period improved any breastfeeding at 24-weeks with 42.2% in the intervention group compared to 32.1% in the control group (2011).

**Summary of Results**

Forty-two percent of studies in this review had statistically significant results for breastfeeding outcomes measured at six weeks to six months. In contrast, selected intervention characteristics were more common among the studies that did have statistically significant results. Three of the four studies that targeted women and support persons showed significant results. Combining education and social support in interventions demonstrated statistically significant results in three of the five studies. Leveraging more than one delivery method had more efficacy than utilizing only one delivery method. Interventions that spanned at least two time periods were most successful.

**Discussion**

Our findings support the positive effect that including support persons as a target/audience into breastfeeding intervention improves breastfeeding outcomes, which is consistent with reviews by McFadden et al. (2017) & Mahesh et al. (2018). Of the thirteen studies that had statistically significant differences, three targeted a support person in addition to the woman. These findings are consistent with a review by Mahesh et al. (2018) that identified that targeting fathers with educational interventions was
associated with improvements in breastfeeding outcomes. Based on these reviews, additional studies of the efficacy of educational interventions that target support persons and women and measure perceived maternal support are required to determine the mechanism or theoretical basis in which support persons can contribute to overall breastfeeding success.

In this review three studies included adolescents and only one of these was designed for the adolescent population. This highlights a gap in what is known to support adolescent women with breastfeeding. The findings of this review are consistent with those from Sipsma et al., (2014) that suggest a need for interventions developed and evaluated for effectiveness with adolescents and their support persons.

This review determined that interventions that combined education and social support were more effective than those with just education alone. This was consistent with reviews by McFadden et al. (2017) and Lumbiganon et al. (2016). The conclusions of the current review align with those of Patnode et al. (2016), calling for primary care interventions combining educational and social support to be explored further, focusing on high quality and well-controlled trials.

Among the nine studies with the most efficacy, the most common delivery methods were a combination of face-to-face and telephone. While this is currently one of the more efficacious combinations of breastfeeding intervention delivery methods, new combinations may emerge as technology advances. Text messaging has recently become a modality of interest showing a great deal of promise when used as a form of two-way communication (Gallegos et al., 2014) or in conjunction with telephone calls (Patel et al., 2018). However, the most efficacious modality for interventions is still unknown.
Researchers need to compare the method of delivery while controlling the content and timing of the interventions to identify the delivery methods that will benefit women and their support persons. Utilizing more than one platform for intervention delivery is an important strategy to ensure ample opportunity to be successful in presenting education. More research is needed to identify the most beneficial delivery methods with an emphasis on new technologies.

Interventions with components that began in the prenatal period and ended in the postpartum period were most successful in improving breastfeeding outcomes. This finding is consistent with other reviews of breastfeeding interventions (Kim et al., 2018; Mahesh et al., 2018; Meedya et al., 2017). Interventions need to be provided to women as they face changing barriers to breastfeeding over time; anticipatory guidance is inadequate. Multiple intervention contacts are required to address women in the prenatal, immediate postpartum, and first six months of life, however the exact number of contacts needed for an efficacious intervention is unknown. Due to varying types of intervention contacts, it is difficult to recommend dose-strength without specific research examining this. Researchers need to test the provision of education and support interventions that span through the child’s first six months of life.

Our findings suggest that the application of theory shows promise for effective breastfeeding interventions. With three of the four studies who implicitly stated their theoretical underpinnings showing statistically significant results, this review emphasizes the importance of designing and evaluating breastfeeding interventions grounded in theory. The seventeen remaining articles included in this review did not implicitly describe any theoretical underpinnings. This leads us to recommend that researchers
develop interventions based on theory and spend adequate time describing the theoretical underpinning of interventions, which is consistent with recommendations of Bai et al., (2019).

In this review we identified a weakness with inadequate descriptions of interventions. This is consistent with findings of Conn (2015), that thorough descriptions of interventions currently lack in the literature. Many of these studies had been published before the publication of the Intervention Content Checklist that we used to examine intervention descriptions. This may be due to manuscript length restrictions determined by journals. However, authors must work towards providing complete descriptions of their interventions to ensure that studies can be replicated, and this may warrant an increase in publication of protocols.

Inconsistent breastfeeding definitions limited our ability to compare studies. The present review is consistent with a review conducted by Wood et al., (2016), which determined that current literature contains measurements of breastfeeding outcomes that are inconsistent and inaccurate. Four different definitions were used as conceptual definitions in this review. None of the articles in this review used the most recent Labbock breastfeeding definition (2012). The World Health Organization has five definitions for infant feeding with exclusive breastfeeding being defined as the infant only receiving breastmilk during the previous 24-hours; no other liquid or solid food can be consumed by the infant to meet this definition (2010). Of the various definitions, WHO (2019) is the only one that explicitly states no other liquid or solid food intake may be ingested in the definition of exclusive breastfeeding. Even though WHO specifically measures solid food intake, only three of the studies considered solid food intake
Invalid measurement of exclusive breastfeeding occurs when researchers do not account for solid foods or other liquids. It is important that researchers use measurement that aligns with their conceptual definitions.

Breastfeeding measurement inaccuracy can occur due to the use of recall. Exclusive breastfeeding was overestimated by 24-hour recall compared to deuterium oxide turnover techniques (Mazariegos et al., 2016). Inaccuracies of recall should be considered while developing ways to assess breastfeeding outcomes. We recommend decreasing the length of time between recall periods by using diaries or mobile applications to help women track breastfeeding behaviors.

This review was limited to articles published in peer-reviewed journals in English, resulting in a disproportionate number of articles from English-speaking industrialized countries. This potentially resulted in limited transferability to countries with different populations, breastfeeding practices, and healthcare systems. Interventions that only implemented Baby Friendly Hospital Initiative or other system-wide approaches were excluded.

Based on this review we recommend that individual-level interventions: (a) target both women and support person/father, (b) have social support and educational components, (c) utilize more than one delivery method, (d) have three or more intervention contacts, and (e) provide intervention contacts during prenatal, immediate postpartum, and during the first six months. Adolescents should be studied in further detail to understand the differences between breastfeeding interventions developed for adolescent or adult women. Future research should either include adolescents or develop
interventions specifically for the adolescent population. Research should be designed to address the methodological weaknesses described in this review. Specifically, studies need clear conceptual definitions and application of a theoretical framework, comprehensive description of the intervention, and valid and reliable measurement of breastfeeding outcomes. Specifically, measurement needs to address the provision of expressed woman’s own milk and donor milk and account for the introduction of solid foods.

Innovative interventions are needed to determine how to effectively intervene with a woman and support person to improve breastfeeding outcomes. The interventions reviewed were ineffective despite adequately powered studies. Lack of statistical significance may be due to ineffective interventions or inadequate measurement of outcomes. Development, implementation, and examination of innovative interventions from prenatal to postpartum periods that include both lactation education and social support are necessary.

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Conflicts of Interest: None.
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<tr>
<th>Article</th>
<th>Country/Design</th>
<th>Purpose</th>
<th>Sample/Setting/Power</th>
<th>Intervention</th>
<th>Outcome measures</th>
<th>Findings</th>
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<tbody>
<tr>
<td>Abbass-Dick et al. (2015)</td>
<td>Canada</td>
<td>Evaluate the effectiveness of a co-parenting intervention on exclusive breastfeeding</td>
<td>Adult primiparous women and fathers as couples IG: n = 107 CG: n = 107 Powered</td>
<td>Face-to-face individual co-parenting materials (included a 15 min video), education at postpartum hospitalization, emails at one and three weeks, and a phone contact at two weeks</td>
<td>Labbok and Krasovec (1990) and WHO definitions Web-based questionnaire or telephone interview</td>
<td>EBF at 6 and 12 weeks ns ABF at 6 weeks ns ABF at 12 weeks SIG IG = 96.2%, CG = 87.6%, p = .02</td>
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<tr>
<td>Bonuck et al. (2014)</td>
<td>USA</td>
<td>Determine the effectiveness of primary care-based and pre- and postnatal interventions to increase breastfeeding.</td>
<td>BINGO N = 666, analyzed 628 IG Lactation Consultant (LC): n = 77 IG Prompt (P): n = 236 IG LC+P: n = 238 CG: n = 77 Underpowered</td>
<td>Prompts in antenatal electronic medical record for health care provider to discuss breastfeeding LC at two antenatal visits, postpartum visit, and phone contacts</td>
<td>WHO definitions Infant Feeding Practices SurveyFein, et al., 2008) Telephone interview</td>
<td>EBF at 3 months SIG IGLC = 11%, IGP = 4.4% IGLC+P = 10.6%, CG = 2.7% OR = 4.24, 95% CI [1.01, 37.94] EBF at 6 months ns ABF at 3 months SIG IGLC = 50.7%, IGP = 44.5% Also measured intensity IGLC+P = 56.2%, CG = 37.8% OR = 2.10, 95% CI [1.23, 3.61] ABF at 6 months ns</td>
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<tr>
<td>Study Source</td>
<td>Country</td>
<td>Study Design</td>
<td>Objective</td>
<td>Intervention Details</td>
<td>Analysis Details</td>
<td>Outcome</td>
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<tr>
<td>Daniele et al. (2018)</td>
<td>Burkina Faso</td>
<td>RCT</td>
<td>Determine whether an intervention to involve the male partners of pregnant women in maternity care influenced care-seeking, healthy breastfeeding, and contraceptive practices after childbirth</td>
<td>IG: Antepartal group session for male partners, antenatal counseling for couples, postpartum counseling for couples, all provided by health workers, the focus was not specifically on breastfeeding</td>
<td>WHO definitions</td>
<td>EBF at 3 months</td>
</tr>
<tr>
<td>Efrat et al. (2015)</td>
<td>USA</td>
<td>RCT</td>
<td>Assess whether a phone-based breastfeeding intervention delivered by lactation educators</td>
<td>Low income Hispanic women IG: Undergraduate research assistants educated as lactation educators provided telephone support starting during the third trimester through 6 months, mean 1.5 antenatal phone contacts for</td>
<td>Labbok and Krasovec (1990) and Aart et al. (2000) definitions</td>
<td>EBF and ABF at 3 and 6 months ns</td>
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<tr>
<td>Study</td>
<td>Country</td>
<td>Study Design</td>
<td>Methodology</td>
<td>Results</td>
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<tr>
<td>Fu et al. (2014)</td>
<td>China</td>
<td>Cluster RCT</td>
<td>Evaluate the effect of two postnatal professional support interventions on the duration of any and exclusive breastfeeding. Clusters randomized every week to one of the groups. Clusters = 3 hospitals. IG hospital: n = 191 (analyzed 190) IG phone: n = 269 (analyzed 261) CG: n = 264 (analyzed 260). Power not stated. IG hospital: during postpartum hospitalization, three educational support sessions lasting 30-45 minutes. IG phone: after postpartum discharge, weekly phone support (20-30 minutes each) for four weeks. CG: usual care.</td>
<td>ABF at 72 hr, 1, 3 &amp; 6 months. EBF at 2 &amp; 3 months ns. OR = 1.48, p = .03, 95% CI [1.04, 2.10]. IG phone: 58.6%, CG: 48.9%. Phone support with lower overall risk of stopping breastfeeding over 6 months, Hazard Ratio = 0.79, 95% CI [.64, .98].</td>
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<tr>
<td>Gross et al. (2016)</td>
<td>USA</td>
<td>RCT</td>
<td>Determine the effects of a child obesity prevention intervention, beginning in third trimester on infant feeding. IG: n = 221 CG: n = 235 Both primiparous and multiparous, low-income Hispanic women. IG: four contacts, (1) during 3rd trimester individual counseling with RD/CLC, (2) during postpartum hospitalization individual counseling with RD/CLC, (3) at one-month nutrition parenting support group (NPSG) with 4-8 women, (4) at two months another NPSG, intervention guided by social learning theory. CG: usual care included breastfeeding class and CLC</td>
<td>On survey EBF at 3 months SIG IG = 33.0%, CG = 23.4% OR = 1.61, p = .03, 95% CI [1.07, 2.44]. On 24 hr recall EBF at 3 months SIG IG = 42.7%, CG = 33.0% OR = 1.51, p = .04, 95% CI [1.03, 2.21].</td>
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<td>Study</td>
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<td>Study Design</td>
<td>Intervention Description</td>
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| Gu et al. (2016)    | China       | RCT          | Investigate the effectiveness of a designed intervention program on the promotion of exclusive breastfeeding | IG: n = 180  
                      |             |                                           |               |                 | WHO definitions                                                         |
|                     |             |              | Chinese primiparous women                                                                 | CG: n = 172  
                      |             |                                           |               |                 | In-person or telephone interview                                         |
|                     |             |              | IG: Based on the Theory of Planned Behavior, three days of individual instruction and one 60-minute group class during postpartum hospitalization, phone support, a group class at six weeks, phone support through six months | (analyzed 157) |                 | EBF at 3 days, 6 weeks, 4 months, & 6 months                            |
|                     |             |              | CG: n = 172  
                      |             |                 |               |                 | IG: 57.3%, CG: 29.7%, p < .001                                          |
|                     |             |              | (analyzed 128) |
| Jolly et al. (2012) | United Kingdom | Cluster RCT | Assess the effectiveness of a peer support worker (PSW) service on breastfeeding continuation. | IG: n = 1267  
                      |             |                                           |               |                 | WHO definitions                                                         |
|                     |             |              | Cluster randomized 66 clinics                                                             | CG: n = 1457  
                      |             |                                           |               |                 | In-person or telephone interview                                         |
|                     |             |              | IG: Based on the WHO curriculum, Antenatal support by PSW in two sessions at clinic and postpartum HV at 24-48 hr and another within the first week, further support by HV or phone was variable, also received usual care | (analyzed 271 at 6 months) |                 | EBF at 4 months SIG                                                      |
|                     |             |              | CG: n = 1457  
                      |             |                 |               |                 | IG: 56.7%, CG: 15.6%, p < .001                                          |
|                     |             |              | (analyzed 301 at 6 months)                                                               |             |                 | EBF at 6 months SIG                                                      |
|                     |             |              | Powered                                                                                 |             |                 | IG: 42.0%, CG: 10.2%, p < .001                                          |
|                     |             |              |                                                                                         |             |                 |                                                                         |
| Khresheh et al.     | Jordan      | RCT          | Test whether the introduction of an educational program supporting breastfeeding would increase the proportion of women who | IG: n = 45  
                      |             |                                           |               |                 | WHO definitions                                                         |
| (2011)              |             |              | IG: n = 45                                                                               | CG: n = 45  
                      |             |                                           |               |                 | Unknown definitions of outcomes                                          |
|                     |             |              | Powered for a 22% difference                                                             |             |                 | Phone interview                                                         |
|                     |             |              |                                                                                         |             |                 | EBF at 6 months ns                                                      |

**EBF** (fully breastfeeding at least once in past 24 hr)
breastfed fully to six months, improve the women’s level of breastfeeding knowledge, and decrease the proportion of infants admitted to hospitals due to gastrointestinal illnesses.

The intervention was provided by nurse researchers.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Country</th>
<th>Study Design</th>
<th>Objective</th>
<th>Study Details</th>
<th>Results</th>
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<tbody>
<tr>
<td>Kronborg et al.</td>
<td>Denmark</td>
<td>RCT</td>
<td>Assess the effect of an antenatal training programme on knowledge, self-efficacy, and problems related to breastfeeding and on breastfeeding duration</td>
<td>Three education (lecture and discussion) sessions lasting three hours each between 30 and 35 weeks of pregnancy, father invited to attend</td>
<td>EBF at 6 weeks ns ABF at 6 weeks ns</td>
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<tr>
<td>Maycock et al.</td>
<td>Australia</td>
<td>RCT</td>
<td>Investigate the effects of an antenatal education session and postnatal support targeted to fathers</td>
<td>IG received 2-hr antenatal education session by a male facilitator and weekly postpartum support to fathers for the first six weeks CG received usual antenatal education and hospital and postpartum care</td>
<td>Full BF at 6 weeks and 6 months ns ABF at 6 weeks SIG IG = 81.6%, CG = 75.2%, unadjusted OR = 1.46 (95% CI, 1.01, 2.13) ABF at 6 months ns</td>
</tr>
<tr>
<td>McDonald et al.</td>
<td>Australia</td>
<td>RCT</td>
<td>Evaluate the effects of an extended midwifery support program on the proportion of women who breastfed to six months</td>
<td>IG received one-to-one education during postpartum hospitalization, weekly HV and two midwife phone calls per week during first six weeks postpartum (most women had 2-4 HV)</td>
<td>Full BF at 6 months ns ABF at 6 months ns</td>
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<tr>
<td>Study Authors</td>
<td>Country</td>
<td>Study Design</td>
<td>Intervention Details</td>
<td>Outcome Measures</td>
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<td>Ochola et al. (2012)</td>
<td>Kenya</td>
<td>Cluster RCT</td>
<td>Determine the impact of facility-based semi-intensive and home-based intensive counselling in improving exclusive breastfeeding (EBF) in a low resource urban setting</td>
<td>CG received standard midwife care, which included one HV during the first postpartum week</td>
<td>Full BF and ABF at 6 months</td>
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<td>Pollard (2011)</td>
<td>USA</td>
<td>RCT</td>
<td>Test the efficacy of a daily feeding log, guided by Bandura's Social Cognitive Learning Theory, on breastfeeding duration and exclusivity in primiparous women</td>
<td></td>
<td>EBF at 3 months SIG IG home 61.4%, CG 36.8%</td>
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<td>Study</td>
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<td>Study Design</td>
<td>Study Objectives</td>
<td>Intervention Details</td>
<td>Control Details</td>
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<tr>
<td>Reeder et al. (2014)</td>
<td>USA</td>
<td>RCT</td>
<td>Test whether a telephone peer counseling program among WIC participants could increase breastfeeding initiation, duration, and exclusivity</td>
<td>Peer counseling based on Loving Support curriculum, Spanish speaking provided for Spanish speaking clients</td>
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<td>IG 8 contacts; $n=645$ ($625$ analyzed)</td>
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<td>IG 4 contacts; $n=646$ ($625$ analyzed)</td>
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<td>CG; $n=657$ ($635$ analyzed)</td>
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<td>Sikander et al. (2015)</td>
<td>Pakistan</td>
<td>Cluster RCT</td>
<td>Test the effectiveness of cognitive-behavioral counseling on the rate and duration of exclusive breastfeeding (EBF) during the first six months compared to routine counseling</td>
<td>All community health workers had basic WHO training in breastfeeding; for the IG units, they also had training in a psycho-educational approach.</td>
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<td>IG: $n=224$</td>
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<td>CG: $n=228$</td>
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Note: higher financial status for IG compared to CG
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<th>Study</th>
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<th>Intervention Details</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Tahir et al. (2013) Study the effectiveness of telephone lactation</td>
<td>Malaysia</td>
<td>RCT</td>
<td>Adult postpartum women IG: n = 179 CG: n = 178 Powered IG: Certified lactation counselors trained in WHO curriculum provided postpartum telephone support twice a month for six months WHO definitions of Exclusive, Predominant, and Complimentary</td>
<td>EBF at 4 &amp; 6 months ns ABF at 4, &amp; 6 months ns</td>
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<td>counselling on breastfeeding practices</td>
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<td>Phone interview for maternal recall of past 24 hours of feeding, EBF at 1, 4, and 6 months</td>
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<tr>
<td>Wambach et al. (2011) Determine if an education and counseling</td>
<td>USA</td>
<td>RCT</td>
<td>Adolescent, most were primiparous IG: n = 128 (97 analyzed) ACG: n = 128 (90 analyzed) CG: n = 134 (102 analyzed) Powered</td>
<td>Breastfeeding duration = number of days Phone interview to collect maternal recall at 3 &amp; 6 weeks and 3 &amp; 6 months</td>
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<td>intervention provided by a lactation consultant-peer counselor team</td>
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<td></td>
<td>Based on the Theory of Planned Behavior and Developmental Theory including Adolescent Decision-Making Theory. Intervention from antenatal through four weeks postpartum. IG: Two antenatal group education classes provided by a lactation consultant and peer counselor (encouraged to bring support person) Peer counselor antenatal two contacts by phone and postpartum counseling one-to-one in person at the hospital and by telephone for five contacts up to four weeks Also received a breast pump ACG: same number of education classes and number/timing of contacts on postpartum recovery and maternal role, provided by</td>
<td>ABF Duration SIG</td>
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<td>increased breastfeeding initiation and duration up to six months</td>
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<td>postpartum among adolescent women.</td>
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<td>Wen et al. (2011)</td>
<td>Australia</td>
<td>RCT</td>
<td>Assess the effectiveness of a home-based early intervention on infant feeding practices and tummy time. The focus of the research was on obesity prevention.</td>
<td>Low income, primiparous women</td>
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<tr>
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<td>RCT</td>
<td>Evaluate the effectiveness of a professional one-to-one antenatal breastfeeding support and education intervention on exclusivity and duration of breastfeeding</td>
<td>Primiparous women $N = 469$</td>
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Note. CG = Control group; ACG = Attention control group; IG = Intervention group; HV = Home visit; ABF = Any breastfeeding; EBF = Exclusive breastfeeding; SIG = Statistically significant; ns = Not statistically significant
<table>
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<tr>
<th>Intervention Characteristics</th>
<th>Intervention Target</th>
<th>Number of Intervention Contacts</th>
<th>Intervention Type</th>
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<th>Intervention Time Frame</th>
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<tr>
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<td>4</td>
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<td>Tahir &amp; Al-Sadat, 2013</td>
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<td>1</td>
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Note. SP = Support Person
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<thead>
<tr>
<th>Study</th>
<th>ABF 6 weeks</th>
<th>EBF 6 weeks</th>
<th>ABF 12 weeks</th>
<th>EBF 12 weeks</th>
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<tr>
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<td>+ (OR = 4.24 (1.01, 37.94)</td>
<td>+ (OR = 2.86 (1.21, 6.76)</td>
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<td>+ (OR = 1.61 (1.07, 2.44)</td>
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<tr>
<td>Gross et al., 2016</td>
<td>+ (OR = 3.46 (1.03, 11.56) *</td>
<td>+ (OR = 3 (0.08, 115.34) *</td>
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<td>Wen et al., 2011</td>
<td>+ (OR = 1.59 (0.70-3.61)</td>
<td>+ (OR = 1.55 (1.08,2.21) *</td>
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</tbody>
</table>

*Note. ABF = Any Breastfeeding, EBF = Exclusive Breastfeeding, NS = Not statistically significant, + = statistically significant difference with positive intervention group outcomes, * = effect size calculated by review author

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This manuscript is a component of a dissertation in a Ph.D. program at South Dakota State University.
Abstract
Breastfeeding has been shown to have substantial infant and maternal health benefits. Despite this, fewer than 25% of women in the United States breastfeed exclusively at six months. Clinicians need effective breastfeeding interventions to use with women and their support persons. The aim of this study is to test the feasibility, acceptability, and preliminary efficacy of a breastfeeding intervention for women and support persons guided by the Social Cognitive Theory. This pilot cluster randomized controlled trial utilizes an intervention and attention-control group. The intervention will target pregnant women/postpartum women and their support persons with face-to-face education, electronic messages, and links to video and educational materials. Eligible participants for this study include women who are 18 years or older, are pregnant with a singleton, are attending prenatal breastfeeding education with a support person, speak and read English, and can receive text or email messages. Support persons will be eligible if they are 18 years or older, are able to speak and read English, and are able to receive text or email messages. This pilot uses a pretest/post-test, unblinded parallel (attention-control) group, cluster randomized controlled trial design. Cluster randomization will be used with the goal of recruiting a minimum of 13 participants in each group. The primary outcome is the feasibility and acceptability of the breastfeeding intervention and study methods. The secondary outcome is efficacy of the intervention on breastfeeding outcomes at six weeks and three months. The tertiary outcome will determine the preliminary efficacy, if any, on intervening variables: support, attitudes, and knowledge. This intervention employs educational and support strategies to women and their identified support persons to help improve breastfeeding outcomes. Results of this pilot
study will guide development of a fully powered study.

Keywords: exclusive breastfeeding, randomized controlled trial, support, education, pregnancy, protocol

Key Messages

• While the United States is meeting goals for breastfeeding initiation rates, duration and exclusivity rates are not at ideal levels.
• An attention-control group will receive Safe Sleep interventions by the same professional on a matched schedule.
• Guided by Social Cognitive Theory, this study will attempt to change the breastfeeding knowledge and attitudes of the support person.
• An innovative intervention leverages strengths and addresses inadequacies of previous studies.

The American Academy of Pediatrics (AAP) recommends that all infants be exclusively breastfed through their first six months of life (Eidelman et al., 2012). Healthy People 2020 (2020) set a target of 25.5% of all infants in the United States to be exclusively breastfed through six months of age. However, despite these recommendations, only 24.9% of newborns were being exclusively breastfed through six months of age in 2018 (Healthy People 2020, 2020). Healthy People 2030 objectives have not been released at the time of this publication; however, we expect the objectives will address this gap between current exclusive breastfeeding rates of about 25% and the recommendation of 100%.

Clinical practices have been inadequate to reach breastfeeding goals due to a limited number of efficacious breastfeeding interventions that have been designed, tested, and translated into practice. Effective interventions are needed to promote breastfeeding success. Characteristics of interventions with preliminary efficacy should be retained and incorporated in innovative breastfeeding interventions. Social theories play an integral role in intervention development. Review of existing literature has identified key components of breastfeeding interventions to include: (a) intervention target, (b) intervention content, (c) delivery strategy, (d) time span of intervention, (e) number of intervention contacts, and (f) theoretical foundation.

Breastfeeding interventions should target women and their support persons. It has been identified that breastfeeding interventions that incorporate support persons have been successful in improving breastfeeding outcomes (Cordell & Elverson, 2020; Mahesh et al., 2018). Through a focus group study with women who have breastfed for
six months or longer, we have obtained preliminary data indicating support persons help develop a breastfeeding routine and overcome breastfeeding barriers (Cordell et al., 2019).

Cordell & Elverson (2020) also identified that interventions should utilize multiple delivery strategies with 60% of reviewed articles that employed face-to-face and telephone modalities together showing statistically significant differences between groups. Studies offering delivery strategies that incorporate both face-to-face modalities and technology-based strategies have found success in health prevention behaviors (Doss et al., 2017; Ratanjee-Vanmali et al., 2020). Text messaging has recently become of interest in breastfeeding interventions as it has shown positive effects on other disease prevention behaviors especially in the areas of: (a) smoking cessation, (b) physical activity, and (c) weight loss (Cole-Lewis & Kershaw, 2010; Head et al., 2013; Fjeldsoe et al., 2009). Participants of interventions that incorporate text messaging are satisfied with the convenience of this delivery strategy (Martinez-Brockman et al., 2017). While this delivery strategy offers promise, the current body of literature suggests that messages be carefully crafted from theoretical foundations (Loescher et al., 2018). Despite the positive promise offered by text messaging, face-to-face interventions still offer a variety of benefits to patients including: (a) feelings of perceived support, (b) ability to ask questions when they arise, and (c) positive patient satisfaction (Bobrowska-Korzeniowska et al., 2020).

The timing of breastfeeding interventions must be heavily considered. A review of prenatal breastfeeding interventions identified that education provided exclusively in the prenatal period does not improve breastfeeding outcomes at 6-months (Lumbiganon
et al., 2016). It is unrealistic to expect a woman to learn everything necessary to successfully breastfeed during the prenatal time period. The immediate post-birth hospitalization is full of physiological, emotional, and physical changes, making meaningful education challenging (Buchko et al., 2012). In reviews of the literature, breastfeeding interventions that span the prenatal, immediate post-birth hospitalization, and postpartum periods have been found to be the most efficacious (Cordell & Elverson, 2020; Jolly et al., 2012; Kim et al., 2018; Meedya et al., 2017; Mahesh et al., 2018).

Existing literature indicates the need for three or more contacts for breastfeeding interventions. The ideal number of intervention contacts is unclear. One review stated that five or more are associated with increased efficacy of breastfeeding interventions (Jolly et al., 2012) and another review recommended four to eight contacts (McFadden et al., 2017).

The use of theory in development, implementation, and testing of breastfeeding interventions has consistently been absent in existing literature. Currently, a limited number of published studies identify a theoretical basis (Cordell & Elverson, 2020). However, interventions that have utilized social theories as a foundation have found success (Gross et al., 2016; Gu et al., 2016; Pollard, 2011; Wambach et al., 2011).

A breastfeeding intervention that combines targeting the pregnant woman/new mother and a support person; including both education and support components; using multiple delivery methods; and spanning prenatal, immediate birth hospitalization, and three months postpartum; a theory based intervention has not been tested for efficacy. This combination will be evaluated in this research study.

Theoretical Framework
This study has a foundation in Social Cognitive Theory (SCT). See Figure 1. Social Cognitive Theory (SCT) is an interpersonal theory that emphasizes the interaction between people, their behavior, and their environment. This interaction is called Triadic Reciprocal Determinism. Triadic Reciprocal Determinism is a main construct of SCT and explains a relationship between a person, their behavior, and their environment in which each affects one another in a reciprocal fashion (Bandura, 1998). This theory examines how individuals learn from their own experiences, the experiences of others and how they interact with their environment (Kelder et al., 2015). The cognitive change process is typically utilized during the early stages of adopting a new behavior and help facilitate movement into behavior changes (Joseph et al., 2014).

Social Cognitive Theory denotes that support provided by a support person is an environmental factor. The basic assumption of SCT and this study is that social support is a modifiable environmental factor. The intervention’s goal thus is to change the breastfeeding knowledge and attitudes of the support person. By changing the knowledge and attitudes of the support person, the support person will be better equipped to provide social support and change maternal perception of breastfeeding support. Maternal breastfeeding intention, maternal breastfeeding attitudes, and breastfeeding self-efficacy are intervening variables.

Definitions

For the purpose of this study, exclusive breastfeeding (point-in-time) has been defined as infants who have only had breastmilk in the past 24 hours, with no other liquids or solid foods (WHO, 2010). Any breastfeeding (point-in-time) has been operationalized as women who have directly breastfed or given their infant mother’s
expressed or donor breastmilk in the past 24 hours (WHO, 2010). Breastfeeding

duration has been operationalized as the number of days that the woman has given her
infant breastmilk, expressed breastmilk, or donor breastmilk (Wambach, 2011; WHO,
2010).

Perceived social support has been defined as the perception of support,
encouragement, and care one receives from a social network (Sherbourne & Stewart,
1991). This intervention aims to improve feelings of maternal perceived social support by
engaging support persons in the breastfeeding process.

Breastfeeding intention has been conceptually defined as the goals for
breastfeeding duration and/or breastfeeding exclusivity (Nommsen-Rivers & Dewey,
2009). Intentions are an important part of any health behavior (Bandura, 1986).

Infant feeding attitudes will be defined as a settled feeling, viewpoint or
preference about the way in which one will feed their infant (De la Mora et al., 1999). For
a summary of variables, conceptual and operational definitions used in this study see
Table 1.

Participants and Methods

Aims

The primary aim is to assess the feasibility and acceptability of the intervention
and study procedures. The purpose of a pilot study is to: (a) evaluate the adequacy of the
planned procedures, (b) test various aspects of the methods, (c) identify potential
confounding variables, and (d) evaluate the acceptability of the intervention implemented
(Conn, 2012; Melnyk & Morrison-Beedy, 2012).

The secondary aim is to determine the preliminary efficacy, if any, an intervention
guided by SCT for women and their identified support persons has on breastfeeding outcomes. The hypotheses of this study are as follows: (a) women whose support persons participate in an educational and support breastfeeding intervention will have higher rates of exclusive breastfeeding at six weeks and three months post-birth, (b) women whose support persons participate in an educational and support breastfeeding intervention will have higher rates of any breastfeeding at six weeks and three months post-birth, and (c) women whose support persons participate in an educational breastfeeding intervention will have longer breastfeeding duration.

The tertiary aim is to determine the preliminary efficacy, if any, the intervention has on intervening variables. We hypothesize the following: (a) women in the intervention group will have higher breastfeeding attitude scores on the Iowa Infant Feeding Attitude Scale (IIFAS) than those in the attention-control group at three months post-birth, (b) women in the intervention group will have higher Breastfeeding Self-Efficacy Short-Form (BSES-SF) scores than those in the attention-control group at three months post-birth, and (c) women in the intervention group will have higher social support scores on the Medical Outcomes Study (MOS) Social Support Survey and Multidimensional Scale of Perceived Social Support (MSPSS) at three months post-birth.

**Design**

This pilot uses a pretest/post-test, unblinded parallel (attention-control) group, cluster randomized controlled trial design.

**Target population**

As an environmental factor in SCT, the source of social support may vary throughout a woman’s pregnancy which is why this study will examine the effect of an
intervention targeted at women and their identified support person. Women in their third trimester and their support person will be attending a prenatal breastfeeding class that occurs at two locations in a Midwest region within a single healthcare system. Site A holds the breastfeeding class four times a month and has an average of 15 pregnant women at each class. Site B offers the breastfeeding class monthly and has an average attendance of three pregnant women in each class.

**Inclusion and Exclusion Criteria**

Eligible participants for this study include women who are 18 years or older, pregnant with a singleton, attending prenatal breastfeeding education with a support person, able to speak and read English, and able to receive text/email messages. Their support persons will be eligible and enrolled if they are 18 years or older, able to speak and read English, and able to receive text/email messages. To mitigate confounding variables associated with breastfeeding success, women pregnant with multiples or who have substantial health problems will be excluded from this study.

**Recruitment Procedure**

To improve the number of women who bring a support person to breastfeeding classes, the following recruitment strategy will be implemented. The leaders of the breastfeeding classes will continue their usual practice to encourage women to bring their support persons. In addition, the researcher will attend childbirth preparation classes to encourage women to bring their support person to subsequent breastfeeding classes.

**Random Assignment**

Cluster randomization was chosen because the intervention will be implemented to a group after a standard breastfeeding class. A statistician will provide sequentially
numbered opaque envelopes to determine the allocation of intervention and attention-control group conditions. After participants have signed consents and HIPAA authorizations and have completed baseline measures (prior to the standard breastfeeding class), the researcher will open an opaque envelope containing the group assignment.

**Participant Withdraws**

Participants have the option to withdraw from the study at any point. If one or both members of the woman/support person dyad choose to withdraw, they will inform the researcher via telephone or email, and the dyad will be withdrawn from the study. Two exit questions will be asked:

1. How do you feel about how frequently you were contacted for this study?
2. What is the reason you are choosing to withdraw from this study?

Participants will be able to refuse the questions. Data collected prior to withdrawal will be analyzed.

**Intervention**

The standard prenatal breastfeeding class conducted by four International Board-Certified Lactation Consultants (IBCLCs) includes information directed at the women: (a) knowledge, (b) attitudes, and (c) local lactation resources. The curriculum is *Breastfeeding: A Great Start!* (Moran & Kallam, 2011). All participants, regardless of group assignment, will receive the standard breastfeeding class prior to the intervention or attention-control conditions.

**Intervention Curriculum**

The intervention was developed by first author Cordell with guidance from International Board-Certified Lactation Consultants (IBCLCs) from a Midwestern
healthcare organization. Bandura’s Social Cognitive Theory was the framework utilized to develop the intervention (Bandura, 1986). For theoretical components of the text messages sent to both groups, see Table 2. Theoretical components of the face-to-face class for the intervention group are available in Table 3 and for the attention-control group, see Table 4. This breastfeeding intervention includes (a) face-to-face education provided by the principal researcher, (b) video, (c) text/email messages, and (d) online brochures. The face-to-face class is approximately 15 minutes, see Table 3 and Table 4. Constructs of SCT were chosen by the first author and International Board-Certified Lactation Consultants (IBCLCs) helped to identify the appropriate timing of the intervention materials. Cultural relevance has been incorporated into this study by working with IBCLCs to make sure the verbiage and message is consistent with the local cultural standards. Readability of materials provided from healthcare providers should be easily read with a grade level readability of less than 8th grade, as that is the national average for U.S. residents (Strossel et al., 2012). The readability of all online brochures utilized in this study were assessed using the Flesch-Kincaid readability index via Word. Readability of the print materials provided to the intervention group range in grade level of 3.0 – 7.9. All intervention materials were from the following: Lactation Education Resources © (2019) and the United States Department of Agriculture Foods and Nutrition Service (2019). All online brochures were free to use from their respective agency.

**Attention-Control Curriculum**

Attention-control group members will receive Safe to Sleep® (2019) education. All attention-control materials are free for use. This intervention includes (a) face-to-face
education provided by the principal researcher, (b) video, (c) text/email messages, and (d) online brochures. Cultural relevance has been incorporated in this study by working with IBCLCs to make sure the verbiage and message is consistent with the local cultural standards. Readability of the online brochures provided to the attention-control group range from 3.0 – 6.0 grade level. See Table 3.

**Intervention and Attention-Control Delivery**

A parallel combination of face-to-face education, text/email messaging, and online videos and brochures will be the mode of delivery for both groups. Face-to-face initial intervention contact will occur after a prenatal breastfeeding class provided by the regional healthcare system. Subsequent contacts will occur exclusively via text/email messaging and links to online information. Each text/email message will have a 24-hour window to be sent; texts will be sent via the Google Voice web application (Google, 2019) and emails will be sent from the researcher’s university email account. All video and brochures will be delivered via the text/email message and available via webpage link. Researchers will account for any text/email messages sent outside of the 24-hour time window. The researcher is the sole interventionist for this study and is a registered nurse.

All study participants will have the opportunity to choose if they receive text or email messages at the time of informed consent. To improve the satisfaction and usefulness of the messages, participants will be asked for an approximate time of day that is preferable to each member of the dyad to receive their text/email messages. All messages will be sent to women and support persons and described in Table 2.

**Data Collection**
Data will be collected utilizing QuestionPro, a web-based survey system, for all data other than breastfeeding outcomes (QuestionPro, 2019). The Breastfeeding Outcome Questionnaire will be collected via telephone interview and transcribed into QuestionPro, allowing the researcher to clarify any questions the woman has and more accurately capture breastfeeding outcome measurements as recommended by Greiner (2014).

The following instruments will be utilized in this study: (a) Demographic questionnaire, (b) Infant Feeding Intention Scale (IFIS), (c) Iowa Infant Feeding Attitude Scale (IIFAS), (d) Breastfeeding Self-Efficacy Scale Short-Form (BSES-SF), (e) Medical Outcome Study (MOS) Social Support Survey (MOS Social Support Survey), (f) Multidimensional Scale of Perceived Social Support (MSPSS), (g) Breastfeeding Outcome Questionnaire, (h) Maternal Chart Abstraction form, and (h) the Acceptability of Intervention Measure (AIM). For schedule of data collection, see Table 5.

**Demographic Questionnaire**

The demographic questionnaire was developed using the CDC’s demographic questionnaire with two questions added. The additional questions added include (a) number of children at home and (b) whether the participant is receiving Women, Infants, and Children (WIC) benefits. The demographic questionnaire is used to determine baseline information about study participants. This questionnaire will be obtained from women and their support persons at the initial visit.

**Infant Feeding Intention Scale**

Intentions are a predictive construct of behavior change (Ajzen, 1991). The Infant Feeding Intention Scale is a 5-item, 5-point Likert-type scale with a range of possible scores from zero to 16 that was developed based on the Theory of Reasoned Action and
the Theory of Planned Behavior to be used during the third trimester of pregnancy (Nommsen-Rivers et al., 2010). A higher score means the participant has a stronger intention to breastfeed for the infant’s first six months of life (Nommsen-Rivers & Dewey, 2009). The total score is obtained by adding the means of items one and two and then adding the total sum of items three, four, and five. In a sample of diverse third trimester women, a Cronbach’s α of 0.90 was obtained (Nommsen-Rivers et al., 2010). The IFIS will be used at baseline to confirm that intervention and attention-control groups have similar intentions to breastfeed at six months. This questionnaire will be obtained from women prior to random assignment.

**Iowa Infant Feeding Attitude Scale**

The Iowa Infant Feeding Attitude Scale (IIFAS) is an atheoretical instrument used to measure attitudes, knowledge, and beliefs, without subscales. This is a 17-item, 5-point Likert-type scale with a total score ranging from 17 to 85, with a higher score indicating the participant has a more positive breastfeeding attitude (De la Mora et al., 1999). Approval to use this instrument was obtained.

Developed to be used in the prenatal and immediate postpartum hospitalization setting to identify new parents’ attitudes on feeding method choice, this self-report tool has been evaluated for reliability and validity in the following populations: (a) prenatal women, (b) postpartum women, (e) formula feeding women, and (d) fathers (Ho & McGrath, 2010). During the prenatal period, the IIFAS had a Cronbach’s α of 0.90 in women and 0.91 to 0.92 in fathers (Abbass-Dick et al., 2015). This questionnaire will be obtained from women and their support persons prior to randomization and from women via QuestionPro at 12 weeks.
Breastfeeding Self-Efficacy Scale Short-Form

Based on SCT, the Breastfeeding Self-Efficacy Scale Short-Form (BSES-SF) is a 14-item, 5-point scale that results in a total score of 14 to 70 (Dennis, 2003). The purpose of this instrument is to measure breastfeeding self-efficacy, which is defined as the individual’s confidence in her ability to breastfeed (Dennis, 2003; Ho & McGrath, 2010). Permission was obtained to use this instrument in this study.

Several studies have shown the BSES-SF to be reliable when used with prenatal women and women through the first three months postpartum (Dennis, 2003). Cronbach’s α ranged from 0.86 (Gregory et al., 2008) to 0.90 (Tokat et al., 2010). This questionnaire will be obtained from women before random assignment and at the 12-week contact.

Medical Outcomes Study Social Support Survey (MOS Social Support Survey)

Social support is the encouragement and care one receives from their social network (Bandura, 1998). Social support will be captured by the Medical Outcomes Study (MOS) and was developed to measure perception of availability of functional social support in patients with chronic illnesses (Sherbourne & Stewart, 1991). No theory was used to develop the tool. It has subsequently been used in pregnant women and postpartum women within five years of their delivery (RAND, 2018a). The current scale available online, has 19 items on a 5-point scale with “none of the time = 1” to “all or the time = 5” and is comprised of a single item measure and four subscales: emotional/information support, tangible support, affectionate support, and positive social interaction. The total possible score ranges from 19-95 with higher scores indicating higher perceived availability of social support (RAND, 2018b). The original scale with
20 items (an additional item concerning the number of close friends and relatives) has been used in pregnant women, and the internal consistency of a total score was 0.98 (Giurgescu et al., 2014) and 0.97 when using the original form of the survey (Simon et al., 2016). Due to the lack of availability of factor analyses to confirm the validity of the subscales for pregnant or postpartum women and limited reliability estimates, the current version and format of the survey will be administered, and total score will be used in analysis. The Medical Outcome Study Social Support Survey is a public document provided by the RAND Health Corporation and is available in the public domain, free of charge (RAND, 2018a). This questionnaire will be obtained from women at the initial visit and the 12-week contact.

**Multidimensional Scale of Perceived Social Support (MSPSS)**

As noted above, social support is the encouragement and care one receives from their social network (Bandura, 1998). Social support has been operationalized by Zimet et al. (1988) in the Multidimensional Scale of Perceived Social Support (MSPSS). This scale is a 12-item, 7-point Likert-type scale with three equally weighted subscales that measure social support from (a) family, (b) friends, and (c) significant other. A total score can also be calculated to determine the overall feelings of perceived support from the entire social support system. The possible total score ranges from one to seven and subscale scores can range from one to seven, with higher scores being associated with higher levels of perceived support (Zimet et al., 1988). In studies conducted with pregnant women, the MSPSS total score yielded Cronbach’s α of 0.92 (Zimet et al., 1990), and 0.81 (Nazari et al., 2015). This questionnaire will be obtained from women at the initial visit and the 12-week contact.
Breastfeeding Outcome and Goals Questionnaire

The Breastfeeding Outcomes and Goals Questionnaire is a researcher developed tool that was adapted from the Infant and Young Child Feeding Module (WHO, 2010). This questionnaire addresses key issues of measuring breastfeeding outcomes by using both a point-in-time and life-long breastfeeding status as recommended by Greiner (2014). The point-in-time breastfeeding measurement will utilize a 24-hour recall. Potential limitations of using a 24-hour recall include capturing mother-infant separations that deviate from usual breastfeeding routine. To address this, the questionnaire includes questions to identify mother-infant separations. This questionnaire will be administered via telephone interview, rather than survey, to address any questions women have regarding the items, as recommended by Greiner (2014). The primary purpose of this questionnaire is to measure the following outcomes: (a) exclusive breastfeeding as a point-in-time, (b) any breastfeeding children, and (c) duration of breastfeeding (in days).

The women will be interviewed via telephone at the 6-week and 12-week contacts. These telephone calls will be completed via Google Voice web application (Google, 2019) at the participants identified ideal time of day and a message was sent via text or email to provide the participant an approximate time they could expect the phone call.

Acceptability of Intervention Measure (AIM)

The Acceptability of Intervention Measure (AIM) will be used to determine the acceptability of each component of the intervention. This four-question questionnaire uses a 5-point Likert-type scale, with higher scores being associated with a higher level of acceptability. This tool has a 5th grade readability and takes less than five minutes to complete; it has yielded a Cronbach’s $\alpha$ of 0.85 when assessing an intervention (Weiner
et al., 2017). This questionnaire will be obtained from women and their support persons following each intervention component via a hyperlink to a QuestionPro questionnaire.

**Maternal Chart Abstraction**

In addition to the contacts with participants, the investigator will abstract information from the maternal chart using the Delivery Stay Abstraction Form. This instrument is used to capture: infant gender, gestational age at birth, infant weight, length of hospital stay, and maternal parity post-birth. This is will be obtained via the electronic medical record at 1-week post-birth hospitalization.

**Sample Size Estimates**

An effect size (Cohen’s $d$) of 0.20 was chosen based on the conclusions of a systematic review that interventions that span the prenatal and early postpartum period have an effect size of 0.2 on breastfeeding outcomes at three months (Jolly et al., 2012). The G*Power 3 Statistical Power Analysis Program (Faul et al., 2013) was used to conduct a power analysis to determine the sample size for Hypothesis 1 of the secondary aim. To achieve a power of 0.80 and an estimated effect size of 0.20—with a significance level of .05, with a Mann-Whitney U Test—the total sample size needed for this pilot study was 190 or 95 for each group (Faul et al., 2013). Per Cocks and Torgerson (2013), a pilot study should have at least 9% of the sample size of the main planned trial. Nine percent of 190 would be 17 participants. To account for 30% attrition, the goal number of participants who will be recruited into this study will be 26, 13 for each group.

**Analysis**
The Breastfeeding Outcome and Goals Questionnaire has been designed to facilitate telephone data collection and computer data entry. QuestionPro data will be downloaded as Excel files. Data will be stored on a computer as a STATA 13.0 file (StataCorp, 2013). Each file will be backed up on two encrypted thumb drives. Data will be cleaned and tested for normalcy prior to any statistical analysis. Baseline characteristics of the two groups will be compared using chi-square test for the following variables: marital status, parity, education level of woman, education level of support person, race, and receiving WIC benefits. Baseline characteristics and baseline variable scores will be compared between the two groups with chi-square and Mann-Whitney tests. Due to the small sample size, researchers anticipate that data will not meet the assumptions of parametric tests; thus, non-parametric statistics will be used to answer questions and hypotheses.

**Primary Aim**

The primary aim of this two-arm cluster randomized controlled trial is to assess the feasibility and acceptability of this intervention and study procedures. Primary aim 1 will be evaluated using descriptive statistics and graphs to identify patterns. The number of participants and their reasons for withdrawal will be described and used to determine feasibility. Researchers will capture the amount of time spent implementing and assessing the intervention by collecting (a) amount of time spent drafting and sending text/email messages, (b) median duration of intervention class component, (c) median amount of time collecting breastfeeding outcomes on the telephone, and (d) the number of text/email messages that did not go through. Scores of the AIM will be collected and analyzed for each contact to determine the acceptability of each component of the
intervention. A mean or median score will be calculated for each of the seven components. Comparisons will be made between AIM scores of the intervention and attention-control group for each contact to ensure that the materials for each group are of comparable acceptance. The scores will also be used to identify components that are less or more acceptable to women or support persons.

**Secondary Aim**

*The secondary aim of this two-arm cluster randomized controlled trial is to determine the preliminary efficacy, if any, an intervention for pregnant women/postpartum women and their identified support persons guided by SCT has on breastfeeding outcomes.* Researchers will test for normalcy of data and will utilize either parametric or non-parametric testing to compare groups for the secondary aim and associated hypotheses. Cohen’s $d$ will be calculated for the difference between groups at six weeks and three months postpartum to identify the efficacy of this intervention.

**Tertiary Aim**

*The tertiary aim is to determine the preliminary efficacy, if any, an intervention for support persons guided by SCT has on intervening variables.* Researchers will test for normalcy of data and will utilize either parametric or non-parametric testing to compare groups for the tertiary aim and associated hypotheses. Cohen’s $d$ will be calculated in *infant feeding attitudes, breastfeeding self-efficacy, and perceived social support* between groups in at six weeks postpartum and three months postpartum to identify the efficacy of this intervention.

**Reliability Analysis**
A Cronbach’s α will be computed for each scale to evaluate internal consistency reliability of each instrument. This will be compared to the Cronbach’s alphas obtained by other researchers for similar sample populations.

**Ethical Considerations**

The study was approved by the Institutional Review Board (IRB) at the healthcare organization with an authorization agreement provided by the university IRB. Participants will provide informed consent prior to the standard breastfeeding class. Informed consent will be completed with trained research personnel and will include statement of research, purpose of study, expected duration of subject’s participation, description of study procedure, identification of any foreseen risks of study participation, description of potential study benefits, disclosure of appropriate alternative course of treatment, confidentiality statement, participants’ rights, and disclosure that participation is voluntary (U.S. Department of Health & Human Services, 2016). If a member of the woman/support person dyad chooses to withdraw from the study, both members will automatically be withdrawn from the study. Participants will also be asked to complete a HIPAA disclosure for chart abstraction. The researcher will obtain all consents and will maintain CITI certification throughout the study.

Participants will be compensated with up to $50 in gift cards: $10 following completion of the 15-minute research component, which follows the usual breastfeeding class; $15 after the 6-week post-birth contact; and $25 after the 3-month post-birth contact.

**Discussion**
In this protocol, we outline a method for a pilot study providing support and education through a face-to-face prenatal class and proactive text/email messaging that spans prenatal, immediate post-birth hospitalization, and the postpartum period. This pilot study is tailored to provide breastfeeding education to women and their identified support persons with the aim of improving feelings of support and self-efficacy to improve breastfeeding outcomes. This study will generate new evidence in the area of breastfeeding interventions. If successful, this study will also result in the development of a fully powered study.

**Acknowledgements**

We would like to thank the lactation services team for assisting with the development of this intervention and allowing us to utilize their prenatal classes as a recruitment location.

**Source of funding**

None.

**Conflict of interest**

The authors declare that they have no conflicts of interest.

**Contributions**


Conn, V. S. (2012). Unpacking the black box: Countering the problem of inadequate


https://doi.org/10.1016/j.midw.2016.09.010


https://doi.org/10.1007/s10995-010-0583-x


https://www.rand.org/health/surveys_tools/mos/social-support.html


StataCorp. 2013. *Stata Statistical Software: Release 13*. College Station, TX: StataCorp LP.


Figure 1
Social Cognitive Theory Applied to Breastfeeding Outcomes

Breastfeeding Outcomes

Behavior Factors:
- Intention
- Self-Efficacy

Personal Factors:
- Knowledge
- Attitudes
- Outcome Expectations

Environmental Factors:
- Social Support
- Professional Support
- Normative Beliefs
Table 1.  
Definitions used in this study

<table>
<thead>
<tr>
<th>Variable</th>
<th>Conceptual Definition</th>
<th>Operational Definition (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perceived Social Support</td>
<td>The perception of support, encouragement and care one receives from their social networks</td>
<td>Medical Outcomes Study (MOS) Social Support Survey (Sherbourne &amp; Stewart, 1991) Total score Multidimensional Scale of Perceived Social Support (MSPSS) (Zimet et al., 1988). Total score</td>
</tr>
<tr>
<td>Breastfeeding self-efficacy</td>
<td>The confidence a person has in their ability to perform a behavior that results in breastfeeding</td>
<td>Breastfeeding Self-Efficacy Short Form (BSES-SF) (Dennis, 2003) total score</td>
</tr>
<tr>
<td>Breastfeeding Intention</td>
<td>Goals for breastfeeding duration and/or breastfeeding exclusivity</td>
<td>Infant Feeding Intentions Scale (IFIS) (Nommsen-Rivers &amp; Dewey, 2009)</td>
</tr>
<tr>
<td>Infant Feeding Attitudes</td>
<td>A settled feeling, viewpoint or preference about the way in which one will feed their infant.</td>
<td>Iowa Infant Feeding Attitudes Scale (IIFAS) (De la Mora et al., 1999)</td>
</tr>
<tr>
<td>Exclusive breastfeeding (point-in-time)</td>
<td>Infants who have only had breastmilk in the past 24-hours. No other liquids or solid foods, including water (WHO, 2010)</td>
<td>Breastfeeding Outcome and Intention Questionnaire</td>
</tr>
<tr>
<td>Any breastfeeding (point-in-time)</td>
<td>Infants who were given mother’s or donor breastmilk in the past 24-hours (WHO, 2010)</td>
<td>Breastfeeding Outcome and Intention Questionnaire</td>
</tr>
<tr>
<td>Breastfeeding duration</td>
<td>The amount of days that the mother has given her baby breastmilk or expressed breastmilk (Wambach, 2010; WHO, 2010)</td>
<td>Breastfeeding Outcome and Intention Questionnaire</td>
</tr>
<tr>
<td>Time</td>
<td>SCT Component Addressed</td>
<td>Intervention Group</td>
</tr>
<tr>
<td>----------------------</td>
<td>-------------------------</td>
<td>------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Within 48 hours of delivery</td>
<td>Knowledge Attitudes</td>
<td>Second Night Syndrome can be challenging, help your loved one by offering to hold, rock or walk with baby to give mom a chance to rest. Lactation Services number Link to Breastfeeding Video</td>
</tr>
<tr>
<td>2-weeks</td>
<td>Knowledge Attitudes</td>
<td>Helping a new mom and baby to develop a breastfeeding routine in the first six weeks by watching for feeding cues, holding your baby skin-to-skin, and saying “I’m proud of you” and “good job” if mom becomes discouraged</td>
</tr>
<tr>
<td>4-weeks</td>
<td>Social Support</td>
<td>Supporting a new mom to breastfeeding can be as easy as making sure mom is comfortable while feeding baby and has water to drink while baby eats</td>
</tr>
<tr>
<td>6-weeks</td>
<td>Social Support</td>
<td>Support groups can help moms with common issues like returning to work, breast pumping, and latch difficulties. Lactation Support Group website</td>
</tr>
<tr>
<td>8-weeks</td>
<td>Social Support</td>
<td>Breastfeeding gives mom, dad, grandparents and the</td>
</tr>
</tbody>
</table>
entire family a reason to be proud and become part of the new baby’s life to help baby sleep safely. How many can you name? For a complete list of safe sleep recommendations, visit the Safe to Sleep website: http://1.usa.gov/1sMq9Aq

<table>
<thead>
<tr>
<th>10-weeks</th>
<th>Knowledge Social Support</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Knowing how to handle and store breastmilk or “liquid gold” helps keep your baby safe</td>
</tr>
</tbody>
</table>

SIDS is less common after 8 months of age, but parents and caregivers should continue to follow safe-sleep practices to reduce the risk of SIDS and other sleep-related causes of infant death until baby’s first birthday.

*Note. Verbatim email/text message italicized*
<table>
<thead>
<tr>
<th>Purpose: Learning Outcomes</th>
<th>Content</th>
<th>Teaching Strategy</th>
<th>Time</th>
<th>Resources</th>
<th>Evaluation Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify 3 benefits of breastfeeding</td>
<td>Breastfeeding Knowledge</td>
<td>Think, pair, share</td>
<td>2 minutes</td>
<td>Notecards and pens</td>
<td>Question and answer</td>
</tr>
<tr>
<td></td>
<td>Breastfeeding Attitudes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Describe breastfeeding challenges</td>
<td>Normative Beliefs</td>
<td>Teach-back</td>
<td>5 minutes</td>
<td>PowerPoint slides</td>
<td>Question and answer</td>
</tr>
<tr>
<td>Examine ways that the support person can assist the mother in breastfeeding</td>
<td>Breastfeeding Knowledge and Support</td>
<td>Lecture-discussion</td>
<td>5 minutes</td>
<td>PowerPoint slides</td>
<td>Question and answer</td>
</tr>
<tr>
<td>Identify 2 ways that the support person can bond with the baby</td>
<td>Breastfeeding Attitudes and Support</td>
<td>Lecture-discussion</td>
<td>3 minutes</td>
<td>PowerPoint slides</td>
<td>Question and answer</td>
</tr>
</tbody>
</table>
### Table 4

*Attention-Control Group Lesson Plan for 15 Minute Face-to-Face Class*

<table>
<thead>
<tr>
<th>Purpose: Learning Outcomes</th>
<th>Content</th>
<th>Teaching Strategy</th>
<th>Time</th>
<th>Resources</th>
<th>Evaluation Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify 3 risks for SIDS</td>
<td>Knowledge</td>
<td>Think, pair, share</td>
<td>2 minutes</td>
<td>Notecards and pens</td>
<td>Question and answer</td>
</tr>
<tr>
<td>Describe safe sleep barriers</td>
<td>Attitudes</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Normative Beliefs</td>
<td>Teach-back</td>
<td>5 minutes</td>
<td>PowerPoint slides</td>
<td>Question and answer</td>
</tr>
<tr>
<td></td>
<td>Knowledge and Support</td>
<td>Lecture-discussion</td>
<td>5 minutes</td>
<td>PowerPoint slides</td>
<td>Question and answer</td>
</tr>
<tr>
<td>Examine ways that the support person can assist the mother in building safe sleep environments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identify 2 ways that the support person can keep baby safe</td>
<td>Attitudes</td>
<td>Lecture-discussion</td>
<td>3 minutes</td>
<td>PowerPoint slides</td>
<td>Question and answer</td>
</tr>
<tr>
<td></td>
<td>and Support</td>
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</tr>
</tbody>
</table>
Table 5

Time schedule for data collection and outcome measurements

<table>
<thead>
<tr>
<th>Measure</th>
<th>Recruitment</th>
<th>24-48 post birth</th>
<th>1- week post birth</th>
<th>2 weeks post birth</th>
<th>4 weeks post birth</th>
<th>6 weeks post birth</th>
<th>8 weeks post birth</th>
<th>10 weeks post birth</th>
<th>12 weeks post birth</th>
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<tbody>
<tr>
<td>Demographics</td>
<td>X*</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>IIFAS</td>
<td>X*</td>
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<tr>
<td>IFIS</td>
<td>X</td>
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<tr>
<td>BSES-SF</td>
<td>X</td>
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<td></td>
<td></td>
<td>X</td>
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<tr>
<td>MOS Social Support Survey</td>
<td>X</td>
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<td>X</td>
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<td>MSPSS</td>
<td>X</td>
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<td></td>
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<td>X</td>
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<tr>
<td>Breastfeeding Outcomes and Goals Questionnaire</td>
<td>X*</td>
<td>X*</td>
<td>X*</td>
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<td>X*</td>
<td>X*</td>
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<tr>
<td>Acceptability of Intervention Measure</td>
<td>X*</td>
<td>X*</td>
<td>X*</td>
<td>X*</td>
<td>X*</td>
<td>X*</td>
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<tr>
<td>MR Abstraction</td>
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</tbody>
</table>

Note. *Also completed by support person; IIFAS = Iowa Infant Feeding Attitude Scale; BSES-SF = Breastfeeding Self-Efficacy Short-Form; MOS Social Support Survey = Medical Outcome Study Social Support Survey; MSPSS = Multidimensional Scale of Perceived Social Support
Breastfeeding Education and Support for Women and Their Support Persons: Pilot Study

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This manuscript is a component of a dissertation in a Ph.D. program at South Dakota State University.
Abstract

**Background:** Breastfeeding is a complex health behavior that is recognized as the ideal feeding method. However breastfeeding rates continue to be suboptimal. Effective breastfeeding interventions are necessary to help women reach their breastfeeding goals.

**Objective:** The objective of this study is to determine the feasibility, acceptability, and preliminary efficacy of a Social Cognitive Theory based educational breastfeeding intervention for women and support persons

**Participants:** Eligible participants for this study included: women who were 18 years or older, pregnant with a singleton, attended prenatal breastfeeding education with a support person, and were able to speak and read English. Fourteen dyads completed each arm of the study.

**Methods:** The intervention targeted women and their support persons with face-to-face breastfeeding education and supportive electronic messages that contained text and web links to documents and videos. Attention-control group members received Safe to Sleep® campaign materials. Intervention and attention-control materials were measured for acceptability following each contact. Telephone interviews were conducted at 6- and 12-weeks postpartum to capture breastfeeding outcomes.

**Results:** This pilot study had a 7% attrition rate at 12-weeks and women and their support persons rated intervention components high on acceptability. At 12-weeks postpartum, women in the intervention group were more likely to report exclusive and any breastfeeding $\chi^2(1, n = 28) = 5.25, p = 0.02$ & $\chi^2(1, n = 28) = 4.09, p = 0.04$.

**Conclusion:** This pilot study indicated feasibility, acceptability, and preliminary efficacy of the intervention.

Keywords: exclusive breastfeeding, randomized controlled trial, support, education, pregnancy, protocol
Breastfeeding is widely recognized as the ideal feeding method for mothers and infants and is associated with reduction in diseases for infants, children and mothers (Victoria et al., 2016). The American Academy of Pediatrics recommends exclusive breastfeeding through the first 6 months of life until complementary foods are introduced (Eidelman et al., 2012). Many women initiate breastfeeding in the United States yet, only 57.6% of infants are breastfed through six months (CDC, 2018). Additionally, only 24.9% of newborns in the United States are breastfed exclusively through the first six months of life (CDC, 2018).

Findings from extant studies suggest that interventions leveraging education and support components can be valuable in improving breastfeeding outcomes (Cordell & Elverson, 2020; Patnode et al., 2016). Specifically, when intervention components begin in the prenatal period and end in during the postpartum period (Kim et al., 2018; Meedya et al., 2017; Mahesh et al., 2018). Mothers face breastfeeding barriers that change over time, interventions should address the educational and support needs these mothers need at the appropriate time (Cordell & Elverson, 2020). In addition to interventions covering various time periods, it is important that interventions contain at least 5 contacts to most effectively impact breastfeeding outcomes (Jolly et al., 2012). Interventions to improve breastfeeding duration are desperately needed and resources are often scarce.

A gap exists regarding the description of theory and theoretical underpinning in breastfeeding interventions (Bai et al., 2019; Cordell & Elverson, 2020). Breastfeeding is a complex health behavior. This study was guided by Social Cognitive Theory (SCT)
which designates that support provided by a support person is an environmental factor.

The basic assumption of SCT and this study is that social support is a modifiable environmental factor (Bandura, 1998). Researchers attempted to change the breastfeeding knowledge and attitudes of the support person. By changing the knowledge and attitudes of the support person, the support person will be better equipped to provide breastfeeding support and change the perception of breastfeeding support. Breastfeeding intention and breastfeeding self-efficacy are mediating variables.

**Methods**

**Design**

This pilot uses a pretest-post-test, parallel (attention-control) group, unblinded cluster randomized controlled trial design. Dyads of women and their support person were recruited from prenatal breastfeeding classes held by a healthcare organization from October 2019 to November 2019 after Institutional Review Board approval was obtained from the healthcare organization and university. A target sample size of 26 (n = 13 for the intervention and n = 13 for the attention-control group) was used for this study recruitment. The details of this research protocol have been reported elsewhere (Cordell et al., 2020).

**Study Aims**

The primary aim was to assess feasibility and acceptability of this intervention and study procedures.

The secondary aim was to determine the preliminary efficacy, if any, of an intervention guided by SCT for pregnant women/postpartum women and their identified support persons on breastfeeding outcomes. The hypotheses of this study were: 1) women
whose support persons participate in an educational and support breastfeeding intervention will have higher rates of exclusive breastfeeding at 6-weeks and 3-months post-birth, 2) women whose support persons participate in an educational and support breastfeeding intervention will have higher rates of any breastfeeding at 6-weeks and 3-months post-birth, and 3) women whose support persons participate in an educational and support breastfeeding intervention will have longer breastfeeding duration.

The tertiary aim was to determine the preliminary efficacy, if any, the intervention has on intervening variables. We hypothesized that: 1) women in the intervention group will have higher Iowa Infant Feeding Attitude Scale (IIFAS) scores than those in the attention-control group at 3-months post-birth, 2) pregnant women in the intervention group will have higher scores of the Breastfeeding Self-Efficacy Short-Form (BSES-SF) than those in the attention-control group at 3-months post-birth, and 3) pregnant women in the intervention group will have higher scores on the Medical Outcomes Study (MOS) Social Support Survey and Multidimensional Scale of Perceived Social Support (MSPSS) at 3-months post-birth.

**Sample**

Women (18+ years of age) were eligible to participate in this study if they were pregnant with a singleton, attended prenatal breastfeeding education with a support person and were able to speak and read English. Participants who were: (a) pregnant with more than one fetus, (b) unable to receive text/email messages, (c) or had substantial health problems were excluded from this pilot study. Their support persons were eligible and enrolled if they were 18 years or older, able to speak and read English, and able to receive text/email messages. Thirty dyads were enrolled in this study.
Procedures

To ensure ample opportunity for potential participants to consider enrollment and improve the number of women who brought support persons to their breastfeeding class, the recruitment strategy for this study included: (a) breastfeeding class leaders continued their usual practice of encouraging women to bring support persons, and (b) the researcher attended childbirth preparation classes to encourage women to bring their support persons to subsequent breastfeeding classes. Women and support person dyads were recruited at the beginning of a breastfeeding class offered by a regional health organization. After consent and HIPAA authorization was obtained, baseline measures were obtained.

Due to the nature of the recruitment strategy and characteristics of the intervention, each breastfeeding preparation class was randomized by group. Ten opaque envelopes (five for each location) containing assignment for intervention and attention-control groups were provided by a statistician to ensure the researcher was blinded to group assignment until participants had enrolled into the study and the standard breastfeeding class had begun. The curriculum for the standard breastfeeding class was *Breastfeeding: A Great Start!* (Moran & Kallam, 2011). Members of the intervention and attention-control group attended the standard breastfeeding class prior to the intervention.

Following the standard breastfeeding class, the groups received their in-person component of their intervention which was a 20-minute in-person class which addressed the following components of SCT: (a) knowledge, (b) attitudes, (c) normative beliefs, and (d) social support. Contact two was a message sent within 24-hours of delivery. Contact three was a message sent at 2 weeks post-delivery. Contact four was a message sent at 4
weeks post-delivery. Contact five was a message sent at 6-weeks post-delivery and telephone call to obtain breastfeeding outcomes with the mother. No support or intervention materials were provided during the telephone call. Contact six was a message sent at 8 weeks post-delivery. Contact seven was a message sent at 10 weeks post-delivery. An eighth contact occurred with the woman only to obtain 12-week post-delivery breastfeeding outcomes; no intervention material was provided at this time.

**Study Interventionist**

In-person sessions, text/email messages, and follow up calls for data collection were completed exclusively by the first author.

**Intervention**

First author Cordell developed the intervention with guidance from International Board-Certified Lactation Consultants (IBCLCs) from a Midwestern healthcare organization. SCT was the intervention theoretical framework. This intervention includes: (a) face-to-face education provided by the principal researcher, (b) text/email messages, (c), hyperlink to video via message and (d) hyperlink to online brochures via message. All intervention online brochures were free to use (or in the public domain) from the following: Lactation Education Resources ©, United States Department of Agriculture Foods and Nutrition Service. The readability of all online brochures utilized in this study were assessed using Flesch-Kincaid readability index via Word. Readability of the print materials provided to the intervention group range in grade level of 3.0 – 7.9.

All attention-control materials were from NIH Safe to Sleep® and are free for use. This intervention includes: (a) face-to-face education provided by the principal researcher, (b) video, (c) text/email messages, and (d) online brochures. Cultural
relevance has been incorporated in this study by working with IBCLCs to make sure the verbiage and message was consistent with the local cultural standards. Readability of the online brochures provided to the attention-control group range from 3.0 – 6.0 grade level.

**Measures**

The primary outcome measures were acceptability and feasibility, as described in the research protocol (Cordell et al., 2020). Acceptability measures were collected via the Acceptability of Intervention Measure (AIM) following each intervention contact.

The secondary outcome measures were exclusive breastfeeding, any breastfeeding, and breastfeeding duration in days. All secondary outcome measures were collected via telephone at 6-weeks and 12-weeks with the woman. For full secondary outcome measure information, please see the research protocol (Cordell et al., 2020).

The tertiary outcome measures were breastfeeding self-efficacy, breastfeeding intention, infant feeding attitudes and perceived social support. Breastfeeding self-efficacy was collected via the Breastfeeding Self-Efficacy Short Form (BSES-SF; Dennis, 2003). Breastfeeding intention was collected on the Infant Feeding Intentions Scale (IFIS; Nommsen-Rivers & Dewey, 2009). Infant feeding attitudes were collected using the Iowa Infant Feeding Attitudes Scale (IIFAS; De la Mora et al., 1999). Perceived social support was collected via two surveys the Medical Outcomes Study (MOS) Social Support Survey (Sherbourne & Stewart, 1991), and Multidimensional Scale of Perceived Social Support (MSPSS; Zimet et al., 1988).

Additionally, a maternal chart abstraction was completed at 1-week post-birth via the electronic medical record. Data captured in this abstraction included: infant gender,
gestational age at birth, infant weight, length of hospital stay, and maternal parity post-birth.

Data Analysis

The Kolmogorov-Smirnov test was used to check for normality of distributions. Baseline characteristics of the two groups were compared using chi-square tests. Baseline variables were compared. After determining that the IFIS data was not normally distributed, comparisons of the baseline IFIS were completed between groups using a Mann–Whitney U test. Maternal scores for IIFAS, BSES-SF, MOS-SSS, and MSPSS were identified as normally distributed; comparisons for each were completed between groups by using an independent $t$-test.

After determining that the AIM data in this study was not normally distributed, comparisons of the AIM scores were completed between groups using a Mann–Whitney U test. Comparisons between groups at 6-weeks and 12-weeks were completed for both any breastfeeding and exclusive breastfeeding by using chi-square tests and odds ratios. Due to the remaining study data evaluated as normal distributions, comparisons between groups on intervening variables were tested using independent sample $t$-tests to compare groups. Effect sizes were calculated using Cohen’s $d$.

Results

Sample

Of the 74 woman/support person dyads that were approached at breastfeeding classes, 38 (51%) were eligible. Of those, 30 (79%) were enrolled in the study and randomized into groups. See Figure 1 for the Consolidated Standards of Reporting Trials (CONSORT) diagram. Nearly all enrolled participants completing the 6-week
questionnaires \((n = 29, 96.7\%)\), and 12-week questionnaires \((n = 28, 93.3\%)\). The demographic characteristics are presented in Table 1. The mean age of the participants was 31.5 years, gestational age at birth \((M = 39.4\ \text{weeks}, \ SD = 0.97)\), newborn weight \((M = 3317\ \text{grams}, \ SD = 467.56)\), and an average birth hospitalization length of stay of 52.63 hours \((SD = 12.47)\). More than half \((n = 20, 66.7\%)\) of the women were primiparous. Participants were mainly white \((n = 52, 87\%)\) and married \((n=51, 85\%)\).

**Participant Demographics**

Comparisons were made of participant demographics to ensure that the two groups were comparable. Significant differences were identified between the groups regarding income \((\chi^2 = 12.85, \ p = 0.04)\). When comparing age of the women between the intervention \((\text{Mdn} = 30, \ SD = 3.66)\) and attention-control group \((\text{Mdn} = 28.9, \ SD = 4.16)\) no differences were identified \(t = 0.79, \ p = 0.22\). When comparing age of the support persons between the intervention \((\text{Mdn} = 33.7, \ SD = 9.19)\) and attention-control group \((\text{Mdn} = 33.4, \ SD = 8.52)\) no differences were identified \(t = -0.10, \ p = 0.46\). Comparisons of the number of children at home showed no differences for women in the intervention \((\text{Mdn} = 1.01, \ SD = 0.26)\) and attention-control \((\text{Mdn} = 1.29, \ SD = 0.59)\) no differences were identified \(t = 1.19, \ p = 0.12\). Support persons number of children at home in the intervention \((\text{Mdn} = 0.73, \ SD = 0.46)\) and attention-control \((\text{Mdn} = 0.8, \ SD = 0.86)\) no differences were identified \(t = 0.84, \ p = 0.4\). For other demographic information see Table 1.

**Baseline Variables**

There were no differences in intention to breastfeeding (IFIS) scores at baseline between intervention \((\text{Mdn} = 14, \ SD = 2.89)\) and attention-control \((\text{Mdn} = 14, \ SD = 1.95)\)
U = 99.5, p = 0.60. At baseline an independent t-test were compared between groups for maternal breastfeeding attitudes (IIFAS) scores, support person breastfeeding attitudes (IIFAS) scores breastfeeding self-efficacy (BSES-SF) scores, and social support (MOS-SSS & MSPSS) scores without any statistically significant differences. See Table2.

Main Outcomes

**Primary Aim**

**Acceptability.** AIM scores were examined for women and their support persons for each contact. The overall AIM scores provided by women ranged from 3.7 to 5 and their support persons 3.5 to 5 in the intervention group indicating that the intervention was overall acceptable. Intervention group AIM score median at each contact see Figure 3. Overall AIM scores provided by women ranged from 3.5-5 and their support person 3-5 in the attention-control group indicting their intervention materials were also acceptable. Attention-control group AIM score median at each contact see Figure 4.

To evaluate the acceptability compared between two groups a two-sample Mann–Whitney U test was completed. The calculated p-value is 0.49 which is greater than 0.05 which indicates which indicates no differences between the two groups at the recruitment contact. The p-value for the delivery, 2-week, 4-week, 6-week, 8-week, and 10-week contacts are 0.41, 0.19, 0.81, 0.76, and 0.79, 0.81 respectively. See Table 3.

Each contact, AIM scores had ceiling effects with 20-43% of participants reporting total scores of 5 for support persons. Women scored high on the AIM instrument for each contact, with total scores of 5s being reported 30-60% of the time.
Feasibility. The overall assessment of the feasibility of this study included the total amount of time that the researcher spent drafting messages. After the completion of this study, the researcher had spent approximately 65 hours drafting text and email messages to participants. The median time that it took to conduct classroom intervention components was 20 minutes. The median amount of time spent collecting breastfeeding outcomes on the phone was 15 minutes. There were no text or email messages that did not go through. The study did not have any participants choose to withdraw; however, two dyads did become lost-to-follow-up. One at 6-weeks and the other at 12-weeks. The researcher did contact via email/text message each dyad member 3 times over the week that the contact was due to occur to provide ample opportunity to complete study questionnaires via QuestionPro. For the telephone contacts with the woman at 6- and 12-weeks, three phone calls were made to the participant before the participant was marked as lost-to-follow-up.

Reliability of instruments. A full range of responses was collected for each instrument with no evidence of significant (10%) floor or ceiling effects. A Cronbach’s α was computed for each total score at the initial assessment. Cronbach’s α ranged from .63-.91, with the IIFAS for women and support persons and the IFIS scoring at undesirable levels below .7 (DeVellis, 2017). See Table 4

Secondary Aim

The secondary aim of this examined breastfeeding outcomes. See Table 5 and Table 6 and specifics in the following paragraphs.
**Breastfeeding outcomes at 6-weeks.** There were no statistically significant differences found between groups for either variable when conducting a chi-square test. See Table 5.

**Breastfeeding at 12-weeks.** At 12-weeks exclusive breastfeeding, any breastfeeding and breastfeeding duration (days) were measured. See Table 5. There were statistically significant differences between the intervention \((n = 11, 78.6\%)\) and the attention-control \((n = 3, 21\%)\) for exclusive breastfeeding at 12-weeks, OR =13.4, 95\% CI [2.21, 81.77]. There were also statistically significant differences between the intervention \((n = 12, 85.7\%)\) and the attention-control \((n = 7, 50\%)\) groups regarding any breastfeeding (OR = 6) There were not statistically significant differences between groups related to breastfeeding duration in days.

**Intervening Variables at 12-weeks**

The tertiary aim of this study evaluated differences between groups for maternal breastfeeding attitudes, breastfeeding self-efficacy, and social support at 12-weeks. See Table 6. The intervention group show statistically significant higher scores on the following scales: 1) IIFAS, 2) BSES-SF, 3) MOS-SSS, and 4) MSPSS. See Table 6 for means, standard deviations and effect sizes.

**Discussion**

This multifaceted intervention was developed based on recommendations made in the existing literature. International Board-Certified Lactation Consultants assisted throughout the intervention development to ensure material was timely, culturally relevant, and consistent with messages sent by clinicians in the community. Collaboration with local IBCLCs was critical for intervention success.
Study enrollment barriers occurred in this pilot study due to the requirement of attending a prenatal breastfeeding class with a support person. Of the 74 women who were assessed at prenatal breastfeeding classes for eligibility 28 (38%) were ineligible for this reason. To reduce this barrier in future studies, it may be advantageous to schedule the recruitment and face-to-face component of this intervention at a different time or location to make it easier for women and their support persons to attend. This may increase the number of women who are eligible and able to participate in this intervention. Additionally, it may be possible to make these face-to-face components available to women and their support persons via online meetings to make this type of intervention more available to those who may struggle with transportation to a face-to-face meeting. This would require the use of a way to capture informed consent via an online avenue.

Of the women and support persons dyads (n = 40) who were eligible for this study there was high agreement to participate at 75% (n =30). The longevity of this study may have been a reason that eligible dyads chose not to participate. It is possible that the number of contacts may have also deterred dyads from enrolling.

The feasibility and acceptability of this intervention were examined using a pilot study. This study is feasible to be completed on a larger scale, however, it would require more study personnel than that required for this pilot. The study participants reported high acceptability for both the intervention and attention-control group contacts, indicating that these interventions were appropriate and helpful for the participants at the time the information was delivered to them. This indicates that the acceptability was comparable to that of the attention-control group, indicating a high level of control. It is
possible the high acceptability of the materials presented to the intervention and attention-control group helped mitigate study attrition.

Based on the AIM scores for each contact, reworking the 4-week messaging may be valuable prior to delivering this intervention on a larger scale. The 4-week message was the least acceptable for both women and their support persons for both groups. It is possible that the 4-week timeframe may be challenging for these dyads. The AIM instrument allowed for free-text comments to be made, however no comments were made by study participants. Focus groups may be able to provide insight for the decreased acceptability at this time point. Support persons also had lower AIM scores related to the 8-week and 10-week messages. Further examination of these messages may be useful to understand why women found them helpful, but support persons were not as accepting.

In this pilot study, the effectiveness of a seven-contact, educational and support breastfeeding intervention to promote breastfeeding in the Midwest was examined. Participants in the intervention group were more likely to report exclusive and any breastfeeding at 12-weeks which is a positive finding. At 12-weeks 78.6% of the intervention group was exclusively breastfeeding their infant which is substantially higher than the national average of 46.9% in 2015 (CDC, 2018). However, at 12-weeks 21% of the attention-control group were exclusively breastfeeding which is considerably lower than the national average. A fully powered study is needed to determine the true effect of this intervention on breastfeeding outcomes at 12-weeks.

Assignment to the intervention group showed positive differences on breastfeeding attitudes, breastfeeding self-efficacy, and social support when compared to the attention-control group at 12-weeks. It is possible that intervening variable
The reliability of the IIFAS for women and their support persons were at undesirable levels ($\alpha = 0.69$ & $\alpha = 0.63$) (DeVellis, 2017). These vary from those identified by Shaker and associates who found a Cronbach’s $\alpha$ of 0.79 in women and Cronbach’s $\alpha$ of 0.77 in fathers (2004). The baselines for this pilot study were obtained in the third trimester, while the Cronbach’s $\alpha$ of Shaker and associates were obtained in the first trimester (2004). More recent assessments of reliability of the IIFAS include a range of Cronbach’s $\alpha$ 0.76 to 0.80 in a study of women and their coparent (Abbass-Dick et al., 2020) and for fathers in the prenatal time period 0.55 and 0.72 at 6-weeks (Abbass-Dick et al., 2015).

The IFIS also had undesirable reliability measures ($\alpha = 0.67$) (DeVellis, 2017) which varied greatly from the Cronbach’s $\alpha$ of 0.90 reported by Nommsen-Rivers, Cohen, Chantry & Dewey (2010). Nommsen-Rivers, et al., obtained this Cronbach’s alpha by measuring this instrument with English- and Spanish-speaking primiparous women (2010), only 66.7% of this pilot study’s sample was primiparous women, but all spoke English.

Two social support instruments were utilized in this pilot study to confirm that social support would be accurately captured in this study. The MSPSS instrument had an acceptable Cronbach’s alpha (0.76) and the MOS-SSS had a good Cronbach’s alpha (0.85) (DeVellis, 2017). Total scores for each instrument were used. However, in a fully powered study, the use of subscales may be advantageous to tease out which aspects of
social support are impacted by the intervention. Utilization of two social support instruments may not be necessary in future studies.

**Strengths**

Strengths of this study include group randomization and minimal attrition at 12-weeks postpartum. The high level of acceptability of the both intervention and attention-control materials is another strength of this study. This acceptance may have contributed to the minimal attrition rates that occurred in this pilot study.

**Limitations**

This study does have several limitations that should be considered in the interpretation of the results. Lack of representativeness in the sample is an issue because participants were primarily White, well-educated, and married, all of which are factors associated positively with breastfeeding. Additionally, the small sample size of this pilot study requires the study to be replicated on a larger scale for a more accurate picture of the effectiveness of this intervention. The recruitment site also presents a limitation for this study because women have sought out breastfeeding education which is also positively associated with breastfeeding outcomes and success.

Self-report of breastfeeding outcomes is another possible limitation as self-report can be vulnerable to social desirability bias. Additionally, the reliability measures for the breastfeeding attitudes of women and their support persons were not ideal. Neither were the breastfeeding intention measures within this study. Additionally, intervening variables were not captured at 6-weeks and could potentially shed light on the relationships between intervening variables and breastfeeding outcomes. These should be considering when working to replicate this study.
Regarding the messaging in this study, all communications were one-way. It is possible this one-way communication reduced the potential perceived social support experienced by participants. Participants were instructed not to message back via text but to email or call the principal investigator to ensure security of their protected health information. This one-way communication may have hindered the full effect of the study by not allowing participants to engage conveniently if questions or concerns arose. Utilizing a HIPAA compliant secure messaging service in the future may allow for two-way communication, which may be more beneficial for women and their support persons.

Another limitation of this study was that the relationship of the support person to the woman was not captured. These relationship dynamics would be of interest for future intervention studies. Additionally, the support persons attitudes at the 6-week and 12-week time points were not collected. This would also be of value to determine if the support person attitudes were different between groups or improving as the intervention progressed.

It is possible that the effect of this intervention may have been greater if delivered by an Internationally Board-Certified Lactation Consultant. In a review conducted by Haase et al. it was identified that IBCLCs are more effective than other providers in breastfeeding education delivery (2019).

**Implications**

The use of a multifaceted intervention that addresses education and support for women and support persons has not yet fully been explored, creating abundant research opportunities. This pilot study suggests that the intervention is acceptable and feasible to complete on a larger scale. It is possible IBCLCs may find more success in delivering this
intervention due to their expertise in the clinical area. Future research should investigate implementation of this type of intervention by an IBCLC.

Future research should capture intervening variables at 6-weeks to determine comparability between groups related to breastfeeding attitudes, breastfeeding self-efficacy, and perceived social support. Increasing the understanding of relationships between these intervening variables and breastfeeding outcomes may hold the key to finding success in breastfeeding intervention development and implementation.

In addition, future research should target low-income women as they are at risk of suboptimal breastfeeding. Future breastfeeding interventions should: (a) employ multiple delivery methods with three or more contacts, (b) intervene during pregnancy, postpartum hospitalization, and postpartum, (c) include women and a support person, and (d) include educational and social support components.

**Conclusions**

This pilot study showed significant differences between the attention-control and intervention groups for any breastfeeding and exclusive breastfeeding at 12-weeks. Women in the intervention group had higher scores for breastfeeding attitudes, breastfeeding self-efficacy, and perceived social support. The intervention was well received by participants and this pilot had very low attrition rates. Implementation of a fully powered study must be completed to validate the results of this pilot study.

**Acknowledgements**

The authors like to thank the lactation services team for allowing us to utilize their prenatal classes as a recruitment location and for assisting with the development of this intervention.
References


https://www.rand.org/health/surveys_tools/mos/social-support.html


Figure 1. Consolidated Standards of Reporting Trails (CONSORT) flow diagram.

Assessed for eligibility (n=74)
- Not eligible (n=34)
  - Pregnant with twins = 2
  - Younger than 18 = 3
  - Did not attend with a support person = 29

Randomized (n=30)
10 Classes

Allocated to intervention (n=15)
5 Classes
4 Site A, 1 Site B
- Lost to follow-up (n=1)
- Analyzed (n=14)
- Lost to follow-up (n=0)
- Analyzed (n=14)

Allocated to attention-control (n=15)
5 Classes
4 Site A, 1 Site B
- Lost to follow-up (n=0)
- Analyzed (n=15)
- Lost to follow-up (n=1)
- Analyzed (n=14)
Table 1
**Participant Characteristic and Baseline Variables**

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<td>3 (5%)</td>
<td>1 (6.7%)</td>
<td>2 (13.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HS degree/GED</td>
<td>11 (18.3%)</td>
<td>2 (13.3%)</td>
<td>4 (26.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some college, no degree</td>
<td>12 (20%)</td>
<td>4 (26.7%)</td>
<td>2 (13.3%)</td>
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<tr>
<td>Associate degree</td>
<td>2 (3.3%)</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Bachelor degree</td>
<td>28 (46.7%)</td>
<td>8 (53.3%)</td>
<td>9 (60%)</td>
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<td></td>
</tr>
<tr>
<td>Graduate or Professional degree</td>
<td>4 (6.7%)</td>
<td>0</td>
<td>3 (20%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married (%)</td>
<td>51 (85%)</td>
<td>12 (80%)</td>
<td>13 (86.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>18 (30%)</td>
<td>5 (33.3%)</td>
<td>4 (26.7%)</td>
<td>5 (33.3%)</td>
<td>4 (26.7%)</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>----------</td>
<td>-----------</td>
<td>-----------</td>
<td>-----------</td>
<td>-----------</td>
</tr>
<tr>
<td>Enrolled in WIC program (%)</td>
<td>1 (3.3%)</td>
<td>0</td>
<td>1 (6.7%)</td>
<td>1.03</td>
<td>0.31</td>
</tr>
<tr>
<td>Previously breastfed (%)</td>
<td>1 (3.3%)</td>
<td>0</td>
<td>1 (6.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primipara (%)</td>
<td>20 (66.7%)</td>
<td>13 (86.7%)</td>
<td>10 (66.7%)</td>
<td></td>
<td>1.67</td>
</tr>
</tbody>
</table>
Table 2  
*Baseline Variables*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention</th>
<th>Attention-Control</th>
<th>t</th>
<th>U</th>
<th>p=</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Woman n=15</td>
<td>Support Person n=15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breastfeeding Intention Score, M(SD)</td>
<td>13.5 (1.95)</td>
<td>12.83 (2.88)</td>
<td>99.5</td>
<td>0.06</td>
<td></td>
</tr>
<tr>
<td>IIFAS Score, M(SD)</td>
<td>64.07 (8.4)</td>
<td>56.29 (6.68)</td>
<td>2.08</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>BSES-SF Score, M(SD)</td>
<td>57.8 (6.71)</td>
<td>53.2 (8.59)</td>
<td>17.52</td>
<td>1.92</td>
<td></td>
</tr>
<tr>
<td>MOS-SSS Score, M(SD)</td>
<td>86.68 (11.58)</td>
<td>76.54 (20.94)</td>
<td>1.68</td>
<td>0.11</td>
<td></td>
</tr>
<tr>
<td>MSPSS Score, M(SD)</td>
<td>5.97 (0.71)</td>
<td>6.02 (0.41)</td>
<td>0.29</td>
<td>0.77</td>
<td></td>
</tr>
<tr>
<td>Support Person IIFAS Score, M(SD)</td>
<td>55.29 (7.65)</td>
<td>55.87 (5.62)</td>
<td>0.41</td>
<td>0.68</td>
<td></td>
</tr>
</tbody>
</table>

*Note.* IIFAS = Iowa Infant Feeding Attitude Scale; BSES-SF = Breastfeeding Self-Efficacy Short-Form; MOS-SSS = Medical Outcome Study Social Support Survey; MSPSS = Multidimensional Scale of Perceived Social Support
Figure 3

*Intervention Group Median AIM Scores at Each Contact*

![Bar chart showing median AIM scores for Intervention Group at each contact point.](image)
Figure 4
Attention-control Group Median AIM Scores at Each Contact

![Attention-control Group: Median AIM Scores at Each Contact](image-url)
Table 3  
**AIM Scores**

<table>
<thead>
<tr>
<th></th>
<th>Intervention Mdn</th>
<th>Attention-Control Mdn</th>
<th>U</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment</td>
<td>4.7</td>
<td>4.8</td>
<td>97.5</td>
<td>0.49</td>
</tr>
<tr>
<td>Delivery</td>
<td>4.7</td>
<td>4.5</td>
<td>93</td>
<td>0.41</td>
</tr>
<tr>
<td>2-Week</td>
<td>4.6</td>
<td>4.5</td>
<td>83</td>
<td>0.19</td>
</tr>
<tr>
<td>4-Week</td>
<td>4.5</td>
<td>4.5</td>
<td>106.5</td>
<td>0.81</td>
</tr>
<tr>
<td>6-Week</td>
<td>4.7</td>
<td>4.6</td>
<td>98</td>
<td>0.76</td>
</tr>
<tr>
<td>8-Week</td>
<td>4.5</td>
<td>4.6</td>
<td>99</td>
<td>0.79</td>
</tr>
<tr>
<td>10-Week</td>
<td>4.4</td>
<td>4.7</td>
<td>55</td>
<td>0.81</td>
</tr>
</tbody>
</table>

*Note.* Mann-Whitney U test
Table 4
*Cronbach's Alphas on Baseline Measures*

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Sample (n=30)</th>
<th>Cronbach’s Alpha</th>
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</thead>
<tbody>
<tr>
<td>IIFAS</td>
<td>Mother</td>
<td>0.69</td>
</tr>
<tr>
<td>IIFAS</td>
<td>Support Person</td>
<td>0.63</td>
</tr>
<tr>
<td>IFIS</td>
<td>Mother</td>
<td>0.67</td>
</tr>
<tr>
<td>BSES-SF</td>
<td>Mother</td>
<td>0.91</td>
</tr>
<tr>
<td>MSPSS</td>
<td>Mother</td>
<td>0.76</td>
</tr>
<tr>
<td>MOS-SS</td>
<td>Mother</td>
<td>0.85</td>
</tr>
</tbody>
</table>

*Note. IIFAS = Iowa Infant Feeding Attitude Scale; BSES-SF = Breastfeeding Self-Efficacy Short-Form; MOS-SSS = Medical Outcome Study Social Support Survey; MSPSS = Multidimensional Scale of Perceived Social Support*
Table 5

*Breastfeeding Outcomes at 6- and 12-weeks*

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>Intervention</th>
<th>Attention-</th>
<th>t</th>
<th>$X^2$</th>
<th>p</th>
<th>OR(CI)</th>
<th>Cohen’s $d$</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBF at 6-Weeks (n=29)</td>
<td>17 (59%)</td>
<td>10 (74.4%)</td>
<td>7 (50%)</td>
<td>0.83</td>
<td>0.36</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABF at 6-weeks (n=29)</td>
<td>27 (93%)</td>
<td>15 (100%)</td>
<td>12 (85.7%)</td>
<td>2.3</td>
<td>0.13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EBF at 12-weeks (n=28)</td>
<td>14 (50%)</td>
<td>11 (78.6%)</td>
<td>3 (21%)</td>
<td>5.25</td>
<td>0.02</td>
<td>13.4</td>
<td>(2.21,81.77)</td>
<td></td>
</tr>
<tr>
<td>ABF at 12-weeks (n=28)</td>
<td>19 (67.8%)</td>
<td>12 (85.7%)</td>
<td>7 (50%)</td>
<td>4.09</td>
<td>0.04</td>
<td>6</td>
<td>(1.97,37.30)</td>
<td></td>
</tr>
<tr>
<td>BF Duration (d), M(SD)</td>
<td>69.43 (23.61)</td>
<td>77.5 (17.23)</td>
<td>61.36 (26.83)</td>
<td>1.89</td>
<td>0.06</td>
<td>0.75</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note.* EBF = exclusive breastfeeding, ABF = any breastfeeding


<table>
<thead>
<tr>
<th></th>
<th>Overall n=28</th>
<th>Intervention n=14</th>
<th>Attention-Control n=14</th>
<th>t</th>
<th>p</th>
<th>Cohen’s d</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIFAS</td>
<td>68.71(11.85)</td>
<td>73.36 (10.62)</td>
<td>64.07 (11.52)</td>
<td>-3.19</td>
<td>0.003</td>
<td>0.84</td>
</tr>
<tr>
<td>BSES-SF</td>
<td>60.07(10.33)</td>
<td>64.21 (8.08)</td>
<td>55.93 (10.92)</td>
<td>2.28</td>
<td>0.015</td>
<td>0.86</td>
</tr>
<tr>
<td>MOS-SSS</td>
<td>84.72(2.08)</td>
<td>87.49 (1.42)</td>
<td>81.96 (2.39)</td>
<td>2.06</td>
<td>0.024</td>
<td>0.78</td>
</tr>
<tr>
<td>MSPSS</td>
<td>5.91(0.85)</td>
<td>6.21 (0.64)</td>
<td>5.60 (0.95)</td>
<td>2.01</td>
<td>0.028</td>
<td>0.75</td>
</tr>
</tbody>
</table>
Chapter 5: Conclusion

During my Ph.D. journey I conducted a focus group study with women who had breastfed through 6-months (Cordell et al., 2018). These women helped direct my research journey throughout this program by highlighting the importance of the support person. Social support had been addressed in the literature, but in speaking with these women, all of whom were adamant that their social support system had led to their breastfeeding success, I knew this would be a foundation of my dissertation study.

Using social support as my guide, I needed to examine behavior health theories that would help direct any research I conducted. I identified two theories that addressed not only social support but the other underlining variables that I had read about in the breastfeeding literature: knowledge, attitudes, outcome expectations, and societal norms. These theories were the Theory of Planned Behavior (Ajzen, 1991) and Social Cognitive Theory (Bandura, 1986) (See Appendix V). I ultimately went with Social Cognitive Theory because of the theory’s triadic reciprocal causation which shows a reciprocal relationship between environment, personal, and behavioral variables (See Appendix W). Throughout the focus group study, I had heard from women how these variables had all been intertwined and would impact one another. Following completion of this graduate program, I will continue to explore the Theory of Planned Behavior because I do believe it holds great promise in breastfeeding research.

Breastfeeding is a complicated health behavior. Many variables can either set a woman up for success or become a barrier to her through her journey. Breaking down these intervening variables using Social Cognitive Theory it was easy to see that breastfeeding knowledge and attitudes, breastfeeding self-efficacy, and social support
were areas in which an intervention could help set women up for success. Completing a thorough examination of the body of existing literature identified the many attempts of researchers to influence breastfeeding behavior.

The included manuscripts described the journey taken in my PhD dissertation. I first examined the literature and identified the vast amount of breastfeeding intervention studies that required an integrative review to fully understand and dissect. This integrative review provided several lessons. I really had to spend sufficient time honing in on my specific aim and making my inclusion criteria reflective of my overall goal. I had to be very specific and intentional with my aim to make certain I was capturing the information needed. A synthesis table helped me to succinctly present this integrative review via poster at the Midwestern Nursing Research Society (MNRS) conference in March of 2019.

Additionally, this integrative review highlighted important research components that I needed to address in my dissertation process including selecting consistent breastfeeding definitions and measurements. Balancing semantics and an efficient way to capture data proved to be challenging, ultimately landing with me adapting an instrument to ensure I captured components that had been missing from those who had preceded me attempts to improve breastfeeding rates. Theory stuck out during this review process. While, I had learned about the importance of theory throughout my graduate coursework, I saw firsthand that studies based on theory consistently were showing positive effects. It was validating in the work I had spent learning various behavioral theories as well as the choice I had made to leverage Social Cognitive Theory for my study. The integrative review provided me with a road map of the components my intervention had to contain:
employing multiple delivery methods with three or more contacts, (b) intervene
during pregnancy, postpartum hospitalization, and postpartum, (c) target mothers and a
support person, and (d) include educational and social support components.

This manuscript also helped me work through my first submission to an academic
journal. While my initial submission to Journal of Human Lactation was not successful in
achieving a publication; it taught me how to target appropriate journals, show
perseverance after an unsuccessful submission, and adapt an existing manuscript for
submission to a subsequent journal. The direction for future research and
recommendations for breastfeeding interventions advance the science by providing a
roadmap for intervention development based on the outcomes from researchers who have
worked to support breastfeeding.

Using my integrative review as a roadmap, I spent time working with IBCLCs at
the local healthcare organization to get insight from the experts in the clinical area.
Working with the IBCLCs, they supported all of my integrative review recommendations
and were essential to develop an intervention that was culturally relevant, timely with
information delivery, and consistent with the verbiage used by their teams in prenatal
breastfeeding classes, during hospitalizations, and outpatient lactation appointments. This
collaboration had been developed during one of my first graduate school classes, where I
spent 200 hours shadowing these expert lactation nurses. The early involvement of this
team truly may have been one of my biggest achievements during this journey. I will
forever hold partnerships as invaluable when conducting research, especially in the
clinical areas.
Writing the protocol manuscript also taught me many lessons about the process of working with other authors, finding a way to verbalize my intervention in a way that someone who was not fully engrained in it could understand. This process also helped me identify components of the study that needed to be adjusted to improve overall recruitment, prevent participant attrition, capture measurements at the right times, and conduct an ethical study. I plan to submit the protocol paper to Maternal & Child Nutrition by August 1, 2020. This will advance the science by providing detailed information on the intervention that I provided during this pilot study for other researchers to either replicate or leverage in intervention development.

Overall, the Institutional Review Board submission process for this pilot study was very eye opening. It was the first time I had submitted a project to two IRBs where an IRB Authorization Agreement was needed. Submission to the Monument Health IRB also provided a variety of lessons. Especially related to the use of text messages and how insecure text messaging is. There are a variety of secure applications that can be used in place of text messaging. While the messages I was sending were benign, concerns were related to participants responding to text messages with personal information. Ultimately the Monument Health IRB allowed me to proceed with my text messaging plan if I provided emails as an alternative for those concerned about the security risk. I only had one participant choose emails but made sure to spend time educating all participants on the importance of not texting back for their own security. Participants were instructed to call the principal investigator if they had any questions. I did receive a few messages back, but they did not include any protected health information (PHI) and were along the lines of “that’s great to know!” and “I had no idea!”
The final manuscript in this dissertation was my report of original research. Multiple times throughout my Ph.D. journey, faculty and peers told me this study may be too much for a dissertation study. It certainly was challenging to juggle the multiple contacts and longevity of this pilot study, but it is so very rewarding to see positive outcomes at 12-weeks for exclusive and any breastfeeding.

The primary aim of this pilot study was to look at the feasibility and acceptability of my intervention. A fully powered study would require more collaborations with lactation teams from various new sites. Additionally, it would require either a streamlined messaging system or collaboration with another researcher to manage the number of messages that need to be delivered in short time periods. The initial results of this study support that women and their support persons are receptive to this type of intervention. The next steps will include focus groups with study participants to identify possible improvements to the intervention. From there a fully powered study would be the next logical step.

Future research also needs to explore the use of this intervention. International Board-Certified Lactation Consultants were still used as the central resource for breastfeeding issues and questions. The feasibility of IBCLCs implementing this intervention in the healthcare setting should be evaluated. In addition to evaluating the feasibility of the IBCLCs implementing this intervention, it is necessary to evaluate the IBCLC’s perception of this intervention and its usability.

Exploring breastfeeding knowledge, breastfeeding attitudes, breastfeeding self-efficacy, and perceived social support in conjunction with breastfeeding outcomes is necessary at different time points, especially those at which breastfeeding rates drop.
Including all these variables will be necessary to identify ways to promote breastfeeding that are efficient and cost-effective for healthcare organizations.

In summary, based on the evidence from this pilot study, it is reasonable to conclude that there is significant value in utilizing this intervention for women and their support persons from the prenatal period, post-birth hospitalization, and postpartum periods. Results strongly support further exploration of this intervention with a fully powered study with a diverse sample from a variety of settings, implemented by interventionists that are clinical experts (i.e. IBCLCs), and with measurements at different timeframes. The breastfeeding care literature is improved with the additional knowledge derived by the three manuscripts included in this dissertation.
References


World Health Organization (WHO). (2010). Indicators for assessing infant and young
child feeding practices: Part 2 measurement.

https://apps.who.int/iris/bitstream/handle/10665/44306/9789241599290_eng.pdf;jsessionid=0CBCC3BE4B8F6FEE85E9AE913AAA963D?sequence=1
Appendix A: Regional Health Outcome Letter

Regional Health Institutional Review Board

Date: October 08, 2019

Protocol Number: Drasey 001
Protocol Title: Drasey 001 - Cluster Randomization Controlled Trial of Breastfeeding Intervention for Mothers and Support Persons
Principal Investigator: Alex Drasey
Protocol Approval Period: 10/08/2019 - 10/07/2020
Review Type: Full
Risk: Minimal

Reason for Submission: Initial Review

Dear Alex Drasey,

The submission material for Drasey 001 - Cluster Randomization Controlled Trial of Breastfeeding intervention for Mothers has been reviewed and approved by the Regional Health Institutional Review Board (RH IRB) according to 45 CFR 46 at the convened meeting on 10/08/2019.

Subjects are required to sign the informed consent form, which has the RH IRB Stamp of approval, prior to initiation of any protocol procedures. Please be sure to provide a copy of the signed informed consent form to each enrolled participant and keep the original(s) on file.

Reportable events must be submitted to the RH IRB as outlined in the reporting policy. Any revisions, updates and/or addendums to the protocol or the informed consent require notification to the IRB and approval prior to initiation, except when necessary to eliminate apparent immediate hazards to the subject.

The expiration date 10/07/2020. Before the expiration date, submission of a request for continuing review is required. If you have any questions or concerns regarding this document or your responsibilities as a Principal Investigator, please feel free to contact the RH IRB office at (605) 755-9032 or 1-877-861-4865.

Respectfully,

Signature applied by Jennifer Hansen  on 10/08/2019 10:25:14 AM CDT

Jen Hansen, Research Compliance Specialist

The IRB operates in compliance with OHRP and FDA regulations. The Regional Health IRB is registered with the Office for Human Subject Protections.

PMA #00026686 Expired 06/27/2023 and IRB #00024471RS #00026806 Expired 06/27/2023

Regional Health


Designated IRB of Record: Regional Health Institutional Review Board (RH IRB) FWA # 00703556

Name of Institution Relying on the IRB of Record: South Dakota State University (Institution) IRB Registration #: 1K10001132 Federally Assured (FWA) # if any: 0000963

The Officials signing below agree the RH IRB is the IRB of Record for review and continuing oversight of its human subject research described below. This agreement is similar to the following specific protocol(s):

Name of Research Project: Cluster Randomized Controlled Trial of Breastfeeding Intervention for Mothers and Support Persons

Name of Principal Investigator (PI): Alexandra Draisay

Name of Student/Resident if not the PI: 

Sponsor or Funding Agency: N/A

Award Number, if any: WIA

RH IRB shall cooperate with the institution’s reasonable requests to perform audits of the RH IRB operations (i.e., meeting minutes, protocols, IGTP’s, etc.) pertaining to this protocol or permit the Institution to conduct such audits, provided that such audits will be at Institution’s expense. The Institution will coordinate with the RH IRB to minimize disruption to the RH IRB’s operations as a result of any such audit, and such audits will be performed during the RH IRB’s normal working hours.

The review performed by the RH IRB will meet the human subject protection requirements of Office of Human Research Protection (OHRP). The RH IRB will report unanticipated adverse events involving participants to the institution’s IRB. Relevant minutes of RH IRB meetings will be made available to the institution’s Site Monitor Official upon request. The Institution remains responsible for ensuring compliance with the terms of its own FWA. This document must be kept on file by both parties and provided to OHRP/Food and Drug Administration (FDA) upon request.

University IRB

By: [Signature] Date: 9/10/2019 14:59 CDT

Print Full Name: James Docitle

Title: Associate VP for Research

Rapid City Regional Hospital, Inc.

By: [Signature] Date: 10/10/19

Print Full Name: Nancy Klunder

Title: VP of Corporate Responsibility / Signature Official

Version: 9/2016
## Participant Eligibility: Education with a Breastfeeding Support Person

<table>
<thead>
<tr>
<th>Collection Date: ____/<strong>/</strong></th>
<th>Interviewer Name: __________________ __________________</th>
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</table>

<table>
<thead>
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<th>Question</th>
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<th>No</th>
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<tbody>
<tr>
<td>Is participant over 18?</td>
<td></td>
<td></td>
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<tr>
<td>![Yes/No]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is participant able to speak and read English?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>![Yes/No]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is participant pregnant with a singleton?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>![Yes/No]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is participant attending prenatal BF education with a support person?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>![Yes/No]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does participant wish to enroll?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>![Yes/No]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study personnel deem eligible?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>![Yes/No]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

______________________________ Study Personnel Signature ____________________

<table>
<thead>
<tr>
<th>Date: ____/<strong>/</strong></th>
</tr>
</thead>
</table>

**After consent completed:**

Assigned Participant ID Number: ____ ____
Appendix D: Participant Consent Form and HIPAA Authorization

REGIONAL HEALTH
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: The New Family Study
Principal Investigator: Alexandra Draisey, RN, PhD Student, South Dakota State University
Faculty Advisor: Cynthia Elverson, Ph.D., RN, NNP-BC, South Dakota State University

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

The purpose of this research study is to determine if breastfeeding rates are improved by providing the pregnant women and a support person education on breastfeeding before and after delivery.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely voluntary. You do not have to be in the study if you do not want to. You may leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study? You are eligible to participate in this study because you are attending a prenatal breastfeeding class with a support person, are 18 years of age or older, are pregnant with one baby, can/will receive text messages or email, and can speak and read English.

3.2 How many people are expected to take part in this study? 30 mother/support person dyads.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
If you agree to take part in this study, you will be asked to do the following: You will be randomly placed into one of two groups: a group who learns about breastfeeding or a group who learns about safe sleep. Today you will be asked to fill out a HIPAA Authorization form, which is a form that allows us access to your records so we can identify that you delivered at Regional Health. Today you will be asked to fill out some questionnaires which include: contact information, personal information, attitudes, and breastfeeding intentions. We estimate that today's visit will add only 30 minutes to your prenatal class. We will contact you via text or email messages with educational materials at the following time periods: 24 hours after delivery of your baby, 2-weeks post-delivery, 4-weeks post-delivery, 6-weeks post-delivery, 8-weeks post-delivery, 10 weeks post-delivery and 3-months post-delivery. Following each text or email message, you be sent a link with a 4 questions about each message.

V2.21.2019

IRB NUMBER: RH-19-769
IRB APPROVAL DATE: 10/08/2019
Mothers only. We will review your delivery record to obtain information including: delivery date, delivery time, and delivery method. At 6-weeks post-delivery we ask that you submit a breastfeeding status questionnaire online which will be sent to you in a link via text or email message. When your baby is 3-months old, we ask that you fill out a breastfeeding status questionnaire and other surveys about confidence, support and attitudes regarding breastfeeding which will be sent to you in a link via text or email message. After submitting these forms, your participation in the study will end. It is approximated that each online submission of questionnaires will take approximately 20 minutes.

4.2 How much of my time will be needed to take part in this study? Completion of this study will take approximately 2 hours of your time. We expect to add 30 minutes to your prenatal breastfeeding class and 10 minutes to review 7 different text or email messages and answer a 4 question survey about each message. Mothers will be asked to take an additional online survey when your baby is 6-weeks old and 3-months old. Each survey is expected to take 20 minutes to complete.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The known or expected risks are: No risks greater than those experienced in ordinary conversations is anticipated.

The researchers will try to minimize these risks by: You do not have to answer any questions you do not want to answer in the surveys. Due to the fact that recruitment into this study happens at a breastfeeding class there is potential for other members of the class to identify that you have chosen to participate in this study. Everyone will be asked to respect the privacy of other group members. All participants will be asked not to disclose anything said within the context of this group discussion, but it is important to understand that other people in this group may not keep all information private.

Additional risks of being in this study include that the principal investigator will be using her personal password protected cell phone to send text messages to you. Text messages, which are sent and stored on servers in plain text, can be intercepted during transit. It is possible the researcher could lose her phone. Your name will not be stored in the researchers phone but your phone number will be stored with your unique participant number. It is still possible the researcher could lose her cell phone. If you do not want to take the risks associated with text messaging you may choose to receive all messages via email.

I understand the risks associated with each communication method and choose the following method to receive messages in the study. Please initial on the line of your preferred messaging method.

_____ Text Messages
_____ Email

5.2 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the additional information gained from this study regarding breastfeeding or safe sleep.
5.3 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study? Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do? You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you decide to leave the study before it is finished, please tell Alexandra Draisey at 605-519-5988 or aadraisey@jacks.sdstate.edu if you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record.

6.2 Could the researchers take me out of the study even if I want to continue to participate? Yes. There are some reasons why the researchers may need to end your participation in the study. Some examples are:
- You do not follow instructions from the researchers.
- You become ineligible to participate.
- The study is suspended or canceled.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study? Each mom/support person dyad will receive up to $50 in gift cards. Each pair will receive a $10 gift card following completion of the initial visit, $15 at completion of the 6-week questionnaires and another $25 gift card after completion of questionnaires of the end study when baby is 3-months old.

8. PROTECTING AND SHARING RESEARCH RECORDS [AND BIOSPECIMENS]

8.1 How will the researchers protect my information? The investigator and faculty advisor will analyze data from this study. Your responses are strictly confidential. No individual participant will be identified or linked to the results. Your identity will not be shared in any presentation of the study results. All information obtained in this study will be kept confidential. All materials including informed consent forms and questionnaires will be stored in a secure location and access will be restricted to study personnel. Study materials will be destroyed 7 years after the completion of the study.

8.2 Who will have access to my research records? There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:
- Study sponsors or funders, auditors, and/or the IRB may need the information to make sure the study is done in a safe and proper manner.

8.3 What will happen to the information collected in this study? We will keep the information we collect about you during the research, for study recordkeeping. We will not keep your name or other information that can identify you directly.

Y2.21.2019
The results of this study could be published in an article or presentation, but will not include any information that would let others know who you are.

9. CONTACT INFORMATION

Who can I contact about this study?
Please contact the researchers listed below to:
• Obtain more information about the study
• Ask a question about the study procedures
• Report an illness, injury, or other problem (you may also need to tell your regular doctors)
• Leave the study before it is finished
• Express a concern about the study

Principal Investigator: Alexandra Draisey
Email: aadraisey@jacks.sdstate.edu
Phone: 605-519-5988

Faculty Advisor: Cynthia Elverson
Email: Cynthia.Elverson@sdstate.edu
Phone: 605-367-8408

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:
Regional Health Institutional Review Board
Telephone: 1-605-755-9037 or 1-877-881-4865
Fax: 1-605-755-9036
E-mail: rhrb@rhregionalth.org

11. YOUR CONSENT

Consent to Participate in the Research Study
By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records and we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: __________________________________________

Signature: __________________________________________________

Date of Signature (mm/dd/yy): ________________________________

2.21.2019
HIPAA Authorization

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to Researchers and their staff at South Dakota State University College of Nursing to use or disclose (release) your health information that identifies you for this research study.

The health information to be used for this research includes: Admission date, delivery date, delivery time, delivery method, delivery type, infant's sex, maternal parity (post-delivery) and gestational age at birth.

The health information listed above may be used by and/or disclosed (released) to: Researchers and their staff of the New Family Study.

South Dakota State University College of Nursing is required by law to protect your health information. By signing this document, you authorize South Dakota State University College of Nursing to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

You may change your mind and revoke (take back) this Authorization at any time, except to the extent that South Dakota State University College of Nursing has already acted based on this Authorization. To revoke this Authorization, you must write to: South Dakota State University College of Nursing Attention: Alexandra Draisey at 1011 11th St, Rapid City, SD 57701.

This Authorization expires at the end of the research study.

__________________________________________   ______________
Signature of participant or participant's personal representative       Date

Printed name of participant or participant's personal representative

If applicable, a description of the personal representative's authority to sign for the participant
Appendix F: Participant Demographic Questionnaire

Participant Demographics: Education with a Breastfeeding Support Person

Participant ID Number: ___ ___

Gender:
- □ Male
- □ Female
- □ Non-binary/third gender
  - □ Prefer not to disclose

Race (check all that apply):
- □ American Indian/Alaskan Native
- □ Asian
- □ Black or African American
- □ Native Hawaiian/Pacific Islander
- □ White/Caucasian

Considers self: Hispanic or Latino?
- □ Yes (Hispanic/Latino)
- □ No (Not Hispanic or Latino)

Age (in years):
___ ___

DOB:
__ __ / __ __ / __ __ __ __

Employment Status:
- □ Employed Full-Time (35+hour/week)
- □ Employed Part-time (<35hour/week)
- □ Not Employed

Total household income before taxes in past 12 months?
- □ Less than $25,000
- □ $25,000 to $34,999
- □ $35,000 to $49,999
- □ $50,000 to $74,999
- □ $75,000 to $99,999
- □ $100,000 to $149,999
- □ $150,000 or more
Educational Level?
- □ Less than high school
- □ High school degree or GED
- □ Some college, no degree
- □ Associate Degree
- □ Bachelor Degree
- □ Ph.D.
- □ Graduate or professional degree

Number of children at home: __ __

Marital Status?
- □ Single (never married)
- □ Single (cohabitating with partner)
- □ Married
- □ Separated
- □ Widowed
- □ Divorced

Receiving WIC Benefits?
- □ Yes
- □ No

Ever breastfed before?
- □ Yes
- □ No

If Yes, How many children have you breastfed? __ __

AND

What was the longest time you breastfed?
- □ 1-month
- □ 2-months
- □ 3-months
- □ 4-months
- □ 5-months
- □ 6-months+
# Appendix G: Infant Feeding Intention Scale (IFIS)

## INFANT FEEDING INTENTIONS SCALE

### I. Feeding intentions

You may not know exactly what your plans are for feeding your baby, but you may have ideas about what you would like or are planning to do. I am going to read you some statements about feeding your baby and I would like you to please choose the answer that most closely matches your opinion, considering both your current feeding plans and the likelihood that you will carry out those plans.

<table>
<thead>
<tr>
<th>Item</th>
<th>Agree</th>
<th>Somewhat Agree</th>
<th>Unsure</th>
<th>Somewhat Disagree</th>
<th>Very Much Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I am planning to only formula feed my baby (will not breastfeed at all).</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. I am planning to breastfeed my baby or at least try.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. When my baby is one-month-old, I will be breastfeeding without using any formula or other milk.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. When my baby is three-months-old, I will be breastfeeding my baby without using any formula or other milk.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. When my baby is six-months-old, I will be breastfeeding my baby without using any formula or other milk.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Scoring**

For item 1: Very much agree = 0, Somewhat agree = 1, Unsure = 2, Somewhat disagree = 3, and Very much disagree = 4.

For items 2, 3, 4 and 5: Very much agree = 4, Somewhat agree = 3, Unsure = 2, Somewhat disagree = 1 and Very much disagree = 0.

Total score = (mean of items 1 + 2) + (sum of items 3, 4, 5). Thus total score ranges from 0 (very strong intention to not breastfeed at all) to 16 (very strong intentions to provide breast milk as sole source of milk for first 6 months).

---

Developed by Laurie A. Nommsen-Rivers, PhD, RD, IBCLC  
laurie.nommsen-rivers@cchmc.org  
Cincinnati Children’s Hospital Medical Center, Cincinnati, OH
Appendix H: Permission to Use Infant Feeding Intention Scale (IFIS)

RE: Infant Feeding Intentions Scale Request

Nommsen-Rivers, Laurie (nommsele) <nommsele@ucmail.uc.edu>
Tue 5/22/2018 9:23 AM

To: Draisey, Alexandra Anne - SDSU Student <aadraisey@jacks.sdstate.edu>

3 attachments (505 KB)
Infant Feeding Intentions validity against BF duration_in print.pdf; Infant Feeding Intentions inter-ethnic validity_in print.pdf; Infant Feeding Intentions Scale.pdf;

Dear Alexandra,

Please find attached the literature on the Infant feeding Intentions Scale. Note that we have slightly modified item 2 as a result of validity testing.
Best wishes with your research.

Sincerely,
Laurie

Laurie A Nommsen-Rivers, PhD, RD, IBCLC
Associate Professor of Nutritional Sciences
Ruth E. Rosevear Endowed Chair of Maternal and Child Nutrition
College of Allied Health Sciences
University of Cincinnati

Department of Nutritional Sciences
3202 Eden Avenue
Cincinnati Ohio 45267-0394

Office: 357 French East
Mobile Phone: 513-335-3256
Email: Laurie.Rivers@uc.edu
Appendix I: Iowa Infant Feeding Attitude Scale (IIFAS)

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Appendix

The Iowa Infant Feeding Attitude Scale

For each of the following statements, please indicate how much you agree or disagree by circling the number that most closely corresponds to your opinion (1 = strong disagreement [SD], 2 = disagreement [D], 3 = neutral [N], 4 = agreement [A], 5 = strong agreement [SA]). You may choose any number from 1 to 5.

<table>
<thead>
<tr>
<th></th>
<th>SD</th>
<th>D</th>
<th>N</th>
<th>A</th>
<th>SA</th>
</tr>
</thead>
<tbody>
<tr>
<td>*1. The nutritional benefits of breast milk last only until the baby is weaned from breast milk.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>*2. Formula-feeding is more convenient than breast-feeding.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. Breast-feeding increases mother–infant bonding.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>*4. Breast milk is lacking in iron.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5. Formula-fed babies are more likely to be overfed than are breast-fed babies.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>*6. Formula-feeding is the better choice if a mother plans to work outside the home</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>7. Mothers who formula-feed miss one of the great joys of motherhood.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>*8. Women should not breast-feed in public places such as restaurants.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>9. Babies fed breast milk are healthier than babies who are fed formula.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>*10. Breast-fed babies are more likely to be overfed than formula-fed babies.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>*11. Fathers feel left out if a mother breast-feeds.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>12. Breast milk is the ideal food for babies.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>13. Breast milk is more easily digested than formula.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>*14. Formula is as healthy for an infant as breast milk.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>15. Breast-feeding is more convenient than formula feeding.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>16. Breast milk is less expensive than formula.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>*17. A mother who occasionally drinks alcohol should not breast-feed her baby</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Note: Items marked with asterisks are reverse-scored and the scores for each item are then summed. Higher scores indicate more positive attitudes toward breast feeding.
Appendix J: Permission to Use Iowa Infant Feeding Attitude Scale (IIFAS)

Re: IIFAS - Permission to Use Request

Delamora, Arlene [SOE] <adelamor@iastate.edu>
Mon 5/21/2018 11:38 AM
To: Drasey, Alexandra Anne - SDSU Student

You have our permission to use the IIFAS in our research per your request. I have attached three documents for you today:

1. A copy of our paper describing the IIFAS and its psychometric properties.
2. A set of instructions and guidelines for scoring
3. A copy of a document that describes our requests for using the IIFAS in your research. Please review the “Use of the IIFAS in Publications” document and let me know if you have any concerns.

Arlene de la Mora

Arlene de la Mora, Ph.D.
Research Scientist
Research Institute for Studies in Education
School of Education
Iowa State University
2005 Lagomarcino Hall
901 Stange Road
Ames, IA 50011

Voice: 515.294.6519
Fax: 515.294.5284
Email: adelamor@iastate.edu
Appendix K: Breastfeeding Self-Efficacy Scale Short Form

**Breastfeeding Self-Efficacy Scale – Short Form**

For each of the following statements, please choose the answer that best describes how confident you are with breastfeeding your new baby. Please mark your answer by circling the number that is closest to how you feel. There is no right or wrong answer.

1 = not at all confident  
2 = not very confident  
3 = sometimes confident  
4 = confident  
5 = very confident

<table>
<thead>
<tr>
<th></th>
<th>I can always determine that my baby is getting enough milk</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I can always successfully cope with breastfeeding like I have with other challenging tasks</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>I can always breastfeed my baby without using formula as a supplement</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>I can always ensure that my baby is properly latched on for the whole feeding</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>I can always manage the breastfeeding situation to my satisfaction</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>I can always manage to breastfeed even if my baby is crying</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>I can always keep wanting to breastfeed</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>7</td>
<td>I can always comfortably breastfeed with my family members present</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>8</td>
<td>I can always be satisfied with my breastfeeding experience</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>9</td>
<td>I can always deal with the fact that breastfeeding can be time consuming</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>10</td>
<td>I can always finish feeding my baby on one breast before switching to the other breast</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>11</td>
<td>I can always continue to breastfeed my baby for every feeding</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>12</td>
<td>I can always manage to keep up with my baby’s breastfeeding demands</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>13</td>
<td>I can always tell when my baby is finished breastfeeding</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
Appendix L: Permission to Use Breastfeeding Self-Efficacy Scale Short Form

RE: BSES-SF Request

Cindy-Lee Dennis <cindyleedennis@utoronto.ca>
Fri 6/22/2018 11:43 AM
To: Daisey, Alexandra Anne - SDSU Student

BSES-SF-pregnancy.doc
39 KB

Dear Alexandra,
Thank you for your email and interest in my Breastfeeding Self-Efficacy Scale. Attached is the short form for pregnancy that can be used in your PhD dissertation. Good luck with your studies.

Warm regards,
Cindy-Lee Dennis

Cindy-Lee Dennis, PhD
Professor in Nursing and Medicine, Dept. of Psychiatry
Canada Research Chair in Perinatal Community Health
Women’s Health Research Chair, Li Ka Shing Knowledge Institute, St. Michael’s Hospital

University of Toronto
155 College St
Toronto, Ontario
Canada M5T 1P8
Tel: (416) 946-8608
www.cindyleedennis.ca

Dr. Cindy-Lee Dennis

Dr. Cindy-Lee Dennis has a simple maxim: “Healthy babies start with healthy parents.” This belief has led Dr. Dennis to focus her research career on rigorously evaluating interventions that can directly improve the health of mothers and fathers, with the overall goal of improving child health and well-being.

www.cindyleedennis.ca
### Social Support Survey Instrument

People sometimes look to others for companionship, assistance, or other types of support. How often is each of the following kinds of support available to you if you need it? Choose one number from each line.

<table>
<thead>
<tr>
<th>Emotional/informational support</th>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Someone you can count on to listen to you when you need to talk</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
<tr>
<td>Someone to give you information to help you understand a situation</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
<tr>
<td>Someone to give you good advice about a crisis</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
<tr>
<td>Someone to confide in or talk to about yourself or your problems</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
<tr>
<td>Someone whose advice you really want</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
<tr>
<td>Someone to share your most private worries and fears with</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
<tr>
<td>Someone to turn to for suggestions about how to deal with a personal problem</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
<tr>
<td>Someone who understands your problems</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
</tbody>
</table>
### Tangible support

<table>
<thead>
<tr>
<th>Item</th>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Someone to help you if you were confined to bed</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
<tr>
<td>Someone to take you to the doctor if you needed it</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
<tr>
<td>Someone to prepare your meals if you were unable to do it yourself</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
<tr>
<td>Someone to help with daily chores if you were sick</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
</tbody>
</table>

### Affectionate support

<table>
<thead>
<tr>
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<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Someone who shows you love and affection</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
<tr>
<td>Someone to love and make you feel wanted</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
<tr>
<td>Someone who hugs you</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
</tbody>
</table>

### Positive social interaction

<table>
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<tr>
<th>Item</th>
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<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Someone to have a good time with</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
<tr>
<td>Someone to get together with for relaxation</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
<tr>
<td>Someone to do something enjoyable with</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
</tbody>
</table>

### Additional item

<table>
<thead>
<tr>
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<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Someone to do things with to help you get your mind off things</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
</tr>
</tbody>
</table>
Appendix N: MOS Social Support Survey

**Multidimensional Scale of Perceived Social Support (Zimet, Dahlem, Zimet & Farley, 1988)**

Instructions: We are interested in how you feel about the following statements. Read each statement carefully. Indicate how you feel about each statement.

Circle the “1” if you Very Strongly Disagree  
Circle the “2” if you Strongly Disagree  
Circle the “3” if you Mildly Disagree  
Circle the “4” if you are Neutral  
Circle the “5” if you Mildly Agree  
Circle the “6” if you Strongly Agree  
Circle the “7” if you Very Strongly Agree

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SO</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SO</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fam</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fam</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SO</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fri</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fri</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fam</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fri</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SO</td>
</tr>
<tr>
<td>11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fam</td>
</tr>
<tr>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fri</td>
</tr>
</tbody>
</table>

The items tended to divide into factor groups relating to the source of the social support, namely family (Fam), friends (Fri) or significant other (SO).
Appendix O: Acceptability of Intervention Measure

<table>
<thead>
<tr>
<th></th>
<th>Completely disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Completely agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. This text message meets my approval.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2. This text message is appealing to me.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. I like this text message.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4. I welcome text message.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
Appendix P: Permission to Use Acceptability of Intervention Measure

<table>
<thead>
<tr>
<th>RE: Acceptability of Intervention Measure Request</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weiner, Bryan <a href="mailto:bjweiner@uw.edu">bjweiner@uw.edu</a></td>
</tr>
<tr>
<td>Tue 5/22/2018 9:23 AM</td>
</tr>
<tr>
<td>To: Draioy, Alexandra Anne - SDSU Student</td>
</tr>
</tbody>
</table>

Dear Alexandra,

You have permission to use the AIM in your research per your request.

Sincerely,
Laurie

Bryan Weiner, PhD
Box 357965
Seattle WA
206-221-7882
bjweiner@uw.edu

[Image of University of Washington logo]
### Appendix Q: Breastfeeding Outcome Questionnaire

<table>
<thead>
<tr>
<th>No.</th>
<th>Question</th>
<th>Coding Categories</th>
<th>Skip Pattern</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Has your baby ever been breastfed?</td>
<td>Yes………………….1 No………………………0</td>
<td>→ Go to 6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Don’t Know…………8</td>
<td>→ Go to 6</td>
</tr>
<tr>
<td>2</td>
<td>Were you separated from your baby in the last 24 hours?</td>
<td>Yes………………….1 No………………………0</td>
<td>→ Go to 3</td>
</tr>
<tr>
<td>3</td>
<td>Why were you separated from your baby?</td>
<td>Work………………………….11 Social Event……………….12</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Was your baby breastfed yesterday during the day or night?</td>
<td>Yes………………….1 No………………………0</td>
<td>→ Go to 6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Don’t Know…………8</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>What was the last day your baby was breastfed?</td>
<td>_ _ / _ _ / _ _ _ _</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Sometimes babies are fed breast milk in different ways, for example, by spoon, cup or bottle. Did your baby consume breast milk in any of these ways yesterday during the day or night?</td>
<td>Yes………………….1 No………………………0</td>
<td>→ Go to 8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Don’t Know…………8</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>What kind of milk was given to your baby via spoon, cup, or bottle?</td>
<td>Mother’s own milk………..14 Donor milk……………….15 Breastfed by another woman………………………..16</td>
<td>→ Go to 9</td>
</tr>
<tr>
<td>8</td>
<td>What was the last day your baby was given breastmilk in one of the above ways?</td>
<td>_ _ / _ _ / _ _ _ _</td>
<td>Never this way………………...9</td>
</tr>
<tr>
<td>9</td>
<td>Are you still expressing breast milk or pumping milk for your baby?</td>
<td>Yes………………….1 No………………………0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Don’t Know…………8</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Now I would like to ask you about some medications and vitamins that are sometimes given to infants. Was your baby given any vitamin drops or other medicines as drops</td>
<td>Yes………………….1 No………………………0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Don’t Know…………8</td>
<td></td>
</tr>
<tr>
<td>No.</td>
<td>Question</td>
<td>Coding Categories</td>
<td>Skip Pattern</td>
</tr>
<tr>
<td>-----</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>11</td>
<td>Next, I would like to ask you about some liquids that your baby may have had yesterday during the day or night. Did your baby have any (ITEM FROM LIST)? Read the list of liquids starting with plain liquid</td>
<td></td>
<td>12. How many times yesterday during the day or night did your baby consume any (ITEM FROM LIST)? Record ‘98’ for don’t know</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>A</td>
<td>Plain Water?</td>
<td>TIMES __</td>
<td>__</td>
</tr>
<tr>
<td>B</td>
<td>Pedialyte?</td>
<td>TIMES __</td>
<td>__</td>
</tr>
<tr>
<td>C</td>
<td>Infant formula such as Similac?</td>
<td>TIMES __</td>
<td>__</td>
</tr>
<tr>
<td>D</td>
<td>Milk such as evaporated, powdered or animal milk?</td>
<td>TIMES __</td>
<td>__</td>
</tr>
<tr>
<td>E</td>
<td>Juice or juice drinks?</td>
<td>TIMES __</td>
<td>__</td>
</tr>
<tr>
<td>F</td>
<td>Clear broth?</td>
<td>TIMES __</td>
<td>__</td>
</tr>
<tr>
<td>G</td>
<td>Yogurt?</td>
<td>TIMES __</td>
<td>__</td>
</tr>
<tr>
<td>H</td>
<td>Thin cereal in a bottle?</td>
<td>TIMES __</td>
<td>__</td>
</tr>
<tr>
<td>I</td>
<td>Herbal tea?</td>
<td>TIMES __</td>
<td>__</td>
</tr>
<tr>
<td>J</td>
<td>Any other liquids?</td>
<td>TIMES __</td>
<td>__</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No.</th>
<th>Question</th>
<th>Coding Categories</th>
<th>Skip Pattern</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>Did your baby eat any solid, semi-solid, or soft foods yesterday during the day or at night?</td>
<td></td>
<td>If Yes, go to 14</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yes…………………1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>No……………………0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Don’t Know……………8</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Go to 15</td>
</tr>
<tr>
<td>14</td>
<td>Solid, semi-solid, or soft foods Please write down other foods in this box that respondent mentions:</td>
<td></td>
<td>Go to 15</td>
</tr>
<tr>
<td>15</td>
<td>How many times did your baby eat solid, semi-solid, or Number of times……[<strong><strong>][</strong></strong>]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix R: Maternal Chart Abstraction

Admission Date: __ __ / __ __ / __ __ __ __

Delivery Date: __ __ / __ __ / __ __ __ __

Discharge Date: __ __ / __ __ / __ __ __ __

Hospital Stay (in hours) __ __

Delivery Type? □ Vaginal Delivery □ Cesarean Section

Infant’s sex: □ Female □ Male □ Ambiguous

Infant’s birth weight? __ __ __ __ g

Infant’s GA at Birth: ____ __ W __ D

Maternal Parity (Post-delivery): __ __
Appendix S: Letter of Support Spearfish Regional Lactation Team

8/13/2018

Terry Ann Scott
Lactation Services
Regional Health
Spearfish, SD 57783

Dear Alex,

This letter confirms my support of your dissertation study *Education with Breastfeeding Support Persons: A Pilot Intervention Study*. As you know, I was a part of development of the breastfeeding intervention you will implement in this study as well as selection of the *Safer Sleep Campaign* educational component for the attention-control group.

You are welcome to use our Breastfeeding Classes as a means for recruitment into the study. I am so excited to see how this intervention works in improving breastfeeding rates for my patients.

All the best,

Terry Ann Scott, RN, IBCLC
Lactation Services
Spearfish Regional Hospital | 1440 N. Main St | Spearfish, SD 57783 | (605) 644-4319 (605) 644-4048
Tscott2@regionalhealth.org |
8/13/2018

Erica Bestgen
Lactation Services
Regional Health
Rapid City, SD 57701

Dear Alex,

We are issuing this letter of support for your dissertation study *Education with Breastfeeding Support Persons: A Pilot Intervention Study*. As you know, Rapid City Lactation Services are very excited to see you implement this study with our patients! We believe this study can help provide our patients with additional resources that can help them to be successful in their breastfeeding goals.

As a part of our contribution to this dissertation study, we have contributed to the development of the breastfeeding intervention and will also assist with recruitment by allowing you to reach out to potential participants at our breastfeeding classes.

Sincerely,

Erica Bestgen, RN IBCLC
Certified Lactation Consultant
Regional Lactation Services
Appendix U: CITI Certification

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT – PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on the requirements reported refer only to completion at the time all requirements for the course were met. See separate transcript report for more recent scores, including those on optional (supplemental) course elements.

- Name: Alex Diaper (ID: 2273076)
- Institution Affiliation: University of South Dakota (ID: 424)
- Institution Role: Researcher
- Phone: 605-719-8595

- Curriculum Group: Human Research
- Course Learner Group: Group 1 Biomedical Research Investigators and Key Personnel
- Stage: Stage 2 – Refresher Course

- Record ID: 12438881
- Completion Date: 03-Jun-2020
- Registration Date: 03-Jun-2020
- Expiration Date: 03-Jun-2023
- Required Passing: 70
- Reported Score: 97

PLANNED AND ELECTIVE MODULES ONLY

<table>
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<th>Module Refresher 1 – History and Ethical Principles (ID: 811)</th>
<th>Date Completed</th>
<th>Score ( % )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biography Refresher 2 – Regulations and Process (ID: 812)</td>
<td>03-Jun-2020</td>
<td>100 (%)</td>
</tr>
<tr>
<td>Biography Refresher 2 – Informed Consent (ID: 814)</td>
<td>03-Jun-2020</td>
<td>100 (%)</td>
</tr>
<tr>
<td>Biography Refresher 2 – NIH Guidelines for Biomedical Research (ID: 815)</td>
<td>03-Jun-2020</td>
<td>100 (%)</td>
</tr>
<tr>
<td>Biography Refresher 2 – Genetic Research (ID: 816)</td>
<td>03-Jun-2020</td>
<td>100 (%)</td>
</tr>
<tr>
<td>Biography Refresher 2 – Records-Related Research (ID: 819)</td>
<td>03-Jun-2020</td>
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</tr>
<tr>
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<td>100 (%)</td>
</tr>
<tr>
<td>Biography Refresher 2 – Research Involving Prions (ID: 820)</td>
<td>03-Jun-2020</td>
<td>100 (%)</td>
</tr>
<tr>
<td>Biography Refresher 2 – Research Involving Genetic Risks (ID: 821)</td>
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<tr>
<td>Biography Refresher 2 – Research Involving Pregnant Women, Fetuses, and Neonates (ID: 822)</td>
<td>03-Jun-2020</td>
<td>100 (%)</td>
</tr>
<tr>
<td>Biography Refresher 2 – FDA-Regulated Research (ID: 825)</td>
<td>03-Jun-2020</td>
<td>100 (%)</td>
</tr>
<tr>
<td>Biography Refresher 2 – IRB and Human Subjests Research (ID: 830)</td>
<td>03-Jun-2020</td>
<td>100 (%)</td>
</tr>
<tr>
<td>Biography Refresher 2 – Controversies in Research Involving Human Subjects (ID: 11948)</td>
<td>03-Jun-2020</td>
<td>100 (%)</td>
</tr>
<tr>
<td>Biography Refresher 2 – Conclusion (ID: 822)</td>
<td>03-Jun-2020</td>
<td>100 (%)</td>
</tr>
</tbody>
</table>

For this report to be valid, the learner identified above must have had a valid affiliation with the CITI Program enrolling institution identified above or have been a paid independent learner.

Verify at: www.citiprograms.com/verif/7532af9261-3c34-4f6b-9ad8-8176d13250a-12438881

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprograms.com
Phone: 844-523-9293
Web: www.citiprograms.com
COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT

NOTE: Scores on this Transcripts Report reflect the most current date completion, including Gilbert (optional supplemental) elements of the course. No list below for details, see course requirements. Report for the reported scores at the time all requirements for the course were met.

- Name: Alex Drees (ID: 2737076)
- Institution Affiliation: University of South Dakota (ID: 420)
- Institution Email: alex.drees@usd.edu
- Institution Unit: Research
- Phone: 605-771-5266
- Curriculum Group: Human Research
- Course Learner Group: Group 1 Biomedical Research Investigators and Key Personnel
- Stage: 1 - Refresher Course

- Report Date: 03-Jun-2020
- Current Score: 97

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<th>MOST RECENT SCORE</th>
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<td>03-Jun-2020 92 (100%)</td>
</tr>
<tr>
<td>Blinded Refresher 2 - Informed Consent (ID: 814)</td>
<td>03-Jun-2020 93 (100%)</td>
</tr>
<tr>
<td>Blinded Refresher 2 - EBM Methodology in Biomedical Research (ID: 816)</td>
<td>03-Jun-2020 94 (100%)</td>
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<td>Blinded Refresher 2 - Research-Based Research (ID: 818)</td>
<td>03-Jun-2020 93 (100%)</td>
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<td>Blinded Refresher 2 - Concluding (ID: 822)</td>
<td>03-Jun-2020 93 (100%)</td>
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For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program enrolling institution identified above or have been a paid independent learner.

Verify at: www.citiprograms.com/verify/5d0b2af6-dc24-41f0-8b88-817b9e123585-12435898

Collaborative Institutional Training Initiative (CITI Program)
Email: canon@citiprograms.org
Phone: 888-202-9829
Web: https://www.citiprograms.org
Appendix V: Social Cognitive Theory Applied to Breastfeeding

Knowledge

Attitudes

Normative Beliefs

Social Support

Intentions

Perceived Self-Efficacy

Breastfeeding Outcomes

Knowledge

Attitudes

Normative Beliefs

Social Support

Intentions

Perceived Self-Efficacy

Breastfeeding Outcomes

Knowledge
Appendix W: Social Cognitive Theory Applied to Breastfeeding Outcomes

Breastfeeding Status at 6 Months

**Behavior Factors:**
- Intention
- Self-Efficacy

**Personal Factors:**
- Knowledge
- Attitudes
- Outcome Expectations

**Environmental Factors:**
- Social Support
- Professional Support
- Normative Beliefs