

A RANDOMIZED CONTROLLED TRIAL COMPARING THE EFFECT OF DURATION
OF MANUAL EXPRESSION AND BREASTFEEDING SELF-EFFICACY
ON MILK VOLUMES IN MOTHERS OF PREMATURE
INFANTS: THE MERIT STUDY

(Manual Expression pRemature InfanTs)

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by
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ABSTRACT

Premature infants in the neonatal intensive care unit (NICU) are extremely vulnerable, and breast milk is best for the well-being of the infant. Most premature infants, however, are not yet able to suck, so other methods are sought to provide the mother's milk to the baby. These techniques include manual expression and electric breast pumps; however, little is known about the duration of manual expression to optimize milk volumes. In addition, the measurement of self-efficacy has frequently been explored with breastfeeding mothers and is thought to be an important variable to identify mothers at risk for early discontinuation of breastfeeding.

The purpose of this study was to determine how the duration of manual expression affects milk volumes and levels of breastfeeding self-efficacy in mothers of premature infants. Mothers were randomly assigned to either three days or seven days of manual

expression prior to electric pump expression and instructed to record milk volumes for 14 days. Self-efficacy scores were measured at baseline and 14 days. Breastfeeding self-efficacy increased significantly for all mothers in the study but did not differ by study group; 3-day group (Mean=65.7, SD=20.1) as compared to the 7-day group (mean = 72.3, SD =15.4, p=0.458). Follow-up self-efficacy score did not differ by manual expression between the two groups; 3-day group (Mean=76.5, SDF=14.7) as compared to the 7-day group (Mean=80.3, SD=9.3, p=0.751). Milk volumes did not differ by manual expression at follow-up for the 3-day group (Mean =582.7, SD=331.2) as compared to the 7-day group (Mean=700.0, SD=550.0, p=0.770). Results indicate, though not statistically significant, milk volumes are trending toward a clinically meaningful increase in the 7-day manual expression group.

Preliminary finding from this study may add to the evidence for the standard of care for premature mothers providing breast milk to their infants. The study interventions, although directly informed by self-efficacy theory, did not result in significant differences in self-efficacy levels according to study group. If the duration of manual expression can be determined, a standardized approach can be established for mothers of premature infants in order to achieve optimal milk volumes.

APPROVAL PAGE

The faculty listed below, appointed by the Dean of the School of Nursing, have examined a dissertation titled “A Randomized Controlled Trial Comparing the Effect of Duration of Manual Expression and Breastfeeding Self-Efficacy on Milk Volumes in Mothers of Premature Infants: The MERIT Study,” presented by Lisa Marie Steurer, candidate for the Doctor of Philosophy degree, and hereby certify that in their opinion it is worthy of acceptance.

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CHAPTER 1

INTRODUCTION

Premature infants, defined as less than 37 weeks gestation, are extremely vulnerable, and human milk feedings are encouraged for their well-being (Schanler, 2011). The benefits of human milk for premature infants are many. Beneficial short-term outcomes include decreased rates of necrotizing enterocolitis, length of stay, and overall mortality and morbidity (Cristofalo et al., 2013; Maayan-Metzger, Avivi, Schushan-Eisen, & Kuint, 2012). Long-term physiological outcomes include a decreased rate of retinopathy of prematurity, which is a condition that can cause severe vision loss or blindness (Cristofalo et al., 2013; Maayan-Metzger et al., 2012). Additionally, there are long-term advantages to the neurodevelopmental outcomes of premature infants as well as decreased rates of hospitalization after discharge (Vohr et al., 2006, 2007). Despite these documented advantages, breastfeeding sustainment rates among mothers of premature infants remain low (Akerström, Asplund, & Norman, 2007; Pineda, 2011). Although greater than 90% of mothers initiate breast milk feedings, approximately 60% are still breastfeeding by the time of infant discharge (Akerström et al., 2007; Pineda, 2011).

Chapter 1 provides significant background information on premature birth, including short and long-term sequela, the cost to society, and implications for nursing. The provision of breast milk for premature infants is then be discussed. This information leads to the identification of the research problem and the research study. This chapter concludes with an overview of the main research questions that were addressed, study aims, and the overall significance of the study.

Background

Complications of Premature Births

The rate of premature birth, defined as delivery of an infant at less than 37 weeks gestation, has continued to rise over the past 30 years, despite technological and medical advances (Saigal & Doyle, 2008). Although significant increases in the rate of survival for the earliest of premature infants (24-27 weeks gestation) have been achieved, there continues to be significant neonatal morbidity (Stoll et al., 2015). In the past 20 years, there have been only modest decreases in the rates of complications such as sepsis, necrotizing enterocolitis, and retinopathy of prematurity (Stoll et al., 2015). In this same time period, the rate of bronchopulmonary disease, a severe form of lung disease, has increased despite the introduction of surfactant in the 1990s (Stoll et al., 2015).

Long-term sequela for these infants includes neurodevelopmental, functional, and behavioral impairment with worsening effects corresponding to lower gestational age at birth (Saigal & Doyle, 2008). Studies of premature infants, especially those of very low birth weight, report continued problems with cognitive deficits, academic underachievement, and an increased need for remedial assistance through adolescence (Saigal & Doyle, 2008). In addition, behavioral complications such as attention deficit disorders, emotional control, and delays in executive function appear in high rates in very low birth weight premature infants (Saigal & Doyle, 2008).

Premature birth is not only a disadvantage for the health of the infant but includes a cost to society (Institute of Medicine, 2006; March of Dimes, 2013). The Institute of Medicine (2006) reports premature birth as a public health concern that costs society at least \$26 billion a year. This figure includes the health care costs of the baby, early intervention

programs for premature infants because of associated learning and behavioral problems, and lost work for people born prematurely due to the long-term health complications (March of Dimes, 2013). Premature infants have more hospitalizations, physician visits, and nursing and medical procedures compared to their full-term counterparts; this continues even into middle and late childhood (Saigal & Doyle, 2008).

The Provision of Breast Milk for Premature Infants

Preterm infants are physiologically unable to suck, swallow, and breathe with coordination if they are less than 32-35 weeks gestation, so they are routinely fed via enteral tubes (Zachariassen et al., 2010). For this reason, breast milk feeding for most premature infants depends upon the mother's ability to initiate and maintain an adequate milk supply through expression by manual or electric pump until the infant is able to nurse at the breast at approximately 34-36 weeks gestation (Becker, Cooney, & Smith, 2011). Manual expression refers to the use of the mother's hand to express milk from the breast (Becker et al., 2011). This should not be confused with manual pump expression, which is the use of a device that operates manually without the use of electric or battery power (Becker et al., 2011). Manual expression is thought to be advantageous over either manual powered or electric pumps in the first few days after delivery (Morton et al., 2009a). Manual expression may be more effective in removing the thick colostrum that is present in the first few days after delivery, thus priming the breast for the onset of lactogenesis III when the full milk supply is available (Morton et al., 2009).

Physiologically, the process of lactation is controlled by the hormones progesterone, prolactin, and oxytocin (Caldwell & Turner-Maffeï, 2012). Progesterone is the hormone responsible for the production of colostrum prior to the delivery of the placenta in

lactogenesis I (Caldwell & Turner-Maffei, 2012). Prolactin is responsible for milk production through the alveolar cells of the breast, whereas oxytocin allows for milk let-down acting directly on the myoepithelial cells (Caldwell & Turner-Maffei, 2012). Early stimulation of the breast is important through manual expression to produce oxytocin and assist in the movement of substances out of the breast by the let-down reflex (Caldwell & Turner-Maffei, 2012). For these reasons, the sequencing and timing of manual expression in conjunction with electric pump expression becomes a potential determinant of breastfeeding success for mothers whose infants are unable to nurse at the breast.

Previous research exploring a manual and electric pump expression have had mixed results (Flaherman et al., 2012; Morton et al., 2009; Ohyama, Watabe, & Hayasaka, 2010; Slusher et al., 2007). Some studies found a significant increase in milk volume when manual and pump expression were combined, whereas others have not (Flaherman et al., 2012; Morton et al., 2009). In addition, the studies had varying designs and combinations of manual and pump expression that were not timed or sequenced, or the studies measured one method over the other versus a combination (Ohyama et al., 2010; Slusher et al., 2007). This dissertation study attempts to address these gaps in the literature by employing a standardized sequence of manual and electric pump expression for a defined period of time to assess milk volumes and breastfeeding sustainment for mothers of premature infants.

Self-efficacy and Breastfeeding

In addition to techniques to increase milk production, the measurement of self-efficacy has frequently been explored with breastfeeding mothers and has been thought to be an important variable to identify mothers at risk for early discontinuation of breastfeeding (Dennis, 2006; Loke & Chan, 2013). Breastfeeding self-efficacy is defined as the mother's

confidence in her ability to breastfeed her infant (Dennis & Faux, 1999). In a descriptive correlation study of Chinese women who delivered full-term infants, women with higher levels of breastfeeding self-efficacy were more likely to be exclusively breastfeeding their infants exclusively six weeks after delivery ($p < 0.001$) (Loke & Chan, 2013). Dennis (2006) sought to develop a multi-factorial predictive model of breastfeeding self-efficacy in the first week postpartum in order to more accurately predict those mothers at risk for early discontinuation of breastfeeding. In the model, based upon self-report data from 594 mothers of full-term infants, several variables were identified, including maternal education, family support, perceptions of breastfeeding progress, and being able to feed the infant as planned as potential risk factors for low breastfeeding self-efficacy (Dennis, 2006). A qualitative study in mothers of premature children in Sweden explored the preterm experience for the mother and development of self-efficacy for feeding behaviors (Swanson et al., 2012). The study suggested several points for intervention to influence feeding behaviors, such as the need to provide knowledge and skills for milk production and to allow practice and reinforcement of those skills (Swanson et al., 2012).

Breastfeeding self-efficacy was important to measure in this study to investigate whether the intervention affects the mother's level of self-efficacy. Breastfeeding is a specific behavior that is supported by Bandura's Self Efficacy Theory (Bandura, 1977). If the intervention increases the mother's level of self-efficacy, it is hypothesized that the behavior will continue based on results of previous research studies (Dennis, 2006; Loke & Chan, 2013).

Study Purpose and Working Hypotheses

The purpose of this study was to determine how the duration of manual expression affects milk volumes and levels of breastfeeding self-efficacy in mothers of premature infants.

Study Aims

The specific aims of this study are to determine if the duration of manual expression in mothers of premature infants will result in: (a) an increase in breastfeeding self-efficacy; (b) a difference in milk volume; and (c) a correlation between breastfeeding self-efficacy and milk volume.

Research Question 1

What is the difference in breastfeeding self-efficacy 14 days after delivery of mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery?

Hypothesis. There will be no difference in breastfeeding self-efficacy 14 days after delivery in mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery.

Research Question 2

What is the difference in the milk volume 14 days after delivery of mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery?

Hypothesis. There will be no difference in milk volumes 14 days after delivery in mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery.

Research Question 3

What is the correlation between breastfeeding self-efficacy and milk volume in mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery?

Hypothesis. There will be a positive correlation between the level of breastfeeding self-efficacy and milk volume in mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery.

Significance

Although previous studies have investigated the benefits of manual expression, the studies were either not randomized, conducted on full-term newborns, or did not employ a consistent sequence of manual and pump expression (Flaherman et al., 2012; Morton et al., 2009; Ohyama et al., 2010; Slusher et al., 2007). The research study examines a defined duration of manual expression prior to electric pump expression to sustain breastfeeding for mothers of premature infants in order to determine the ideal duration of manual expression. There is no research to date that has explored the optimal duration of manual expression for the mothers of premature infants. This is the first study to have both the powerful design and use self-efficacy theory (Bandura, 1977) for the theoretical framework.

The significance of the study is its ability to address the previous studies' limitations. A randomized controlled trial design, the most powerful design to detect cause and effect, was used. Manual expression was taught to mothers of premature infants within 24 hours after delivery. One group performed manual expression for seven days after delivery, and the other group performed manual expression for three days after delivery. This study was

the first to compare this sequence of milk extraction in a randomized design with mothers of premature infants. The desired outcome was to determine the optimal duration of manual expression and the effect on milk volume. By examining the optimal duration of manual expression, it was hypothesized that breastfeeding would be sustained and the level of maternal breastfeeding self-efficacy would increase within two weeks after delivery.

CHAPTER 2

REVIEW OF THE LITERATURE

This chapter provides a review of the literature related to the breastfeeding of premature infants. This chapter begins with an overview of the physiologic process of lactation and how the interventions in this dissertation study may assist this process. The next section is an overview of the research to date on the importance of human milk for premature infants, including the long- and short-term physiological and neurocognitive benefits. In addition, this section describes potential benefits for the mother based on previous research. This section concludes with the statistics relevant to the initiation and sustainment of lactation for premature infants discharged from the neonatal intensive care unit both in the United States and abroad. Following that, reviews of the literature pertaining to the factors that affect lactation, both modifiable and non-modifiable, are explored. The final section of the chapter reviews previous research on the use of manual expression to support lactation efforts.

The Physiologic Process of Lactation

The Role of Hormones and the Central Nervous System

Complete development of the mammary glands occurs during pregnancy when breasts increase in size and weight (Riordan, 2005). The process of lactation after delivery of an infant is controlled by hormones that travel to the breast through the blood stream, and several tissues within the breast contribute to the production of milk (Caldwell & Turner-Maffei, 2012). The milk making cells, alveolar cells, have important receptor sites and are surrounded by myoepithelial cells and the capillary network (Caldwell & Turner-Maffei, 2012). Ductal tissues create pathways from the alveolar cells to the nipple, and the

myoepithelial cells serve as a contractile unit responsible for milk ejection out of the milk ducts (Caldwell & Turner-Maffei, 2012; Riordan, 2005).

Two separate hormones regulated by the pituitary gland control lactation: prolactin and oxytocin (Caldwell & Turner-Maffei, 2012). Prolactin is essential for both initiating and sustaining lactation, whereas oxytocin is related to milk ejection out of the ducts (Riordan, 2005). Prolactin levels increase in the immediate postpartum period after the delivery of the placenta; however, these levels rise and fall according to the frequency, intensity, and duration of nipple stimulation (Riordan, 2015). Earlier stimulation of the breast stimulates the receptor sites and fills the alveolar cells with prolactin, which is the hormone responsible for creating mature milk (Caldwell & Turner-Maffei, 2012). During the first week after birth, prolactin levels decrease by half and return to non-pregnant levels by seven days postpartum if the nipple stimulation does not occur (Riordan, 2005). More than eight breastfeeding sessions per 24 hours prevents the decline of prolactin before the next breastfeeding (Riordan, 2005). In response to infant sucking and nipple stretching, the hormone oxytocin causes the milk ejection reflex so that milk is released from the myoepithelial cells (Riordan, 2005). Therefore, oxytocin also plays a significant role in the continuation of lactation (Riordan, 2005). Hand massage or manual expression helps to release oxytocin, thereby allowing movement of the milk out of the breast (Caldwell & Turner-Maffei, 2012).

Stages of Human Milk Production

The process of making milk is divided into three stages of lactogenesis (Caldwell & Turner-Maffei, 2012). The secretory differentiation stage (lactogenesis I) is prior to delivery and is controlled by the placental hormones; predominantly progesterone, whereby

colostrum is produced (Caldwell & Turner-Maffei, 2012). Lactogenesis II is marked by the onset of copious milk secretion after birth and the delivery of the placenta and occurs anywhere from two to eight days postpartum (Riordan, 2005). Lactogenesis II is initiated by the rapid drop in progesterone that occurs after the delivery of the placenta (Riordan, 2005). At the onset of lactogenesis III, mature milk is created under the regulation of prolactin (Caldwell & Turner-Maffei, 2012).

Milk Composition

The composition of human milk changes over the course of lactation but the bioavailability of nutrients in human milk makes it easily absorbable in the gut (Caldwell & Turner-Maffei, 2012). At the onset of lactogenesis II, there is a significant drop in the level of sodium chloride and protein but an increase in the milk lipids and protein (Riordan, 2005). Besides the nutritional aspects of human milk in regard to water, fat, lactose, and protein, important human species bio-active components create a unique microbiome (Caldwell & Turner-Maffei, 2012). The pH and iron levels in the gut are lower in breast-fed babies, lowering the multiplication of unwanted bacteria (Caldwell & Turner-Maffei, 2012). Antibodies and other hormones create a mature gut that is less easily penetrated by invading organisms (Caldwell & Turner-Maffei, 2012).

The Importance of Human Milk for Premature Infants

Several studies have addressed the benefits of human milk for premature infants (Cristofalo et al., 2013; Maayan-Metzger et al., 2012; Schanler, 2011; Vohr et al., 2006, 2007). Preterm milk appears to have a different composition in the first 30 days after delivery with higher levels of protein, fat, and electrolytes (Caldwell & Turner-Maffei, 2012). Short-term benefits to the premature infant include lower rates of necrotizing

enterocolitis (NEC) and retinopathy of prematurity (ROP); long-term benefits include improved neurodevelopmental outcomes and a decreased rate of re-hospitalization (Maayan-Metzger et al., 2012; Schanler, 2011; Vohr et al., 2006, 2007).

Cristofalo et al. (2013) compared the incidence of NEC and number of parenteral nutrition days in extremely premature infants who were fed human milk versus formula. Although the incidence of NEC alone was not statistically significant, infants who were randomized to human milk feedings required less surgical correction of NEC ($p = .04$). In addition, parenteral nutrition days were significantly lower in the infants who received human milk only ($p = .04$).

In a retrospective review of 400 premature infants less than or equal to 32 weeks gestation, Maayan-Metzger et al. (2012) found lower rates of NEC in all gestational age subgroups fed human milk as opposed to formula. In addition, a decreased rate of stage III retinopathy of prematurity was found in those infants receiving human milk in the 24-26 week gestational age subgroup (Maayan-Metzger et al., 2012).

Schanler (2011) reviewed the literature to determine the long-term effects of a human milk diet on premature infants in the NICU. In the review of nearly a dozen descriptive and a few quasi-randomized studies over the past 25 years, human milk feedings resulted in improved neurodevelopmental outcomes, nutritional status, and a decreased rate of metabolic syndrome in the premature infant (Schanler, 2011).

In earlier studies, researchers examined the extended benefits of human milk for premature infants at both 18 and 30 months of age (Vohr et al., 2006, 2007). In a multi-center, prospective assessment of 1,035 premature low birth weight infants, neonatal morbidity, interim histories, and neurodevelopmental/growth outcomes were assessed at 18

months corrected age (Vohr et al., 2006). Multivariate analysis confirmed a significant association of breast milk in the following outcomes: Mental Development Index, Psychomotor Development Index, Behavior Rating Scale, and incidence of re-hospitalization (Vohr et al., 2006). For every 10-ml/kg per day increase in human milk ingestion, all index scores increased, and the rate of re-hospitalization decreased by six percent (Vohr et al., 2006). The researchers further studied this same cohort of premature infants at 30 months corrected age with similar findings (Vohr et al., 2007).

The benefits of human milk feeding are realized not only for the infant but for the mother as well (Bernaix, Schmidt, Jamerson, Seiter, & Smith, 2006; Boucher, Brazal, Graham-Certosini, Carnaghan-Sherrard, & Feeley, 2011; Wigert, Johansson, Berg, & Hellström, 2006). Despite the difficulties with pumping and transporting milk, when interviews were conducted with mothers of premature infants, they reported that providing breast milk was the one thing they could do to support their sense of mothering (Bernaix et al., 2006). Other studies focusing on the breastfeeding experience in the NICU, noted the trauma experienced by the mother when separated from the premature infant, and the need to be an active participant in the infant's care (Boucher et al., 2011; Wigert et al., 2006). When the mother is nearby and supplying milk, there is a sense of active participation rather than exclusion (Wigert et al., 2006). Mothers reported that human milk was the only thing they could give their infant in the NICU to contribute to their growth and well-being, and it provided a physical connection between the mother and the child (Boucher et al., 2011).

Despite all the advantages breastfeeding provides for both mother and infant, breastfeeding sustainment rates for premature infants are low (Akerström et al., 2007; Furman, Minich, & Hack, 2002; Pineda, 2011; Zachariassen et al., 2010). Previous studies

both within and outside the United States report similar findings (Akerström et al., 2007; Furman et al., 2002; Pineda, 2011; Zachariassen et al., 2010). Breastfeeding initiation rates ranged from 78% to 92% but then dropped to 34% to 60% by the time of infant discharge (Akerström et al., 2007; Furman et al., 2002; Pineda, 2011; Zachariassen et al., 2010).

Factors Affecting Lactation

Several factors have been noted in the literature that create obstacles for the mother of the premature infant to successfully sustain lactation both during and after the infant's hospitalization (Furman et al., 2002; Sisk, Quandt, Parson, & Tucker, 2010). When mothers of premature infants have been interviewed, main obstacles to the breastfeeding experience include physical exhaustion and access to mechanical breast pumps at home (Sisk et al., 2010). In addition, distance from the NICU and having to transport milk creates additional barriers (Sisk et al., 2010).

Studies of breastfeeding initiation and duration in mothers of premature infants have focused upon the modifiable and non-modifiable factors that affect lactation (Flacking, Wallin, & Ewald, 2007; Furman et al., 2002; Pineda, 2011). Among the non-modifiable factors that inhibit lactation are decreased socioeconomic status, younger maternal age, and non-white ethnicity (Flacking et al., 2007; Furman et al., 2002; Lessen & Crivelli-Kovach, 2007). Conversely, non-modifiable factors that promote lactation include married marital status, previous breastfeeding experience, and multiple birth pregnancy (Furman et al., 2002; Lessen & Crivelli-Kovach, 2007; Pineda, 2011).

There are also several factors that have been found to have no effect on lactation. Birth weight and gestational age are not associated with breastfeeding duration, and the degree of prematurity, size of the infant, or the presence of neonatal disorders has not been

shown to affect breastfeeding behaviors (Flacking et al., 2007; Pineda, 2011). Contrary to maternal perception, anxiety and stress are not always associated with milk volume and the mother's ability to sustain lactation and produce the hormones for lactation (Chatterton et al., 2000; Hill et al., 2009; Hill, Aldag, Chatterton, & Zinaman, 2005c). Although Hill and Aldag (2005) found the stress levels, fatigue, and sleep difficulties to be higher in mother of premature infants versus full-term infants, this did not have a significant influence on milk production at six weeks post-partum. In addition, the main hormones of lactation (oxytocin and prolactin) have been studied to assess correlations of hormone levels with milk production, and limited evidence has been found to support the association (Chatterton et al., 2000; Hill et al., 2009).

However, delayed milk expression and perceived or actual low milk volume have been found to be prevalent modifiable factors that can inhibit lactation sustainment in mothers of premature infants (Furman et al., 2002; Killersreiter, Grimmer, Bührer, Dudenhausen, & Obladen, 2001; Lessen & Crivelli-Kovach, 2007). Earlier research focused upon pumping style and found that simultaneous rather than sequential pumping and breast massage immediately prior to expression resulted in increased milk production (Fewtrell et al., 2001; Hill, Aldag, & Chatterton, 1999; Jones, Dimmock, & Spencer, 2001). Additional studies focused upon the effect of time interval since birth and the frequency of pumping to determine optimal milk production and showed that earlier initiation and more frequent milk expressions (5 or more per day) resulted in increased milk production (Hopkinson, Schanler, & Garza, 1988). Hill, Aldag, and Chatterton (2001) had similar findings showing that milk volume was much lower among those mothers late in initiating expression and having a low pumping frequency.

More recent research continues to focus on the importance of early initiation of expression to achieve greater milk volumes (Hill & Aldag, 2005; Hill, Aldag, Chatterton, & Zinaman, 2005a, 2005b; Murase et al., 2014). A retrospective review of infants delivered prematurely found mothers with lower milk volumes on the fourth day after delivery have greater odds of formula feeding at discharge (Murase et al., 2014). Subsequently, caesarian delivery was found to be a strong predictor of low milk volume on day four (Murase et al., 2014).

Hill and Aldag (2005) stressed the importance of early milk production as a significant predictor for later milk volume adequacy. In their study of 81 mothers of non-nursing premature infants, mothers with the lowest milk production on day four were 9.5 times more likely to have an inadequate milk supply at six weeks post-partum (Hill & Aldag, 2005). In a subsequent study by Hill et al. (2005b), secondary mediators defined as early initiation of breast stimulation, early frequency of breast stimulation, and early milk output were all found to be predictive of adequate milk output at six weeks post-partum.

However, a more recent study of 40 very low birth weight premature infants compared milk volume and the onset of lactogenesis II (early secretory milk supply) among mothers who initiated breast milk expression within six hours of delivery versus those whose first expression was after six hours (Parker, Sullivan, Krueger, & Mueller, 2015). Due to the fact that many mothers of premature infants are often ill themselves, it is common for women not to be able to express their breast milk in the desired six-hour time frame. No statistically significant difference in the timing of lactogenesis II was seen between the two groups (Parker et al., 2015). The mothers in the early initiation group produced more total milk volume in the first seven days postpartum, but the difference was

not statistically significant (Parker et al., 2015). Furthermore, when the mothers who expressed within one hour of delivery were excluded, there were no differences in mean milk volumes (Parker et al., 2015). However, due to the small sample size in this pilot, it was difficult to achieve statistical significance.

A retrospective study of 138 premature infants in Sweden also found an association between early milk production and breastfeeding duration (Wilson, Christensson, Brandt, Altman, & Bonamy, 2015). Early provision of mother's own milk in the first seven days following delivery was associated with increased breastfeeding sustainability of premature infants who were between 36-40 weeks postmenstrual age (PMA) (Wilson et al., 2015). The infants receiving mother's own milk at postnatal day seven were 1.18 times more likely to sustain breastfeeding until 36 weeks PMA (Wilson et al., 2015).

Manual Expression of Breast Milk

One of the major contributing factors for the cessation of breastfeeding in the premature population of infants is decreased milk production (Hill, Aldag, Zinaman, & Chatterton, 2007; Murase et al., 2014; Sisk et al., 2010). Because most premature infants are unable to initially feed at the breast, artificial methods to maintain milk supply such as manual and electric pump expression have been explored (Flaherman et al., 2012; Morton et al., 2009a; Ohyama et al., 2010; Slusher et al., 2007).

Studies by Flaherman et al. (2012) and Slusher et al. (2007) both used a randomized design to address manual versus pump expression and its effect on milk volume. Flaherman et al. studied a population of 68 full-term infants feeding poorly at the breast for two months after delivery in a United States academic medical center and randomized the mother to either manual expression or electric pump expression. Slusher et al. allocated mothers of 65

premature infants admitted to an African special care nursery to manual expression, manual powered pedal pump, or an electric pump for six to ten days after delivery. Both studies found the electric pump to yield higher volumes of milk than manual expression (Flaherman et al., 2012; Slusher et al., 2007). Slusher et al. found a statistically significant increase in milk volume with the electric pump when compared to manual expression ($p<0.01$). No mean differences in demographics between the three groups were found. Flaherman et al. also reported higher milk volumes with the electric pump, but the comparison failed to reach statistical significance ($p=0.07$). Although failing to reach statistical significance on milk volume, Flaherman followed participants for two months and reported higher rates of continued breastfeeding among the mothers who had initially used hand expression ($p=0.02$). In addition, Flaherman et al. (2012) measured self-efficacy using the Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF) (Dennis, 2003) at baseline, one week, one month, and two months after delivery. However, there were no significant differences between the groups for breastfeeding self-efficacy (Flaherman et al., 2012).

Two studies investigated a combination of manual and electric pump expression (Morton et al., 2009; Ohyama et al., 2010). Morton et al. (2009) combined hand expression and electric pumping whereas Ohyama (2010) used manual expression or electric pump expression. In the study by Morton et al. (2009) a prospective observational design was used to examine milk production for eight weeks after delivery for mothers who were instructed to use an electric pump and manually express as much as possible in the first three days post-partum with no particular sequencing. In this sample of 67 mothers of premature infants, Morton was able to find an increased milk production at two weeks for those mothers that hand expressed greater than five times a day ($p<0.05$). Ohyama (2010) also

studied mothers of premature infants in a Japanese neonatal intensive care unit using a crossover design that studied a combination of manual and electric pump expression techniques. The mothers were sequentially allocated to either manual or electric pump expression and then alternated the method until seven sessions had been completed for each method (Ohyama, 2010). Net milk yield was significantly higher with manual expression ($p<0.05$) as compared to pump expression in the first 48 hours after delivery (Ohyama et al., 2010). Both of these studies support the potential benefit of manual expression for early removal of colostrum prior to the onset of mature milk.

A pilot feasibility study using a combined sequence of manual and pump expression intervention for the first three days after delivery was conducted on the mothers of premature infants whose infants were hospitalized in a NICU in the proposed study population and setting (Steurer, 2014). Mothers of premature infants ($n=6$) were asked by staff nurses in the intra-partum and post-partum units to perform manual expression prior to electric pump expression for the first three days after delivery and record milk volumes on a breastfeeding log for three weeks after delivery. Women who had not begun an initial expression within six hours after delivery were initially excluded. Previous literature indicates the delay in time from delivery to expression can be an important variable in overall milk production (Hill et al., 2005b). Due to the infeasibility of the women being able to begin their first pumping session within six hours of delivery due to complications of delivery or other logistical issues within the healthcare setting, the inclusion criteria for recruitment was extended from six hours to 24 hours after delivery. The intervention of manual expression was able to be delivered on all of the mothers in the study, thus providing important information on the feasibility of teaching this intervention in this population of

mothers. However, because only half of the mothers in the study were able to complete the milk volume log, revisions in the amount and duration of study variables for the larger study have been considered (Steurer, 2014).

Limitations of Previous Studies on Manual Expression

Of the studies reviewed, only three included premature infants, and only two were randomized trials; thus causation is difficult to establish. There was conflicting evidence whether electric pump expression or manual expression yielded higher milk volumes, and a standard sequencing method was not always employed in the research design. All of the studies reported relatively low sample sizes and failed to mention the use of a power analysis, which can lead to a Type I error. Most of the studies were focused on physiological outcomes as the primary measure and did not incorporate a theoretical framework. The studies were based on the physiological theory that early and frequent pump expression after delivery is essential to maintain milk supply in mothers who may be separated from their infants or when infants are feeding poorly.

Despite the mixed results of previous studies, it is becoming standard practice for many hospitals to instruct all mothers on manual expression as a result of the recommendation of the Baby-Friendly Hospital Initiative (BFHI) (Baby-Friendly USA, 2012). The BFHI is a global initiative endorsed by the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF), whose primary goal is to assist all mothers in being able to successfully initiate and sustain breastfeeding (Baby-Friendly USA, 2012). The BFHI recognizes hospitals that are successful in meeting their guidelines for breastfeeding quality and outcomes (Baby-Friendly USA, 2012). The number of U.S. hospitals applying for the BFHI certification has increased since 2010 when the U.S.

Department of Health and Human Services incorporated the promoted practices into federal goals (Schulte, 2014). As part of the BFHI global goal, 80% of mothers must report that they have been taught how to hand express their milk for both mothers feeding at the breast and for those mothers who are separated from their babies (World Health Organization and UNICEF, 2009).

The duration of manual expression was not defined by the BFHI, and previous studies incorporating manual expression have not measured how many days of manual expression may be optimal (Baby-Friendly USA, 2012; Flaherman et al., 2012; Morton et al., 2009; Ohyama et al., 2010; Slusher et al., 2007). Of the studies reviewed that incorporated manual expression as an independent variable, most were not combined with electric pump expression (Flaherman et al., 2012; Ohyama et al., 2010; Slusher et al., 2007). The duration of manual expression varied across all studies, anywhere from three to eight days after delivery (Flaherman et al., 2012; Morton et al., 2009; Ohyama et al., 2010; Slusher et al., 2007).

As previously discussed, lactogenesis II is marked by the onset of copious milk secretion after birth and the delivery of the placenta and occurs anywhere from two to eight days postpartum (Riordan, 2005). Due to the variability of when mature milk is created, the timing of the colostrum period may vary by individual. Comparing the duration of manual expression may reveal insights into the optimal timing of this expression technique for mothers of premature infants. No studies reviewed focused on the duration of manual expression as an independent variable. This study was the first to focus on the duration of manual expression as the primary outcome variable of interest.

CHAPTER 3

THEORETICAL FRAMEWORK AND METHODOLOGY

This study is a randomized controlled trial to compare the duration of manual expression on milk volumes, breastfeeding sustainment, and self-efficacy in mothers of premature infants. The first section of this chapter provides an overview of the theoretical framework applied to breastfeeding behavior and potential prediction of important outcomes. The second section of this chapter discusses the overall research design selected to answer the research questions.

Theoretical Framework

Contemporary empiricism does not rely solely on strictly controlled experimentation but also includes the subjective nature of inquiry inherent in the human experience (McEwen & Willis, 2014). The concept of contemporary empiricism as described by Giuliano (2003) proposes a strong argument in bridging the gap between the knowledge obtained in nursing research and application to practice. The focus of interpretive methods is on understanding the human experience, and subjectivity is emphasized rather than objectivity (Giuliano, 2003). As a result, induction rather than deduction is the main method of reasoning in an interpretive approach. Inductive reasoning is a logical process of attributing a generalization to a whole population based upon some sampling of that population (Dahnke & Dreher, 2011). Giuliano further describes that interpretive methods tend to embrace a more holistic approach to research and are a key element to understanding the philosophy of contemporary empiricism. Therefore, contemporary empiricism is defined as a philosophy in nursing that applies the scientific facts gained from empirical methods

and combines them with the subjective knowledge gained by identifying and measuring the human response (Giuliano, 2003).

In the context of the research involving sustaining milk production for mothers of premature infants, contemporary empiricism as a philosophy takes into account the importance of empirical knowledge obtained by testing various methods to express human milk to optimize production. The empirical approach has been used previously in determining best techniques to produce optimal volumes when expressing breast milk (Morton et al., 2009; Ohyama et al., 2010). However, adding subjective assessment that seeks to understand the experience of the mother when providing expressed milk to her premature infant and investigation into the underlying motivations for behavior is equally important in understanding the phenomenon. A pure empirical approach does not uncover the essence of understanding the motivation needed to continue the behavior which is needed in practice to sustain lactation for the infant. For these reasons, every intervention for the mother must take into consideration her confidence and ability to perform the tasks necessary to sustain lactation.

Ethical considerations to consider have been highlighted by other scientists in breastfeeding research (Nelson, 2006). In the development of a situation-specific theory of breastfeeding, Nelson (2006) brought to light the notion of paternalism in healthcare and that practitioners may be unknowingly coercive in their attempts to encourage women to breastfeed. The approach that nurses use to encourage breastfeeding should avoid the presentation as a mandate but rather a respectful communication that supports an individual's right to self-determination (Nelson, 2006). In addition, the nurse should support

the women's decision whether to breastfeed and incorporate that decision into the treatment plan (Nelson, 2006).

When exploring a theory to consider for the sustainability of breastfeeding, the subjective experience of the mother must be an integral part of the decision in order to support the philosophy of contemporary empiricism. A middle-range theory that is congruent with the philosophy of contemporary empiricism is Albert Bandura's Theory of Self-efficacy (Bandura, 1977). The theory is based upon the principle that a relationship exists between an individual's perceived self-efficacy and behavior change (Bandura, 1977). The expectations of their degree of self-efficacy directly predict the amount of time, energy, and effort an individual will put forth to accomplish a behavior in the face of a difficult experience (Bandura, 1977). The theory fits into the person aspect of the nursing metaparadigm and is considered inductive, for it moves from the observation of particular behaviors to create a predictive global hypothesis about behavior (Bandura, 1977). The major concepts of Bandura's theory (1997) are efficacy expectations and outcome expectations. Efficacy expectation is the conviction that one can successfully execute the behavior required to produce outcomes, and an outcome expectation is defined as a person's estimate that a given behavior will lead to that outcome (Bandura, 1977). These two concepts are differentiated because individuals can believe that a particular behavior will produce outcomes, but if they lack self-efficacy in their ability to perform that behavior, the desired outcome may not be achieved (Bandura, 1977).

Bandura (1977) further explained the important sources of efficacy expectations and associated direct linkages between the source and the predication of behavior; thus the theory is at a predictive rather than explanatory or prescriptive level. The four major sources

of efficacy expectations are: performance accomplishments, vicarious experience, verbal persuasion, and emotional arousal (Bandura, 1977). Performance accomplishments are defined as one's personal mastery of experiences (Bandura, 1977). Performance accomplishments raise mastery expectations and repeated failures lower them; however, if initial failures are later overcome by determined effort and motivation, this can strengthen the self-motivated persistence of the behavior (Bandura, 1977). Vicarious experience, or seeing others succeed in the difficult task, can motivate behavior, and verbal persuasion is based on the proposition that people are led, through suggestion, into believing they can successfully accomplish a task or behavior (Bandura, 1977). Although verbal persuasion is more closely aimed at raising outcome expectations rather than enhancing self-efficacy, one can attribute successes achieved after corrective performance to the influences of verbal persuasion (Bandura, 1977). Therefore, if people are provided instruction with helpful correction, they are more likely to succeed than people given instruction alone (Bandura, 1977).

Emotional arousal is cited as the final major source of efficacy expectation by Bandura and he theorized when an individual perceives a higher level of self-efficacy, they control the adverse effect of the emotional arousal upon performance. This presumes, although the stress may be present, if a person has a higher level of self-efficacy, they are better able to maintain behavior.

The model to support Bandura's Theory of Self-efficacy (see Figure 1.1) distinguishes efficacy expectations from outcome expectations, because a person's expectations about their ability to perform a behavior directly affect their willingness to engage in the behavior, which in turn affects individual outcomes (Bandura, 1977). The

sources of efficacy expectation and the modes of induction for each source interrelate. Thus repeated performance accomplishments, while increasing expectations, can also extinguish emotional arousal (Bandura, 1977).

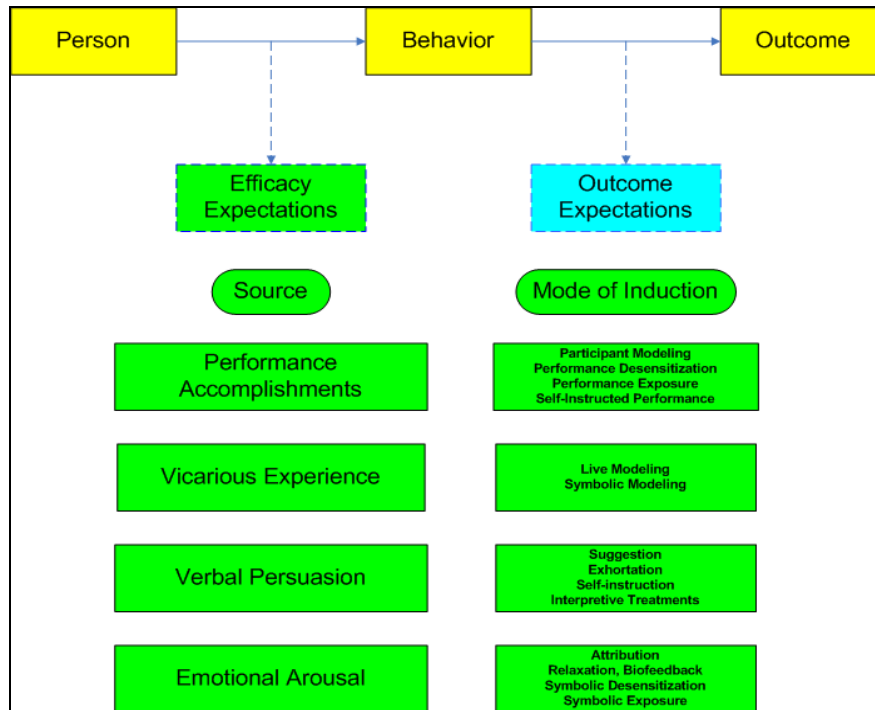


Figure 1.1 Schematic of Albert Bandura's Theory of Self-Efficacy. Adapted from "Self-efficacy: toward a unifying theory of behavioral change", by A. Bandura, 1977, *Psychological review*, 84(2), p. 193 & 195.

The study fits well with the theoretical model, for the person's efficacy expectations about their ability to produce milk will have an ultimate effect upon sustainment of the behavior. In addition, the modes of induction in the breastfeeding experience for mothers of premature infants are associated directly with the four sources of efficacy expectation. Through the ability to perform manual expression for a defined period of time, it was hypothesized that the mother will increase self-efficacy by raising the level of performance accomplishments for breastfeeding.

Performance accomplishment can be strengthened further when the mother may initially face a challenge with the expression of milk that is later overcome. Mothers of premature infants will be exposed to other mothers in the same situation, and seeing them succeed in producing milk can further provide motivation for the behavior. Lactation consultants, nurses, staff, and families are readily available to provide verbal persuasion and emotional support to encourage the breastfeeding experience. Lastly, if higher levels of self-efficacy are achieved, the mother will be less likely to be affected by the adverse effect of stress and anxiety inherent in the delivery of a premature infant. Bandura's Theory of Self-efficacy (1977) is considered middle-range because the concepts can be operationally defined and the propositions can be measured by empirical testing (Fawcett, 2005). The theory guided the study by implementing the four main sources of self-efficacy as interventions for each step of the research (see Figure 1.2).

A modifiable concept that has been frequently explored in breastfeeding research is maternal confidence and the relationship of confidence and breastfeeding duration (Blyth et al., 2002; Dennis, 1999). Maternal confidence in breastfeeding has been defined as breastfeeding self-efficacy, and Bandura's (1977) theory has often been used as a theoretical framework to study breastfeeding confidence (Blyth et al., 2002; Dennis, 1999; Kingston, Dennis, & Sword, 2007). Dennis (1999) is a nurse researcher who believes modifiable risk factors such as breastfeeding confidence need to be discussed from a theoretical perspective. Dennis described the basic propositions of self-efficacy theory in relation to breastfeeding behaviors and developed a breastfeeding self-efficacy scale. In choosing and maintaining a given behavior, individuals draw upon the four major sources of efficacy expectations

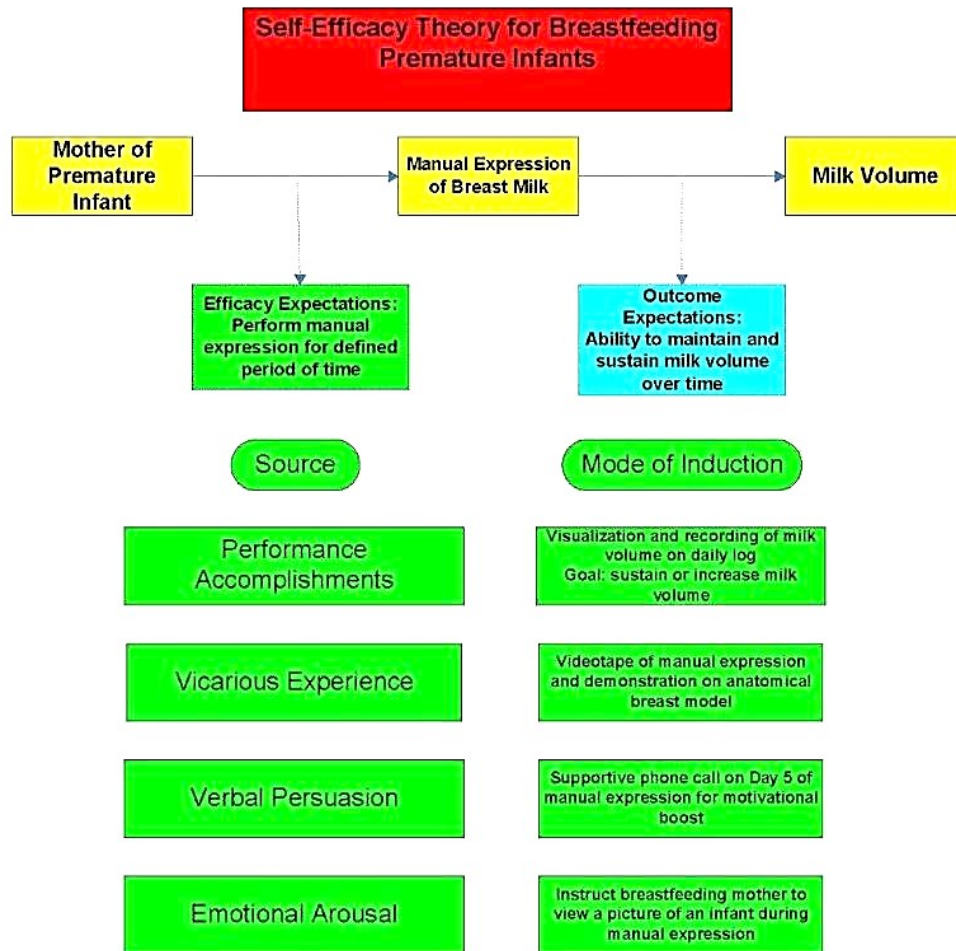


Figure 1.2. Schematic of Albert Bandura's Theory of Self-Efficacy for Breastfeeding. Adapted from "Self-efficacy: Toward a unifying theory of behavioral change", by A. Bandura, 1977, *Psychological review*, 84(2), pp. 193 & 195.

(Dennis, 1999). In regard to breastfeeding behaviors, performance accomplishments tend to boost perceptions of self-efficacy, whereas attention to unsuccessful aspects of the performance tend to lower perceptions of self-efficacy (Dennis, 1999). The observation of the breastfeeding experience, whether through live, recorded, or printed performance, can directly influence behavior, especially when peers are serving as role models (Dennis, 1999). The verbal persuasion or appraisal of others, especially lactation consultants, nurses, peers, or family members can impact the breastfeeding mother's level of self-efficacy

(Dennis, 1999). Emotional arousal can enhance self-efficacy when it is positive, such as excitement or satisfaction, but it can also reduce self-efficacy when it is negative, such as when fatigue, anxiety, or pain are part of the breastfeeding experience (Dennis, 1999).

In order to identify breastfeeding mothers and plan interventions, Dennis developed an instrument based on self-efficacy theory to measure breastfeeding confidence. The Breastfeeding Self-efficacy Scale (BSES) is a 33-item self-report instrument that has been psychometrically tested and validated in new mothers (Dennis & Faux, 1999). More recent research has focused on implementing interventions to increase self-efficacy in the four major sources of efficacy and subsequently measuring the success of the interventions on self-efficacy by using the BSES (Kingston et al., 2007).

A prospective survey was conducted with 300 women in the last trimester of pregnancy by a clinic in Australia in which telephone interviews were conducted at one week and four months postpartum to assess infant feeding methods and breastfeeding confidence using the BSES (Blyth et al., 2002). The antenatal and one-week BSES scores were significantly associated with breastfeeding outcomes at one week and four months (Blyth et al., 2002). Mothers with high breastfeeding self-efficacy were significantly more likely to be breastfeeding than mothers with low breastfeeding self-efficacy (Blyth et al., 2002). Although these studies demonstrated that maternal self-efficacy is a strong predictor of breastfeeding duration, the studies were conducted on mothers of full-term infants feeding directly at the breast (Blyth et al., 2002; Kingston et al., 2007). The BSES questions specifically ask about latching on the breast; therefore, this tool would not be valid for mothers of premature infants who are expressing their breast milk (Dennis & Faux, 1999).

Fortunately, the BSES has subsequently been shortened and psychometrically tested, resulting in a reduction from the original 33 items to 14 items (Dennis, 2003). In addition, the short form has been revised and tested among mothers of ill and premature infants and has been found to be a valid and reliable tool for measurement in this population (Wheeler & Dennis, 2013). The BSES short form (BSES-SF) assisted in measuring a change in level of self-efficacy for the mothers in this study.

Methodology

Research Design

This study employed a randomized controlled trial design. Mothers of premature infants were randomly assigned to one of two groups using a table of random numbers. Both groups completed a Breastfeeding Self-Efficacy Scale Short Form (Wheeler & Dennis, 2013) survey at baseline. Group one received training on manual expression before electric pump expression of breast milk for the first seven days after delivery. Group two received training on manual expression before electric pump expression of breast milk for the first three days after delivery. Both groups were instructed to pump eight to ten times per day as per standard care. Milk volume was recorded by the mothers for two weeks after delivery in both the experimental and control groups.

Sample

A convenience sample of 90 mothers of premature infants was sought for enrollment. The inclusion criteria were (a) mother intended to breastfeed; (b) infant gestational ages between 23-34 weeks gestations; (c) infants were admitted to a neonatal intensive care unit. Gestational age selection was based on criteria for pump dependency for two weeks prior to initiation of milk feeding at the breast. Participants were excluded if (a) non-English

speaking; (b) critically ill; (c) history of breast augmentative surgery. Participants who were critically ill were defined as those unable to perform manual expression or electric pump expression due to illness, weakness, or sedation as determined by the primary physician providing care to the mother. Participants who had undergone breast augmentation surgery were excluded due to the fact surgical techniques for both reduction and enhancement can cut or obstruct the milk ducts, and mothers are often unable to produce and express milk (Roberts, Ampt, Algert, Sywak, & Chen, 2015). Participants nursing at the breast did not need to exclusively express milk via artificial methods and were excluded. The sample size was calculated based on power analysis of two-sided alpha of 0.05 at 80% power with a 0.6 effect size (Hulley, Cummings, Browner, Grady & Newman, 2007).

Study Setting

Participants were recruited from the antepartum and postpartum unit of a Midwestern academic hospital. The hospital delivers an average of 70 premature infants per month, which met inclusion criteria that required admission to the neonatal intensive care unit. Based upon the pilot feasibility study (Steurer, 2014), the proposed sample size allowed completion of recruitment within 12 months. A letter of support from this research was obtained by the study hospital (see Appendix A).

Instruments

Demographic data. Baseline demographic data were collected on each participant and premature infant. Maternal data collected included the following: age, gender, race, gravida, para, mode of delivery, diagnosis, breastfeeding experience, history of premature delivery, education level, and marital status. Infant data collected included gestational age and birth weight (see Appendix B).

Measurement of self-efficacy. All of the participants were asked by the Principal Investigator (PI) to complete the BSES-SF (Wheeler & Dennis, 2013) at baseline and then 14 days after delivery (see Appendix C). Permission was secured from the author for use in this research (see Appendix D). Self-efficacy was a dependent variable in this study. The BSES-SF has been modified for mothers of premature infants and tested for reliability (Cronbach's $\alpha=0.88$) (Wheeler & Dennis, 2013). Exploratory factor analysis was conducted to assess construct validity and all factors loading exceeded 0.30 (Wheeler & Dennis, 2013). Criterion-related validity was confirmed through negative correlation of the H&H Lactation Scale ($r=-0.84, p<.001$) (Wheeler & Dennis, 2013). Predictive validity was determined by comparing one-week post-discharge scores and infant feeding method at six weeks post discharge (Wheeler & Dennis, 2013). Significant differences were found with mothers continuing to provide breast milk ($M=83.44, SD=8.23$) and those who had discontinued by six weeks after discharge ($M=75.51, SD=10.08; t= 4.09, p < .001$) (Wheeler & Dennis, 2013).

Milk volume and manual expression. All of the participants in the study were asked to record the time and volume of milk expressed in milliliter pump bottles provided by the hospital for each pumping session for 14 days on the breastfeeding data collection log. Participants in both groups were instructed on volume collection by the Principal Investigator, and milk volumes were assessed for accuracy after the first pumping session. Volume of milk served as the dependent variable. Participants in the 7-day group recorded how often manual expression was performed prior to electric pump expression in the first seven days after delivery (see Appendix E). Participants in the 3-day group recorded how often manual expression was performed prior to electric pump expression in the first three

days after delivery (see Appendix F). Manual expression duration served as the independent variable with milk volume as the dependent variable. Participants in both groups were instructed by the PI on electric pump expressions as per standard care (see Appendix G).

Breastfeeding sustainment: Participants in the 7-day group received a phone call by the PI on the fifth day after delivery to encourage continued manual expression and answer questions through the 7-day period. All participants received a stamped, addressed envelope to mail the log to the PI. This envelope was given at the time of enrollment. The PI either called or texted a reminder to the participant at 14 days to mail the completed log, or the PI arranged to pick up the log from the mother if the infant was still admitted.

Procedure

Permission to conduct the study was obtained by the University of Missouri-Kansas City and the Washington University in St. Louis Institutional Review Boards (see Appendix H). The participants who were eligible for inclusion in the study were identified by the Principal Investigator after consultation with the charge nurse on the nursing unit based on inclusion criteria for all patients in the ante-partum or post-partum unit of the hospital. Informed consent was obtained by the PI from all participants (see Appendix I). The elements of informed consent including the explanations of risks and benefits as well as alternatives were explained. Following consent, participants were asked to complete a demographic data sheet and the Breastfeeding Self-Efficacy Scale Short Form (BSES-SF). Participants were given a unique study number by the PI upon enrollment.

Randomization. Each study number had a separate sealed envelope containing information on allocation to the 7-day or 3-day manual expression group. Participants were

allocated using a 1:1 allocation ratio. Randomization blocks of four were generated by a computerized random number generator to ensure equal allocation of groups.

Intervention for 7-day group. Participants were praised for their decision to breastfeed and advised of all the benefits of breast milk for their premature infant. Participants received individualized instruction on the Stanford Technique (Morton, 2009) for manual expression by the PI with video instruction and return demonstration on an anatomical model for reinforcement (see Appendix J). This teaching occurred over approximately 15 minutes. Participants were asked to perform breast milk expression prior to each electric pumping session for seven days after delivery. Participants were instructed to view their own infant or a photograph of an age- and gender-matched infant during pumping sessions. On the fifth day after delivery, the mother received a phone call by the PI to encourage continuation of manual expression until seven days and to answer any questions related to breast milk expression.

Intervention for 3 day group. Participants were praised for their decision to breastfeed and advised of all the benefits of breast milk for their premature infant. The 3-day group received individualized instruction of the Stanford Technique for manual expression by the PI with video instruction and return demonstration on an anatomical model for reinforcement. This teaching occurred over approximately 15 minutes. Participants in the 3-day group were asked to perform breast milk expression prior to each electric pumping session for three days after delivery. Participants were instructed to view a photograph of their own infant or of an age- and gender-matched infant during pumping sessions.

Milk volume. Participants in both groups were instructed to document the time of pumping and volume of milk expressed for 14 days after delivery on a breastfeeding data collection log. This was completed approximately five minutes after each pumping session.

Protocol fidelity. See Appendix K for Study Protocol. The PI was certified as a lactation counselor. The PI was observed by a board-certified lactation specialist when teaching the manual expression and electric pump expression prior to the first participant to ensure correct technique. No further education was needed as determined by the lactation specialist.

Attrition. The pilot feasibility study had a 20 % attrition rate (Steurer, 2014). The primary reason for attrition was failure to complete the breastfeeding log. The breastfeeding log had been revised to lower the burden for the mothers by decreasing the amount of information needed from each pumping session and decreasing the duration of data collection from 21 to 14 days. Previous studies with similar prospective designs have reported attrition rates between 20 and 30% (Flaherman et al., 2012; Morton et al., 2009). Based on these calculations, the plan was to recruit 20% over the initial sample size, for a total of 108 patients in order to account for attrition. Participants were thanked for their participation by being given a \$50 gift card upon completion of the breastfeeding log.

Data Analysis

Data were double-entered into SPSS Version 20 by the PI (IBM Corp., 2011). Statistical analysis was performed by a biostatistician using IBM SPSS Statistics for Mac version 24.0 (IBM Corporation, Somers, NY, USA). Demographic information was summarized using descriptive statistics; e.g., proportions, means, and standard deviations, and the two groups were examined at baseline for differences using non-parametric

inferential statistics. A Spearman's rank correlation coefficient was also computed to assess the statistical dependence between the ranking of milk volume on day 1 and day 14 with each of the continuous demographic variables, which were assumed to violate parametric assumptions of normality. Milk volume of day 1 and day 14 were compared by binary demographic variables using a series of Mann-Whitney U tests. An analysis of variance was used to compare milk volumes on day 1 and day 14 by categorical demographic variables; a non-parametric Kruskal-Wallis test was used when parametric assumptions were not upheld. An alpha level of 0.05 was used for the study. Additional statistical analysis was performed to compare descriptive demographic data and baseline self-efficacy scores between participants who completed the study versus those who did not return their log. For this analysis, a Mann U Whitney test was used because parametric assumptions of the data were not upheld.

Research Question 1

What was difference in breastfeeding self-efficacy 14 days after delivery of mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery?

Hypothesis. There will be no difference in breastfeeding self-efficacy 14 days after delivery in mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery.

The breastfeeding self-efficacy score served as an interval level dependent variable with duration of manual milk expression as the independent variable. Parametric assumptions were not upheld in the data distribution; therefore a Mann-Whitney U test was conducted to examine the difference in breastfeeding self-efficacy levels between the two

groups 14 days after delivery (Hulley et al., 2007). A repeated measures ANOVA was used to assess the stratified BSES-SF score by study group at baseline and follow-up.

Research Question 2

What was the difference in the milk volume 14 days after delivery of mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery?

Hypothesis. There will be no difference in milk volumes 14 days after delivery in mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery.

Milk volume served as the interval level dependent variable with duration of milk expression as the independent variable. A Mann-Whitney U test was conducted because parametric assumptions were not upheld to examine the differences in milk volume between the two groups 14 days after delivery (Hulley et al., 2007).

A subset analysis of 13 participants with valid values for milk volume at both baseline and follow-up was conducted. In this context, valid means both an actual number (as opposed to missing/invalid) and of reasonable range (e.g., within normal limits of volume for a single pumping session). A repeated measures analysis of variance was used to assess a change in the continuous outcome variable of milk volume over time by manual expression study group.

Milk volume was also assessed statistically over time on a subset of 10 participants with valid values on each of the 14 days. A repeated measures ANOVA with a time-varying covariate was used to assess a change in milk volume over time by the manual expression group while controlling for the frequency of valid daily count sessions.

Research Question 3

What was the correlation between breastfeeding self-efficacy and milk volume in mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery?

Hypothesis. There will be a positive correlation between the level of breastfeeding self-efficacy and milk volume in mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery?

Association was measured between two interval level dependent variables, breastfeeding self-efficacy score, and milk volume. Spearman's rank correlation coefficient was conducted to assess the relationship between milk volume and breastfeeding self-efficacy 14 days after delivery because parametric assumptions were not upheld (Hulley et al., 2007).

Funding

This research was funded by the St. Louis Children's Hospital Foundation: Internal Research Grant (see Appendix L).

CHAPTER 4

RESULTS

Maternal Characteristics

The anticipated goal of 90 participants was not reached, and these results are based on an interim analysis. There were 34 participants in the study, with varying levels of data completion. The enrollment data is presented in Figure 2.1. A baseline comparison of demographic characteristics between the two study groups was conducted. There were no statistical differences on the variables of interest per study group, indicating the randomization sequence effectively reduced the risk of variation in group characteristics. A Mann-Whitney U test was used when parametric assumptions were not upheld (see Table 1.1). Categorical variables were analyzed using Chi-square statistics; Fisher's exact test were used when expected cell sizes of comparisons was too small (see Table 1.2).

An additional analysis was conducted to compare day 1 and day 14 milk volumes by binary demographic variables using a series of Mann-Whitney U tests. An analysis of variance was used to compare milk volume on day 1 and day 14 by categorical demographic variables; a non-parametric Kruskal-Wallis test was used when parametric assumptions were not upheld. A Spearman's rank correlation coefficient was computed to assess the statistical dependence between the ranking of milk volume on day 1 and day 14 with each of the continuous demographic variables, which were assumed to violate parametric assumptions of normality.

Day 1 milk volume was higher for mothers with prior experience breastfeeding (Mean= 54.6, SD 82.2) as compared to those without breastfeeding experience (Mean = 7.1, SD=11.4, U=12.5, p=0.011). This result is displayed graphically in Figure 3.1. The day 1

milk volume was higher for mothers delivering twins (Mean=41.3, SD=41.6) as compared to a singleton delivery (Mean=26.8, SD =69.3, U= 10.0, p=0.026) as displayed graphically in Figure 3.2. There was a strong positive correlation between day 1 milk volume and para, which was statistically significant ($r_s(16) = 0.714$, p=0.001). There was a moderate negative correlation between day 14 milk volume and gravida, which was statistically significant ($r_s(22) = -0.432$, p=0.035) as well as moderate negative correlation between day 14 milk volume and maternal age, which was statistically significant ($r_s(22) = -0.477$, p=0.018). No other differences in day 1 and day 14 milk volumes were detected for the remaining variables of recruitment location, maternal race, mode of delivery, premature history, education, mother's diagnosis, or marital status.

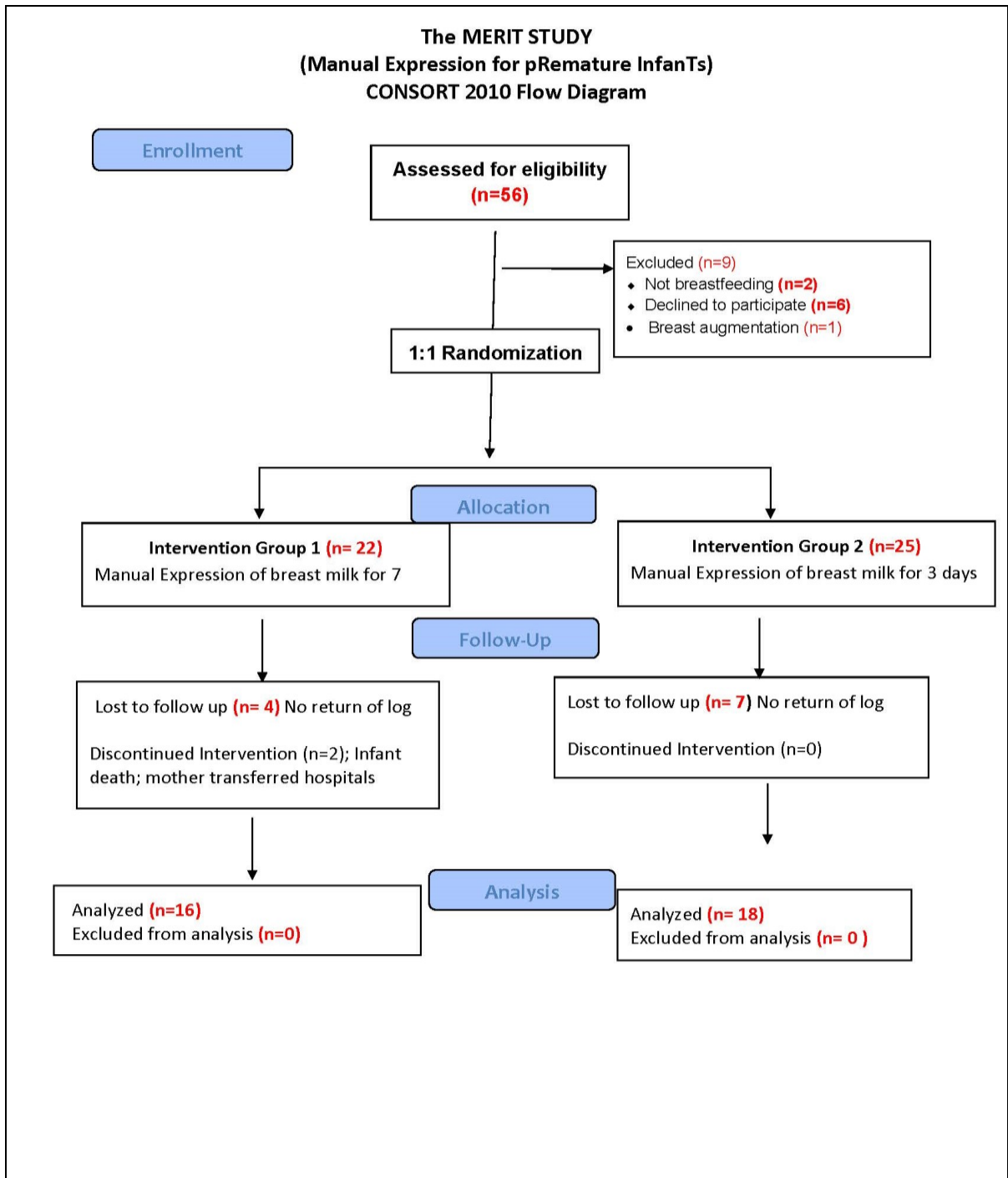


Figure 2.1. Enrollment Data for MERIT study using Consort Guidelines (Moher, D., Hopewell, S., Schulz, K.F, Montori, V., Gøtzsche, P.C., Devereaux, P.J., Elbourne, D., Egger, M., Altman, D.G. [2010]. CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. *Journal of Clinical Epidemiology*, 63(8), e1-e37).

Table 1.1

Descriptive-Ordinal Variables of Demographic Data (N=34) ^a

| Variable | 3 Day Group (n= 18) | | 7 Day Group (n=16) | | Difference | | |
|-------------------------|---------------------|-----|--------------------|-----|------------|-------|----------------------|
| | Mean | SD | Mean | SD | Mean | U | p-value ^b |
| Maternal Age (years) | 31.4 | 6.4 | 30.1 | 6.3 | - 1.3 | 125.0 | 0.528 |
| Gestational Age (weeks) | 31.9 | 1.8 | 31.4 | 3.0 | - 0.5 | 143.5 | 0.986 |
| Gravida | 2.7 | 1.3 | 3.7 | 2.7 | 1.0 | 125.0 | 0.528 |
| Para | 2.3 | 1.1 | 2.4 | 1.7 | 0.2 | 137.0 | 0.825 |
| 4 PBD (months) | 3.5 | 6.3 | 4.6 | 8.1 | 1.1 | 131.0 | 0.901 |

Note: PBD = Prior Breastfeeding Duration^a Ordinal demographic statistics between 3-day and 7-day group were not statistically significant ($p > 0.05$)^b Mann-Whitney U

Table 1.2

Descriptive – Categorical Variables of Demographic Data (N=34) ^a

| Variable | 3 Day Group (n= 18) | | 7 Day Group (n=16) | | | Difference | |
|------------------------|---------------------|------|--------------------|------|-------|------------|--------------------|
| | n | % | n | % | % | Chi-Square | p-value |
| Recruitment Location | | | | | | 0.017 | 0.897 |
| Antepartum | 12 | 66.7 | 11 | 68.8 | 2.1 | | |
| Postpartum | 6 | 33.3 | 5 | 31.3 | - 2.0 | | |
| Birth weight of infant | | | | | | 0.424 | 0.515 |
| ≤ 1500 grams | 7 | 38.9 | 8 | 50.0 | 11.1 | | |
| > 1500 grams | 11 | 61.1 | 8 | 50.0 | -11.1 | | |
| 43 Maternal Race | | | | | | | 0.487 ^b |
| White | 11 | 61.1 | 8 | 50.0 | -11.1 | | |
| African American | 6 | 33.3 | 8 | 50.0 | 16.7 | | |
| Hispanic | 1 | 5.6 | 0 | 0.0 | -5.6 | | |
| Mode of Delivery | | | | | | | 0.125 ^b |
| Vaginal | 7 | 38.9 | 2 | 12.5 | -26.4 | | |
| Cesarean | 11 | 61.1 | 14 | 87.5 | 26.4 | | |
| Previous Breastfeeding | | | | | | 0.472 | 0.492 |
| Yes | 10 | 55.6 | 7 | 43.8 | -11.8 | | |
| No | 8 | 44.4 | 9 | 56.3 | 11.9 | | |

Table continues

| Variable | 3 Day Group (n= 18) | | 7 Day Group (n=16) | | | Difference | |
|--------------------|---------------------|------|--------------------|------|-------|------------|---------|
| | n | % | n | % | % | Chi-Square | p-value |
| Premature History | | | | | | 1.794 | 0.180 |
| Yes | 4 | 22.2 | 7 | 43.8 | 21.6 | | |
| No | 14 | 77.8 | 9 | 56.3 | -21.5 | | |
| Education | | | | | | 9.515 | 0.218 |
| Grade School | 0 | 0.0 | 4 | 25.0 | 25.0 | | |
| High School/GED | 6 | 33.3 | 4 | 25.0 | - 8.3 | | |
| Some College | 2 | 11.1 | 3 | 18.8 | 7.7 | | |
| Technical Degree | 2 | 11.1 | 0 | 0.0 | -11.1 | | |
| Associates | 1 | 5.6 | 1 | 6.3 | 0.7 | | |
| Bachelors | 4 | 22.2 | 2 | 12.5 | -9.7 | | |
| Masters Degree | 1 | 5.6 | 2 | 12.5 | 6.9 | | |
| Doctorate | 2 | 11.1 | 0 | 0.0 | -11.1 | | |
| Mother's Diagnosis | | | | | | 3.201 | 0.363 |
| PROM | 7 | 38.9 | 10 | 62.5 | 23.6 | | |
| AEDF | 4 | 22.2 | 2 | 12.5 | -9.7 | | |
| Pre-Eclampsia | 5 | 27.8 | 4 | 25.0 | -2.8 | | |
| Preterm Labor | 2 | 11.1 | 0 | 0.0 | -11.1 | | |

Table continues

| Variable | 3 Day Group (n= 18) | | 7 Day Group (n=16) | | Difference | |
|-------------------------|---------------------|------|--------------------|------|------------|--------------------|
| | n | % | n | % | % | Chi-Square p-value |
| Mother's Marital Status | | | | | | 1.186 0.553 |
| Single | 3 | 16.7 | 3 | 18.8 | 2.1 | |
| Married | 12 | 66.7 | 8 | 50.0 | - 16.7 | |
| Cohabiting | 3 | 16.7 | 5 | 31.3 | 14.6 | |
| Multiplicity | | | | | | 0.999 ^b |
| Singleton | 14 | 77.8 | 12 | 75.0 | - 2.8 | |
| Twin | 4 | 22.2 | 4 | 25.0 | 2.8 | |

Note: PROM= Premature Rupture of Membranes; AEDF= Absent End Diastolic Flow

^a Categorical demographic statistics between 3-day and 7-day group were not statistically significant ($p > 0.05$)

^b Fisher's Exact Test

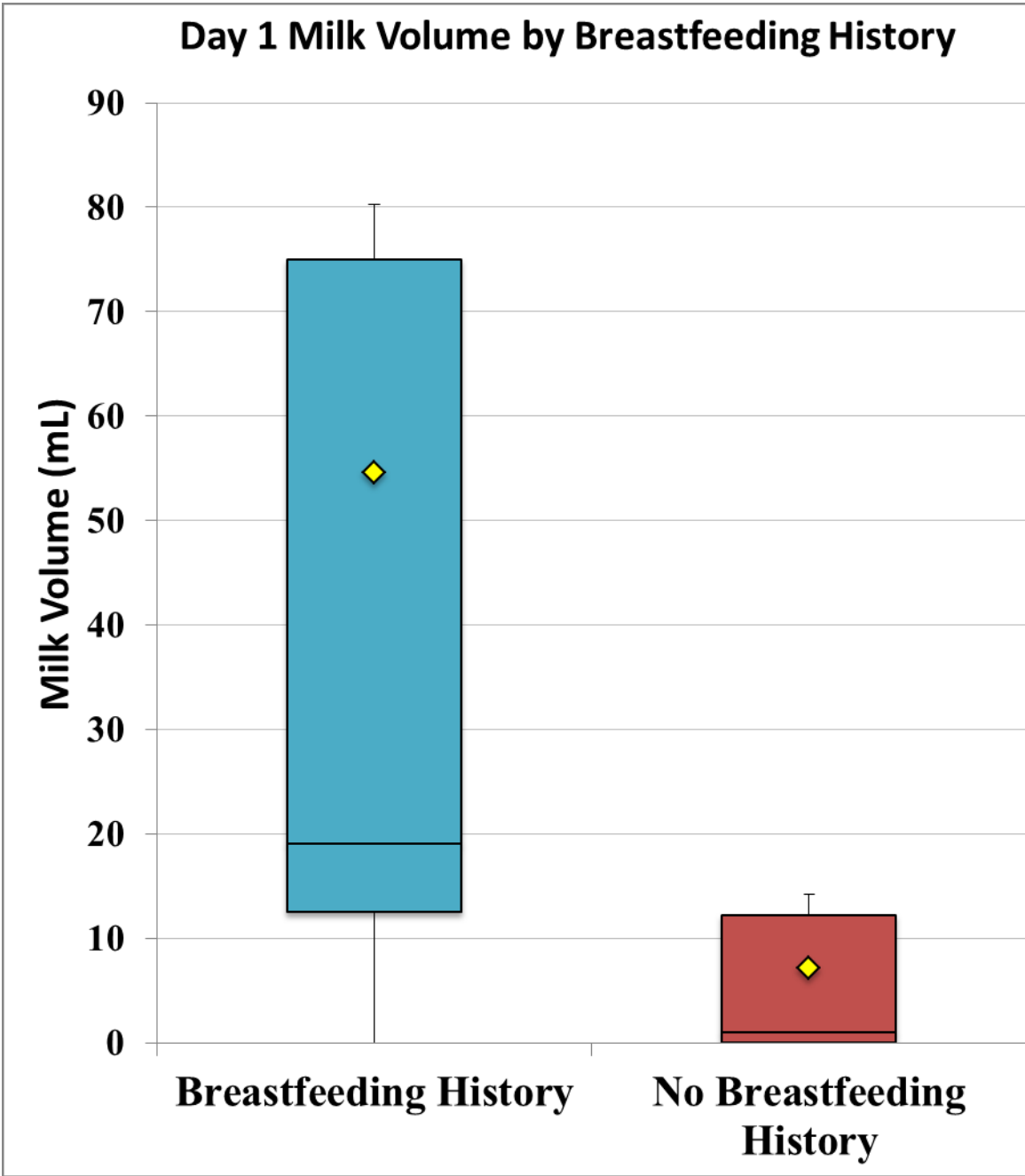


Figure 3.1. Mean day 1 Milk Volumes for Participants with Prior Breastfeeding Experience as Compared to No Experience.

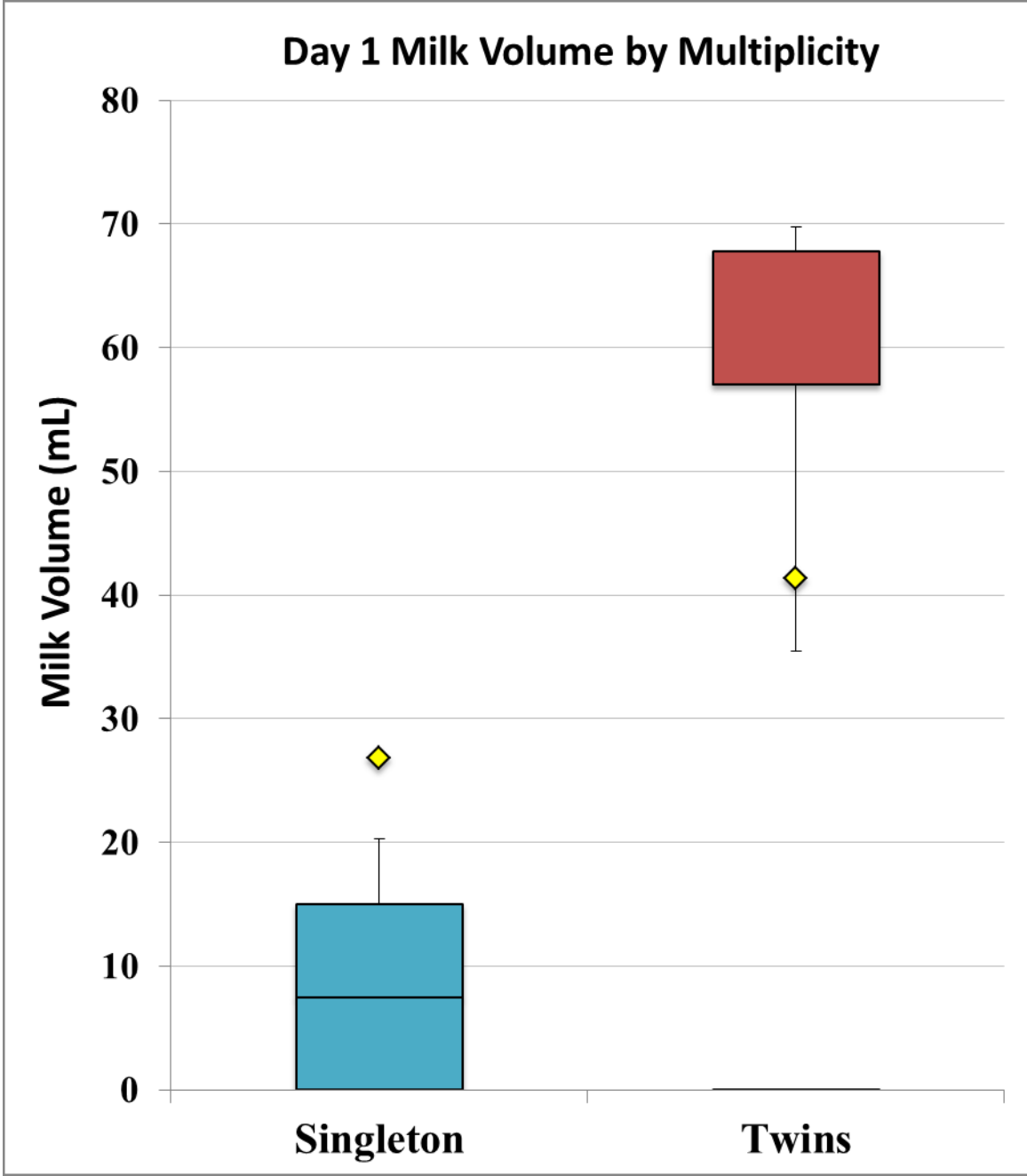


Figure 3.2. Mean Day 1 Milk Volume for Delivery of Singleton versus Twin Birth.

Maternal Characteristics by Completion Status

In the present study 47 women were enrolled in the study, but 11 of these women did not complete the study as evidenced by a failure to return a study log. This resulted in an attrition rate of 24%. Demographic and clinical summary statistics by study completion or attrition status are reported in Table 2.1. Only mother's marital status differed by completion or attrition status, with more married participants completing the study ($X^2 = 8.576$, $p = 0.035$). All other study variables were not statistically different ($p < 0.05$).

Table 2.1

Demographic and Clinical Summaries by Study Completion or Attrition Status (n=45)

| Variable | Completed (n = 34) | | Attrition (n = 11) | | Difference ^a | | |
|-------------------------|--------------------|------|--------------------|------|-------------------------|-------|---------|
| | Mean | SD | Mean | SD | Mean | U | p-value |
| Maternal Age (years) | 30.8 | 6.3 | 31.4 | 6.3 | 0.6 | 163.0 | 0.540 |
| Gestational Age (weeks) | 31.7 | 2.4 | 30.7 | 3.4 | - 0.9 | 161.0 | 0.506 |
| Gravida | 3.2 | 2.1 | 3.1 | 1.4 | - 0.1 | 172.0 | 0.706 |
| Para | 2.4 | 1.4 | 2.8 | 1.4 | 0.5 | 147.0 | .302 |
| PBD (months) | 4.0 | 7.1 | 6.4 | 11.7 | 2.4 | 169.0 | 0.749 |
| Baseline BSES-SF Score | 68.8 | 18.1 | 68.9 | 16.5 | -0.2 | 184.5 | 0.948 |

| Variable | Completed | | Attrition | | Difference | | |
|------------------------|-----------|------|-----------|------|------------|------------|--------------------|
| | n | % | n | % | % | Chi-square | p-value |
| Intervention | | | | | | | 0.729 ^b |
| 3 Days | 18 | 52.9 | 7 | 63.6 | 10.7 | | |
| 7 Days | 16 | 47.1 | 4 | 36.4 | - 10.7 | | |
| Recruitment Location | | | | | | | 0.284 ^b |
| Antepartum | 23 | 67.6 | 5 | 45.5 | - 22.1 | | |
| Postpartum | 11 | 32.4 | 6 | 54.5 | 22.1 | | |
| Birth weight of infant | | | | | | | 0.736 ^b |
| ≤ 1500 grams | 15 | 44.4 | 4 | 36.4 | - 8.0 | | |
| > 1500 grams | 19 | 55.9 | 7 | 63.6 | 7.7 | | |
| Maternal Race | | | | | | | 0.473 ^b |
| White | 19 | 55.9 | 4 | 36.4 | - 19.5 | | |
| African American | 14 | 41.2 | 7 | 63.6 | 22.4 | | |
| Hispanic | 1 | 2.9 | 0 | 0.0 | - 2.9 | | |

Note: PBD= Prior Breastfeeding Duration

^a Mann-Whitney U Test

^b Fisher's Exact Test

Table continues

| Variable | Completed | | Attrition | | % | Difference | |
|------------------------|-----------|------|-----------|------|-------|------------|--------------------|
| | n | % | n | % | | Chi-square | p-value |
| Mode of Delivery | | | | | | | 0.705 ^b |
| Vaginal | 9 | 26.5 | 2 | 18.2 | - 8.3 | | |
| Cesarean | 25 | 73.5 | 9 | 81.8 | 8.3 | | |
| Previous Breastfeeding | | | | | | 0.069 | 0.793 |
| Yes | 17 | 50.0 | 5 | 45.5 | - 4.5 | | |
| No | 17 | 50.0 | 6 | 54.5 | 4.5 | | |
| Premature History | | | | | | | 0.467 ^b |
| Yes | 11 | 32.4 | 2 | 18.2 | -14.2 | | |
| No | 23 | 67.6 | 9 | 81.8 | 14.2 | | |
| Education | | | | | | 4.937 | 0.668 |
| Grade School | 4 | 11.8 | 1 | 9.1 | - 2.7 | | |
| High School / GED | 10 | 29.4 | 3 | 27.3 | - 2.1 | | |
| Some College | 5 | 14.7 | 3 | 27.3 | 12.6 | | |
| Technical Degree | 2 | 5.9 | 1 | 9.1 | 3.2 | | |
| Associates | 2 | 5.9 | 2 | 18.2 | 12.3 | | |
| Bachelors | 6 | 17.6 | 0 | 0.0 | -17.6 | | |
| Masters | 3 | 8.8 | 1 | 9.1 | 0.3 | | |
| Doctorate | 2 | 5.9 | 0 | 0.0 | -5.9 | | |

^b Fisher's Exact Test

Table continues

| Variable | Completed | | Attrition | | % | Difference | |
|-------------------------|-----------|------|-----------|------|--------|------------|--------------------|
| | n | % | n | % | | Chi-square | p-value |
| Mother's Diagnosis | | | | | | 7.163 | 0.128 |
| PROM | 17 | 50.0 | 4 | 36.4 | -13.6 | | |
| AEDF | 6 | 17.6 | 2 | 18.2 | 0.6 | | |
| Pre-eclampsia | 9 | 26.5 | 3 | 27.3 | 0.8 | | |
| Preterm Labor | 2 | 5.9 | 0 | 0.0 | - 5.9 | | |
| Abruptio/Other | 0 | 0.0 | 2 | 18.2 | 18.2 | | |
| Mother's Marital Status | | | | | | 8.576 | 0.035 * |
| Single | 6 | 17.6 | 5 | 45.5 | 27.9 | | |
| Married | 20 | 58.8 | 2 | 18.2 | - 40.6 | | |
| Cohabiting | 8 | 23.5 | 3 | 27.3 | 3.8 | | |
| Divorced | 0 | 0 | 1 | 9.1 | 9.1 | | |
| Multiplicity | | | | | | | 0.416 ^b |
| Singleton | 26 | 76.5 | 10 | 90.9 | 14.4 | | |
| Twin | 8 | 23.5 | 1 | 9.1 | -14.4 | | |

Note: PROM= Premature Rupture of Membranes; AEDF= Absent End Diastolic Flow

* Married mothers were statistically more likely to have completed the study (p < 0.05)

^b Fisher's Exact Test

Specific Aim One

Specific Aim One was to determine if the duration of manual expression in mothers of premature infants will result in an increase in breastfeeding self-efficacy.

Research Question 1

What is the difference in breastfeeding self-efficacy 14 days after delivery of mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery?

Hypothesis. There will be no difference in breastfeeding self-efficacy 14 days after delivery in mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery.

A Mann-Whitney U test was used to compare baseline and follow-up BSES-SF per study group as parametric assumptions were not upheld. Overall BSES-SF score at baseline and follow-up is displayed graphically in Figure 4.1. The mean score between baseline and follow-up increased from 68.1 to 78.3; the median increased from 68.5 to 83.0. The baseline BSES-SF score did not differ by manual expression group for the 7-day group (Mean= 72.3, SD=15.4) as compared to the 3-day group (Mean= 65.7, SD =20.1 ,U= 122.5, $p=0.458$) Follow-up BSES-SF score did not differ by manual expression group for the 7-day group (Mean=80.3, SD=9.3) as compared to the 3-day group (Mean=76.5, SD=14.7, U=90.5, $p=0.751$).

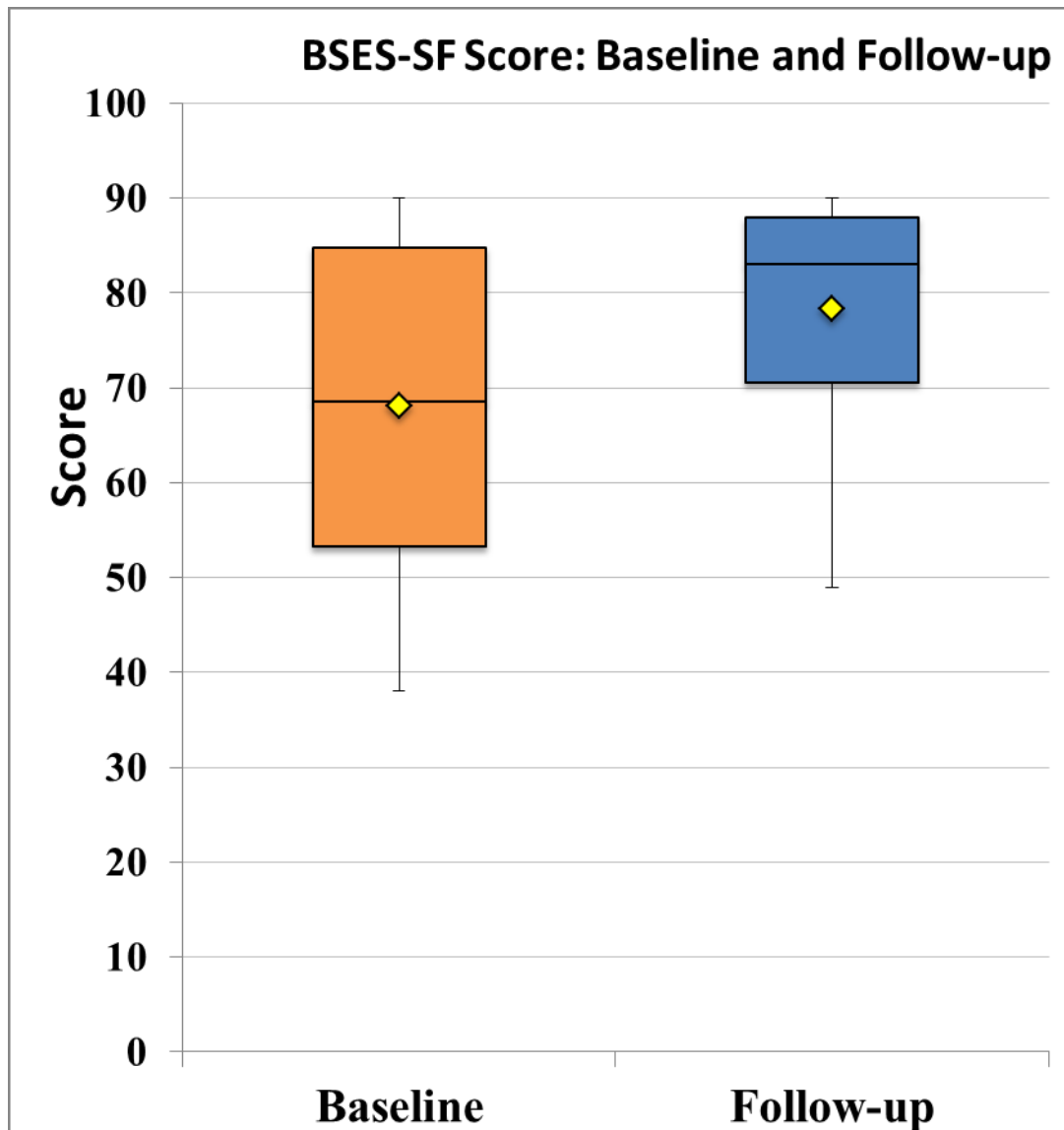


Figure 4.1. Overall BSES-SF Score at Baseline and Follow-up by Duration of Manual Expression Study Group (N = 34).

A repeated measures ANOVA was used to assess the stratified BSES-SF score by study group and baseline and follow-up. These results are displayed graphically in Figure 4.2. The mean score of the 3-day group between baseline and follow-up increased by 10.8 from 65.7 to 76.5; mean score of the 7-day group increased by 8.1 from 72.3 to 80.3.

Though there was a highly statistically significant change in score over time ($F=12.385$, $p=0.002$), that change was not altered by study group ($F=0.225$, $p=0.639$).

In summary, all the mothers in the study had a statistically significant increase in breast-feeding self-efficacy over time, although this did not differ by study group. In this case, the null hypothesis was upheld. There was no difference in self-efficacy levels for those mothers who performed manual expression for 3 days as compared to 7 days.

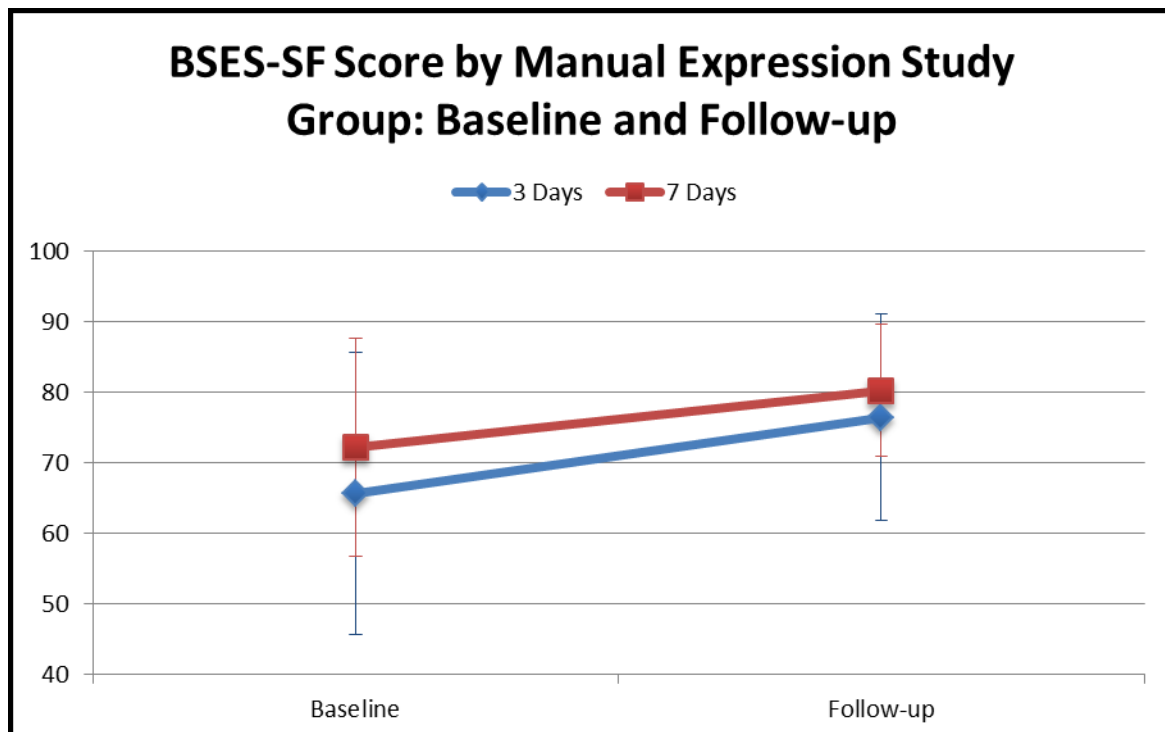


Figure 4.2. Mean Baseline and Follow-up BSES-SF per Study Group. Baseline (n=34); Follow-up (n= 28).

Specific Aim Two

Specific Aim Two was to determine if the duration of manual expression in mothers of premature infants will result a difference in milk volume.

Research Question 2

What is the difference in the milk volume 14 days after delivery of mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery?

Hypothesis. There will be no difference in milk volumes 14 days after delivery in mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery.

A Mann-Whitney U test was performed to assess differences in milk volume between the 7-day and 3-day group. These results are displayed in Figure 5.1. Milk volume did not differ by manual expression at follow-up for the 7 day group (Mean=700.0, SD=550.0) as compared to the 3-day group (Mean=582.7, SD=331.2, $U=62.0$, $p=0.770$). To address research question two, no statistically significant difference in milk volumes at 14 days was detected between mothers of premature infants who manually expressed for seven days as compared to three days. The null hypothesis was upheld.

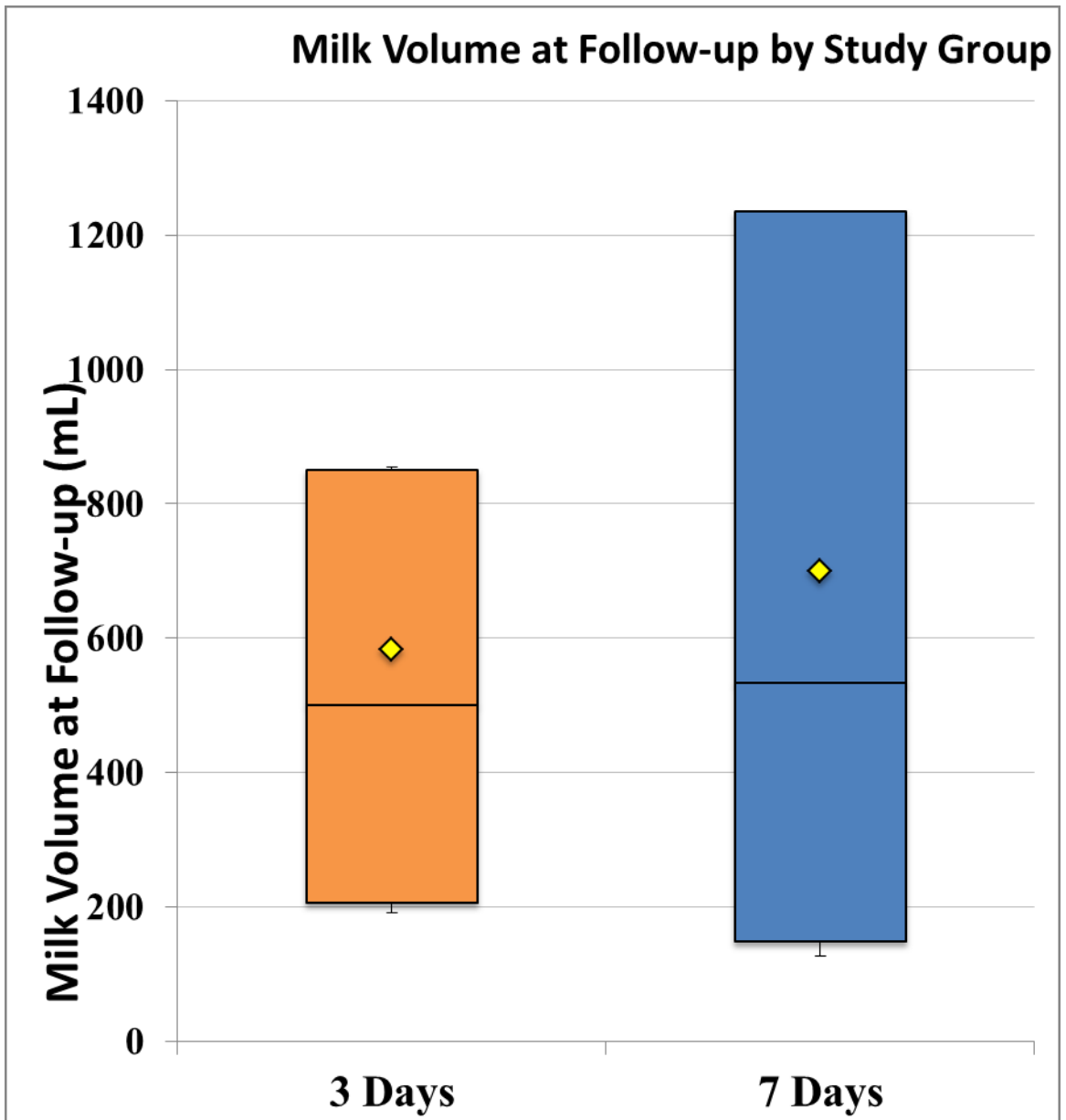


Figure 5.1. Milk Volume at 14 Days after Delivery for Mothers Who Manually Expressed for Seven Days as Compared to Three Days.

A subset analysis of 13 participants with valid values for milk volume at both baseline and follow-up was conducted, as displayed in Figure 5.2. In this context, valid means both an actual number (as opposed to missing/invalid) and of reasonable range (e.g., within normal limits of volume for a single pumping session). A repeated measures analysis of variance was used to assess a change in the continuous outcome variable of milk volume over time by manual expression study group. Milk volume did statistically increase between baseline and follow-up ($F=25.009, p < 0.001$) but did not differ by study group in their change over time ($F= 1.001, p=0.339$).

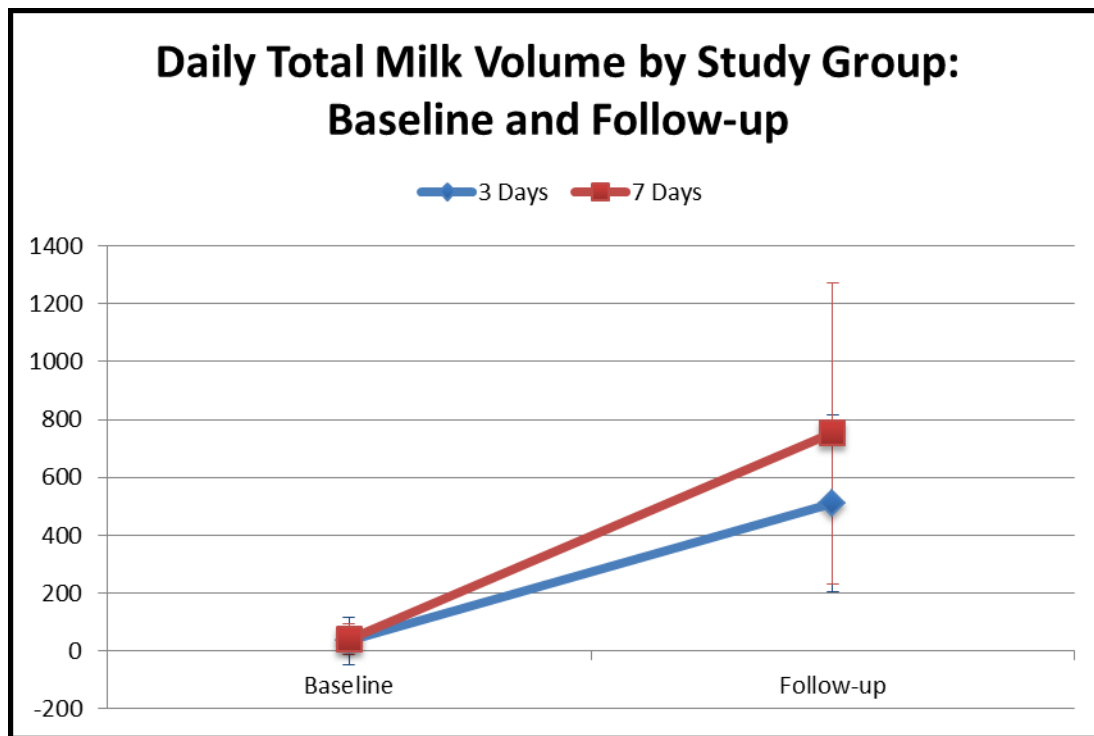


Figure 5.2. Daily Total Milk Volume at Baseline and Follow-up (n=4 in the 7 day group; n=9 in the 3-day group).

Milk volume was also assessed statistically over time on a subset of 10 participants with valid values on each of 14 days. Milk volume did statistically increase over time ($F=4.976$, $p=0.017$), but did not differ per study group in their change over time ($F=0.185$, $p=0.999$) and was not impacted by the frequency of valid daily count of sessions ($F=1.973$, $p=0.161$). These results are displayed graphically in Figure 5.3.

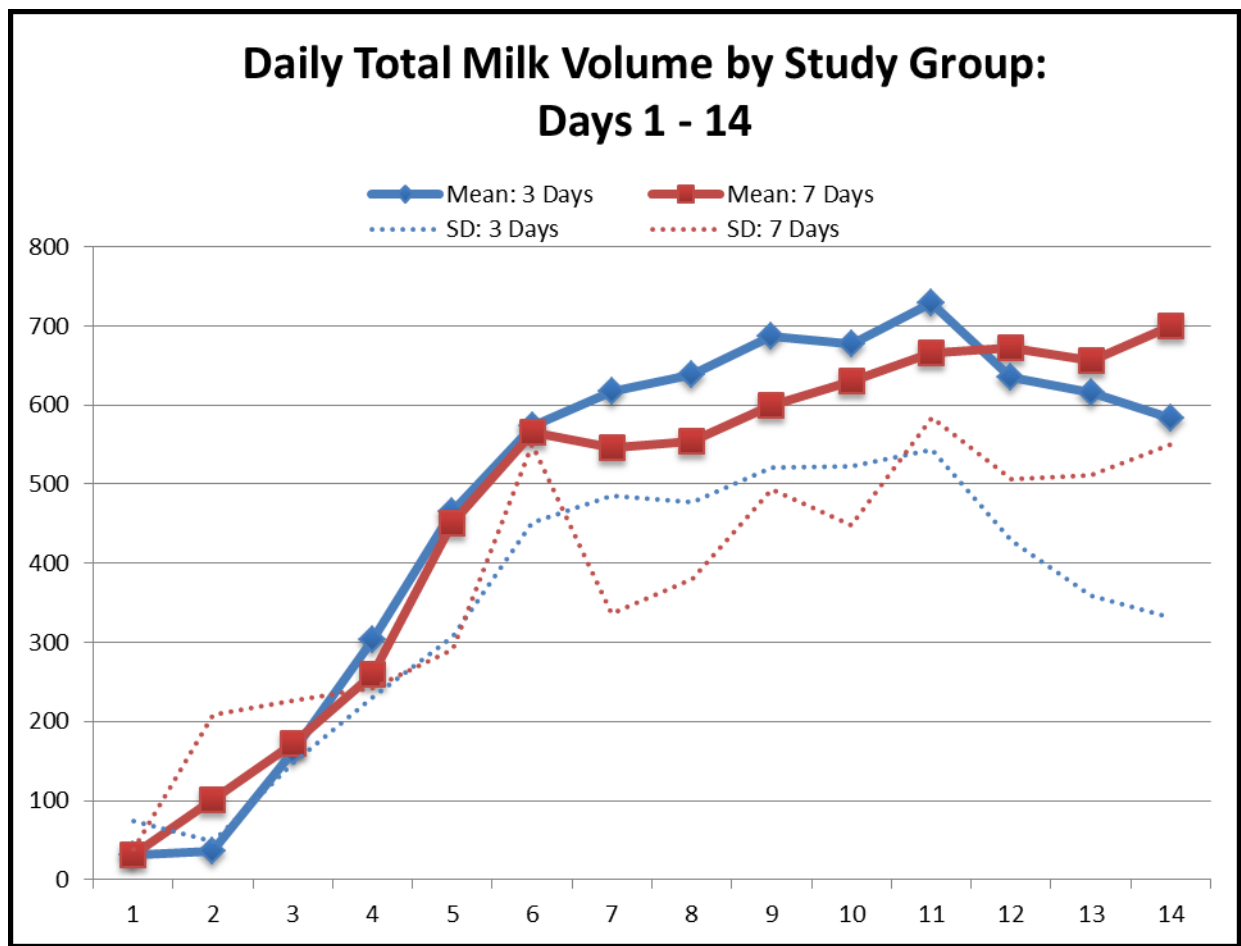


Figure 5.3. Daily Total Milk Volume from Baseline to 14 Days with Time as a Covariate for Participants in the 7-day Study Group (n=4) as Compared to the 3-day Study Group (n= 6)

Specific Aim Three

Specific Aim Three was to determine if the duration of manual expression in mothers of premature infants will result in a correlation between breastfeeding self-efficacy and milk volume.

Research Question 3

What is the correlation between breastfeeding self-efficacy and milk volume in mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery?

Hypothesis. There will be a positive correlation between the level of breastfeeding self-efficacy and milk volume in mothers of premature infants who perform manual expression prior to electric pump expression for seven days after delivery as compared to three days after delivery.

A Spearman's rank correlation coefficient was computed to assess the statistical relationship between the day 14 ranking of total milk volume and day 14 BSES-SF score by the study group, which assumed to violate parametric assumptions of normality. The association for the 7-day group was not found to be statistically correlated ($r = 0.084$, $p = 0.757$); no statistically significant correlation was found for the 3 day group ($r = 0.069$, $p = 0.784$). To address research question number three, no statistical correlation was detected between the level of breastfeeding self-efficacy and milk volume in mothers of premature infants who performed manual expression for seven days as compared to three days after delivery. The original hypothesis was not upheld, and the null hypothesis was rejected.

CHAPTER 5

DISCUSSION

Findings from this study have important clinical and research implications for nurses caring for mothers of premature infants who intend to breastfeed. This is the first study to examine the optimal number of days to perform manual expression in combination with electric pump expression after the delivery of a premature infant. This study also reinforces that mothers who are pump dependent after delivery can perform manual expression for a prescribed number of days after delivery.

Specific Aim One

Duration of Manual Expression and Self-efficacy

Findings from this study suggest that while self-efficacy levels did improve from baseline to 14 days for the mothers, there were no differences based on the duration of manual expression, 3 days versus 7 days. These results are similar to a previous study that employed manual and electric pump expression as a sole intervention (Flaherman et al., 2012). In this study, self-efficacy was measured at one point in time after the mother was instructed to either manually express or pump express, and there were no differences found between the two groups (Flaherman et al., 2012). However, the infants were full-term, able to latch to the mother's breast intermittently, and were not required by the study protocol to continue the instructed method for subsequent sessions. For these reasons, it may be that the intervention was too short to affect the mother's self-efficacy. In addition, these mothers were enrolled 12-36 hours after birth when the infants were already determined to be feeding poorly, and this may have also affected the mother's baseline level of self-efficacy.

Conversely, the present study sought premature infants who were unable to latch as the sample of interest in order for the participants to remain pump dependent for at least 14 days in order to measure baseline and self-efficacy levels after a prescribed intervention.

The interventions employed in the present study were directly informed by previous research, which sought to explain the efficacy-enhancing experiences on breastfeeding self-efficacy. Previous qualitative research found vicarious experience (seeing other mothers breastfeed) contributed to self-efficacy and sustained breastfeeding (Kingston et al., 2007). Specifically, woman who had viewed audiovisual tapes of women performing breastfeeding had higher levels of self-efficacy than those who did not (Kingston et al., 2007). In the present study, audiovisual demonstration of manual expression of breast milk was employed as a specific study intervention and may have explained the increase in self-efficacy rates from baseline to 14 days but could not be explained by duration of manual expression.

Previous research incorporating breastfeeding self-efficacy has examined the association between level of breastfeeding self-efficacy and breastfeeding sustainment. (Blyth et al., 2002; Loke & Chan; 2013). However, no studies reviewed examined baseline levels and attempted to establish a change in self-efficacy over time after a specific intervention. This is the first study to examine duration of manual expression as the independent variable with level of self-efficacy as the dependent variable, and while the results are not statistically significant, this remains a novel approach to exploring the impact of specific interventions to increase breastfeeding self-efficacy over time.

Comparison of BSES-SF scores. The BSES-SF is an 18-item questionnaire with scores ranging from 18 to 90, with higher scores representing higher levels of self-efficacy.

The current study found the range of the scores at baseline to range from 32 to 90 and at 14 days to range from 49 to 90. The mean scores for the 3-day (Mean=65.7) and the 7-day group (Mean=72.3) were similar at baseline. These were also similar at 14 days with the 3-day group (Mean=76.5) and the 7-day group (Mean=80.3). Previous research in mothers of premature infants revealed similar mean scores. Wheeler and Dennis (2013) analyzed the one-week post-partum BSES-SF scores of mothers of premature infants and reported a mean of 79.39, which is 88% of the maximum score of 90. The means reported in the premature population were much higher than means reported with mothers of full-term infants. A sample of 63 full-term mothers who were exclusively breastfeeding were assessed within 48 hours post-partum and four weeks after delivery. The baseline mean scores were 50.94 at baseline and 62.2 at follow-up (Kingston et al., 2007). The difference in these two populations could be examined more closely with further research assessing the reasons why there are differences .

Specific Aim Two

Duration of Manual Expression and Milk Volume

This is the first study to examine differences in milk volume based on days of manual expression employed in combination with electric pump expression. Several studies have examined the effect of hand expression on milk volume, but most were using manual expression as a sole intervention (Flaherman, et al., 2012, Ohyama et al., 2010; Slusher et al., 2007). Slusher et al. studied the mothers of premature infants in an African nursery, the methods compared manual, electric, and pedal pump interventions on milk volume. The electric pump produced significantly higher milk volumes than hand expression alone over

an average of eight days following delivery. Similarly, Ohyama et al. studied mothers of premature infants in a Japanese Neonatal Intensive Care Unit. In that study, manual expression and electric pump were employed in a sequential crossover design. Results revealed a significant increase in milk volume with hand expression over electric pump expression, but mothers were assessed for only 48 hours after birth. Flaherman et al. also conducted a study randomizing mothers of full-term infants who were feeding poorly to either manual or electric pump expression for 12 to 36 hours after birth. Although there were no statistically significant differences in milk volume between groups, mothers who were taught manual expression were more likely to be breastfeeding at two months ($p=0.02$). All of these studies offered insight into the role of manual expression early after delivery but did not establish the duration of manual expression over a prescribed period of time. All studies employed manual expression as a sole intervention. Based on this earlier research, lactation practices have changed, and a combination of hand expression and electric expression for each pump session is now the standard of care. All of these studies assessed milk volume over a relatively short period of time. The present study evaluated milk volume over a two-week period.

One study used a combination of manual and pump expression as the main study intervention. Morton et al. (2009) conducted a prospective observational study of milk volumes in mothers of premature infants for eight weeks after delivery. In the study mothers were instructed to perform manual expression as much as possible in the first three days after delivery along with electric pumping eight times per day. The study results showed a significant increase in milk volume over the first two weeks for those mothers that manually

expressed greater than five times per day. This study informed the present study by establishing the importance of hand expression frequency as a potential confounder and established the present study to exclude women who failed to pump at least four times per day. In addition, the videotape instruction used in the present study was created by the principal investigator, Dr. Morton (Morton, 2009). While this study laid the groundwork for manual expression in combination with electric pump, it assessed only hand expression for three days after delivery. The present study attempted to compare three versus seven days of manual expression to allow for the variability of full milk production (lactogenesis II) among women after delivery.

The present study is the only study that examined duration of manual expression (three days versus seven days) and milk volume at 14 days. Although the present study failed to reach statistical significant differences in milk volume, when a subset of 12 participants were analyzed with valid values at baseline and at 14 days, milk volume did statistically increase over time ($p=0.001$) but did not differ by study group ($p = 0.339$). However, the mean difference in volumes, although not yet statistically significant, is trending toward higher volumes in the 7-day group. The mean volumes are also clinically meaningful (mean volume of 7-day group 751.8 versus 438.6 in the 3-day group). In the clinical setting, based on a 1.8 kg birth weight, even if the infant is advancing well on feedings, the maximum amount of milk needed on day 14 would be 150 mL/kg. This equates to a volume of 270 mL per day. For these reasons, the change in mean milk volume is clinically meaningful. A further subset of 10 patients with valid values on each of the 14 days did have significant increases of breast milk over time ($p=0.044$) although no

differences were found between groups. These findings will be important as the study continues and higher sample sizes and adequate power are achieved. The population demographics of this study is unique, in that approximately 40% of the participants were African American, as compared to the U.S. average of 12.2% (U.S. Census Bureau, 2015). This is particularly important because previous research has suggested that minority populations are much more at risk for early breastfeeding discontinuation as compared to Whites (Flacking et al., 2007; Furman et al., 2002; Lessen & Crivelli-Kovach, 2007). The two studies analyzed from the U.S. were samples of predominantly white, upper middle class women (Flaherman, et al., 2012; Morton et al., 2009).

Comparisons of milk volumes. The current study analyzed the 14-day milk volumes of mothers of premature infants who used a combination of manual and electric pump expression at least four times per day. The mean milk volumes for the 3-day group (Mean= 582.7, SD =331.2) and the 7-day group (Mean= 700.0, SD=550.0) were similar to previous studies. Morton et al. (2009), in a sample of 63 mothers of premature infants combining hand and electric pump expression for at least five sessions per day, reported a 14-day mean milk volume of 780, SD= 496. Interestingly, however, in Morton's study, these reported 14-day volumes were much lower with less than five pumping sessions per day (Mean= 488, SD= 352). The results of this aforementioned study assisted to inform the current study to control for frequency of pumping sessions. The final analysis of this study will be enhanced by stratifying mothers into low, medium, or high pumpers based on the number of sessions completed per day.

Specific Aim Three

Correlation of Milk Volume and Self-efficacy

Previous studies have found a positive correlation with milk volume and levels of breastfeeding self-efficacy (Blyth et al. 2002, Dennis, 2006; Swanson et al., 2012). When mothers of premature infants were interviewed they describe how providing breast milk could either be a positive or a negative experience depending on the ability to provide sufficient milk volume (Swanson et al., 2012). This would seem consistent with one of the main efficacy expectations of self-efficacy theory being performance accomplishments (Bandura, 1977). Further empirical evidence supports that the number one reason for breastfeeding discontinuation was insufficient milk supply and breastfeeding self-efficacy scores are directly related to breastfeeding outcomes (Blyth et al., 2002). In the present study no correlation was found between breastfeeding self-efficacy scores and milk volume. This may be interpreted by the fact that the mothers in the study who returned study logs after 14 days were more likely to be meeting their breastfeeding goals. There was a relatively high rate of attrition among the mothers enrolled in the study and those mothers failed to return a 14 day log. Unfortunately we were unable to measure how self-efficacy levels may have compared in the participants who may not have achieved their breastfeeding goals. However, for both groups in the study, the baseline to 14 day self-efficacy scores increased and were highly statistically significant ($p=0.002$). This may be due to the self-efficacy interventions that were part of the study design for both groups. This included daily recording of milk volumes to support performance accomplishments, videotape of manual expression technique and instruction on anatomical model to support vicarious experience,

encouragement and support for the decision to breastfeed as part of verbal persuasion, and the suggestion to visualize their baby during pumping sessions as a part of emotional arousal. Perhaps the study interventions based on self-efficacy theory could account for the increase in self-efficacy over time more than milk volume or duration of manual expression. In addition, there may have been a bias of those mothers with lower levels of breastfeeding self-efficacy failing to return logs due to low milk volume and the inability to meet their breastfeeding goals.

Conclusion

This is the first study that examines the duration of manual expression and the effect on milk volumes and breastfeeding self-efficacy in mothers of premature infants. This study demonstrates that mothers can be taught hand expression and perform the technique for a prescribed number of days. Although statistically significant differences were not found between study groups in regard to milk volume, there is a trend toward increased milk volume that is clinically meaningful in the seven day expression group. The lack of statistical significance may be a factor of small sample size and establishes the need to continue recruitment in this study until adequate power is achieved. Although no differences were found in groups related to self-efficacy, all mothers in the study achieved statistically significant differences in their self-efficacy scores from baseline to 14 days. This may imply that the study interventions that were based upon self-efficacy theory allowed the mothers who returned their logs to achieve their breastfeeding goals. In addition, all mothers in the study did achieve significantly higher milk volumes from baseline until 14 days; there were just no differences noted based on the duration of manual expression.

Limitations

There are several limitations to this study. First, the sample size of 34 does not achieve the power needed to obtain statistically significant results. The goal for this study was to enroll 90 mothers to detect differences at 80 percent power and an effect size of 0.6. At this time, that goal has not been achieved and is the basis for ongoing recruitment into the study. If the study is underpowered, there is a risk to making a Type 1 error and assuming there is a difference when in fact the null hypothesis is true.

The second major limitation in this study is subject attrition. This can be a threat to both the internal and external validity of the study. This study reports an attrition rate of 23 percent which is similar to rates reported by previous studies using similar data collection methods of self-report with breastfeeding mothers (Flaherman et al., 2012; Morton et al., 2009). The internal validity is affected because we are unsure if the mothers who failed to return logs may have not achieved their breastfeeding goals. This is a potential bias in that only women obtaining positive results would return logs. Although, this may not affect the central research question of the duration of expression on milk volume, it could affect the levels of breastfeeding self-efficacy. However, group characteristics were measured between the completed and attrition groups to counteract the effect on external validity. The only significant difference found was the mothers who completed the study were more likely to be married. This is consistent with what we know from previous research that mothers who meet their breastfeeding goals are more likely to be married and that is speculated to be a factor based upon spousal support of the breastfeeding experience (Flacking et al., 2007;

Furman et al., 2002; Lessen & Crivelli-Kovach, 2007). The study, moving forward, could be strengthened by surveying the women for reasons why they did not return their logs.

Self-report measures are also a cited weakness within research design. Although practical, self-report has implicit bias and increases the burden of the research to the participant. Self-report measures depend on the willingness of the respondent to be truthful and can be invalid or unreliable (Polit & Beck, 2012). The self-report measure may have been a factor in attrition as mothers may have been more unwilling to return a log with low milk volumes. In addition, the women who did not return logs may have stopped pumping before 14 days.

An additional limitation was study recruitment occurred in two different units in the hospital. Although study location did not differ between the groups, mothers who received the study interventions in the antepartum unit may have been more receptive to the education and had more time to learn the breastfeeding techniques. Mothers who were recruited post-partum (within 24 hours after delivery) were often feeling ill or in pain and may not have been as receptive to the education provided. The mothers in this study were only followed for 14 days after delivery and the infants would have variations in length of stay based upon gestational age at birth. The study intervention, therefore, can only measure the effect of the intervention on milk volume and self-efficacy for a relatively short period of time. There was no measure to assess long-term effect of the study intervention on sustained breastfeeding.

Recommendations for Future Research

Although this research has several limitations, it has laid the foundation for future research that could have a direct effect on breastfeeding support for mothers who are pump-dependent after delivery. Future research should examine the mothers for a longer period of time after delivery, perhaps one month and three months after delivery, to examine the effect of the intervention on sustained breastfeeding. Because of the relatively high attrition rate with self-report data collection methods, alternative methods should be considered. In the Neonatal Intensive Care Unit at the study institution, all breast milk is bar code scanned when mothers deliver their milk. Techniques to capture the volume of milk at the time of bar code scanning could provide reliable milk volume data while not depending on the participant to complete their own data collection. This could dramatically improve the rate of attrition.

Further research could also examine the hormonal impact of duration of manual expression. Prolactin levels could be measured at different periods of time in the two groups to assess for any differences. Measuring the prolactin levels could explain differences in milk volumes. Going forward, research could be designed to compare prolactin levels of pump-dependent mothers as compared to mothers nursing at the breast. If equivalent or higher levels of prolactin are achieved between pump-dependent and nursing mothers, this could provide encouragement to the pump-dependent mother that she can achieve levels similar to feeding at the breast.

Anecdotally, the primary investigator found the delivery of breastfeeding education to be more easily received for women in the ante-partum unit. Often women are admitted to

ante-partum for weeks or months before delivery. At the study institution, lactation support is only provided after delivery. A randomized controlled trial could be designed comparing breastfeeding outcomes in mothers admitted to the ante-partum unit who receive breastfeeding education prior to delivery versus after delivery. This could provide insights to optimal timing of breastfeeding education for mothers with high risk pregnancies.

Implications for Practice

Findings from this study could have a direct impact on the standard of care for mothers of premature infants who are pump-dependent in order to provide milk for their babies. Once adequate sample size and power are achieved, the results can inform lactation consultants and nurses caring for mothers of premature infants on the number of days to perform manual expression for optimal milk volumes. These findings will have important implications for nurses caring for premature infants by standardizing practice. In addition, the study interventions employed in this research could serve as a basis to standardize the education that women of premature infants receive in regard to breastfeeding. The study interventions are based on the theory of self-efficacy and therefore could serve as a direct incorporation of theory into nursing practice.

APPENDIX A
INSTITUTIONAL APPROVAL LETTER



February 3, 2016

Lisa Steurer, MSN, RN, CPNP-PC, CLC
APN Professional Practice & Systems
St. Louis Children's Hospital PL-25

Ms Steurer:

This letter is to formally acknowledge administrative approval of your proposed research protocol, "A randomized trial comparing the effect of duration of manual expression and breastfeeding self-efficacy on milk volumes in mothers of premature infants: the Merit Study". Your previous pilot study, which was conducted here at Barnes-Jewish Hospital, shows your commitment to improving the knowledge of care of mothers and their premature infants. You are developing an admirable research program.

We will support your continued research, allowing you access to eligible mothers on our mother-infant units. Best of luck with your study and please let our department know if we can assist.

Sincerely,

A handwritten signature in black ink that reads "Patricia Potter".

Patricia Potter RN, PhD, FAAN
Director of Research
Patient Care Services
Barnes-Jewish Hospital

APPENDIX B

BREASTFEEDING MOTHERS' DEMOGRAPHIC DATA

Recruitment Location: ante-partum (duration _____) post-partum date of recruitment: _____ Date & time of delivery: _____

Maternal Age: _____

Race: White Hispanic Non-Hispanic African American Asian Pacific Islander Native American Middle-Eastern Arabic
Other _____

Gravida: _____ **Para:** _____ **Mode of Delivery:** Vaginal C-section

Previous Breastfeeding Experience: Y N **If yes, duration for each child** _____

Previous History of Premature Delivery: Y N

Education Level: Grade completed: _____ High School Diploma or GED _____ Some College: _____
Technical Degree: _____ Associates Degree: _____ Bachelor's Degree: _____ Masters: _____ PhD: _____

Mothers' Diagnosis: _____

Marital Status: Single Married Cohabiting Divorced

Infant (s): singleton ___ twin ___ triplet ___ quadruplet ___ **Gestational age of infant (s) at delivery:** _____ weeks ≤ 1500 or > 1500

How would you like to be contacted 2 weeks for follow-up questions for the study?

Phone: text or call (please circle): phone number: _____ /e:mail: _____

Address: _____

Baby's Name: _____ **TARGET** or **WALMART**

APPENDIX C

BREASTFEEDING SELF-EFFICACY SCALE FOR MOTHERS OF ILL AND/OR PREMATURE INFANTS (BSES-SF)

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

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

- | | |
|---|-----------|
| 1. I can pump enough milk for my baby | 1 2 3 4 5 |
| 2. I can deal with the fact that breast pumping and breastfeeding can be time consuming | 1 2 3 4 5 |
| 3. I can successfully cope with the breastfeeding situation (pumping and actual breastfeeding) like I have with other challenging tasks | 1 2 3 4 5 |
| 4. I can manage the breastfeeding situation to my satisfaction | 1 2 3 4 5 |
| 5. I can keep wanting to breastfeed | 1 2 3 4 5 |
| 6. I can be satisfied with my breastfeeding experience | 1 2 3 4 5 |
| 7. I can get help with breastfeeding if and/or when I need it | 1 2 3 4 5 |
| <u>When my baby is ready to actually breastfeed:</u> | |
| 8. I will be able to determine when my baby needs to be fed | 1 2 3 4 5 |
| 9. I will be able to ensure that my baby is properly latched on for the whole feeding | 1 2 3 4 5 |
| 10. I will be able to determine that my baby is getting enough milk | 1 2 3 4 5 |
| 11. I will be able to manage to breastfeed even if my baby is crying | 1 2 3 4 5 |
| 12. I will be able to breastfeed my baby without using formula as a supplement | 1 2 3 4 5 |
| 13. I will be able to comfortably breastfeed with my family members present | 1 2 3 4 5 |
| 14. I will be able to finish feeding my baby on one breast before switching to the other breast | 1 2 3 4 5 |
| 15. I will be able to breastfeed my baby for every feeding | 1 2 3 4 5 |
| 16. I will be able to manage to keep up with my baby's breastfeeding demands | 1 2 3 4 5 |
| 17. I will be able to tell when my baby is finished breastfeeding | 1 2 3 4 5 |
| 18. I will be able to switch from mostly pumping to mostly or completely breastfeeding my baby | 1 2 3 4 5 |

APPENDIX D

BSES-SF PERMISSION FROM AUTHOR

Page 1 of 2

Lisa Steurer - RE: BSES-SF

From: Cindy-Lee Dennis <cindylee.dennis@utoronto.ca>
To: Lisa Steurer <lisami@bjc.org>
Date: 3/30/2015 1:18 PM
Subject: RE: BSES-SF
Attachments: BSES-NICU.doc

Hi Lisa,

Thank you for your interest in my Breastfeeding Self-Efficacy Scale. Attached is the short-form for use in your doctoral studies. Good luck with your dissertation.

Warm regards,

Cindy-Lee

Cindy-Lee Dennis, PhD
Professor in Nursing and Medicine, Dept. of Psychiatry;
Canada Research Chair in Perinatal Community Health;

Shirley Brown Chair in Women's Mental Health Research, Women's College Research Institute;

University of Toronto
155 College St
Toronto, Ontario
Canada M5T 1P8
Tel: (416) 946-8808
www.cindyleedennis.ca



From: Lisa Steurer [lisami@bjc.org]
Sent: March 2, 2015 10:35 AM
To: Cindy-Lee Dennis
Subject: BSES-SF

Hello Dr. Dennis

file://C:\Users\lmi8177\AppData\Local\Temp\XPgrpwise\55194D3Bslchmedservices1001... 4/28/2015

APPENDIX E

BREASTFEEDING MOTHERS' PUMPING DIARY LOG – EXPERIMENTAL GROUP

Breastfeeding Mothers' Pumping Diary Log (14 Days)

Date: _____ Day 1 Baby's weight in grams: _____ _____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Hand Express (Y) (N) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 2 _____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Hand Express (Y) (N) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 3

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Hand Express (Y) (N) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 4

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Hand Express (Y) (N) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 5

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Hand Express (Y) (N) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 6

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Hand Express (Y) (N) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 7

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Hand Express (Y) (N) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 8

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 9

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 10

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 11

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 12

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 13

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 14

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

APPENDIX F

BREASTFEEDING MOTHERS' PUMPING DIARY LOG – CONTROL GROUP

Breastfeeding Mothers' Pumping Diary Log (14 Days)

Baby's weight in grams: _____

Date: _____ Day 1

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Hand Express (Y) (N) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 2

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Hand Express (Y) (N) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 3

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Hand Express (Y) (N) | | | | | | | | | | |

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 9

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 10

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 11

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 12

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 13

_____ 24 Hour Milk Total

| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

Date: _____ Day 14

_____ 24 Hour Milk Total

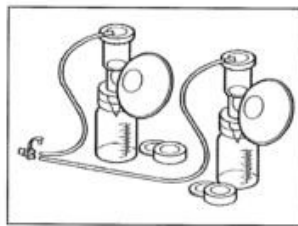
| | | | | | | | | | | |
|------------------------------|--|--|--|--|--|--|--|--|--|--|
| Time Pumping Started (am/pm) | | | | | | | | | | |
| Milk amount (mL) | | | | | | | | | | |

APPENDIX G

ST. LOUIS CHILDREN'S HOSPITAL (SLCH) GUIDE TO BREAST PUMPING;
HOW TO USE THE AMEDA PLATINUM ® BREAST PUMP THE FIRST 3 DAYS

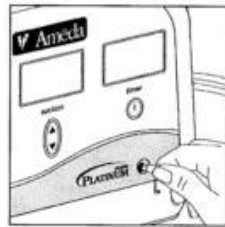


The milk collection system is pre-assembled.

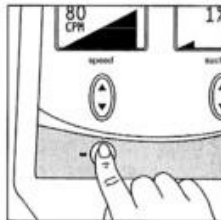
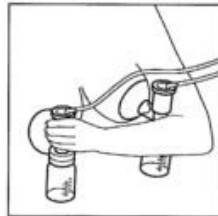


The bottles that come with the kit are too large. Please attach the colostrum containers your nurse gave you.

1. Push the tubing adapter into the pump.



2. Center the nipples into the breast flanges. Use your free hand to turn pump on by pressing the RED power button.

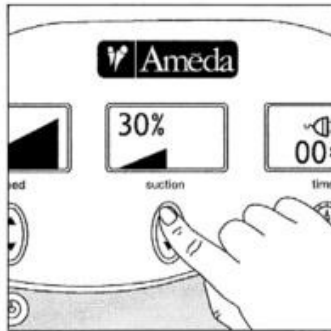


This handout is for your general information only. The lists above are guidelines and do not include all symptoms. This document is not a substitute for your child being seen by a doctor. Always call your child's doctor if you have any questions or problems. If your child's condition gets worse, call your child's doctor or go to the emergency department.

St. Louis Children's Hospital
One Children's Place
St. Louis MO 63110
R5209 - 11-2014

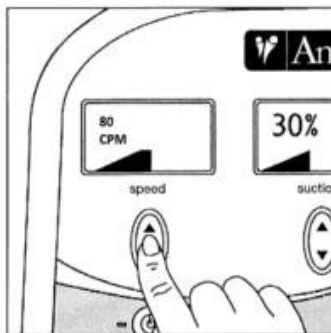
Guide to Breast Pumping

3. **Set Suction**—Press arrow to increase suction until reaching *maximum comfortable level*. Increase the suction gradually. Once it becomes uncomfortable, turn the suction down to comfort.



4. **Set Speed**—Pump starts at fast speed (80cpm).
Note: If the pump kit is not properly connected to the pump during pumping, "Check Kit" will appear in suction window.

From birth until the baby is 3 days old (73 hours old) leave the speed at 80 cpm.



This handout is for your general information only. The lists above are guidelines and do not include all symptoms. This document is not a substitute for your child being seen by a doctor. Always call your child's doctor if you have any questions or problems. If your child's condition gets worse, call your child's doctor or go to the emergency department.

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St. Louis, MO 63110
RS209 11-2014

Guide to Breast Pumping

5. Position Hands -- Hold your breast and the pump flange at the same time.

NOTE: Here is one way you can position your hands --

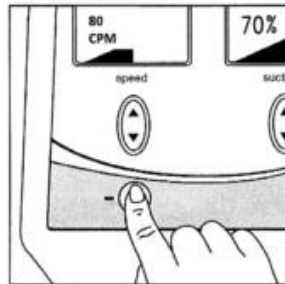
Place your thumb and palm on the breast. Place your pointer finger on the top of flange. Place your middle finger on bottom of flange, like a scissor hold. Place your ring and pinkie finger on the bottom of the breast for support and massage.



Close up picture of hand position.

6. Pump for 15 minutes.

7. Turn off the pump.



This handout is for your general information only. The lists above are guidelines and do not include all symptoms. This document is not a substitute for your child being seen by a doctor. Always call your child's doctor if you have any questions or problems. If your child's condition gets worse, call your child's doctor or go to the emergency department.

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APPENDIX H

UMKC IRB APPROVAL LETTER



UMKC
5319 Rockhill Road
Kansas City Missouri
TEL: 816 235-5927
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NOTICE OF NEW APPROVAL

Principal Investigator: Cynthia Russell
2464 Charlotte
Kansas City, MO 64108

Protocol Number: 16-052

Protocol Title: A RANDOMIZED CONTROLLED TRIAL COMPARING THE EFFECT OF DURATION OF MANUAL EXPRESSION AND BREASTFEEDING SELF-EFFICACY ON MILK VOLUMES IN MOTHERS OF PREMATURE INFANTS: THE MERIT STUDY (Manual Expression pRemature Infants)

Type of Review: Designated Review

Date of Approval: 05/02/2016

Date of Expiration: 05/01/2017

Dear Dr. Russell,

The above referenced study, and your participation as a principal investigator, was reviewed and approved, under the applicable IRB regulations at 21 CFR 50 and 56 (FDA) or 45 CFR 46 (OHRP), by the UMKC IRB. You are granted permission to conduct your study as described in your application.

Your protocol was approved under Expedited Review Regulatory Criteria at 45 CFR 46.110 or 21 CFT 56.110 under Category #4 as follows: "Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing". (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Your protocol was approved under Expedited Review Regulatory Criteria at 45 CFR 46.110 or 21 CFT 56.110 under Category #7 as follows: "Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies".

This approval includes the following documents:

Attachments

Tool permission-04282015123450
Approval letter Barnes Jewish Hospital
SLCH Steurer Grant Letter 2015
Electric pump directions-02172016124736
Appendix E Morton2
Partial Waiver of Consent.Washington University
Methods section
MERIT RCT FIGURE

APPENDIX I

UMKC APPROVED INFORMED CONSENT FORM

UMKC IRB # 16-052

CONSENT FORM FOR PARTICIPATION IN A RESEARCH STUDY

A RANDOMIZED CONTROLLED TRIAL COMPARING THE EFFECT OF DURATION OF MANUAL EXPRESSION AND BREASTFEEDING SELF-EFFICACY ON MILK VOLUMES IN MOTHERS OF PREMATURE INFANTS: THE MERIT STUDY (Manual Expression pRemature InfanTs)

Introduction

You are being asked to volunteer for a research study. This study is being conducted at Barnes Jewish Hospital.

The researcher in charge of this study is Dr. Cynthia Russell. While the study will be run by her other qualified persons who work with her may act for her. This study is being supported by the St. Louis Children's Hospital Foundation.

The study team is asking you to take part in this research study because you have delivered a premature baby and you want to breastfeed. Research studies only include people who choose to take part. Please read this consent form carefully and take your time making your decision. The study doctor or staff will go over this consent form with you. Ask him/her to explain anything that you do not understand. Think about it and talk it over with your family and friends before you decide if you want to take part in this research study. This consent form explains what to expect: the risks, discomforts, and benefits, if any, if you consent to be in the study.

Background

- You told the nurses that you would like to breast feed your baby. Your baby may not be able to suck at the breast right now. Your baby can still take breast milk in a bottle or by a feeding tube. When you get the milk out, your breast will fill back up. In order to keep your milk supply, you need to continue to get the milk out.
- An electric breast pump machine can get the milk out. However, another way to get the milk out is by squeezing the milk out with your hands. We call this manual expression.
- Mothers with premature babies are taught both methods to get the milk out. What we do not know is how many days to instruct mothers to manually express prior to their electric breast pump sessions. This is what we would like to test.

Purpose

- The purpose of this research study is to see if the number of days of manual expression makes a difference in the volume of breast milk that you produce. If you are able to make more milk, you may be able to breastfeed longer.

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Subject Initials _____

- You will be one of about 90 subjects in the study at Barnes Jewish Hospital.

Study Procedures and Treatments

If you decide to join in the study, you will be asked some questions about you and your baby.

- Your age and race
- Method of delivery (vaginal or C-section)
- The number of times you have been pregnant
- The number of weeks you have been pregnant
- You and your baby's diagnosis
- Marital status
- Occupation
- Information about your years of school
- If you have breast fed in the past and for how long
- You will be asked a set of questions about your confidence in being able to breastfeed your baby

After birth, your baby was taken to the neonatal intensive care unit at either Barnes Jewish Hospital or St. Louis Children's Hospital.

You will be randomly assigned to one of two groups. This means you will be assigned to a group by chance, like the flipping of a coin.

- One group will be asked to perform manual expression prior to each electric pump session for 3 days after delivery.
- The other group will be asked to perform manual expression prior to each electric pump session for 7 days after delivery

All subjects who join will be asked to document information on a piece of paper after you express your milk. This will include the date and time your milk is taken out and the amount of milk you get each time you express your milk. You will also be asked to record if you performed the manual expression before each electric pump expression. You will be asked to record this information for 14 days after your baby is born.

If you agree to take part in this study, you will be involved in this study for 14 days after delivery.

- A researcher will contact you by phone 5 days after your delivery if you are in the group that performs manual expression for 7 days. This will be to ask you how you are doing and answer any questions and encourage you to continue to manually express for the full 7 days.
- All subjects will be contacted by phone 14 days after delivery to see if you are still providing breast milk for your baby and to repeat the set of questions you answered after birth about your confidence in breastfeeding your baby.



The following study visits and procedures will occur:

The day you deliver your baby:

- The same day that you deliver your baby, you will be asked by a study researcher to join in the study. If you choose to be in the study you will be assigned randomly, like the flip of the coin or pulling numbers from a hat, to one of two groups. You have a 1 in 2 chance of being in either group. One group will be asked to perform manual expression prior to electric pump expression for 3 days after delivery. The other group will be asked to perform manual expression prior to electric pump for 7 days after delivery.
- Subjects in both groups will be asked to answer some questions about you and your baby. This will take about 5 minutes.
- Subjects in both groups will be asked a set of questions about how confident they feel in being able to breastfeed their baby. This will take about 5 minutes.
- Subjects in both groups will be instructed on how to perform manual expression. The researcher will provide you with a videotape that you may keep that instructs on the technique for manual expression. The researcher will also demonstrate how to perform this technique on an anatomical model and ask for you to demonstrate on the model. The teaching of manual expression is routine care for all mothers whether or not you are in the research. However, only mothers in the research study are given the videotape to keep and instructed with the anatomical model. Teaching this will take approximately 15 minutes.
- Subjects in both groups will be instructed on electric pump expression. This will take approximately 15 minutes. This is standard care for all mothers whether or not they are in the research.

Day of delivery and every day for 14 days after delivery

- Subjects in both groups will be asked to record the date and time of each expression session, whether manual expression prior to electric pump expression was completed and the amount of milk obtained each time. This will be documented on a paper log that will be provided to you. This will take approximately 5 minutes each pumping session.
- Subjects in both groups will be asked to pump at least 8 times a day, which is part of routine care and not a part of the research.

5 days after delivery

- Subjects in the 7 day group will be contacted by phone 5 days after your delivery. This will be to ask you how you are doing and answer any questions and



encourage you to continue manually expression for the full 7 days. This will take approximately 5 minutes.

14 days after delivery

- Subjects in both groups will be contacted by phone 14 days after delivery. They will be asked if they are continuing to breast feed. You will also be asked to repeat the set of questions about how confident you are in being able to breastfeed. You will also be asked to return your paper log with the self-addressed envelope provided upon enrollment in the study. We can also arrange to have the log picked up by the researcher if needed. This will take approximately 10 minutes.

Possible Risks or Side Effects of Taking Part in this Study

Risks associated with manual expression duration:

- Hand expression may be painful
- Hand expression may be embarrassing to the mother
- Manual expression may not be able to produce milk
- Fatigue with performing the manual expression

Risks of answering questions and documenting information:

- Subject may become uncomfortable with answering personal questions
- Subject may experience fatigue having to write down milk collection each time they pump

Risk of private information:

- There is a risk that someone other than researchers may gain access to subject's personal information.

Possible Benefits for Taking Part in this Study

- A potential benefit to you for participating in the study is the ability to supply enough breast milk to meet the feeding needs of your baby. You may gain more confidence in your ability to provide breast milk. Because of this, you may want to breastfeed for a longer period of time.
- Other people may benefit from the information obtained in this study. The knowledge gained from the study may result in a better way to instruct mothers on how many days to manually express milk after delivery to improve milk volume.



Costs for Taking Part in this Study

You will not have to pay for any equipment or instruction materials associated with this study.

You will be responsible for doctor and or hospital costs as usual except for those directly related to the research study.

Payment for Taking Part in this Study

You will be given a \$50 gift card to Target or Walmart (your choice) after you have completed and returned the breastfeeding log.

Alternatives to Study Participation

If you do not wish to participate in this study, you will receive the usual care that all breastfeeding mothers of premature infants receive. This would include instruction on manual and electric pump expression. The time period for manual expression is usually prescribed for 3-5 days or until full milk comes in.

Confidentiality and Access to your Records

The results of this research may be published or presented for scientific purposes. You will not be named in any reports of the results. Your study or applicable medical records that have your identity in them may be shown to the Institutional Review Board (IRB) (a committee that reviews and approves research studies), or other governing agencies. This is to prove which study procedures you completed and to check the data reported about you. They may also review your medical records for any treatment you received before you agreed to take part in this study. This is to confirm your medical history and that you meet the requirements to be in this study. The study team will keep all information about you confidential as provided by law, but complete confidentiality cannot be guaranteed.

If you leave the study or are removed from the study, the study data collected before you left may still be used along with other data collected as part of the study. For purposes of follow-up studies and if any unexpected events happen, subject identification will be filed at the office of the lead researcher under appropriate security and with access limited to medical research personnel only.

If you sign this consent form, you are allowing the study team and these other agencies to see your medical records.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.



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The University of Missouri-Kansas City appreciates people who help gain knowledge by being in research studies. It is not the University's policy to pay for or provide medical treatment for persons who participate in studies. If you think you have been harmed because you were in this study, please call the researcher, Dr. Cynthia Russell at [816-235-5927](tel:816-235-5927).

Contacts for Questions about the Study

You should contact the IRB Administrator of UMKC's Institutional Review Board at 816-235-5927 if you have any questions, concerns or complaints about your rights as a research subject. You may call the researcher Dr. Cynthia Russell at 816-235-2881 if you have any questions about this study. You may also call her if any problems come up.

A copy of this consent form will be copied for you to keep.

Demographic Information Only- If you do not want to be in the full study, we would like to obtain your age, ethnicity, educational level and marital status. This information cannot be connected in any way to you. It will be anonymous. We would like this information so that we can describe, in general, the group of people who did not decide to be in our study.

My demographic data as described above may be collected even I do not want to be in the full study.

Yes No

Initials Initials

Will you save research data to use in future research studies?

- As part of this study, we are obtaining data from you. We would like to use this data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding breastfeeding for mothers of premature infants or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur.
- We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at other research centers and institutions or industry sponsors of research. We

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may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

- If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My data may be stored and used for future research as described above.

____ Yes ____ No

Initials Initials

My data may be shared with other researchers and used by these researchers for the future research as described above.

____ Yes ____ No

Initials Initials

Voluntary Participation

Taking part in this research study is voluntary. If you choose to be in the study, you are free to stop participating at any time and for any reason. If you choose not to be in the study or decide to stop participating, your decision will not affect any care or benefits you are entitled to. The researchers, doctors or sponsors may stop the study or take you out of the study at any time

- if they decide that it is in your best interest to do so,
- if you experience a study-related injury,
- if you need additional or different medication/treatment,
- if you no longer meet the study criteria, or
- if you do not comply with the study plan.

They may also remove you from the study for other administrative or medical reasons. You will be told of any important findings developed during the course of this research.



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You have read this Consent Form or it has been read to you. You have been told why this research is being done and what will happen if you take part in the study, including the risks and benefits. You have had the chance to ask questions, and you may ask questions at any time in the future by calling Dr. Russell at 816-235-2661. By signing this consent form, you volunteer and consent to take part in this research study. Study staff will give you a copy of this consent form.

| | | |
|--|---------------|---|
| _____ Signature (Volunteer Subject) | _____ Date | _____ Printed Name (Volunteer Subject) |
| _____ Signature of Person Obtaining Consent | _____ Date | _____ Printed Name of Person Obtaining Consent |

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Subject Initials _____

APPENDIX J

“MAKING ENOUGH MILK: THE KEY TO SUCCESSFUL BREASTFEEDING

PLANNING FOR DAY ONE”

By: Jane Morton, MD

Objectives: To instruct mothers on hand expression to remove early milk and colostrum; This will be the only portion of the video covered as other techniques in the video are part of standard care (electric pump instruction and hands-on pumping with electric pump expression)

Outline:

- Instructs to hand express for the first 3 days
- Visual instruction of the hand expression technique proposed by Dr. Jane Morton
- Stresses importance of few drops to a teaspoon with initial hand expression
- May get no milk or colostrum but still priming the breast in the beginning

Manual Expression Technique Step By Step

- Have the mother upright
- Warm towel to stimulate the breast
- Apply gentle massage
- Place fingers 1 inch from the areola making a c-shape
- Do not stretch the skin of the areola
- Apply steady pressure *inward* toward the breast
- Back and very gently together
- Press, compress, relax
- Go back and forth from left to right breast

APPENDIX K

STUDY PROTOCOL

General Instructions

Recruitment Phase

The PI will consult with the charge nurse on the antepartum and labor and delivery unit each morning for mothers eligible or potentially eligible for recruitment into the study. The PI will approach each eligible participant and ask if they would be interested in participating in the study. When the participant agrees to participate, the PI will provide informed consent of all study procedures. Eligible participants will then proceed to the intervention phase and participant information will be recorded on the study log. All participants who are not eligible or who choose not to join the study will also be recorded on the study log and the PI will record explaining the reason for failure to participate and document demographic data only.

Intervention Phase

The PI will then obtain a packet only identified by Study ID on the outside. Mothers will be block randomized in sequential numerical order according to study number. Once the packet is opened, the PI and the participant will be informed to which group assigned.

Seven Day Intervention Group:

- Step 1: The mother will complete the demographic sheet – 5 minutes
- Step 2: The mother will complete the Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF)- 5 minutes
- Step 3: Mother will be praised by the PI for the decision to breastfeed and inform of the benefits of breast milk for their premature baby.
- Step 4: The PI will review the videotape entitled “Making Enough Milk, The Key to Successful Breastfeeding” by Jane Morton, MD Version 2 (See Appendix E). The mother will be given the videotape to review again for further reinforcement. -10 minutes
- Step 5: The PI will reinforce instruction of the manual expression technique on a anatomical breast model with return demonstration. -10 minutes
- Step 6: The PI will ask the mother if she has additional questions concerning the manual expression technique described in the videotape or through instruction with the breast model.
- Step 7: All mothers in the seven day group will receive instruction on the use of an electric pump by PI. Ameda Platinum ® Breast Pump: Model 17803- 15 minutes
- Step 8: The mother will be instructed to perform manual expression before each electric pump session for 7 days after delivery and asked to record whether or not manual expression was performed on the breastfeeding log.
- Step 9: The mother will be instructed to record milk volumes for each pumping session for 14 days after delivery on the breastfeeding log.

- Step 10: The mother will be asked to view a photograph of gender and race matched photo during pumping sessions
- Step 11: On day 5, the PI will call the mother by phone to offer encouragement and answer questions regarding manual expression and to continue until day 7.
- Step 12: After 14 days, the PI will contact the mother via telephone or e-mail and ask her to repeat the BSES-SF.
- Step 13: The PI will then ask the mother how she can obtain her breastfeeding log. Options include a self-addressed stamped envelope or PI can receive from mother if her infant is still admitted to the neonatal intensive care unit.
- Step 14: Upon receipt of the breastfeeding log, the mother will be mailed or given a \$50 gift card to Target or Walmart in appreciation for participation in the study.

Three Day Intervention Group:

- Step 1: The mother will complete the demographic sheet – 5 minutes
- Step 2: The mother will complete the Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF)- 5 minutes
- Step 3: Mother will be praised by the PI for the decision to breastfeed and inform of the benefits of breast milk for their premature baby.
- Step 4: The PI will review the videotape entitled “Making Enough Milk, The Key to Successful Breastfeeding” by Jane Morton, MD Version 2 (See Appendix E). The mother will be given the videotape to review again for further reinforcement. -10 minutes
- Step 5: The PI will reinforce instruction of the manual expression technique on a anatomical breast model with return demonstration -10 minutes
- Step 6: The PI will ask the mother if she has additional questions concerning the manual expression technique described in the videotape or through instruction with the breast model.
- Step 7: All mothers in the three day group will receive instruction on the use of an electric pump by PI. Ameda Platinum ® Breast Pump: Model 17803-15 minutes
- Step 8: The mother will be instructed to perform manual expression before each electric pump session for 3 days after delivery and asked to record whether or not manual expression was performed on the breastfeeding log.
- Step 9: The mother will be instructed to record milk volumes for each pumping session for 14 days after delivery on the breastfeeding log.
- Step 10: The mother will be asked to view a photograph of gender and race matched photo during pumping sessions
- Step 11: After 14 days, the PI will contact the mother via telephone or e-mail and ask her to repeat the BSES-SF.

Step 12: The PI will then ask the mother how she can obtain her breastfeeding log. Options include a self-addressed stamped envelope or PI can receive from mother if her infant is still admitted to the neonatal intensive care unit.

Step 13: Upon receipt of the breastfeeding log, the mother will be mailed or given a \$50 gift card to Target or Walmart in appreciation for participation in the study.

APPENDIX L

SLCH RESEARCH GRANT AWARD LETTER



One Children's Place
St. Louis, Missouri 63110

September 4, 2015

Lisa Steurer, PhD(c), MSN, RN, PNP-PC, CLC
APN Professional Practice & Systems
St. Louis Children's Hospital

Dear Ms. Steurer:

I am pleased to inform you that your project entitled, "A Randomized Trial Comparing the Effect of Duration of Manual Expression and Breastfeeding Self-Efficacy on Milk Volumes in Mothers of Premature Infants: THE MERIT STUDY (Manual Expression pRemature InfanTs)" has been approved by the SLCH Research and EBP Advisory Committee and will be awarded \$5700 in funding through the St. Louis Children's Hospital Research Grant program. This grant is made possible by generous contributions to the St. Louis Children's Hospital Foundation. To access the funds as needed, please contact either Dr. Karen Balakas or Misty Delong at 454-6276 or mmd5014@bjc.org.

Please complete the following steps to begin the implementation process:

- Sign and return the enclosed Letter of Agreement to Dr. Karen Balakas at SLCH
- Develop an IRB proposal for the Washington University's HRPO. Please contact me if you need assistance accessing or completing the required forms.
- Provide a copy of the Washington University IRB approval to Dr. Karen Balakas before beginning work on your project.
- Submit quarterly progress updates and expenditures as indicated on the attached form yearly by the following dates:
 - April 1st
 - July 1st
 - October 1st
 - January 1st

Sincerely,

Karen Balakas, PhD, RN, CNE
Karen Balakas, PhD, RN, CNE
Director of Research
St. Louis Children's Hospital

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VITA

Lisa M. Steurer was born and raised in St. Louis, Missouri. Her primary and secondary education were through the Catholic school system. After graduating with her Bachelor's of Science in Nursing from St. Louis University, St. Louis, Missouri, in 1990, she began her career as a pediatric intensive care unit nurse at Cardinal Glennon Children's Hospital in St. Louis, Missouri, and then at Cedar-Sinai Medical Center in Beverly Hills, California. Upon her return to St. Louis, she obtained employment in the Emergency Unit at St. Louis Children's Hospital. She remained a staff nurse in the department until completing her Master's Degree in Nursing from the University of Missouri-St. Louis in 1997. After certification as a Pediatric Nurse Practitioner, she remained in the Emergency Unit as both a practitioner and educator, and later as interim management. After 12 years in the department, she transferred to her current role as an APN for Patient Safety, Quality, and Performance Excellence at St. Louis Children's Hospital.

Ms. Steurer has been actively involved in developing the Evidence-Based Practice and Research Fellowships for the hospital. To date, Ms. Steurer has authored three pediatric research articles and had an invited publication for her work on the hospital-based Evidence-Based Practice Fellowship. Ms. Steurer is a member of Sigma Theta Tau, Midwest Nursing Research Society, and the American Nurses Association and has been selected as a Jonas Nurse Scholar in Leadership. She became certified as a lactation counselor and continues to pursue research efforts focusing on the breastfeeding sustainment of premature infants. She most recently authored a manuscript in Public Health Nursing on the impact of workplace policies and maternity leave on breastfeeding sustainment.