

A Randomized Controlled Trial Evaluating Lanolin for the Treatment of Nipple Pain Among Breastfeeding Women

by

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A thesis submitted in conformity with the requirements
for the degree of Doctor of Philosophy
Graduate Department of Nursing Science
University of Toronto

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2014

Abstract

It is widely accepted that breast milk is the optimal source of infant nutrition. Despite the World Health Organization (WHO) recommendation of exclusive breastfeeding for the first 6 months of infant life, many women discontinue breastfeeding as a result of perceived difficulties. Nipple pain is a highly prevalent, significant reason for breastfeeding cessation. Among the numerous interventions for nipple pain, the application of lanolin is commonly recommended, with endorsement by Health Canada, The La Leche League, and International Board Certified Lactation Consultants. The few studies that have evaluated the effectiveness of lanolin on nipple pain have lacked methodologic rigor, and are thus not reliable or generalizable. As such, the purpose of this trial was to rigorously evaluate the effect of lanolin for the treatment of nipple pain among breastfeeding women.

This single-site randomized controlled trial (RCT) compared the application of lanolin (treatment) to usual postpartum care (not applying lanolin) for the treatment of nipple pain. The primary outcome for this trial was the effect on pain severity, as measured by a numeric rating scale (NRS) at 4 days post-randomization.

Of 186 participants, 93 were randomized to the treatment group and 93 to the usual care group. At 4 and 7 days post-randomization there were no statistically significant differences in pain scores between groups. It is noteworthy that by 7 days post-randomization there were clinically relevant decreases in nipple pain in both groups. However, there were no statistically significant differences between groups for other outcomes, including pain measured with the short-form McGill Pain Questionnaire, breastfeeding duration, breastfeeding exclusivity, and breastfeeding self-efficacy. Despite these findings, women in the treatment group were significantly more satisfied receiving lanolin for their nipple pain than those receiving usual care.

Since the use of lanolin is no more effective than applying nothing to the nipples for the management of nipple pain, the widespread use of lanolin is questionable. Further research is required on the role of interventions to prevent nipple pain and damage, and the effect of anticipatory guidance on improving breastfeeding outcomes for those experiencing nipple pain in the early postpartum period.

Acknowledgments

The journey of working towards a PhD is never a sole endeavor. It is through the collective support and guidance of mentors, academic committee members, and family and friends that this thesis has come to be.

First, I would like to thank the outstanding scholars who dedicated their time and energy in support of my work. I first met my academic supervisor Dr. Cindy-Lee Dennis in 2005, and since then, she has never ceased to inspire, motivate, and illuminate me. Thank-you for having faith in me, for sharing your sage wisdom, and for the innumerable moments where I learned from you. I have also had the extraordinary privilege of having two phenomenal scholars on my thesis committee: Dr. Michael McGillion, and Dr. Ellen Hodnett. Thank-you for your invaluable feedback, advice, and mentorship.

I wish to extend many thanks to the nurses and staff who helped to support my research and a special thanks to the 186 women who participated in the trial. In addition, I would like to acknowledge the sources of funding for this trial, including: the Canadian Institutes of Health Research, the Registered Nurses' Foundation of Ontario, the Soroptomist Foundation of Canada, and the Lawrence S. Bloomberg Faculty of Nursing.

I would like to extend a special thank-you to a dear friend and mentor, Dr. Heather Arthur. Her passion, dedication, knowledge and grace will forever inspire me. Thank-you Heather – for being a part of my journey, and for being my friend.

I have had the good fortune of being blessed with many colleagues and friends, who have made the PhD experience more enjoyable. In the cookies of life, you are the chocolate chips! Jessica and Quinn – although this journey has put miles between us, I will always cherish our wonderful friendship. Very special thanks to Dr. Sheila O'Keefe-McCarthy, Dr. Phil Medeiros

and (soon to be Dr.) Nicole Novielli. Thank-you to my friends and colleagues at Western University – Dr. Sandra Regan, Dr. Richard Booth, Dr. Yolanda Babenko-Mould, Eileen Denomy, Denice Litzan, and Eileen Marion-Bellamere.

I wish to extend my deepest thanks to my mother, father and sister. Mom and Dad: thank-you for being the wonderful parents that you are. Thank-you for instilling the value of education, hard-work and tenacity; for your faith in me and for your unconditional love. Thank-you Mom, for your countless hours of hard work in support of my research despite facing one of the greatest challenges in life. You are a survivor, and your strength is truly inspirational. To my best friend and sister Sissa, you are my Godsend. I cannot imagine how I would have gotten here without you. Your belief in me, your support, your friendship and love has meant the world to me. Mom, Dad and Sissa: I love you all infinitely.

I wish to thank my extended family. To Mom and Dad, Jen and Tom, and Rusty and Tom, thank you for your love, kindness, friendship and support. I feel very blessed, and am so happy and proud to be part of the Jackson family.

Finally, I wish to thank my husband and children. To my husband Dwayne, you have been an immeasurable source of love, support and companionship. Thank you for being my best friend, and for helping me to navigate the academic world. You will forever be a source of inspiration. I am so blessed to be your wife, and I love you dearly. To my girls: Madeline and Eden, to me, you are the epitome of joy – you are what gives my life meaning. You have been my constant, and have been my source of inner strength. Thank you for being the sweet, kind-hearted, exceptional human beings that you are, and for your patience and understanding through this long journey. I love you “to the universe and back”, and wish to dedicate this thesis to you both.

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Chapter 1

Introduction and Problem Statement

It is widely accepted that breast milk is the optimal source of infant nutrition and is important to the health and well-being of both infants and mothers. The World Health Organization (WHO) asserts that breastfeeding has beneficial effects for both infant and maternal health (Butte, Lopez-Alarcon & Garza, 2002). Furthermore, it may be life-saving in developing countries. Breastfeeding is also associated with positive psychological, economic and environmental outcomes (American Academy of Pediatrics, 1997) and these benefits may be optimized when infants receive breast milk exclusively. As such, leading health organizations including the WHO (Butte, Lopez-Alarcon & Garza, 2002), the Canadian Pediatric Society (CPS) (Bolan, 2005), and the American Academy of Pediatrics (AAP, 1997) recommend exclusive breastfeeding for the first 6 months of life, with continued breastfeeding along with complimentary foods up to 2 years of age and beyond.

Despite what is recommended, breastfeeding initiation and exclusivity rates fail to meet these targets. In Canada, approximately 87.3% of mothers initiate breastfeeding, yet only 23.1% of breastfeeding mothers breastfeed exclusively for the first 6 months (Statistics Canada 2011). There are many complex and interrelated factors that contribute to a woman's decision to initiate and continue breastfeeding. Evidence supports that most women discontinue breastfeeding before the recommended 6 months because of perceived difficulties with breastfeeding rather than maternal choice (Dennis, 2002).

Nipple pain is a common occurrence for breastfeeding women and has been cited as an important reason for breastfeeding cessation, second only to maternal perceptions of inadequate milk (Fetherston, 1995; Yeoung, Pennell, Leung & Hall, 1981). The prevalence rate of nipple

pain in the first weeks postpartum is high, with reports ranging from 77% (Heads & Higgins, 1995) to 96% (Hewat & Ellis, 1987; Ziemer, Paone, Schupay & Cole, 1990).

Despite the widespread occurrence of nipple pain, the etiology is not well understood. Proper breastfeeding technique that includes correct infant positioning and attachment at the breast is considered important in effective milk transfer and in the prevention of nipple damage and pain (Morton, 1992; Righard & Alade, 1992; Royal College of Midwives, 1991). An ineffective milk transfer as a result of poor positioning or attachment results in unrelieved suction applied to the nipple surface, and this may elicit suction or friction trauma and subsequent pain (Woolridge, 1986a, 1986b). Further, a Cochrane systematic review on breastfeeding technique associated poor positioning and attachment with reduced milk supply, premature cessation of breastfeeding and nipple trauma (Renfrew & Lang, 1999).

Aside from being an unpleasant stimulus for breastfeeding mothers, pain has an inhibitory effect on the release of oxytocin, the hormone responsible for the release of milk (Spangler, 2000). With the inhibition of milk release, pain may have a crucial role in preventing the efficient transfer of milk from the alveoli to the nipple (Woolridge, 1986a). Inadequate milk transfer may result in either non-nutritive sucking and/or breast engorgement that are both potential causes of nipple trauma, and thus the cycle of pain, milk inhibition, and trauma is repeated.

There are various interventions aimed at treating nipple pain such as breastfeeding education, dressings, compresses, ointments, tea bags, and expressed breast milk (EBM). Among all of the published nipple pain studies, no single treatment has been demonstrated to be effective. Additionally, many of the studies lack methodological rigour or have small sample sizes which threaten the internal and external validity of the results. A recent Cochrane review

(Dennis, Allen, McCormick & Renfrew, 2009) evaluating interventions to treat nipple pain among breastfeeding women was inconclusive, suggesting that no one intervention for the treatment of nipple pain or trauma has been found to be more effective than another.

Among the numerous interventions that have been studied, lanolin is the only treatment aside from EBM that has received continued endorsement by the La Leche League International, the most predominant global, community-based breastfeeding support network for women. The use of lanolin to treat sore nipples is also recommended by International Board Certified Lactation Consultants (IBCLC) and is included in their core curriculum for lactation consultant practice (Mannel, Martens & Walker, 2008). In addition, small sample tubes of lanolin are commonly offered in-hospital to North American breastfeeding mothers with nipple pain. Lanolin is considered a pure and safe intervention (containing no preservatives, additives, water, chemicals or perfume), aimed at creating a moist healing environment for nipple trauma, and providing a semi-occlusive barrier that promotes retention of internal moisture and prevents dryness (Martin, 2000). Lanolin may provide a moist dermal environment to prevent eschar formation, promote epithelial regrowth and decrease nipple pain (Cable, Stewart & Davis, 1997; Pugh et al., 1996). In order to understand the effectiveness of lanolin for the reduction of nipple pain and its impact on breastfeeding outcomes, a rigorously conducted randomized controlled trial was required.

Problem Statement

Despite the benefits of breastfeeding to infants and mothers, many women who initiate breastfeeding will discontinue by the recommended 6 months postpartum. Although there are several factors that influence breastfeeding initiation and duration rates, the experience of nipple

pain is frequently reported as a key reason why women stop breastfeeding (Fetherston, 1995; Yeoung et al., 1981).

The La Leche League International and IBCLCs currently recommend the application of lanolin for painful nipples. However, a Cochrane systematic review (Dennis et al., 2009) concluded that there is a lack of evidence to support the use of any one treatment – including the use of lanolin – for nipple pain among breastfeeding women. As such, there remains a lack of methodologically strong studies evaluating the effect of this intervention on nipple pain, and the impact on breastfeeding duration and exclusivity.

A randomized controlled trial (RCT) was conducted to evaluate the effect lanolin has on nipple pain for breastfeeding women. The primary objective of the trial was to evaluate the effect of the application of lanolin on nipple pain severity in the first postpartum week among breastfeeding women when compared with a control group who do not apply lanolin to their nipples.

Chapter 2

Review of the Literature and Conceptual Framework

This chapter provides a review of the benefits of breastfeeding and the problem of nipple pain. The prevalence and etiology of nipple pain will be reviewed, in addition to a critique of current studies and systematic reviews evaluating the various prevention and treatment interventions. The literature evaluating the effect of lanolin for the treatment of nipple pain will be also be examined, and gaps identified. Finally, the mechanisms of skin trauma and wound healing will be discussed, in addition to the relevance of pain mechanisms that support the use of lanolin as a treatment for nipple pain.

Benefits of Breastfeeding

Extensive research has been conducted on the effects of breastfeeding on infant and maternal health. In a 2007 systematic review, Ip et al. included 43 primary studies of maternal health outcomes, 43 primary studies of infant health outcomes, and 29 systematic reviews. The results from the review found that in developed countries, breastfeeding has numerous infant and maternal health benefits. Similarly, on the basis of a systematic review on optimal breastfeeding duration (Kramer & Kakuma, 2002), the WHO concluded that there is strong evidence that regardless of country of origin, breastfeeding has a protective effect for both infant and maternal health, and that this protective effect may be life-saving for infants in developing nations.

Infant Outcomes

Cumulative evidence suggests that breast milk provides strong protective effects to infants against a wide range of infectious diseases, and is associated with numerous infant health benefits. A cluster RCT of 31 maternity hospitals in Belarus randomly assigned hospitals to receive either an intervention in which health care workers provide assistance with initiation and

maintenance of breastfeeding (modeled on the WHO Baby-Friendly Hospital Initiative) (World Health Organization, 2009) or to a group receiving usual infant feeding practices and policies (Kramer et al., 2001). Infants in the intervention group were more likely to be breastfed at 3, 6, and 12 months of age and were less likely to have gastrointestinal infections (9.1% versus 13.2%; adjusted OR = 0.60, 95% CI = 0.40-0.91) and atopic eczema in the first year of life (3.3% versus 6.3%; adjusted OR = 0.54, 95% CI = 0.31-0.95) (Kramer et al., 2001). Infants from the same RCT were followed up at 6.5 years for IQ scores on the Weschler Abbreviated Scales of Intelligence (WASI) and teacher evaluations of academic performance. For children from the experimental group, higher mean differences were found on the WASI measures for verbal IQ (cluster adjusted mean differences of +7.5 (95% CI, 0.8-14.3)), thus providing evidence supporting improved cognitive development for children who are breastfed (Kramer et al., 2008).

It is unethical to randomize individual healthy term infants to be breastfed or to receive an alternate source of nutrition. As such, much of the literature pertaining to breastfeeding outcomes are based on either cohort or case-control observational studies. The internal validity and generalizability of these studies may be limited by biases such as misclassification of exposure, confounding from self-selection and other residual confounding variables (Ip et al., 2007). Many of the studies on breastfeeding outcomes require cautious interpretation, and any associations found do not infer causality. Despite these potential limitations, there are numerous systematic reviews and meta-analyses that have demonstrated positive health effects associated with infants who are breastfed.

Meta-analyses of cohort and case control studies showed significant reduction in risk of the following infant diseases with breastfeeding: acute otitis media (Ip et al., 2007; Uhari, Mantysaari, & Niemela, 1996); atopic dermatitis (Gdalevich, Mimouni, David & Mimouni,

2001); gastrointestinal infections (Chein & Howie, 2001); lower respiratory tract diseases (Bachrach, Schwarz, & Bachrach, 2003); childhood leukemia (Guise, Austin & Morris, 2005; Kwan, Buffler, Abrams & Kiley, 2004); sudden infant death syndrome (SIDS) (Ip et al., 2007); and necrotizing enterocolitis (Ip et al., 2007) (see Appendix A for summary of studies).

Other positive outcomes related to breastfeeding have been suggested where additional research is required. Breastfed individuals may have reductions in rates of lymphoma, Hodgkin's disease, and hypercholesterolemia when compared with those who were non-breastfed (AAP, 2005). Although most studies on the benefits of breastfeeding are observational, the evidence to-date suggesting risk reduction for infectious and atopic illness provides continued impetus for further research toward breastfeeding promotion.

Maternal Outcomes

The benefits of breastfeeding may also extend to maternal health. Breastfeeding immediately following birth increases oxytocin levels, which aids in uterine involution and subsequent reduction in blood loss for postpartum women (Chua, Arulkumaran, Lim & Ratnam, 1994; Heinig & Dewey, 1997). Breastfeeding also induces prolonged lactational amenorrhea, which is associated with increased duration between pregnancies (Kennedy, Labbok & VanLook, 1996).

There is good evidence supporting the association between breastfeeding and a reduced risk of both ovarian and breast cancers (see Appendix B). Meta-analyses of case control and cohort studies from developed and developing countries found a reduction in breast cancer risk for women who breastfed versus those that did not, and that risk may be further decreased when total duration of breastfeeding exceeds 12 months (Collaborative Group on Hormonal Factors in Breast Cancer, 2002; Bernier, PluBureau, Bossard, Ayzac & Thalabard, 2000). Similarly, a

systematic review by Ip et al. (2007) showed an association between breastfeeding duration greater than 12 months and a reduction in risk for ovarian cancer versus women who never breastfed. Finally, a large prospective cohort study of US nurses between 1976 and 2005 showed an inverse association between breastfeeding duration and risk of developing type II diabetes (Stuebe, Rich-Edwards, Willett, Manson & Michels, 2005). Although studies on maternal health benefits associated with breastfeeding are observational and more rigorous research is required, the best available evidence is suggestive of benefit to maternal health and should therefore continue to be promoted (see Appendix A for a table summarizing studies of maternal and infant outcomes related to breastfeeding).

Societal outcomes

Breastfeeding also yields socioeconomic and societal benefits. It has been estimated that in the United States there is a potential savings in annual health care costs of approximately \$3.6 billion (USD) due to decreased risk of illness associated with breastfeeding (Ball & Wright, 1999; Weimer, 2001). Similarly, preliminary calculations by the Great Britain Department of Health (DOH) estimated that the National Health Service could save 10 per breastfed infant due to prevention of childhood diabetes mellitus. Further, savings of 35 million annually are estimated in relation to reductions in infant gastroenteritis (DOH, 1995). Beyond medical-expenditure cost savings are also a reduction in costs associated with work absenteeism to care for ill infants (Cohen, Mrtek & Mrtek, 1995).

Overall, there are several health, psychological and economic benefits that may be associated with breastfeeding that impact infants, mothers, and society. Breastfeeding has therefore been advocated as the ideal source of infant nutrition, requiring continued promotion in order to meet recommended rates of duration and exclusivity.

Breastfeeding Duration and Exclusivity

Exclusive breastfeeding (breastfeeding without the addition of any other food or water) for the first 6 months of life with the addition of complimentary foods up to 2 years of age and beyond is recommended by the WHO (WHO, 2008), the CPS (Boland, 2005), and AAP (AAP, 2005). In Canada, breastfeeding initiation rates have been rising. Between 2001 and 2009/2010, Canadian breastfeeding initiation rates increased from 81.5% to 87.3% (Statistics Canada, 2011). In Ontario, breastfeeding initiation rates rose from 62% in 1990 to 88.5% in 2009-2010 (Statistics Canada, 2011).

Despite the increasing number of women who initiate breastfeeding, many discontinue well before the recommended duration of 6 months. According to the Public Health Agency of Canada (2009), among women who initiated breastfeeding, approximately 68% were practicing any breastfeeding at 3 months postpartum and only 54% breastfed to 6 months postpartum.

Breastfeeding initiation rates have also been increasing in the US. Findings from the US Centers for Disease Control and Prevention (CDC) showed that the percentage of infants breastfed increased from 60% between 1993 and 1994 to 77% in 2010 (CDC, 2013). Although rates of breastfeeding initiation are rising, the US rates for breastfeeding duration fall short of the WHO recommendation, with only 49% of women continuing to breastfeed for 6 months (CDC, 2013).

Although progress has been made with improved rates of breastfeeding initiation and duration, rates of breastfeeding exclusivity fall well below the current recommendations. Based on a survey of 6420 Canadian postpartum women, 51.7% exclusively breastfed to 3 months postpartum, and only 14.4% exclusively breastfed to 6 months postpartum (Public Health Agency of Canada, 2009).

Several studies have identified reasons for premature breastfeeding discontinuation. A survey of 1250 Ontario breastfeeding women identified three reasons for breastfeeding discontinuation, including: perceived inadequate milk supply (43.8%), sore nipples (7.1%), and difficulty with breastfeeding technique (2.7%) (Sheehan, Watt, Krueger & Sword, 2006).

Other studies have supported the relationship between breastfeeding discontinuation and the experience of pain for breastfeeding women. Early descriptive studies have demonstrated that nipple pain is a predominant factor for women discontinuing breastfeeding prematurely. Gulick (1982) had 251 U.S. primigravidas complete questionnaires at 5 to 6 weeks postpartum to identify variables predictive of breastfeeding success. Of the 17.5% ($n = 44$) of women who had discontinued breastfeeding by 6 weeks postpartum, 11.4% reported nipple pain as a reason for discontinuation. In a similar U.S. descriptive study of 150 primigravidas, Rentschler (1991) found that 28.7% ($n = 43$) of women discontinued breastfeeding by 6 weeks postpartum, and among these mothers, 42% ($n = 16$) reported sore nipples as a reason for discontinuation. More recently, two U.S. descriptive studies identified nipple pain as a common reason for breastfeeding discontinuation. Ahluwalia, Morrow and Hsia (2005) used data from the Pregnancy Risk Assessment and Monitoring System taken from 31 states during 2000 and 2001 to evaluate reasons for breastfeeding cessation. Among the women who initiated breastfeeding, 3.6% ($n = 1105$) stopped within 1 week, and 13.3% ($n = 4687$) stopped within 4 weeks. Of the women who discontinued in the first week (3.6%, $n = 1105$), 34.9% ($n = 386$) cited nipple pain as the reason for discontinuing. For women discontinuing within 4 weeks (13.3%, $n = 4687$), 30.2% ($n = 1415$) did so because of nipple pain. Finally, in the Lewallen et al. (2005) study of 379 postpartum women from the Southeastern U.S., it was found that 24.5% ($n = 30$) of women who stopped breastfeeding by 8 weeks postpartum did so because of nipple pain/latch problems.

The results from this study and descriptive research have supported the negative impact of nipple pain on breastfeeding outcomes, primarily premature breastfeeding discontinuation.

Variables Affecting Breastfeeding Outcomes

There are numerous, often interrelated factors that may contribute to early breastfeeding discontinuation or reductions in breastfeeding frequency. Factors influencing breastfeeding behaviours include maternal personal, attitudinal and interpersonal characteristics; intrapartum and hospital experiences; and sources of support and breastfeeding interventions (Dennis, 2002). Research has consistently identified specific factors influencing breastfeeding outcomes, including: maternal age (Pande, Unwin & Haheim, 1997; Piper & Parks, 1996; Savage, Reilly, Edwards & Durnin, 1998); socioeconomic status (Barber, Abernathy, Steinmetz & Charlebois, 1997; Hunkeler, Aebi, Minder & Bossi, 1994; Savage et al. 1998); ethnicity (Colley, Johnson, Morrow, Gaffield & Ahluwalia, 1999; Ryan, Rush, Krieger & Lewandowski, 1991); smoking status (Hill & Aldag, 1996; Minchin, 1991); intention to breastfeed (Grossman, Fitzsimmons, Larsen-Alexander, Sachs, & Harter, 1990; Lawson & Tulloch, 1995; Quarles, Williams, Hoyle, Brimeyer, & Williams, 1994; Wiemann, DuBois, & Berenson, 1998); breastfeeding confidence (O'Campo, Faden, Gielen & Wang, 1992; Buxton et al., 1991); early feeding supplementation (Hill, Humenick, Brennan & Wolley, 1997; Martin-Calama et al., 1997); continuous labour support during childbirth (Langer, Campero, Garcia & Reynoso, 1998; Scott, Klaus & Klaus, 1999); and levels of lay support for breastfeeding (Buckner & Matsubara, 1993; McNatt & Freston, 1992).

Sheehan et al. (2006) conducted an Ontario-based survey aimed at identifying risk factors for early breastfeeding discontinuation. Twenty variables were statistically associated with breastfeeding discontinuation at 4 weeks post-discharge. Logistic regression analysis was then

utilized to identify factors that significantly predicted breastfeeding cessation. Nine factors were identified as risk factors for breastfeeding cessation: (1) intention to breastfeed for less than 4 months or unsure about intended breastfeeding duration; (2) being born in Canada; (3) infant received formula while in hospital; (4) not anticipating reliance on mom's group or drop-in centre once discharged; (5) wanting more information on bottle feeding while in hospital; (6) infants having one or more visits to a walk-in clinic; (7) perceiving breastfeeding information was anything other than supportive; (8) viewing breastfeeding advice as influencing their choice of feeding method; and (9) infant readmission to hospital (excluding circumcision).

Breastfeeding and Maternal Confidence

Although there are numerous factors that may influence breastfeeding behaviours, research has consistently demonstrated that maternal breastfeeding confidence is predictive of breastfeeding outcomes. Evidence has supported the association between maternal confidence and breastfeeding outcomes both antenatally (O'Campo et al., 1992) and postnatally (Loughlin, Clapp-Channing, Gehlbach, Pollard & McCutchen, 1985; Ertem, Votto & Leventhal, 2001; Taveras et al., 2003). Research on postpartum factors associated with breastfeeding duration identified lack of maternal confidence in breastfeeding as an important risk factor for early breastfeeding cessation (Ertem et al., 2001; Taveras et al., 2003). For example, in a prospective U.S. study of 1163 mothers (Taveras et al., 2003), lack of confidence in breastfeeding ability at 1 to 2 days postpartum was associated with breastfeeding discontinuation at 2 weeks postpartum (OR = 2.8; 95% CI = 1.02 – 7.6). Similarly, Dunn, Davies, McCleary, Edwards & Gaboury (2005) also found that among maternal vulnerability factors, maternal confidence was the strongest predictor of breastfeeding outcomes. The results of this study suggest that women with

low confidence in their breastfeeding ability are at greater risk for earlier breastfeeding discontinuation than women with high confidence.

Breastfeeding Self-Efficacy

Breastfeeding self-efficacy influences breastfeeding behaviours and is predictive of breastfeeding outcomes (Dennis, 1999; Dennis, 2006). Breastfeeding outcomes are significantly impacted by a woman's level of breastfeeding self-efficacy, whereby higher levels of self-efficacy are associated with longer breastfeeding durations and higher levels of exclusivity (Blyth et al., 2002; Dennis, 2003). As such, breastfeeding self-efficacy is an important variable to measure when evaluating breastfeeding outcomes such as duration and exclusivity.

Breastfeeding self-efficacy is defined as a mother's perceived ability to breastfeed her infant resulting from the culmination of four sources of information: (1) performance accomplishments, (2) vicarious experiences, (3) verbal persuasion, and (4) inferences made from physiologic and affective states (Dennis, 1999).

Breastfeeding Self-Efficacy and Nipple Pain

The experience of nipple pain encountered by many women in the first postpartum weeks can impact a woman's breastfeeding self-efficacy and may impact breastfeeding outcomes.

According to breastfeeding self-efficacy theory (Dennis, 1999), interpretation of one's physiologic state can impact the level of breastfeeding self-efficacy, whereby positive interpretations can enhance breastfeeding self-efficacy, and negative interpretations diminish it.

Evidence has demonstrated that women experiencing breastfeeding pain had lower breastfeeding self-efficacy than women having no pain (Kingston, Dennis, & Sword, 2007). A woman's level of breastfeeding self-efficacy can also impact how breastfeeding-related pain is experienced. If a woman has high breastfeeding self-efficacy she may be better able to cope with pain, and will

find it less threatening than a woman with low breastfeeding self-efficacy. Further, if a woman persists with breastfeeding despite having pain, her successes will reinforce her sense of self-efficacy (Bandura, 1977), thus increasing the likelihood of positive outcomes.

Nipple Pain

Prevalence

Nipple pain is a common occurrence among breastfeeding mothers with prevalence rates ranging from 77% to 96%. In a Canadian study of 23 breastfeeding women, 95% of subjects reported nipple pain on at least one side during the first 10 days of breastfeeding, with greatest pain intensity on the third day postpartum (Hewat & Ellis, 1987). Similarly, a U.S. study of 100 breastfeeding women found that 96% of participants experienced nipple pain within the first 6 weeks of breastfeeding with most participants experiencing the highest pain intensity between postpartum days 3 and 7 (Ziemer et al., 1990). Ziemer and Pigeon (1993) conducted a longitudinal descriptive study of nipple changes during the first week of lactation. Of the 20 Caucasian, U.S. women, 90% reported nipple pain during the first week of breastfeeding. Finally, in an Australian study of 69 breastfeeding women, 75% of participants experienced nipple pain at the outset of breastfeeding (within the first minutes of a breastfeeding session), with 22% experiencing ongoing pain after feeding was established and the let-down reflex was experienced (Heads & Higgins, 1995). Although there is variability across studies in both the measurement of and conceptualization of pain, nipple pain appears to be prevalent for many breastfeeding women regardless of their country of origin.

Etiology

The etiology of nipple pain is not well understood; however, many researchers have identified poor positioning and/or improper latch of the baby at the breast as a common cause

(Woolridge, 1986a; Tait, 2000). As an outcome of poor attachment at the breast, mal-positioning, or inadequate milk-transfer, it has been theorized that frictional and suction trauma may lead to subsequent pain (Woolridge, 1986b). Seminal work by Gunther (1945) revealed that nipple trauma is frequently characterized by ulcerative/fissure lesions, and/or erosive/petechial lesions. Based on her measurements of intra-oral pressure changes within infants' mouths during sucking, it was found that petechial lesions corresponded with the area of maximal suction. Although levels of intra-oral pressure vary throughout a feeding, non-nutritive sucking at the breast produced negative sustained pressures of 200 mm Hg; thus, excessive negative pressure was theorized to cause the petechial lesions (Gunther, 1945). During feeding, milk released from the nipple relieves pressure exerted within the infants' mouth. An ineffective milk transfer as a result of poor positioning or attachment may result in unrelieved suction applied to the nipple surface and this may result in nipple trauma and pain (Woolridge, 1986a; Woolridge, 1986b).

Less commonly, nipple pain may also result from bacterial or fungal infections. Nipple damage is associated with colonization of organisms including *Candida albicans* (*C. albicans*) (Amir & Pakula, 1991; Amir, 1996; Tanguay, McBean & Jain, 1994), and staphylococcus aureus (*S. aureus*) (Livingstone & Stringer, 1999; Livingstone, Willis & Berkowitz, 1996), and these infections are associated with breast pain and nipple soreness. Livingstone et al. (1996) evaluated the correlation between sore nipples and the presence of *S. aureus* in a cohort study of 227 breastfeeding women. A significant relationship was found between pain intensity and positive *S. aureus* cultures ($\chi^2 = 22.41, p < 0.001$). Similarly, an Australian case control study of 51 breastfeeding women showed strong associations between *C. albicans* infections of the nipple with persistent nipple pain ($p < 0.001$) (Amir & Pakula, 1991).

Other less common causes of nipple pain have been identified. Case studies have suggested that nipple pain without trauma or infection may be a result of nipple vasospasm, especially for women with a history of Reynaud's syndrome (Garrison, 2002; Page & McKenna, 2006; Anderson, Held & Wright, 2004). Although not well understood, some women experience vasospasm of the nipple that causes severe, episodic, and sometimes prolonged nipple pain during breastfeeding. Vasospasm has been observed as blanching of the nipple during painful episodes during and following feeds and is relieved by the administration of nifedipine (Garrison, 2002; Page & McKenna, 2006).

Nipple pain has also been associated with infants identified as having a shorter than normal frenulum; otherwise known as ankyloglossia, or tongue-tie (Hogan, Westcott & Griffiths, 2005; Dollberg, Botzer, Grunis & Mimouni, 2006). In a randomized trial of 25 mother / neonate dyads based in Israel, Dollberg et al. (2006) found a significant decrease in nipple pain scores ($p = 0.001$) after neonates underwent surgical frenotomy (clipping the frenulum). In addition, standardized latch scores approached significance ($p = 0.06$) for improvement following frenotomy for mothers with improved pain scores. Although the small sample size prohibits generalization of the results, they suggest physical causes of latch problems and subsequent nipple pain.

Aside from poor positioning and latch, other factors contributing to nipple pain have been suggested. Breast engorgement (L'Esperance, 1980; Newton, 1952), use of drying soaps, lack of exposure to sunlight, vitamin deficiencies, non-nutritive sucking, vigorous sucking by the infant (Newton, 1952), improper removal of the infant from the breast, use of nipple shields, and altering the frequency or duration of feeds have been suggested as contributors to nipple pain (Morland-Schultz & Hill, 2005).

Nipple trauma is commonly experienced by breastfeeding women (Ziemer & Pigeon, 1993) and is often associated with nipple pain (Morland-Schultz & Hill, 2005). Reports of prevalence rates for nipple trauma have varied between 55% (Heads & Higgins, 1995) and 100% (Ziemer & Pigeon, 1993). In a descriptive study of skin changes of the nipple during the first week of lactation, Ziemer and Pigeon (1993) found that 100% of subjects ($N = 20$) had some level of skin changes, with 65% of the subjects having severe skin damage. For women with inflammation and eschar on the nipple, mean pain scores were significantly higher ($p < 0.05$). Heads and Higgins (1995) evaluated the nature and degree of nipple trauma and nipple pain for 69 Australian postpartum women. These authors also found a significant positive correlation between the degree of nipple damage and all measures of pain. Despite these positive findings, three women with nipple trauma reported no pain, and 16 women with no apparent nipple trauma reported pain.

Nipple Skin Trauma

To date, only two studies have evaluated skin trauma to the nipple resulting from breastfeeding. In 1945 Gunther observed 400 breastfeeding women and found that many developed swelling, petechiae, and ulcerative fissures on the nipple within the first few days of lactation. To understand the cause of tissue trauma, measurements of intra-oral pressure related to the infant's suckling were obtained during both nutritive and non-nutritive feeds. It was found that sustained negative pressures up to 200 mm Hg occurred during non-nutritive feeds where there was a lack of milk transfer. Correspondingly, Gunther theorized that the nipple swelling and petechiae related to the areas of maximal suction. Conversely, it was suggested that the ulcerative or fissure-type lesions on the nipple were a result of mechanical trauma (Gunther, 1945). Later, Zeimer and Pigeon (1993) documented skin changes of the nipple during the first

week of breastfeeding for 20 Caucasian U.S. women. It was found that all women had some skin changes to the nipple, including: edema (100%), erythema (90%), blisters (80%), and fissures or skin breakdown (65%).

To understand the mechanics of infant sucking at the breast, Woolridge (1986b) conducted ultrasound scans of maternal-infant dyads during breastfeeding. The scans demonstrated that tongue compression creates negative pressure within the infant's mouth, which serves to keep the nipple in close contact to the infant's palate. It was concluded that excessive suction within the infant's mouth as a result of low milk flow or improper positioning was a major cause of nipple lesions (Woolridge, 1986b).

Although there is a paucity of literature describing the skin changes to the nipple that result from breastfeeding, literature regarding skin trauma to other areas may be useful in understanding the histology and healing of blisters and other trauma of the nipple related to breastfeeding. Typically, blisters and other tissue damage will result from frictional or other mechanical forces applied to the skin (Naylor, 1955). Friction results from movement between two contacting surfaces where there is resistance. If forces are applied to produce movement between the surfaces, the frictional force increases correspondingly (Naylor, 1955). The most important forces in blister formation are dynamic shear forces, comprised of vertical forces, fore and aft shear, lateral shear and torque (Spence & Sheilds, 1968; Naylor, 1955; Root, Orien & Weed, 1977). Frictional and net shear forces result in epidermal separation causing blistering. The physics of shear forces behind skin trauma are complex, thus it has been difficult to quantify what specific force is required to form a blister (Akers & Sulzberger, 1977).

Human and animal studies were conducted to study the effect of frictional forces on the skin (Naylor, 1955). Naylor demonstrated that rupture of the skin was the product of frictional

force and the number of rubs on the skin. Skin appeared to tolerate low frictional forces, even with a high number of rubs. However, the skin would produce blisters with a low number of rubs if the frictional forces were high enough (Naylor, 1955). During breastfeeding, milk is expressed from the nipple by a repeated wave of compression by the infant's tongue, pressing it against the infant's soft palate (Woolridge, 1986b). Without adequate milk ejection, intraoral pressure increases, placing greater mechanical forces on the nipple. Additionally, Naylor (1955) identified that water on the skin impacts frictional forces such that large amounts of water decreased frictional forces, and small amounts of water on the skin increased frictional forces. As such, if there is ineffective transfer of milk to the infant's mouth, an environment conducive to tissue trauma and blister formation may be created.

Other variables impacting friction on the skin were identified in later studies. Sulzberger, Cortese, Fishman and Wiley (1966) demonstrated that thinner skin would produce blisters with less frictional force than thick skin. Additionally, warmer skin was found to blister more quickly than cooler skin (Cortese, Griffin, Layton & Hutsell, 1969). Biomechanically, the stratum corneum and the dermis maintain stiffness unless they are exposed to humidity or increases in temperature (Wildnauer, Bothwell & Douglass, 1971; Papir, Hsu & Wildnauer, 1975). Under these conditions, the skin has more ability to elongate, putting collagen fibres and other cellular structures under strain and at risk for trauma (Sanders, Goldstein & Leotta, 1995).

The early signs of tissue breakdown from mechanical forces may present as redness or a change in skin colour, excoriation, or blisters (Sanders et al., 1995). When skin is exposed to friction by repeated rubbing, the skin will first redden, and will then develop a fluid-filled cleft in the epidermis between the stratum spinosum and the stratum granulosum (Jagoda, Madden & Hinson, 1981). The most superficial layer of the skin, the epidermis, is comprised of several

cellular layers. Most superficially is the stratum corneum, followed by the stratum granulosum, stratum malpighian, and the stratum basale respectively. The stratum basale is next to the dermis and is the deepest layer of the epidermis. Examination of skin exposed to friction demonstrated that shearing forces cause damage between the epidermis and the dermis, causing a blister to form within the epidermis (Akers & Sulzberger, 1972).

The Relevance of Pain Theory

Pain is a multidimensional experience resulting from a complex interplay of sensory, affective and cognitive factors that vary from person to person (Basbaum, Bushnell & Davor, 2005). As defined by the International Association for the Study of Pain (IASP), pain is “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (Merskey & Bogduk, 1994, p.210). This definition, and much of what is understood about pain today, is built upon the tenets of the Gate Control Theory (GCT) introduced by Melzack and Wall in 1965. Gate Control Theory (Melzack & Wall, 1965) was the first pain theory that proposed the integration of the physical and psychological aspects of the pain response, suggesting that the experience of pain is not merely the direct result of tissue damage. Rather, pain is a highly subjective experience shaped by individual and cultural factors such as prior experience with pain, attention to pain, one’s meaning of the pain, personality, upbringing and age among other factors (Melzack, 1999). Since then, pain knowledge has evolved significantly. Gate Control Theory led to further research that contributed to our current understanding of pain mechanisms such as sensitization and central nervous system plasticity (DeLeo, 2006).

When GCT was introduced by Melzack and Wall in 1965, it challenged two predominant pain theories, the specificity and pattern theories (von Frey, 1894; Goldscheider, 1894).

Specificity theory (von Frey, 1894) proposed that nociceptive impulses were transmitted directly from specific pain receptors to a pain centre in the brain, thus suggesting that pain was proportional to the degree of tissue damage. This theory has since been disproven, with the discovery that surgical ablation of 'pain pathways' often resulted in the continuance of pain (Basbaum & Jessell, 2000). Although Melzack and Wall (1965) supported the idea of specialized receptors, fibres and spinal pathways, their theory affirmed that pain perceptions were modulated in the central nervous system (CNS). Melzack and Wall built upon the concepts of a collection of pain theories, coined 'pattern theory' (Goldschneider, 1894; Livingston, 1943; Noordenbos, 1959). Noordenbos' theory that activity in large, fast myelinated fibres could inhibit painful input from small, slow unmyelinated fibres was integral to the development of GCT (Basbaum et al., 2005).

GCT (Melzack & Wall, 1965; 1973; 1982) suggested that inter-neurons of the substantia gelatinosa (SG) function as a 'gate', regulating the input of large and small fibres to lamina V cells. Further, GCT proposed that pain was not simply a sensory experience, but a complex experience involving central mechanisms. The perception of pain is modulated centrally through descending mechanisms that may be influenced by people's past, attention and emotion, and is a dynamic interplay of ascending and descending neural systems and balance of inhibitory-excitatory mechanisms. As such, the experience of pain and related response are unpredictable and variable for each person and experience.

Two discrete types of afferent axons fire impulses when stimulated by pain or inflammation. The small unmyelinated C fibres signal heat/mechanical and/or poorly localized pain, whereas the myelinated A-delta and beta fibres signal heat, cold and localized painful stimuli. Conversely, large, myelinated A-beta fibres are non-nociceptive and respond to light

pressure. These fibres synapse in the substantia gelatinosa (SG) of the dorsal horn of the spinal cord, where modulation of neural impulses takes place. GCT proposed that injured tissues initiate activity of small nociceptive (A-delta and C) fibres. Sufficient activity in the large, non-nociceptive A-beta fibres close the gate by inhibiting the transmission of noxious messages via small fibres to the transmission (T) cells in the SG (Melzack & Wall, 1965, 1973, 1996). If noxious impulses are not inhibited by large fibre activity and they reach a critical threshold, the gate will remain open (or partly open) and will allow transmission to second-order neurons in the SG, and then to the thalamus and cerebral cortex resulting in the perception of pain (Melzack & Wall, 1965, 1973, 1996). However, nociceptive impulses can also be inhibited by descending mechanisms that influence dorsal horn neuronal activity, and is activated by sensory-discriminative and motivational-affective information from the brainstem, thalamus and cerebral cortex (Melzack & Wall, 1965; 1973; 1996).

It is now understood that the regulation of noxious impulses goes beyond the gating mechanisms described in the GCT. Pain is the result of a dynamic interaction of ascending and descending inputs, while balancing inhibitory-excitatory mechanisms in an already active nervous system. Endogenous neurotransmitters such as opioids, serotonin and norepinephrine have excitatory and inhibitory roles that are involved in descending control (Basbaum & Jessell, 2000). Furthermore, the CNS is a substrate of past experiences with pain and prior activity, and is influenced by attention to pain and emotional responses to pain. The transmission of noxious stimuli is influenced by cognitive processes, such as the meaning of pain. As such, pain is understood to be a highly individualized and variable experience, where the perception and response to pain are unpredictable. (Melzack & Wall, 1973; 1982).

Since GCT, considerable advancements in the field of pain neuropathophysiology have led to an understanding of the role of plasticity of the nervous system in peripheral and central sensitization (Basbaum & Jessell, 2000). The neurochemical processes of the peripheral and central nervous system undergo changes when exposed to persistent noxious stimuli. This process, called sensitization, results in an amplified responsiveness of nociceptors that ensues as a result of locally released inflammatory mediators, whereby the action potential for neural transmission falls. This enhanced responsiveness is responsible for primary hyperalgesia, which is an increased sensitivity to pain. Tissue breakdown results in the release of chemicals that surround nerve endings, and resultant disruption of mast cells release other inflammatory agents that either cause pain or contribute to sensitization of primary afferents (Melzack & Wall, 1996). Following activation and degranulation of mast cells, proinflammatory mediators are liberated such as histamine, cytokines and serotonin. These substances over-stimulate afferents, causing release of more allogeneic ligands such as substance P, which contribute to inflammation and subsequent hyperalgesia (Metcalf, Baram & Mekori, 1997).

At the same time peripheral sensitization takes place, second and third order sensory neurons in the CNS can also undergo molecular, cellular and circuit changes that cause an exaggerated responsiveness to normal peripheral input. This process is termed central sensitization (Basbaum et al., 2005). During influxes of nociceptive activity to the CNS from the periphery, glutamate released from primary afferents binds to NMDA receptors causing calcium to flood the postsynaptic neuron. This results in biochemical changes that lead to pain amplification. As a result, non-noxious stimuli may be perceived as painful (allodynia). Although normally transient, continued noxious peripheral inputs may result in prolonged or indefinite central sensitization (Basbaum et al., 2005).

Although much of research on pain control has focused on peripheral and spinal cord mechanisms, emerging evidence supports the role of modulating mechanisms in the nervous system accessed via contextual and cognitive manipulation. (Fields, 2000). It is now understood that attentional state, emotional context, attitudes and expectations alter both the transmission and perception of pain. It is suggested that techniques to alter these variables may alter the sensory and affective aspects of pain perception by modulation of neural activity in the limbic or sensory brain regions (Villemure & Bushnell, 2009). The neural mechanisms underlying the modulation of pain by cognitive and emotional factors are not fully understood, but most likely involve many levels of the CNS (Villemure & Bushnell, 2009). Descending pathways from the frontal cortex, the periaqueductal gray matter (PAG), rostral ventral medulla and the dorsal horn of the spinal cord have demonstrated involvement in attentional and / or emotional modulation of pain (Fields, 2000).

Nipple pain experienced in the early postpartum period is acute, and acute pain is often initiated by tissue damage (Melzack & Wall, 1996). Acute tissue damage activates inflammation and activates nociceptors that initiate peripheral and central sensitization. As a result, non-noxious stimuli (such as an infant suckling or brushing of the skin against clothes) can activate the normally high-threshold nociceptors resulting in allodynia. Pain that results from minor tissue injury usually has a protective effect, as it signals the presence of potentially harmful stimuli and encourages an individual to withdraw or avoid further injury. However, problems arise when the injury or inflammation producing the pain persists (Basbaum & Julius, 2006). In the case of nipple pain, the tissue is exposed to repeated cycles of tissue trauma, inflammation and healing. Although acute pain such as nipple pain will often stop once the noxious stimulus is removed, inflammation may result in pain for hours, days or longer (Basbaum et al., 2005). As

such, to prevent women from avoiding pain associated with breastfeeding, it is imperative to interrupt the inflammatory cycle, to enhance healing, and minimize non-breastfeeding related stimulus to damaged tissue. Lanolin, an ointment that promotes moist wound healing, may serve to alleviate pain by two mechanisms. Moisture retention and enhanced wound healing may interrupt the inflammatory process and shorten the duration of pain associated with acute tissue damage. Furthermore, lanolin serves as a physical barrier between the nipple and the clothing, thus providing protection from further stimuli.

Wound Healing

The skin serves important functions of protecting the body from pathogens and damage, (Proksch, Brandner & Jensen, 2008) and any break in the skin must be rapidly repaired (Martin, 1997). Damage to the skin of the nipple by way of blistering, excoriation or fissuring is common for breastfeeding mothers (Zeimer & Pigeon, 1993; Gunther, 1945) and often leads to pain (Zeimer & Pigeon, 1993; Heads & Higgins, 1995). Furthermore, nipple tissue is especially vulnerable to breakdown and risk of infection (Livingstone et al., 1996) since nipple wounds are exposed to both maternal and infant oral flora, and is in constant variation between a wet and dry environment. These factors may result in a cycle of tissue trauma, healing and tissue re-damage with accompanying pain (Livingstone et al., 1996).

Damaged nipple tissue undergoes the same phases of healing as other superficial wounds involving the epidermis (Cable et al., 1997). Nipple skin is consistent with the integumentary system and is comprised of epidermal, dermal, and subcutaneous layers (Vorherr, 1974). The epidermis is keratinized and layered, and is the outermost layer of the nipple skin providing the first line of defense against pathogens and mechanical harm (Martin, 1997). The dermal layer is collagen-rich connective tissue that supports and nourishes the epidermis (Martin, 1997).

Superficial trauma to the nipple epidermis will result in a complex healing process involving numerous tissues and cellular structures (Martin, 1997; Aukhil, 2000).

The healing of adult skin is a complex interplay of many tissues and cells, and takes place in four to five distinct phases (Martin, 1997; Aukhil, 2000; Clark, 1988). Typically, wounds undergo an inflammatory phase first, followed by granulation, fibroplasia, epidermization and ending in the maturation phase (Clark, 1988). When skin is first damaged, leakage of blood from damaged vessels forms a clot that serves as a temporary repair (Martin, 1997). The clot consists of platelets and a fibrin mesh matrix liberated from thrombin cleavage of fibrinogen, in addition to small amounts of plasma fibronectin, vitronectin and thrombospondin (Martin, 1997; Aukhil, 2000). Aside from plugging damaged vessels, the clot also holds cytokines and growth factors that are released once platelets degranulate. The combination of growth factors calls inflammatory cells to the wound, which 'kick-starts' the wound repair process (Martin, 1997; Aukhil, 2000). While inflammatory cells are being recruited, the clot also signals neutrophils and monocytes. Neutrophils eliminate wound debris by the release of toxic products and enzymes (Clark, 1996) and have pro-inflammatory cytokines that act as early signals for fibroblasts and keratinocytes (Hubner et al., 1996). Macrophages are converted from monocytes and mark the end of the inflammatory phase (Clark, 1988). Macrophages phagocytose bacterial, cellular and other matrix debris in addition to synthesizing and secreting growth factors and cytokines (Aukhil, 2000, Martin, 1997).

Granulation, the second phase of wound healing, is when skin reconstruction is initiated. The fibrin clot formed during the inflammatory phase acts as a matrices that becomes coated with fibronectin generated from serum and fibroblasts. Endothelial cell buds and activated fibroblasts migrate over the fibronectin, gluing itself to the fibrin. The migrating fibroblasts

synthesize more fibronectin, glycosaminoglycans and collagen. Slowly, fibrin is lysed and is replaced by collagen. Endothelial cells begin to migrate into the matrix and new capillaries are formed (Clark, 1988).

The third stage of healing involves morphologic changes among fibroblasts to myofibroblasts, allowing them to migrate into the wound. Around 7 days post-tissue damage, the myofibroblasts, resembling muscle cells, begin to exert contractile forces on the wound edges. The duration for contraction of scars will depend on the size of the tissue damage, and may continue beyond the last stage of healing (Clark, 1988).

The final stage of wound healing occurs when keratinocytes advance from wound edges and epidermization begins to take place (Clark, 1988). Keratinocytes move forward in a migration over the wound matrix and wound dermis (Clark, 1996). Locomotion of keratinocytes is facilitated by contraction of intracellular actinomyosin filaments (Mitcheson & Cramer, 1996). Keratinocytes bore a pathway through the fibrin clot by dissolving the fibrin barrier with fibrinolytic enzymes, such as plasmin (Martin, 1997). Finally, once the wound surface is covered with a layer of keratinocytes, a new layer of epidermis develops from the wound margins inward (Gipson, Spurr-Michaud & Tisdale, 1988).

Wound healing is a complex process that results from coordinated actions of inflammatory cells, keratinocytes, fibroblasts and endothelial cells. Many of the events that occur in wound healing are triggered and stopped by a complex network of signals (Aukhil, 2000). Many wound signals control more than one cellular activity, and there are redundancies and ‘cross-talk’ among the signals. As a result, tissue repair is not entirely understood (Martin, 1997). The complexity of wound healing presents challenges to health care providers who seek efficient and effective treatment approaches. Although management of nipple tissue trauma has been

managed in different ways over the years (Cable et al., 1997), current management of skin wounds are based on the principles of moist wound healing (Cable et al., 1997).

Moist Wound Healing

Seminal work on the outcomes of moist wound healing was introduced by George Winter in 1962. Winter discovered that wounds on young pigs that were kept moist with a polythene film epithelialized at twice the rate than those left to air dry. During normal healing, leukocytes migrate from the dermis into the fibrous tissue just below the wound surface. Epidermal migration takes place from the wound margins and around hair follicles, and moves through the fibrous tissue. With the wound surface kept moist, leukocytes migrate from the dermis into the serous exudate on the wound surface. Subsequent epidermal migration takes place through the serous exudate on the wound surface above the fibrous tissue instead of through it (Winter, 1962). Winter theorized that the dermis becomes partially dehydrated during normal wound healing, and this causes leukocytes to become trapped at the dermal surface, thus slowing the rate of epidermal migration (Winter, 1962).

Since Winter's discovery, the advantages of moist wound healing have become more widely recognized. Advantages of wound healing under moist conditions include: (1) reduced dehydration and cell death (Keast & Orsted, 2010); (2) increased angiogenesis (Knighton, Silver & Hunt, 1981); (3) increased re-epithelialization (Haimowitz & Margolis, 1997); and (4) decreased pain (Keast & Orsted, 2010). While there are clear advantages to moist wound healing, the type of treatment required will depend on the nature of the wound, phase of healing, and the needs of the individual (Keast & Orsted, 2010). For trauma to nipple tissue, lanolin provides a bacteriostatic, semi-occlusive barrier that allows for moisture retention. Since lanolin is odorless, tasteless and non-toxic, it may enhance healing of nipple tissue damage, while being

safe and non-offensive for the breastfeeding infant.

Lanolin

Medical grade lanolin is a single-ingredient ointment used as a moisture-retaining barrier for the relief of painful or damaged nipples. Lanolin is a waxy secretion produced by the sebaceous glands of sheep and is extracted from sheep fleece after shearing. Medical grade lanolin such as Lansinoh® HPA® is processed to be free of lanolin alcohols, detergent and pesticide residues, colour and odor forming impurities.

Lanolin is considered an emollient, which softens the skin by assisting rehydration and preventing dehydration. The emollient mechanisms of lanolin include its occlusive and humectant properties. Lanolin provides a layer of oil on the skin that slows the loss of water by evaporation and maintains moisture of the stratum corneum (Orr, 1996; Orr & Steel, 1997). Additionally, because lanolin is semi-occlusive, it allows for the retention of water without the occurrence of waterlogging or maceration of the skin (Orr & Steel, 1997).

In addition to having moist wound healing properties, lanolin is thought to protect nipple wounds from external stimuli. When a (approximately 3 mm) layer of lanolin is applied to the entire nipple it acts as a protective barrier, preventing contact and stimulation from the environment (such as clothing) (Mann-Mertz, 1990). As such, for damaged nipples, lanolin may reduce pain by facilitating healing and by reducing stimuli to the nipple.

Systematic Review of Treatments for Nipple Pain

A Cochrane systematic review by Dennis et al. (2008) evaluated interventions to treat painful nipples among breastfeeding women. As a result of statistical heterogeneity among the included studies, pooled estimates of effect could not be generated. Three studies between 2004 and 2008 were included in the review, with each study recruiting from different countries

(Latvia, Iran, and Canada) under varied circumstances. With the exception of lanolin, the interventions to treat pain were diverse. All studies (Cadwell et al., 2004; Dennis, Schottle, Hodnett & McQueen, 2012; Mohammadzadeh, Farhat & Esmaily, 2005) included lanolin as either an intervention or control. Other interventions included EBM (Mohammadzadeh et al., 2005), breast shells (Cadwell et al., 2004), glycerin gel (Cadwell et al., 2004) and an all-purpose nipple ointment (Dennis et al., 2012) (containing mupirocin, miconazole and hydrocortisone). Although the analysis was qualitative, the authors provided a narrative summary that considered the direction, size, and strength of evidence for treatment effects. Despite the rigorous methodology of the review, the results are not generalizable. The review included three studies, incorporating less than 500 women with varying interventions, participants, study outcome measures and standards of usual care. As such, the results were inconclusive with limited external validity (see Appendix B for a summary of studies evaluating prevention/treatment of nipple pain). The review concluded that there is no evidence that one intervention improved the experience of nipple pain for breastfeeding women, and there is insufficient evidence to recommend any intervention for the treatment of nipple pain or trauma. As such, further rigorous research is required to evaluate commonly used treatments, utilizing sound methodology, having adequately powered sample sizes, and including diversity of subjects to increase the generalizability of findings.

Conceptual Framework

The primary outcome for this trial is severity of nipple pain at 4 days post-randomization. The secondary outcomes include breastfeeding duration and exclusivity. The conceptual framework for this study is guided by the tenets of the GCT (Melzack & Wall, 1965; 1973; 1982), the neurochemical mechanisms of acute pain, and principles of moist wound healing.

Nipple pain is a complex phenomenon influenced by many interrelated factors. While there are several theories regarding the etiology of early nipple pain among breastfeeding women, it is generally accepted that improper positioning and poor latch are important causative factors (Heads & Higgins, 1995). Improper latch and/or poor positioning may cause tissue damage by way of excessive suction or friction. Improper latch and poor positioning may also lead to inadequate milk transfer, causing an increase in negative intra-oral pressures and subsequent suction trauma to the nipple. The resultant nipple trauma causes a cascade of inflammatory processes including the release of nociceptive substances such as histamines, bradykinins, and substance P, resulting in pain (see Figure 1). Finally, improper positioning and poor latch can cause compression and tensile mechanical forces that may result in pain for women while breastfeeding.

Pain is an unpleasant stimulus for breastfeeding women, and often leads to women decreasing breastfeeding frequency or breastfeeding cessation. Pain also has an inhibitory effect on the release of oxytocin, the hormone responsible for the release of milk at the cellular level. With the inhibition of milk release, pain may hinder efficient transfer of milk from the alveoli to the nipple sinuses. Inadequate milk transfer then results in either non-nutritive sucking and/or engorgement, causing nipple trauma/pain/oxytocin inhibition (see Figure 1). It is therefore important to interrupt this cycle by providing an intervention aimed at reducing or eliminating pain.

There is consensus among wound care specialists that support principles of moist wound healing (Cable et al., 1997). Lanolin is considered a facilitator of moist wound healing commonly recommended to breastfeeding women as a treatment for nipple pain. Lanolin provides a semi-occlusive, moisture-retaining barrier that allows for accelerated migration of

epithelial cells through moist exudate, and speeds healing. After initial tissue trauma, erythema and pain occurs followed by clot formation. Providing damaged nipple tissue with a medium that promotes moisture retention prevents eschar formation, promotes epithelial re-growth, thus enhancing the healing process and reducing pain.

When nipple tissue is traumatized, chemicals such as histamines, bradykinins, and substance P are liberated, causing a nociceptive response in small non-myelinated C fibres. Lanolin may provide enhanced healing through moisture retention in damaged tissue. Therefore, lanolin may increase the rate of healing, thus reducing the amount or duration of exposure to allergenic substances that contribute to sensitization of peripheral nociceptors. In addition, moisture barriers may protect sensitized tissues from external stimuli. Less nociceptive activity generated in the periphery may prevent a critical threshold from being reached in the dorsal horn; as such, nociceptive impulses would not continue to the higher processing centres of the CNS and pain would not result. As such, applying lanolin to sore nipples may lead to reductions in pain.

Nipple pain may lead to a reduction in the frequency of feedings and is one of the primary reasons for discontinuing breastfeeding. However, it is unclear how breastfeeding behaviour is impacted by the experience of nipple pain. Although many women discontinue breastfeeding after experiencing nipple pain, other women experiencing nipple pain will persevere. There are numerous factors that may contribute to early breastfeeding discontinuation. Factors influencing breastfeeding behaviours include maternal personal, attitudinal and interpersonal characteristics; intrapartum and hospital experiences; sources of support and breastfeeding interventions (Dennis, 2002). As such, it is important to identify the variables that would place a mother at risk for early breastfeeding discontinuation.

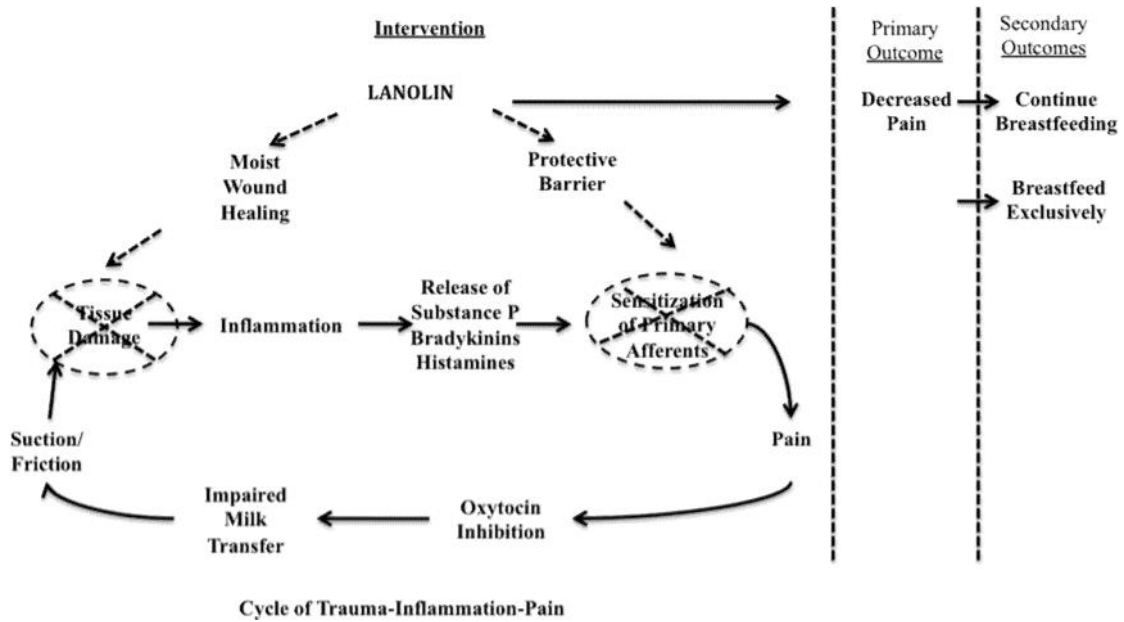


Figure 1. Conceptual Framework

Research Questions

Primary Research Question

1. Compared to usual care for breastfeeding women with nipple pain, what is the effect of the application of lanolin on nipple pain intensity at 4 days post-randomization?

Secondary Research Questions

1. Compared to usual care for breastfeeding women with nipple pain, what is the effect of the application of lanolin on any breastfeeding at 12 weeks postpartum?

2. Compared to usual care for breastfeeding women with nipple pain, what is the effect of the application of lanolin on breastfeeding exclusivity at 12 weeks postpartum?

Exploratory Research Questions

1. What is the effect of the application of lanolin on nipple pain intensity at 7 days post-randomization?

2. Compared to usual care for breastfeeding women with nipple pain, what is the effect of the application of lanolin on pain as measured by the MPQ-SF at 4 days post-randomization?

3. Compared to usual care for breastfeeding women with nipple pain, what is the effect of the application of lanolin on breastfeeding self-efficacy at 4 days post-randomization?

4. Is there a difference in satisfaction levels among breastfeeding women using lanolin for nipple pain versus women receiving usual care?

Chapter 3 Methods

Overview

A randomized controlled trial was conducted to evaluate the effect of the application of lanolin on nipple pain among breastfeeding women with nipple trauma when compared with a control group receiving standard care. A diagram representing the trial schema is shown in Figure 2. In-hospital breastfeeding women within 3 days postpartum (72 hours) were assessed for eligibility. Eligible and consenting participants were randomly allocated to one of two study groups: (1) a lanolin group, in which mothers applied a pea-sized amount of lanolin to their painful nipples after every feed; and (2) a control group, in which mothers received usual care and did not apply lanolin to painful nipples. All mothers had access to standard postpartum and community care. Random allocation was facilitated by using consecutively numbered, sealed opaque envelopes assembled by a third party external to the study. A research assistant blinded to group allocation collected all outcome data at 4 and 7 days post-randomization, and at 4 and 12 weeks postpartum.

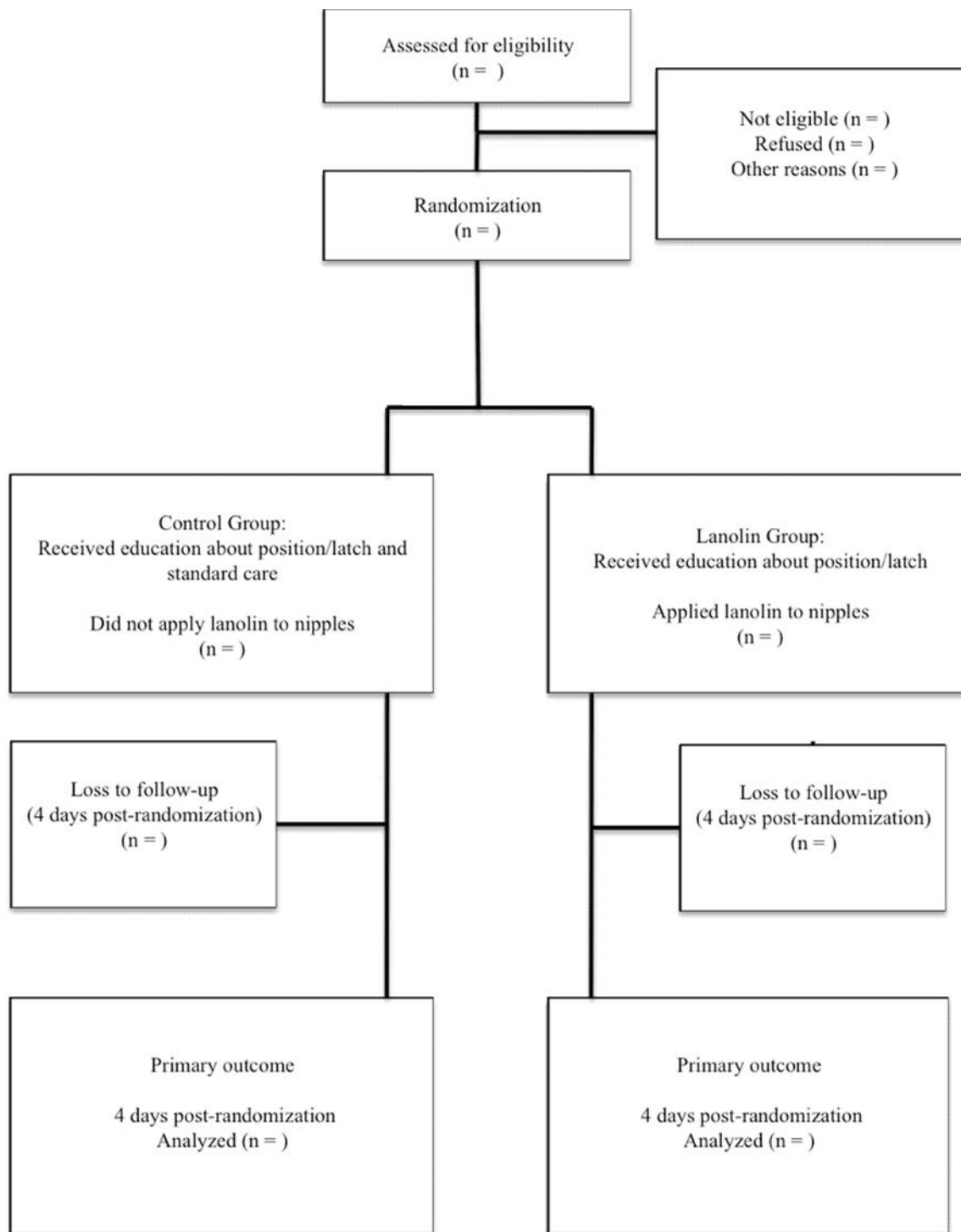


Figure 2. Trial Schema

Sample and Setting

Participants were recruited from an acute-care teaching hospital in the Hamilton-Wentworth region of Southern Ontario. The birth rate for the site is approximately 3700 births per year.

In-hospital breastfeeding mothers were recruited within the first 72 hours postpartum who met the following inclusion criteria:

1. Maternal complaint of nipple pain with any sign of nipple trauma to one or both nipples, such as blistering, crusting, redness, bleeding, swelling, cracking, discoloration or peeling.
2. Infant delivered at, or greater than 37 weeks gestation.
3. Singleton birth.
4. Speaks and understands English.
5. Access to telephone.

Mothers having the following were excluded from the study:

1. Infant not expected to be discharged home with mother.
2. Infant with congenital abnormalities that would impair breastfeeding, such as cleft palate or ankyloglossia (tongue-tie).
3. Maternal allergy to lanolin.
4. Maternal health conditions that may interfere with breastfeeding (physical or mental illness) as determined by hospital staff.
5. Expressed aversion to, or, strong desire to use lanolin.

Sampling

A convenience sample was recruited. Recruitment took place from Monday to Friday. The PI was responsible for both recruitment and delivery of the intervention to ensure consistency of educational information provided to all mothers. In addition, the PI collected all baseline data at the time of recruitment.

Manoeuvre

RCT Manoeuvre for All Participants Prior to Randomization

Prior to the commencement of recruitment, ethics approval was obtained from The University of Toronto ethics board, in addition to obtaining ethics approval from the participating recruitment (hospital) site. Nurses (RNs/RPNs) working on the obstetric unit were advised of the trial via detailed in-services conducted by the PI.

Mothers providing verbal consent to hospital nurses to hear a detailed study explanation were approached by the PI. The PI then provided a detailed study explanation to eligible participants to provide pertinent details of the study, confirm the participant's eligibility, and to obtain written consent to participate. Once consent was obtained, baseline data were collected and the participant was randomized and advised of group allocation.

Randomization

Participants were randomly assigned to either the treatment or control group by using sealed, opaque, sequentially numbered envelopes assembled by a researcher external to the trial. A Registered Nurse (RN) assigned to the participant opened the next sequentially numbered envelope in the queue to reveal the group allocation to the participant. To maintain an audit-trail, random group allocation was documented by the RN on a hard-copy form and date-stamped with a unique participant identification number.

RCT Manoeuvre Following Randomization for All Groups

Participants in both groups were provided with education by the PI regarding proper positioning and latch for effective breastfeeding. An intervention checklist was completed for each participant to ensure that all information and education was provided.

A research assistant blinded to random group allocation telephoned all the participants at 4 and 7 days post-randomization at 4 and 12 weeks postpartum to collect follow-up data.

Study Groups

Mothers in both groups received usual postpartum in-hospital and community care. Usual postpartum care in-hospital included breastfeeding education and assistance by a RN/RPN or lactation consultant, which may have included variable advice depending on the individual nurse's knowledge, experience and beliefs. Assessment of breastfeeding and corrective education on positioning, and latch was provided if needed. Acceptable strategies for pain relief included: application of warm or cool washcloths to the breast, application of ice packs to the nipples, analgesia such as ibuprofen or acetaminophen, air-drying the nipples or the use of breast shields. Once discharged from hospital, standard community resources were available to all mothers including: public health breastfeeding programs, outpatient hospital breastfeeding clinics, La Leche League, community based breastfeeding support groups, and hospital telephone assistance ('warm line'). All mothers could proactively seek support from any or all of these resources.

Control Group

Participants allocated to the control group received usual care (as described above) that was provided in-hospital and in the community following discharge, and were not to apply lanolin to their nipples. Nurses on the postpartum unit and in the outpatient breastfeeding clinic

were also instructed not to offer or recommend lanolin to women in the control group.

Participants were asked at each follow-up if they used lanolin to treat their nipple pain.

Treatment Group: Lanolin

Participants randomized to the lanolin treatment group received usual care in-hospital and usual community postpartum care following discharge, and also received a tube of lanolin and a handout with instructions. Participants were instructed by the PI to wash their hands, and to gently apply a pea-sized amount of lanolin (manufacturer's recommended 'dose') to the nipple and the areola immediately surrounding the erectile portion of the nipple following every feed until resolution of symptoms or the end of the study period.

Study Outcomes

Nipple Pain Intensity

The International Association for the Study of Pain (IASP) defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.” (IASP, 2003). The primary outcome of nipple pain was measured using an 11-point numeric rating scale (NRS) at baseline and at 4 days post-randomization (see Appendix F). For many mothers, nipple pain appears to have the greatest intensity between the third and seventh day postpartum, with a peak in severity on the third day postpartum (Ziemer et al., 1990; Hewat & Ellis, 1987). Noting that many women would be 1 or 2 days postpartum when they enrolled in the study, the follow-up at 4 days post-randomization was chosen to capture the period where pain severity tends to be the greatest, and to allow time for the intervention to take effect.

Breastfeeding Duration

Breastfeeding duration was measured by asking women if they have breastfed within the past 24 hours or not (Appendix G). Breastfeeding duration was measured at 4 and 12 weeks postpartum. The 4-week postpartum follow-up was chosen since most women that discontinue breastfeeding due to difficulties would have done so within this time frame.

Breastfeeding Exclusivity

Breastfeeding exclusivity is defined as the receipt of breast milk only with no additional food or liquid, including water. Maternal breastfeeding exclusivity was categorized utilizing Labbok & Krasovec's (1990) framework for breastfeeding definition (Table 1). Breastfeeding level was categorized at baseline, 4 and 7 days post-randomization and at 4 and 12 weeks postpartum.

Table 1

Definitions of Infant Feeding Categories (Labbok & Krasovec, 1990)

Category of Infant Feeding	Requires that the Infant Receive	Allows the Infant to Receive	Does not Allow the Infant to Receive
Exclusive Breastfeeding	Breast milk (including milk expressed)	Vitamins, minerals, medicines	Anything else
Almost Exclusive Breastfeeding	Breast milk as the predominant source of infant nourishment	< 1 bottle/week of non-human milk, water, water-based drinks, fruit juice, ORS, ritual fluids	Anything else
High Breastfeeding	Breast milk as the predominant source of infant nourishment	> 1 bottle/week of non-human milk or any other food or liquid	1 bottle/day of non-human milk
Token Breastfeeding	Non-human milk or any food or liquid as the predominant source of infant nourishment	Breast is used for comfort or to console the infant with minimal nutritional contribution	
Bottlefeeding	Any non-human food or liquid		Breast milk

Instruments

Numeric Rating Scale (NRS)

The primary outcome of nipple pain intensity was measured at 4 days post-randomization using an 11-point numeric rating scale (NRS) (Appendix F). The NRS is an 11-point scale whereby a participant is asked to rate their pain from 0 to 10, where 0 represents no pain on the intensity continuum and 10 represents pain as bad as it could be. The NRS is commonly used to assess pain intensity among a variety of adult populations in both research and clinical settings (McDowell, 2006). Other commonly used scales for measuring pain intensity include visual analogue scales (VAS) and verbal rating scales (VRS) (Jensen, Karoly & Braver, 1986). Although all three pain scales are valid and reliable tools for measuring pain intensity (Williamson & Hoggart, 2005), the NRS is favoured by researchers and clinicians for its simplicity, ease of administration, and utility among a diversity of patient populations (Jensen & Karoly, 2001; Jensen et al., 1986). The NRS takes seconds to complete, does not require tools such as paper or pencil, and can be completed over the phone. Because of its simplicity, the NRS has a high rate of participant compliance (Jensen & Karoly, 2001).

The validity of the NRS has been well established (Jensen & Karoly, 2001). Although there are no studies that specifically address the validity of the NRS among breastfeeding women, numerous studies of both acute and chronic pain among various adult populations have shown positive and significant correlations with other pain intensity measurements (Jensen et al., 1986; Jensen, Karoly, O’Riordan, Bland & Burns, 1989; Paice & Cohen, 1997; Seymour, 1982). For example, Jensen et al. (1989) assessed eight measures of pain intensity among 69 adult post-operative patients. Correlation coefficients were all significant ($p < 0.001$) and ranged from 0.46 to 0.89 with a median r of 0.60. Similarly, Bijur, Latimer & Gallagher (2003) found that NRS

scores were strongly correlated to VAS scores at all time periods for emergency room admissions ($r = 0.94$, 95% CI = 0.93 – 0.95). Finally, a study of post-operative dental pain found high correlations between pain scores from two identical VASs and the NRS ($r = 0.9073$, $p < 0.001$, and $r = 0.9151$, $p < 0.001$ for the two VASs respectively) (Seymour, 1982).

The NRS has shown sensitivity to treatments expected to impact pain intensity among those with acute pain (Jensen & Karoly, 2001). A comparison of pain rating scales by sampling from clinical trial data found approximately equal sensitivity of the NRS and the VAS when evaluating acute post-operative pain intensity (Breivik, Gudmundur & Skovlund, 2000). One study evaluating interventions to treat nipple pain used the NRS to detect a significant difference between groups. Brent, Rudy, Redd, Rudy and Roth (1998) found significantly larger reductions in feeding pain for those using breast shells and lanolin versus a hydrogel dressing when evaluated with an 11-point NRS. As such, the NRS is a commonly used, simple measurement with established validity and sensitivity to detect clinical changes in self-report of pain intensity.

McGill Pain Questionnaire – Short Form (MPQ-SF)

The McGill Pain Questionnaire - Short Form (MPQ-SF) was utilized to measure nipple pain intensity and quality, and to provide a further description of pain at baseline and at 4 and 7 days post-randomization (Appendix F). The MPQ-SF is comprised of a Pain Rating Index (PRI), the Present Pain Intensity (PPI) and a Visual Analogue Scale (VAS). The PRI measures pain quality using 15 descriptors of sensory ($n = 11$) and affective ($n = 4$) dimensions. Subjects choose the adjectives that describe their pain, and rank the severity on a 4-point scale from 0 = none to 3 = severe (Jensen & Karoly, 2001). The PRI subscales are summed to acquire scores for sensory (PRI-S), affective (PRI-A) and total (PRI-T) from 0-33, 0-12 and 0-45 respectively. The PPI is a 5-point intensity scale ranging from 0 = mild to 5 = excruciating. Finally, the MPQ-SF

includes a visual analogue scale (VAS). However, as mentioned previously, the VAS was replaced with an 11-point NRS to facilitate administration over the telephone.

The MPQ-SF was derived from the McGill Pain Questionnaire (MPQ) (Melzack, 1975), one of the most frequently used tools to measure clinical pain (Lowe, Walker & MacCallum, 1991). The MPQ has been utilized among many populations, including women of childbearing years having menstrual and obstetric pain (Melzack, 1975). The MPQ-SF was developed for use in research settings where time to obtain information is limited (Melzack & Katz, 2001). The MPQ-SF provides a more rapid measurement of pain than the MPQ, requiring approximately 2-5 minutes to complete. As such, the SF-MPQ was considered less burdensome to study participants than the original MPQ (Melzak, 1984).

The MPQ has demonstrated reliability and validity (Melzack, 1983). Melzack (1975) conducted a test-retest study to evaluate consistency among the PRI subclasses. Ten patients were given the questionnaire three times at intervals between 3-7 days. Consistency of choice of subclasses ranged from 50% to 100% with a mean of 70.3%. Melzack also reported high correlations between PRI sensory and affective scores, ranging from 0.51 to 0.85 depending on the type of pain being evaluated (McDowell, 2006).

The MPQ-SF is highly correlated with the major PRI indices (Sensory, Affective, and Total) of the MPQ and is sensitive to interventions such as analgesics, epidural blocks and TENS (Melzack, 1987). For example, high correlation coefficients were found between the MPQ and MPQ-SF among women receiving epidural analgesia for labour pain ($n = 20$; $r = 0.92$, $p = 0.001$) (Melzack, 1987). Furthermore, concurrent validity has been demonstrated by significant correlations between the MPQ and the MPQ-SF among studies of postsurgical pain ($r = 0.77$),

musculoskeletal pain ($r = 0.70$) (Melzack, 1987) and cancer pain ($r = 0.77$ to 0.88) (Dudgeon, Raubertas & Rosenthal, 1993).

There is mounting evidence to support the strong psychometric properties of the MPQ-SF. For example, one study examined the test-retest reliability of the MPQ-SF (Grafton, Dphil & Wright, 2005) among patients with osteoarthritis. High interclass correlation coefficients were found for the total, sensory, affective and average pain scores (95% CI; ICC = 0.96; 0.95; 0.88; 0.89, respectively). Internal consistency of the SF-MPQ was evaluated among postoperative patients and found adequate reliability for sensory ($\alpha = 0.81$) but not affective dimensions of pain ($\alpha = 0.63$) when pain was recalled over 24 hours. The total MPQ-SF pain score had adequate internal consistency for pain over 24 hours ($\alpha = 0.85$) and present pain ($\alpha = 0.72$) (Zalon, 1999).

Although the MPQ-SF has shown sensitivity to detect differences among different interventions to relieve pain in a wide variety of clinical contexts (McDonald & Weiskopf, 2001), it has not been widely used with breastfeeding women. One RCT ($n = 151$) evaluating a nipple pain treatment has been identified that used the MPQ-SF to measure pain outcomes (Dennis et al., 2012). However, no significant differences in nipple pain were found between the study groups. One quasi-experimental nipple pain study used the full MPQ to evaluate the difference in pain between breasts having breast shells versus no intervention (Gosha & Tichy, 1988).

In summary, the MPQ-SF has demonstrated sound psychometric properties and utility for assessing pain among a diversity of acute and chronic pain conditions.

Breastfeeding Self-Efficacy Scale - Short Form

Breastfeeding self-efficacy is an important predictor of breastfeeding outcomes. To measure levels of breastfeeding self-efficacy at baseline and at 4 days post-randomization, the Breastfeeding Self-Efficacy Scale Short Form (BSES-SF) (Dennis & Faux, 1999) was utilized. The BSES was introduced in 1999 (Dennis & Faux, 1999) and utilized 33 self-report items to assess breastfeeding self-efficacy among primiparous women. The instrument has been psychometrically tested and validated for construct and predictive validity. The BSES has been tested for clinical utility, and scores are predictive of which women continue to breastfeed to six weeks postpartum ($F = 9.89, p < .001$) (Dennis & Faux, 1999). Further testing of the BSES revealed high Cronbach's alpha coefficients and multiple factor loadings, which led to the reduction of items and development of the BSES Short Form (Dennis, 2003).

The BSES-SF is a 14-item instrument with all items being positively phrased, and beginning with "I can always", using a 5-point Likert scale ranging from 1 ("not at all confident"), to 5 ("always confident"). Scores are summed and range from 14-70, with higher scores representing higher levels of breastfeeding self-efficacy. The BSES-SF has been psychometrically tested and has demonstrated that it is an excellent measure of breastfeeding self-efficacy (Dennis, 2003). An internal consistency analysis demonstrated high reliability of the BSES-SF with a Cronbach's alpha coefficient of 0.94. Further, evidence supports the validity and reliability of BSES-SF as a tool to identify at-risk mothers for breastfeeding cessation prior to four weeks postpartum (Kingston et al., 2007). Since the inception of the BSES, it has been translated and validated into other languages such as Chinese and Spanish (Dai & Dennis, 2003; & Torres, Torres, Rodriguez & Dennis, 2003). The BSES-SF has also been translated and validated in Polish (Wutke & Dennis, 2007) and has been psychometrically tested among an

ethnically diverse sample of women based in the United Kingdom (Gregory, Morrison, Penrose, Dennis & MacArthur, 2008).

Maternal Satisfaction Questionnaire

General acceptability of the intervention and participation in the study was evaluated at 12 weeks postpartum. Participants were asked questions about general satisfaction, how likely they would use the intervention again, and if they would recommend it to others (Appendix I). All acceptability questions included five-point verbal responses where 1 = “very satisfied”, and 5 = “very dissatisfied”. Compliance with the intervention was ascertained by asking how often lanolin was used during the study period, including responses ranging from “never” to “100% of the time”. The questionnaire also included an open-ended question to determine reasons (if any) for breastfeeding discontinuation.

Table 2

Summary of Instruments and Measurement Times

Study Variable	Measure	When
Baseline Maternal Information	Baseline Questionnaire	Prior to randomization
<u>Primary Outcome</u>		Baseline and at 4 days post-randomization
1. Pain intensity	11-point NRS	
<u>Secondary Outcomes</u>		
1. Breastfeeding duration	Breastfeeding or not	4 and 7 days post-randomization and at 4 and 12 weeks postpartum
2. Breastfeeding exclusivity	Labbok & Krasovec's levels of breastfeeding	Baseline, 4 and 7 days post-randomization and at 4 and 12 weeks postpartum
<u>Other Outcomes</u>		
1. Pain intensity	11-point NRS	7 days post-randomization
2. Pain Quality	MPQ-SF	4 days post-randomization
3. Breastfeeding self-efficacy	BSES-SF	4 days post-randomization
4. Maternal satisfaction with intervention	Maternal Satisfaction Questionnaire	12 weeks postpartum

Maternal Characteristic Information

Prior to randomization, baseline maternal characteristics that may have influenced breastfeeding outcomes were collected by the PI using the Baseline Questionnaire (Appendix E). Maternal characteristics included: demographic information (age, address, educational level, ethnicity, marital status, and household income); antenatal and postpartum information (parity, prior breastfeeding experience, planned breastfeeding duration/exclusivity level, any infant supplementation with formula, type of delivery, and support of a companion during labour and delivery); neonatal information and characteristics (date of delivery, ICU admission(s), gestational age, birth weight, and gender); and breastfeeding social support (spousal, family and friends); and nipple trauma (skin changes to the nipple, pain management strategies, and time of occurrence) as a result of breastfeeding.

Sample Size

The sample size of this trial was based upon the mean change in NRS pain intensity scores for women receiving lanolin. In an RCT by Dennis et al., (2012), mean NRS pain scores decreased by 23% for women using lanolin for their nipple pain when measured at 1-week post-randomization. Estimating 90% power, an anticipated 20% reduction in pain scores for women in the intervention group, and a 30% loss to follow up, a sample size of 93 was required per group for a total of 186 randomized women. Although the primary research question was related to the beneficial effects of lanolin on pain, a two-tailed error of 0.05 was chosen. Among the studies evaluating the effect of lanolin on nipple pain, one study (Mohammadzadeh, Farhat & Esmaeli, 2005) found significantly longer healing times for women using lanolin versus EBM. Although the methodological quality of this study was poor, a two-tailed test was required based

on the possibility of the control group having significantly lower pain scores than the intervention group.

Compliance

Compliance was measured at the final follow-up interview. To strengthen the likelihood of compliance, during recruitment eligible participants were provided with education regarding their potential involvement in the study. Emphasis was placed on the importance of compliance in order to obtain data that is accurate and meaningful. Once the two study groups were described, only participants who were agreeable to randomization to either group were enrolled. Eligible subjects who expressed a desire to have a specific group allocation were not enrolled in the study. At the final follow-up interview compliance was measured by asking participants questions regarding their adherence to their respective group. This included questions regarding how long and how frequent the intervention was used, or if it was not used.

There is no established ideal ‘dose’ for lanolin. The manufacturer of Lansinoh® HPA® Lanolin recommends applying lanolin after every feed until the resolution of symptoms. For those in the intervention group, compliance was considered adequate if lanolin was used for 75% of the feeds or greater up until the 7th day post-randomization, or until pain was completely resolved. To monitor compliance in the intervention group, a log sheet including a self-addressed/stamped envelope was provided to the participants (Appendix K). For the seven-day study period, participants were asked to record the time of each feed, and to indicate if they used lanolin for each feed. Participants were reminded at their final-follow up to return the log sheets to the PI using the self-addressed/stamped envelope that was provided during recruitment.

Contamination

To reduce the risk of contamination, only one study participant was recruited per hospital room. Participants who felt strongly that they preferred one group assignment over another were not randomized. Prior to the trial commencing, the staff RNs and RPNs were provided with in-depth education regarding the importance of subject adherence to the study protocol. The staff were asked not to offer lanolin to any participants enrolled in the study. Finally, contamination was assessed at each follow-up interview and at the final follow-up where participants in the control group were asked if they used lanolin to treat their nipple pain (Appendix I).

Co-intervention

Participants were free to use other interventions to manage their pain such as analgesia (acetaminophen/ibuprofen), warm and cold compresses, and EBM as part of standard care. It was anticipated that these diverse strategies would be equally distributed between groups due to randomization. Co-interventions were measured at each follow-up interview by asking participants what other pain relieving methods they utilized during the study period, and what health services they utilized (Appendix E, Appendix F).

Loss to Follow-up

Follow-up interviews were estimated to take approximately 10 minutes to complete over the telephone, therefore having minimal participant burden. During recruitment, information regarding the optimal time to contact the participant was obtained. Secondary telephone numbers (such as a cellular telephone number or a parent's telephone number) were also collected to minimize losses to follow-up. Participants were followed on four occasions within a 12-week timeframe. A similar Ontario based trial had a 96% response rate at a one-week postpartum

telephone follow-up (Dennis et al., 2012). Therefore, the goal for this trial was to obtain at least a 70% response rate at the 12-week follow-up.

Data Management

Baseline data were collected by the PI from the participant and from medical records. A research assistant blinded to group allocation collected all outcome data. All data collected by the PI and research assistant were documented onto hard copy forms. Forms were date-stamped and logged for tracking, and filed in a locked cabinet. With the exception of the Administrative Database and open-ended questions, all data were coded numerically. For example, for yes/no responses a numerical value of “1” or “0” respectively, were assigned. For other responses, numbers “1”, “2”, “3”, etc. were assigned.

The data were entered into SPSS Statistics (Version 20). A separate computer housed confidential data such as subject contact information. Computers were password protected and housed in a locked space with access to only the PI. The research assistant had limited access to the trial database and no access to the subject’s personal information. Both computer systems were backed up onto disc on a weekly basis with a scheduled reminder set on Microsoft Outlook© calendar. Backup discs were also locked in a separate space. Paper forms were collected, date stamped and logged in the database as “completed” and were then kept in a locked cabinet accessible only to the PI. Data were double-entered by the research assistant and the PI for accuracy monitoring purposes.

Participants were given a three-digit unique identification number (such as 001). The unique identifier was the common link for all data forms. The participant’s date of birth was used as a secondary identifier that matched the unique identification number (in the event of keying or other errors, the study participant would still be identifiable). For baseline data collection, the

forms were sequentially pre-numbered by the PI to prevent duplication of unique identification numbers.

The PI checked the database daily for participant follow-up dates and for overdue data. Once a participant was randomized and entered into the database, reminders were set in Microsoft Outlook© to alert the PI of dates to expect data for each subsequent follow-up. A table of follow-up interviews were provided to the research assistant via email as required.

Data Analysis

Data were analyzed using intention-to-treat principles. All data were analyzed using SPSS software package, version 20, using a two-tailed level of significance of 0.05. Descriptive statistics (means, standard deviations) were determined for all continuous data. To summarize data, baseline data were analyzed using descriptive statistics including means and standard deviations for continuous data, and frequencies were obtained for categorical variables.

Primary Outcome: Pain Intensity

To determine the effect of lanolin on nipple pain intensity, the mean difference in change scores between the groups was computed, and Student's t-test was used to detect a significant difference in change between groups on NRS scores at 4 days post-randomization.

Secondary Outcomes: Breastfeeding Duration & Exclusivity

To determine differences between the lanolin and standard care group for any breastfeeding at 12 weeks postpartum a chi-square test was utilized. To determine differences for breastfeeding exclusivity levels between the two groups at 12 weeks postpartum, a chi-square test was conducted.

Exploratory Research Questions

To determine the effect of lanolin on nipple pain intensity at 7 days post-randomization, the mean difference in change scores between the groups were computed, and Student's t-test was used to detect a significant difference in change between groups for NRS scores. Similarly, to determine differences in mean MPQ-SF scores between the groups from baseline to 4 days post-randomization, the mean difference in change scores between the groups were computed, and Student's t-test was conducted to detect if there was a significant difference between the groups. To determine the effect of lanolin on breastfeeding self-efficacy at 4 days post-randomization, mean change scores were calculated for both groups on BSES-SF scores, then the mean difference in change scores between groups was computed and Student's t-test was used to detect significant difference between groups. Finally, chi-square analysis was conducted to determine if there was a difference in satisfaction levels among breastfeeding women using lanolin versus those receiving usual care.

Risks and Benefits

This trial presented no known risks to participants. All trial participants received usual care while in-hospital and had usual access to standard community resources upon their discharge home. Lansinoh® HPA® Lanolin is ultra-pure with no preservatives or residues or other additives. There are no documented cases of allergic reactions to Lansinoh® HPA® Lanolin (Clark et al., 1981). Lansinoh® HPA® Lanolin is odorless and tasteless to the breastfeeding infant.

Prior to this trial, evidence regarding the effectiveness of lanolin for the reduction of nipple pain was equivocal. As such, there were no known direct benefits associated with participation in this trial. It was anticipated that participants in the treatment group might

experience potential psychological benefit. Mothers may cope better with their pain if they feel they are doing ‘something’, regardless of its established effectiveness or ineffectiveness.

Expected Contributions

Nipple pain is a common problem for breastfeeding women, and is a significant reason for breastfeeding discontinuation. To support women in their decision to breastfeed, it is important to ensure that the recommended interventions to treat nipple pain are efficacious. The goal of this trial was to determine if the use of lanolin leads to reduced nipple pain intensity for breastfeeding women, and if its use improves breastfeeding outcomes. It was anticipated that the results of this study would serve to fill a gap in the research around this understudied intervention, to facilitate sound treatment recommendations by health care professionals and those supporting women in their efforts to breastfeed.

Chapter 4 Results

This chapter reviews the study results related to: (a) the derivation of the sample, and randomization and attrition of participants; (b) the description of the sample according to sociodemographic characteristics; (c) comparisons made between participants lost to follow-up and those who completed the study; and (d) the primary and secondary research questions.

Sample

Recruitment. A total of 283 breastfeeding women were assessed for inclusion during the study period of May 9, 2011 to March 30, 2012. Among the potential participants, 186 were included, 35 were excluded, and 62 refused (See Figure 3). Reasons for refusal to participate included: (a) a strong desire to use lanolin ($n = 42, 67.7\%$); (b) not wishing to participate in a research study (no specific reason given) ($n = 9, 14.5\%$); (c) feeling overwhelmed with having a newborn / breastfeeding ($n = 7, 11.3\%$); and (d) an aversion to using lanolin ($n = 4, 6.5\%$). Reasons for exclusion included: (a) participants were greater than 72 hours postpartum ($n = 10, 28.6\%$); (b) maternal language barrier ($n = 9, 25.7\%$); (c) infant was staying in the NICU ($n = 5, 14.3\%$); (d) infant was less than 37 weeks gestation ($n = 4, 11.4\%$); (e) multiple birth ($n = 2, 5.7\%$); (f) mother was sharing a room with a participant already randomized ($n = 2, 5.7\%$); (g) maternal health condition ($n = 2, 5.7\%$); and (h) infant had ankyloglossia ($n = 1, 2.9\%$). The acceptance rate for enrollment among those eligible was 78%.

Randomization. One hundred and eighty six consenting participants were randomized, with 93 participants allocated to the usual care (control) group, and 93 participants allocated to the lanolin (treatment) group (Figure 3).

Attrition. Four follow-up telephone interviews were conducted to complete outcome measurements. For the primary research question, 186 participants were telephoned at four days post-randomization. Among the 186 participants, 21 (treatment group, $n = 13$; usual care group, $n = 8$) could not be contacted by telephone resulting in a 14% loss to follow-up (LTF) rate for the treatment group, and a 8.6% LTF rate for the usual care group for the primary outcome (Figure 3). The overall LTF rate was 11.3%. For the secondary research questions, participants who were still breastfeeding at the 4-week postpartum follow-up ($n = 155$) were telephoned again at 12 weeks postpartum. Among the 155 participants, 22 (treatment group, $n = 13$; usual care group, $n = 9$) did not complete post-test measures, resulting in a 16% LTF rate for the treatment group and a 12.2% LTF rate for the usual care group. The overall LTF rate was 14.2%. All of the participants who did not complete post-test measures could not be contacted by telephone despite three telephone calls followed by an emailed request for continued participation.

Compliance. For the purpose of this trial, compliance with the intervention was defined as using lanolin after 75% of the feeds, or greater, for the 7-day study period: 78.8% of participants ($n = 63$) in the treatment group reported that they used lanolin per the trial protocol. Among the 80 participants in the treatment group who completed post-test measures at 4 days post-randomization, all reported using lanolin to treat their nipple pain. Almost half of the participants in the treatment group reported using lanolin after every feed ($n = 39$, 49%) and 30% of participants ($n = 24$) used lanolin after approximately 75% of feeds. Twenty-one percent of participants ($n = 17$) used lanolin 50% of the time, or less. Among the 85 participants in the usual care group who completed post-test measures at 4 days post-randomization, 10 (12%) reported using lanolin to treat their nipple pain. However, among the 83 women in the usual care group who completed the maternal satisfaction questionnaire at their final follow-up, 13

participants (16%) reported that they had used lanolin at some point during the study period.

Among the 13 participants, 9 (11%) reported using lanolin after every feed, and 4 (5%) reported using lanolin after 75% of feeds. Figure 3 summarizes the derivation of the sample, randomization, pre and post-test data collection, and LTF.

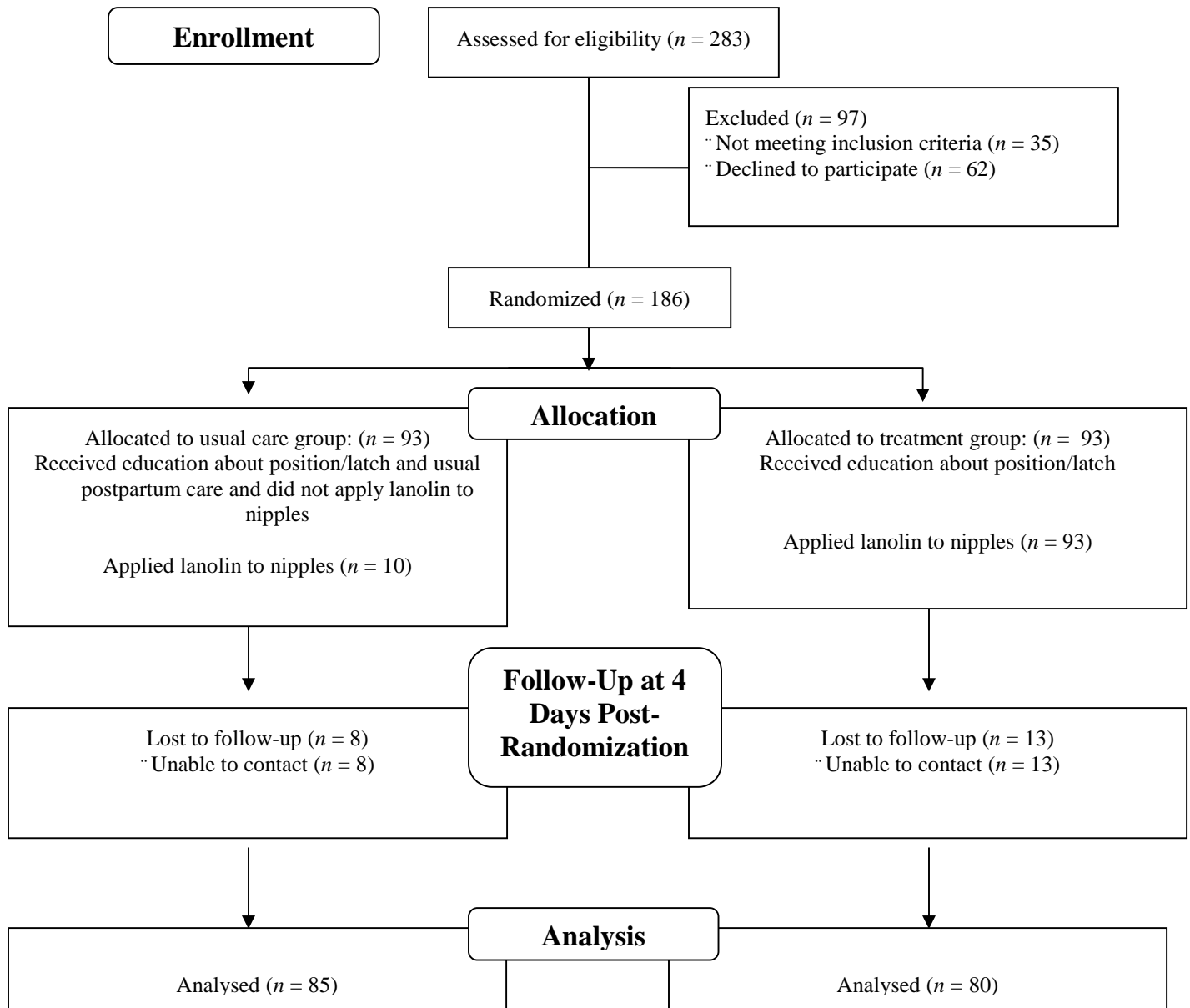


Figure 3. Participant Flowchart

Baseline Characteristics

Baseline demographic characteristics of the study participants were abstracted via chart review and from the baseline data questionnaire, and are presented in Table 3. The mean age of the treatment group was 30 (*SD* 5.3) and the mean age of the usual care group was 29 (*SD* 4.9). The majority of the mothers were married or living common-law (treatment group $n = 86$, 93%; usual care group $n = 88$, 95%), Caucasian (treatment group $n = 81$, 87%; usual care group $n = 81$, 87%), had completed post-secondary education (treatment group $n = 75$, 81%; usual care group $n = 69$, 74%), and had an annual family income greater than \$60,000 (treatment group $n = 65$, 70%; usual care group $n = 58$, 62%).

The majority of women decided to breastfeed prior to becoming pregnant (treatment group $n = 72$, 77%; usual care group $n = 69$, 74%). With respect to the participants' intended duration to breastfeed, the vast majority of women wanted to breastfeed for 6 to 12 months (treatment group $n = 77$, 83%; usual care group $n = 82$, 88%). Although many of the participants had no prior breastfeeding experience (treatment group $n = 58$, 62%; usual care group $n = 61$, 66%), among those who had prior breastfeeding experience (treatment group $n = 35$, 38%; usual care group $n = 32$, 34%), most breastfed their infants for longer than 12 weeks postpartum (treatment group $n = 21$, 60%; usual care group $n = 21$, 66%). Many of the participants had some breastfeeding education during pregnancy (treatment group $n = 64$, 69%; usual care group $n = 58$, 62%), either from a health care provider or from a pre-natal class. In relation to perceived breastfeeding support, the majority of women felt that their partners (treatment group $n = 80$, 86%; usual care group $n = 81$, 87%), and their families (treatment group $n = 65$, 70%; usual care group $n = 72$, 77%) were "very supportive" of their decision to breastfeed. With respect to perceived breastfeeding support from peers, the majority of participants felt that their friends

were either “very supportive” (treatment group $n = 52$, 56%; usual care group $n = 55$, 59%) or “supportive” (treatment group $n = 28$, 30%; usual care group $n = 23$, 25%).

Table 3

Baseline Demographic Characteristics of Usual Care and Treatment Groups

Characteristic	Usual Care N = 93	Treatment N = 93
Age, mean (SD)	29 (4.9)	30 (5.3)
	<i>n</i> (%)	<i>n</i> (%)
Marital status		
Married/Common-law	88 (94.6)	86 (92.5)
Single	5 (5.4)	7 (7.5)
Ethnicity		
Caucasian	81 (87.1)	81 (87.1)
First Nations	0	2 (2.2)
Chinese	0	2 (2.2)
Arab/West Asian	3 (3.2)	2 (2.2)
Filipino	1 (1.1)	0
South East Asian	0	1 (1.1)
Latin American	4 (4.3)	3 (3.2)
African American	4 (4.3)	2 (2.2)
Education		
Elementary	0	4 (4.3)
High school	24 (25.8)	14 (15.1)
College	30 (32.3)	33 (35.5)
University	25 (26.9)	32 (34.4)
Graduate degree	14 (15.1)	10 (10.8)
Annual household income ^a		
<\$20,000	7 (8.2)	9 (10.2)
\$20,000-39,999	12 (14.1)	5 (5.7)
\$40,000-59,999	8 (9.4)	9 (10.2)
\$60,000-89,999	17 (20.0)	20 (22.7)
\$90,000-99,999	4 (4.7)	9 (10.2)
>\$100,000	37 (43.5)	36 (40.9)
Decision to breastfeed		
Before pregnancy	69 (74.2)	72 (77.4)
During pregnancy	20 (21.5)	21 (22.6)
After birth	4 (4.3)	0

^a Participants did not wish to disclose their annual household income (usual care group, *n* = 8; treatment group, *n* = 5)

Table 3 (continued).

Baseline Demographic Characteristics of Usual Care and Treatment Groups

Characteristic	Usual Care <i>N</i> = 93 <i>n</i> (%)	Treatment <i>N</i> = 93 <i>n</i> (%)
Planned breastfeeding duration		
2-4 months	4 (4.3)	8 (8.6)
4-6 months	2 (2.2)	1 (1.1)
6-12 months	82 (88.2)	77 (82.8)
>12 months	5 (5.4)	7 (7.5)
Prior breastfeeding experience		
None	61 (65.6)	58 (62.4)
Up to 4 weeks	7 (7.5)	8 (8.6)
5-12 weeks	4 (4.3)	6 (6.5)
>12 weeks	21 (22.6)	21 (22.6)
Breastfeeding education		
Yes	58 (62.4)	64 (68.8)
No	35 (37.6)	29 (31.2)
Partner breastfeeding support ^b		
Very supportive	81 (87.2)	80 (86.0)
Supportive	6 (6.5)	6 (6.5)
Neither supportive nor unsupportive	0	1 (1.1)
Unsupportive	1 (1.1)	0
Family breastfeeding support		
Very supportive	72 (77.4)	65 (69.9)
Supportive	12 (12.9)	22 (23.7)
Neither supportive nor unsupportive	6 (6.5)	4 (4.3)
Unsupportive	3 (3.2)	2 (2.2)
Friend breastfeeding support		
Very supportive	55 (59.1)	52 (55.9)
Supportive	23 (24.7)	28 (30.1)
Neither supportive nor unsupportive	13 (14.0)	13 (14.0)
Unsupportive	1 (1.1)	0
Very unsupportive	1 (1.1)	0

^b Participants who were single did not respond to question pertaining to partner breastfeeding support (usual care group, *n* = 5, treatment group, *n* = 7)

Table 4 presents the baseline data for delivery and postpartum characteristics. The majority of participants were primiparous (treatment group $n = 59$, 63%; usual care group $n = 56$, 60%). Most had an uncomplicated (without forceps or vacuum) vaginal delivery (treatment group $n = 61$, 66%; usual care group $n = 59$, 63%). All but three participants (all in the usual care group) reported they had a companion continuously present during labour.

In relation to infant data, 87 infants were male (46.8%), and 98 (52.7%) were female. Missing data for one participant was due to her preference to not report the infant's gender. The mean gestational age was 39.2 weeks ($SD = 1.2$) with a range of 37 to 42 weeks. Two (1.1%) infants spent time in the NICU, with durations of 4 and 12 hours respectively.

Most of the participants first breastfed their infants within one hour of birth (treatment group $n = 75$, 81%; usual care group $n = 78$, 84%). At the time of recruitment, most of the participants were exclusively breastfeeding their infants (treatment group $n = 67$, 72%; usual care group $n = 69$, 74%). Almost all of the participants experienced skin changes/damage to their nipples on either the first (treatment group $n = 48$, 52%; usual care group $n = 47$, 51%) or second (treatment group $n = 38$, 41%; usual care group $n = 44$, 47%) day of breastfeeding. A majority of participants noticed damage to their nipples bilaterally (treatment group $n = 72$, 77%; usual care group $n = 66$, 71%). Similar to the onset of nipple damage, most of the participants experienced nipple pain on either the first (treatment group $n = 55$, 59%; usual care group $n = 52$, 56%) or the second (treatment group $n = 36$, 39%; usual care group $n = 39$, 42%) day of breastfeeding. The vast majority of participants found both nipples to be painful (treatment group $n = 86$, 93%; usual care group $n = 80$, 86%). Many of the participants had used lanolin to manage their nipple pain prior to their recruitment into the study (treatment group $n = 39$, 42%; usual care group $n = 25$, 27%).

Table 4

Baseline Delivery and Postpartum Characteristics of Usual Care and Treatment Groups

Characteristic	Usual Care <i>N</i> = 93 <i>n</i> (%)	Treatment <i>N</i> = 93 <i>n</i> (%)
Parity		
1	56 (60.2)	59 (63.4)
2 or more	37 (39.8)	34 (36.6)
Delivery type		
Vaginal birth	59 (63.4)	61 (65.6)
Vaginal birth with vacuum	8 (8.6)	4 (4.3)
Vaginal birth with forceps	1 (1.1)	0
Elective Caesarean section	10 (10.8)	12 (12.9)
Unplanned Caesarean section	15 (16.1)	16 (17.2)
Continuous presence of a companion during labour		
Yes	90 (96.8)	93 (100.0)
Infant gender ^a		
Male	43 (46.2)	44 (47.8)
Female	50 (53.8)	48 (52.2)
Gestational age		
<40 weeks	59 (63.4)	57 (61.3)
40 weeks or more	34 (36.6)	36 (38.7)
NICU admission	2 (2.2)	0
Time to first breastfeed		
1 hour or less	78 (83.9)	75 (80.6)
>1 hour	15 (16.1)	18 (19.4)

^a Participant did not wish to disclose her infant's gender (treatment group, *n* = 1)

Table 4 (continued)

Baseline Delivery and Postpartum Characteristics of Usual Care and Treatment Groups

Characteristic	Usual Care N = 93 n (%)	Treatment N = 93 n (%)
Breastfeeding category		
Exclusive	69 (74.2)	67 (72.0)
Almost exclusive	11 (11.8)	18 (19.4)
High	9 (9.7)	6 (6.5)
Partial	4 (4.3)	2 (2.2)
Onset of nipple skin changes		
Day 1 of breastfeeding	47 (50.5)	48 (51.6)
Day 2 of breastfeeding	44 (47.3)	38 (40.9)
Day 3 of breastfeeding	2 (2.2)	7 (7.5)
Nipples affected with skin changes		
Right	11 (11.8)	11 (11.8)
Left	16 (17.2)	10 (10.8)
Both	66 (71.0)	72 (77.4)
Onset of nipple pain		
Day 1 of breastfeeding	52 (55.9)	55 (59.1)
Day 2 of breastfeeding	39 (41.9)	36 (38.7)
Day 3 of breastfeeding	2 (2.2)	2 (2.2)
Nipples affected with nipple pain		
Right	4 (4.3)	3 (3.2)
Left	9 (9.7)	4 (4.3)
Both	80 (86.0)	86 (92.5)
Breastfeeding problems		
Perceived insufficient milk	1 (1.1)	1 (1.1)
Other	0	1 (1.1)
None	92 (98.9)	91 (97.8)
Using (or had used) lanolin prior to recruitment	25(26.9)	39(41.9)

Pre-Test Data

Summary pretest data are reported in Table 5, including mean pretest scores (*SD*) for usual care and treatment groups on the NRS, MPQ-SF and BSES-SF. All pretest data were checked for missing values; all data were complete. Each variable was assessed for departures from normality and for outliers defined as 3 SD units above or below the mean. Numeric Rating Scale scores met parametric assumptions of normality (Norman & Streiner, 2000). Although the MPQ-SF scores met parametric assumptions of normality (Norman & Streiner, 2000), the scores were positively skewed. In addition, two outliers were identified from these data. These outliers were not extreme, were not errors, and fell within the expected range of the MPQ-SF. As such, these values were included in the analysis. Present Pain Intensity scores had a discrete distribution at pretest. This distribution is expected as the measure only has six possible values (0, 1, 2, 3, 4, 5). Breastfeeding Self-Efficacy Scale (Short Form) scores were normally distributed, meeting parametric assumptions (Norman & Streiner, 2000); however, scores were negatively skewed.

Table 5

Pre-Test Scores by Group

Variable	Usual Care N = 93 Mean (SD)	Treatment N = 93 Mean (SD)
NRS – Nipple pain intensity	6.5 (2.3)	6.2 (2.2)
S-PRI – Nipple pain	7.3 (5.0)	6.9 (4.2)
A-PRI – Nipple pain	1.0 (1.8)	1.1 (1.9)
T-PRI – Nipple pain	8.4 (6.3)	7.9 (5.5)
PPI – Nipple pain intensity	2.7 (1.3)	2.7 (1.1)
MPQ-SF Total – Nipple pain	17.7 (8.4)	16.9 (7.9)
BSES-SF	55.5 (9.2)	55.6 (8.9)

Note. NRS = Numeric Rating Scale (0-10); S-PRI = Sensory Pain Rating Index (0-33); A-PRI = Affective Pain Rating Index (0-12); T-PRI = Total Pain Rating Index (0-45); PPI = Present Pain Intensity (0-5); MPQ-SF = McGill Pain Questionnaire – Short Form (0-60); BSES-SF = Breastfeeding Self-Efficacy Scale – Short Form (0-70)

Comparison of Those Who Completed the Study to Those LTF

Baseline characteristics and pre-test scores were compared statistically between those who completed the study ($n = 165$) and those who were LTF ($n = 21$). Chi-square analyses were conducted on baseline demographic and delivery/postpartum variables. These analyses revealed no significant differences among those LTF and those who completed the study. The Student's t-test was conducted on pre-test scores and revealed no significant differences between those LTF and those who completed the study.

Post-Test Outcome Data

All post-test data were checked for missing values, outliers and departures from normality. Data from the 165 participants who completed the first follow-up at 4 days post-randomization were complete, and all data (with the exception of those with discrete distributions) were normally distributed.

Primary Research Question

To determine the effect of lanolin on nipple pain intensity, the following research question was addressed: Compared to usual care for breastfeeding women with nipple pain, what is the effect of the application of lanolin on nipple pain intensity at 4 days post-randomization? To address this question, mean change scores ($T_2 - T_1$) were calculated for both groups on the NRS (Table 6). The mean difference in change scores between groups ($T_{\Delta} - UC_{\Delta}$) was then computed and Student's t-test was used to detect a significant difference in change between groups on NRS scores (Table 7). No significant difference in NRS change scores was found between groups.

Table 6

Pre (T_1), Post (T_2) and Change (T_2-T_1) Scores for the NRS by Group at 4 Days Post-Randomization

Variable (Range)	Usual Care			Treatment		
	T_1 $M(SD)$	T_2 $M(SD)$	$T_2 - T_1$ $M(SD)$	T_1 $M(SD)$	T_2 $M(SD)$	$T_2 - T_1$ $M(SD)$
NRS (0-10)	6.6(2.3)	6.1(2.5)	-0.5(3.0)	6.4(2.2)	5.7(2.5)	-0.7(3.1)

Table 7

Independent Samples T-Test for Significant Differences in Change Scores on the NRS at 4 Days Post-Randomization

Variable (Range)	Usual Care	Treatment	Mean Difference Between Groups (T - UC)	$t(df)$	P
	$\Delta(T_2 - T_1)$ $M(SD)$	$\Delta(T_2 - T_1)$ $M(SD)$	$T_\Delta - UC_\Delta$ $M(SD)$		
NRS (0-10)	-0.5(3.0)	-0.7(3.1)	-0.3(0.5)	-0.5(163)	0.6

Secondary Research Questions

To determine the impact of using lanolin on breastfeeding outcomes, the following secondary research questions were addressed: (1) Compared to usual care for breastfeeding women with nipple pain, what is the effect of the application of lanolin on any breastfeeding at 12 weeks postpartum; and (2) Compared to usual care for breastfeeding women with nipple pain, what is the effect of the application of lanolin on breastfeeding exclusivity at 12 weeks postpartum?

To understand the effect of lanolin on breastfeeding duration, an analysis was conducted comparing the number of women still breastfeeding at 12 weeks postpartum among the usual

care and treatment groups. A total of 164 participants were followed up at 12 weeks postpartum. Participants were asked if they were still breastfeeding their infant, or not, within the past 24 hours. Although there were a greater percentage of women who discontinued breastfeeding in the usual care group ($n = 31, 37\%$) versus the treatment group ($n = 22, 28\%$), the difference was not statistically significant, $\chi^2(1, N = 164) = 1.7, p = 0.2$.

To understand the effect of the use of lanolin on level of infant feeding at 12 weeks postpartum, a chi-square analysis was conducted comparing the levels of infant feeding among groups (Table 8). Data were collected at 12 weeks postpartum on participant levels of infant feeding including categories of: “exclusive”, “almost exclusive”, “high”, “partial”, “token”, or “bottle-feeding”. Due to a small number of frequencies ($n < 5$) among some variables, categories were collapsed to form three new variables: “exclusive or almost exclusive”, “high or partial”, and “token or bottle-feeding”. As shown in Table 8, frequencies for each level of breastfeeding were similar between groups. Chi-square analysis revealed no statistical differences. To explore whether breastfeeding level was affected at another time point during the study period, chi-square analyses were conducted on frequencies among groups for data collected at 4 weeks postpartum (Table 8). Similarly, there was no significant difference found between the groups.

Table 8

Chi-Square Analysis of Level of Infant Feeding at 4 and 12 Weeks Postpartum

Time	Infant Feeding Category	Usual Care (N = 84) n (%)	Treatment (N = 78) n (%)	$\chi^2(df)$	p
4 Weeks Postpartum	Exclusive or Almost Exclusive	52 (61.9)	51 (63.0)	3.2(2)	0.2
	High or Partial	12 (14.3)	18 (22.2)		
	Token or Bottle-Feeding	20 (23.8)	12 (14.8)		
		Usual Care n (%)	Treatment* n (%)		
12 Weeks Postpartum	Exclusive or Almost Exclusive	42 (50.0)	43 (55.1)	1.5(2)	0.5
	High or Partial	11 (13.1)	13 (16.7)		
	Token or Bottle-Feeding	31 (36.9)	22 (28.2)		

*n = 81

Exploratory Research Questions

Nipple pain intensity at 7 days post-randomization. This study addressed four exploratory research questions. The first exploratory question sought to determine the effect of lanolin on nipple pain intensity compared to usual care at 7 days post-randomization. To address this question, mean change scores ($T_2 - T_1$) were calculated for both groups on the NRS (Table 9). The mean difference in change scores between groups ($T_{\Delta} - UC_{\Delta}$) was then computed and Student's t-test was used to detect a significant difference in change between groups on NRS scores (Table 10). Similar to the analysis at 4 days post-randomization, no significant difference in NRS change scores was found between groups at 7 days post-randomization.

Table 9

Pre (T_1), Post (T_2) and Change ($T_2 - T_1$) Scores for the NRS by Group at 7 Days Post-Randomization

Variable (Range)	Usual Care			Treatment		
	T_1 $M(SD)$	T_2 $M(SD)$	$T_2 - T_1$ $M(SD)$	T_1 $M(SD)$	T_2 $M(SD)$	$T_2 - T_1$ $M(SD)$
NRS (0-10)	6.5(2.3)	4.0(2.5)	-2.5(3.0)	6.1(2.3)	3.6(2.5)	-2.5(3.2)

Table 10

Independent Samples T-Test for Significant Differences in Change Scores on the NRS at 7 Days Post-Randomization

Variable	Usual Care	Treatment	Mean Difference Between Groups (T-UC)	$t(df)$	P
	$\Delta(T_2 - T_1)$ $M(SD)$	$\Delta(T_2 - T_1)$ $M(SD)$	$T_\Delta - UC_\Delta$ $M(SD)$		
NRS	-2.5(3.0)	-2.4(3.2)	0.0(0.5)	0.0(158)	0.9

Nipple pain. The second exploratory question sought to determine the effect of lanolin on nipple pain, as measured by the MPQ-SF, compared to usual care at 4 days post-randomization. To address this question, mean change scores ($T_2 - T_1$) were calculated for both groups on the MPQ-SF for MPQ-SF (total), S-PRI, A-PRI, and PPI scores (see Table 11). The mean difference in change scores between groups ($T_\Delta - UC_\Delta$) was then computed for all variables, and the Student's t-test was used to detect a significant difference in change between groups for each set of scores (see Table 12). No significant differences were found among groups for either the total MPQ-SF scores or the S-PRI, A-PRI, or PPI subscale scores.

Table 11

Pre (T_1), Post (T_2) and Change (T_2-T_1) Scores for the MPQ-SF (Total, S-PRI, A-PRI, and PPI) by Group at 4 and 7 Days Post-Randomization

Time	Variable	Usual Care			Treatment		
		T_1 <i>M(SD)</i>	T_2 <i>M(SD)</i>	$T_2 - T_1$ <i>M(SD)</i>	T_1 <i>M(SD)</i>	T_2 <i>M(SD)</i>	$T_2 - T_1$ <i>M(SD)</i>
4 Days P.R.	MPQ-SF	17.4(8.1)	19.9(10.4)	2.5(10.6)	17.0(7.9)	18.3(10.3)	1.3(11.4)
	S-PRI	7.1(4.7)	9.8(6.7)	2.7(6.4)	6.8(4.1)	8.6(6.1)	1.8(6.6)
	A-PRI	0.8(1.7)	1.6(1.9)	0.8(2.1)	1.1(2.0)	1.8(2.4)	0.7(2.2)
	PPI	2.8(1.3)	2.4(1.3)	-0.4(1.6)	2.7(1.2)	2.3(1.2)	-0.4(1.4)
7 Days P.R.	MPQ-SF	16.8(8.1)	11.5(7.8)	-5.3(8.6)	16.2(7.5)	11.9(9.6)	-4.3(11.0)
	S-PRI	6.8(4.8)	5.1(4.4)	-1.7(4.9)	6.6(4.1)	5.9(5.8)	-0.8(6.4)
	A-PRI	0.7(1.5)	0.8(1.2)	0.1(1.6)	0.9(1.5)	0.8(1.4)	-0.1(2.1)
	PPI	2.7(1.3)	1.6(1.0)	-1.1(1.5)	2.6(1.1)	1.4(1.0)	-1.2(1.3)

Note. T_1 = Baseline; T_2 = Follow-Up; S-PRI = Sensory Pain Rating Index (0-33); A-PRI = Affective Pain Rating Index (0-12); PPI = Present Pain Intensity (0-5); MPQ-SF = McGill Pain Questionnaire – Short Form (0-60); P.R. = Post-Randomization

Table 12

Independent Samples T-Test for Significant Differences in Change Scores on the MPQ-SF at 4 and 7 Days Post-Randomization

Time	Variable	Usual Care	Treatment	Mean Difference Between Groups (T- UC)	<i>t(df)</i>	<i>p</i>
		$\Delta(T_2 - T_1)$ <i>M(SD)</i>	$\Delta(T_2 - T_1)$ <i>M(SD)</i>	$T_\Delta - UC_\Delta$ <i>M(SD)</i>		
4 Days P.R.	MPQ-SF	2.5(10.6)	1.3(11.4)	-1.2(1.7)	-0.7(163)	0.5
	S-PRI	2.7(6.4)	1.8(6.6)	-0.9(1.0)	-0.9(163)	0.4
	A-PRI	0.8(2.1)	0.7(2.2)	-0.1(0.3)	-0.3(163)	0.8
	PPI	-0.4(1.6)	-0.4(1.4)	-0.0(0.2)	-0.1(163)	1.0
7 Days P.R.	MPQ-SF	-5.3(8.6)	-4.3(11.0)	1.0(1.6)	0.6(158)	0.5
	S-PRI	-1.7(4.9)	-0.8(6.4)	1.0(0.9)	1.1(158)	0.3
	A-PRI	0.1(1.6)	-0.1(2.1)	-0.1(0.3)	-0.5(158)	0.6
	PPI	-1.1(1.5)	-1.2(1.3)	-0.0(0.2)	-0.1(158)	0.9

Note. S-PRI = Sensory Pain Rating Index (0-33); A-PRI = Affective Pain Rating Index (0-12); PPI = Present Pain Intensity (0-5); MPQ-SF = McGill Pain Questionnaire – Short Form (0-60); P.R. = Post-Randomization

Breastfeeding self-efficacy. The third exploratory research question aimed to evaluate the effect of the use of lanolin on breastfeeding self-efficacy, measured using the BSES-SF, at 4 days post-randomization. Mean change scores ($T_2 - T_1$) were calculated for both groups on the BSES-SF scores (Table 13). The mean difference in change scores between groups ($T_\Delta - UC_\Delta$) was then computed for all variables, and the Student's t-test was used to detect a significant

difference in change between groups for each set of scores (Table 14). No significant differences were found among groups for breastfeeding self-efficacy.

Table 13

Pre (T₁), Post (T₂) and Change (T₂-T₁) Scores for the BSES-SF by Group at 4 Days Post-Randomization

Variable	Usual Care			Treatment		
	T ₁ M(SD)	T ₂ M(SD)	T ₂ - T ₁ M(SD)	T ₁ M(SD)	T ₂ M(SD)	T ₂ - T ₁ M(SD)
BSES-SF	55.7(9.5)	56.3(11.8)	0.6(10.3)	55.6(8.5)	55.4(10.4)	-0.2(9.0)

Note. BSES-SF = Breastfeeding Self-Efficacy Scale – Short Form (0-70)

Table 14

Independent Samples T-Test for Significant Differences in Change Scores on the BSES-SF at 4 Days Post-Randomization

Variable	Usual Care	Treatment	Mean Difference Between Groups (T-UC)	t(df)	P
	$\Delta(T_2 - T_1)$ M(SD)	$\Delta(T_2 - T_1)$ M(SD)	T _Δ - UC _Δ M(SD)		
BSES-SF	0.6(10.3)	-0.2(9.0)	-0.8(1.5)	-.5(160)	0.6

Note. BSES-SF = Breastfeeding Self-Efficacy Scale – Short Form (0-70)

Maternal satisfaction. The fourth exploratory research question sought to determine if a difference in satisfaction levels existed between groups. To address this question, a chi-square analysis was conducted comparing satisfaction levels among groups (i.e., satisfaction with usual care versus satisfaction with lanolin) (Table 15). Data were collected from the 160 participants who were still breastfeeding (at 4 weeks postpartum) at 12 weeks postpartum. Participants were surveyed on their satisfaction with their group allocation. Participants could choose among five

responses including: “very satisfied”, “satisfied”, “neither satisfied nor dissatisfied”, “dissatisfied” and “very dissatisfied”. Due to a small number of frequencies ($n < 5$) among some variables, categories were collapsed to form three new variables: “very satisfied”, “satisfied”, and “less than satisfied”. Overall, a majority of participants in the treatment group ($n = 42$, 53%) were “very satisfied” with having received lanolin for their nipple pain. Conversely, only 22% ($n = 18$) of participants in the usual care group were very satisfied with the management of their nipple pain. Those who were less than satisfied constituted 1% ($n = 1$) and 14% ($n = 11$) of the treatment and control groups, respectively. The difference between groups was statistically significant at $p \leq .001$ based on the chi-square test (Table 15).

Table 15

Chi-Square Analysis of Satisfaction with Group at 12 Weeks Postpartum

	Usual Care ($N = 81$)	Treatment ($N = 79$)	$\chi^2(df)$	P
	n (%)	n (%)		
Very Satisfied	18 (22.2)	42 (53.2)	20.8(2)	≤ 0.001
Satisfied	52 (64.2)	36 (45.1)		
Less than Satisfied	11(13.6)	1(1.3)		

Summary of Results

There was one primary research question, two secondary research questions and four exploratory research questions in this trial. The first question sought to determine the effect of lanolin (treatment) on nipple pain severity when compared to usual care, at 4 days post-randomization. There were no significant differences found between the groups. The secondary research questions sought to determine if the use of lanolin for nipple pain had an effect on breastfeeding duration or exclusivity at 12 weeks postpartum when compared to usual care. No

significant differences were found for either breastfeeding duration or exclusivity at 12 weeks postpartum.

Among the four exploratory research questions, two questions sought to determine the impact of the use of lanolin on: (a) perception of pain as measured by the MPQ-SF at 4 days post-randomization; and (b) severity of pain at 7 days post-randomization as measured by the NRS, when compared to usual care. Regardless of the tool of measurement or the time of measurement, no significant differences existed among the groups. Similarly, there were no significant differences found among groups for changes in breastfeeding self-efficacy at 4 days postpartum.

The final exploratory question sought to determine if a difference existed between groups for satisfaction with their management of nipple pain with usual care versus standard care. Despite the lack of difference in pain outcomes among the groups, participants in the treatment group were significantly more satisfied with their group allocation than those in the usual care group.

Chapter 5 Discussion

This chapter begins with a discussion about the methodological strengths and limitations of the trial. The chapter then continues with a discussion about the primary and secondary research questions, addressing the effect of the treatment (lanolin) versus usual care on nipple pain intensity, and the effect of lanolin versus usual care on breastfeeding duration and exclusivity level. Exploratory questions are then discussed in relation to: (a) the effect of lanolin versus usual care on nipple pain intensity at 7 days post-randomization; (b) the effect of lanolin versus usual care on nipple pain (measured by MPQ-SF) at 4 days post-randomization; (c) the effect of lanolin versus usual care on breastfeeding self-efficacy at 4 days post-randomization; and (d) satisfaction level of participants using lanolin versus those who received usual care.

Strengths and Limitations

This randomized controlled trial prevented selection bias by random generation of group assignment. Participants were allocated to group by a system of sequentially numbered, sealed, opaque (impermeable to light) envelopes. This method is considered a sound allocation concealment method when developed and monitored with diligence (Moher et al., 2010). At the end of the trial, all of the numbered envelopes were accounted for. In addition, the research assistant who collected all outcome data was blinded to group allocation.

Compliance with the intervention was very good. Among the 93 women in the treatment group, 78 were available to report on compliance at the 12-week postpartum follow-up. The majority of participants in the treatment group used lanolin after every feed ($n = 61, 78\%$). For the purpose of this trial, compliance with the intervention was defined as using lanolin after 75% of the feeds, or greater, until the resolution of symptoms. Although there is no established

therapeutic ‘dose’, the manufacturer of Lansinoh® HPA® Lanolin recommended the application of lanolin after every feed until the resolution of symptoms (Lansinoh® HPA® Lanolin Booklet, n.d.). Compliance for this trial was established on the basis of the manufacturer’s recommended dose, while balancing the feasibility of postpartum women remembering to use the treatment and having it accessible at all feeds. Although the importance of compliance was emphasized during recruitment, 14% of participants ($n = 11$) only used lanolin for approximately half of the feeds and 8% ($n = 6$) used lanolin after 25% of the feeds or less. Based on the self-reported data, approximately 22% of participants were noncompliant with the recommended treatment.

Several mechanisms were employed to reduce the risk of contamination in this trial. Only one participant was recruited per hospital room, and participants with a strong desire for a specific group assignment were not randomized. In addition, staff nurses were provided with a detailed in-service and ongoing education (as needed) on the importance of participant adherence to the trial protocol, and were asked not to provide lanolin samples to any participants enrolled in the trial. Finally, staff nurses were asked to neither promote nor discourage the use of lanolin among participants. Contamination was assessed at 4 and 7 days post-randomization and at the final follow-up at 12 weeks postpartum. At 4 days post-randomization, 12% ($n = 10$) of participants in the usual care group reported that they had used lanolin for their nipple pain. Similarly, at 7 days post-randomization 11% ($n = 9$) of participants in the usual care group reported using lanolin. Finally, among the 82 participants in the usual care group available for follow up at 12 weeks postpartum, 10% ($n = 8$) reported using lanolin at some point to treat their nipple pain. Among the prior nipple pain studies that included lanolin, only one reported on data pertaining to contamination (Abou-Dakn, Fluhr, Gensch & Wockel, 2011). In this quasi-experimental study, significant reductions in pain and improved rates of healing for women using

lanolin versus EBM were found. They reported 100% compliance, and no participants in the EBM group reported using lanolin.

Participants reported using a range of other strategies to assist with their nipple pain, such as pain medication (acetaminophen/ibuprofen), and the application of ice, heat, or EBM. The groups were found to be comparable for use of any other interventions to manage nipple pain.

A potential limitation to this trial may be its usage of a single recruitment site. Although utilizing a single recruitment site may have advantages in terms of providing a homogeneous sample, it may also limit the external validity of results.

Primary Research Question

The primary research question addressed the effect of lanolin versus usual care (not applying lanolin) on nipple pain intensity at 4 days post-randomization. No significant difference was found among the groups for mean changes in nipple pain intensity scores. At baseline, the usual care group had a mean score of 6.6 ($SD = 2.3$), compared to 6.4 ($SD = 2.2$) for the lanolin group. Both groups had moderate to severe pain (Serlin, Mendoza, Nakamura, Edwards & Cleeland, 1995). At 4 days post-randomization, the usual care group had a mean score of 6.1 ($SD = 2.5$) compared to 5.7 ($SD = 2.5$) for the lanolin group. The baseline scores were comparable to the moderate 5.6 ($SD = 2.3$) mean baseline NRS nipple pain scores reported by Dennis, Hodnett, Schottle and McQueen (2012), and the moderate baseline VAS pain ratings reported by Abou-Dakin et al. (2011) (range of 5-6). While the quasi-experimental study by Abou-Dakin et al. (2011) showed a significant decrease in NRS pain scores for those using lanolin versus those using EBM on the third day after study recruitment, methodological limitations render the results questionable.

Although compliance was defined as using lanolin after 75% of feeds or more, it is plausible that this frequency was insufficient to achieve a therapeutic effect. Prior literature reporting on the effect of lanolin on nipple pain has been inconsistent with respect to what is considered a therapeutic dose, and how compliance is defined and measured (Cadwell et al., 2004; Mohammadzadeh et al., 2005; Dennis et al., 2012; & Abou-Dakn et al., 2011). Among the four studies, each had different conceptualizations of compliance to treatment. In their 2004 RCT, Cadwell et al. instructed women to use lanolin after every feed. No data were reported on compliance to treatment, and no significant differences were found between groups for nipple pain when compared to glycerin gel and breastfeeding education. A 2005 RCT comparing lanolin to EBM and a control group found a significant improvement in healing time and reduction of irritation for women using lanolin (Mohammadzadeh et al., 2005). In this study, women in the lanolin group were instructed to use lanolin three times per day for the 7 day study period. There were no data reported on compliance of those in the treatment (lanolin) group. Dennis et al. (2012) compared lanolin to an all-purpose nipple ointment and defined compliance as using lanolin 50% of feeds or greater. Among the participants contacted at the one week follow up, 81% reported being compliant with treatment. There were no significant differences found between groups for nipple pain. Finally, a quasi-experimental study comparing lanolin versus EBM (Abou-Dakn et al., 2011) had participants use lanolin “at all times” during their 14 day study period. Compliance was assessed at each of the three follow-ups and was deemed to be 100% for all participants. This study found significantly lower NRS pain scores, and significantly improved healing for participants in the lanolin group. Although this study has methodological limitations that prevent generalizing of results, these results may be suggestive

of a dose-effect whereby the amount of lanolin, and frequency of use may impact outcomes of nipple damage/healing and pain.

Since the discovery of moist wound healing (Winter, 1962), the advantages have been well documented. Wound healing under moist conditions offer reduced cellular dehydration and death (Keast & Orsted, 2010), increased angiogenesis (Knighton et al., 1981), increased re-epithelialization (Haimowitz & Margolis, 1997) and decreased pain (Keast & Orsted, 2010). The 'ideal' dressing for moist wound healing include characteristics such as: high humidity at the wound interface, thermally insulating, and allowing for gaseous exchange (Turner, 1979). Although there is no clear evidence regarding the approach to treating nipple damage, consensus exists among wound care specialists that treatments which support moist wound healing directly influence and improve the phases of healing (Wound Care Canada, 2009). In a 1988 wound treatment study, lanolin was found to increase epithelial healing by 35% (Chvapil, Gains & Gilman, 1988). The effect of lanolin on increased epithelial healing has also been supported in a study on full-thickness wounds (Steel & Marks, 1996). In sum, the overall goal of moist wound healing is to keep wounds *continuously* moist throughout the stages of re-epithelialization. In this study, women would not have continuous moist wound healing. Furthermore, it would be unfeasible to expect under real-world conditions that women would be able to keep their nipples covered with lanolin 100% of the time. Clothing and movement results in lanolin wearing off over time, leading to periods where the nipple tissue would become dry. As such, in this trial the reasonable and expected use of lanolin did not have an effect on the severity of nipple pain when compared to usual care.

Secondary Research Question

The secondary research question addressed the effect of lanolin compared with usual care, on breastfeeding duration and exclusivity at 12 weeks postpartum. Although a greater number of women discontinued breastfeeding in the usual care group ($n = 31$, 37%) versus the lanolin group ($n = 22$, 28%) the difference was not statistically significant. Among previous treatment studies including lanolin, only two reported the effect of lanolin on breastfeeding duration and/or exclusivity (Dennis et al., 2012; Abou-Dakin et al., 2011). Similar to this trial, 21% of all participants in the trial by Dennis et al. (2012) had discontinued breastfeeding by 12 weeks postpartum. Although a greater percentage of women in the treatment group (using an all-purpose nipple ointment) had discontinued breastfeeding ($n = 20$, 28%) when compared to those who used lanolin ($n = 11$, 15%), the differences were not statistically significant. In the quasi-experimental trial by Abou-Dakn et al. (2010) a significant difference was found in breastfeeding rates between mothers using lanolin versus those using EBM for their nipple pain. After 14 study days 15% ($n = 6$) of participants in the usual care group had discontinued breastfeeding, while only 7% ($n = 3$) of participants had discontinued in the lanolin group. Unfortunately, these data were not comparable to the 12 week follow-up for this trial, as there were large differences in the outcome assessment periods. The 32 weeks postpartum follow-up by Abou-Dakn et al. did not reveal any differences between groups for breastfeeding duration.

Approximately 33% of all participants in this study had discontinued breastfeeding by 12 weeks postpartum. This is consistent with Canadian data on breastfeeding duration. According to the Public Health Agency of Canada (2009), among women who initiate breastfeeding approximately 32.4% will discontinue by 12 weeks postpartum.

When considering factors which may influence breastfeeding duration, it is important to note the possible impact of a mother's decision to stop breastfeeding on her ongoing participation in a breastfeeding study. In this trial, despite numerous attempts to contact participants by telephone, 22 (14%) participants (usual care $n = 9$; treatment $n = 13$) were unable to be contacted and lost to follow-up (LTF) at the 12 week postpartum follow-up. Since this was the final follow up, the reasons for LTF remain undetermined. A systematic review on mothers' experiences with bottle-feeding suggests that many mothers who introduce formula experience negative emotions such as shame, guilt, anger and a sense of failure (Lakshman, Ogilvie, & Ong, 2009). In a study by Lee (2007), 50% of breastfeeding women experienced unreasonable pressure to breastfeed, and many women reported feeling worried about what health professionals might say about their decision to stop breastfeeding. Although the reasons for LTF are likely multifactorial, it is plausible that some participants who were LTF may have avoided contact with the outcome assessor as a result of their decision to stop breastfeeding.

The second part of the secondary outcome addresses the effect of lanolin versus usual care on breastfeeding exclusivity. According to Statistics Canada (2011) data collected in 2009-2010, approximately 44% of Canadian mothers exclusively breastfed their infants for 4 months. For this trial, at 12 weeks postpartum 46% ($n = 37$) of women in the lanolin group and 49% ($n = 41$) of women in the usual care group were exclusively breastfeeding. The frequencies observed for each breastfeeding level were similar between groups at the 12 week postpartum follow-up with no statistical differences. Only one other study reported breastfeeding levels between groups. In their RCT evaluating an all-purpose nipple ointment to lanolin for the treatment of nipple pain, Dennis, et al. (2012) found similar breastfeeding levels between treatment groups at 12 weeks postpartum, and these levels were comparable to those found in this trial. Dennis et al.

found at 12 weeks postpartum that approximately 59% of participants were exclusively or almost exclusively breastfeeding; 19% were high or partial breastfeeding; and 22% were token or bottle-feeding at the 12 week follow-up. There were no significant differences found among the groups for breastfeeding exclusivity.

Exploratory Research Questions

Nipple pain intensity at 7 days post-randomization. Similar to the findings at 4 days post-randomization, there were no significant differences found between the groups for mean changes in NRS scores at 7 days post-randomization. The usual care group had a mean baseline NRS of 6.5 ($SD = 2.3$), and the mean baseline NRS for the treatment group was 6.2 ($SD = 2.2$), both bordering between moderate and severe pain (Serlin et al., 1995). While at 4 days post-randomization the NRS scores remained within the moderate to severe range, the NRS scores at 7 days post-randomization were in the mild range for both the usual care ($M = 4.0$, $SD = 2.5$) and treatment groups ($M = 3.6$, $SD = 2.5$). This is similar to the findings reported by Dennis et al. (2012), where mean NRS scores for the lanolin group were within the mild range (Serlin et al., 1995) ($M = 3.3$, $SD = 2.8$) at the 7 day post-randomization follow-up. While no significant differences were found between groups for this quasi-experimental trial, Abou-Dakn et al. (2011) found a significant difference in NRS scores when comparing lanolin to EBM at 7 days post-recruitment; those in the lanolin group reported significantly lower scores than those in the EBM group. At 7 days post-recruitment mean NRS scores approximated 3 to 4 out of 10 for the lanolin group, and 1 to 2 out of 10 for the EBM group; both groups were within the mild pain range (Serlin et al., 1995). However, based on the data from this trial and those from Dennis et al., (2012), it is suggested that regardless of the use of lanolin or usual care, it is expected that nipple pain intensity scores will decrease by approximately seven to ten days postpartum.

Nipple pain. This was the first clinical trial to use the MPQ-SF to measure nipple pain at 4 days post-randomization. There were no significant differences found among groups for mean changes in MPQ-SF scores at 4 days post-randomization. At baseline, the usual care group had a mean total score of 17.4 ($SD = 8.1$), compared to 17.0 ($SD = 7.9$) for the lanolin group. At 4 days post-randomization the usual care group had a mean score of 19.9 ($SD = 10.4$) compared to 18.3 ($SD = 10.3$) for the lanolin group. Similar to the mean NRS scores, mean MPQ-SF (Total) scores were also reduced at 7 days post-randomization for both the treatment and usual care groups, with no significant differences found among the groups. Mean MPQ-SF scores were similar to those reported by Dennis et al. (2012) with a mean reduction from baseline ($M = 14.2$) to 7 days post-randomization ($M = 7.1$) for those receiving lanolin.

Breastfeeding Self-Efficacy. This was the first time the Breastfeeding Self Efficacy Scale – Short Form (BSES-SF) was used in a clinical trial to evaluate the effect of an intervention for nipple pain (lanolin) on BSES-SF scores. No significant difference was found among the groups for breastfeeding self-efficacy scores at 4 days postpartum. At 4 days post-randomization, the usual care group had a mean score of 55.4 ($SD = 10.4$) compared to 56.3 ($SD = 11.8$) for the lanolin group. Mean BSES-SF scores were similar to scores reported by Kingston et al. (2007). Interestingly, Kingston et al. found that mothers experiencing moderate to severe pain during the first 48 hours postpartum had significantly lower BSES-SF scores ($M = 41.7$, $SD = 12.6$) than those experiencing no pain ($M = 53.3$, $SD = 5.9$). This is in contrast to this trial, where BSES-SF scores were high despite all women experiencing some degree of nipple pain. It is plausible that the BSES-SF scores were high for this trial as a result of the recruitment site having Baby Friendly Hospital Initiative (BFHI) status, where women would receive various efficacy-enhancing experiences from staff such as the provision of assistance and guidance with

breastfeeding and encouragement and verbal persuasion. Pain often leads to a decreased perception of self-efficacy to perform specific behaviours such as breastfeeding (Dennis, 1999). Since pain is one source of information that determines if a mother is efficacious with breastfeeding, the lack of impact of the intervention on breastfeeding self-efficacy may be attributable to the lack of impact on pain management. In addition, many mothers in this trial continued to breastfeed despite their nipple pain. Continued breastfeeding will contribute strongly to performance accomplishments, which may be a greater source of self-efficacy information than the physiological arousal that would result from experiencing pain.

Maternal Satisfaction. This is one of the first clinical trials to evaluate maternal satisfaction with using lanolin versus those receiving usual care. Participants receiving lanolin were significantly more satisfied than those receiving usual care to manage their nipple pain. It is plausible that participants using lanolin may have felt a greater sense of control over their nipple pain by doing something rather than nothing, in turn leading to a greater sense of satisfaction. In the clinical trial by Dennis et al. (2012) evaluating an all-purpose nipple ointment, they found that participants in the lanolin group had significantly higher levels of satisfaction with breastfeeding versus those in the all-purpose nipple ointment group ($p < .01$). However, no significant differences were found regarding maternal satisfaction with the use of any ointment.

Chapter 6

Summary, Implications, and Conclusions

This study was the first randomized controlled trial comparing the use of lanolin to usual care for the treatment of nipple pain among breastfeeding women. In addition, this trial also determined the effect of lanolin on breastfeeding outcomes, breastfeeding self-efficacy, and maternal satisfaction. This trial rigorously evaluated a commonly used, commercially available ointment that is routinely recommended and endorsed by nurses, among other health care professionals. The conceptual framework of this trial focused on the principles of moist wound healing, and the effect of pain on breastfeeding outcomes.

There were 186 participants randomized to either a control group (usual care) or a treatment group (lanolin). Participants were considered similar at baseline and were primarily married, Caucasian women who completed post-secondary education. Ninety-three participants were randomized to the usual care group where they received usual postpartum care for their nipple pain management, and were asked to not use lanolin for their nipples for the 7 day study period. Ninety-three participants were randomized to the treatment group; they also received usual postpartum care, but were also asked to apply a pea-sized amount of lanolin to their nipples after every feed for the 7 day study period. Pain was measured using an 11-point NRS at four and seven days post-randomization in addition to the MPQ-SF. Breastfeeding self-efficacy was measured at 4 days post-randomization using the BSES-SF, and other breastfeeding outcomes (duration and exclusivity) were measured at 4 and 12 weeks postpartum. Maternal satisfaction was assessed at the final follow up at 12 weeks postpartum. An intention-to-treat analysis was used for all outcome data.

No significant differences were detected for pain using the NRS nor the MPQ-SF at either the 4 or 7 day post-randomization follow up. Additionally, there were no differences in breastfeeding outcomes, including duration, exclusivity and self-efficacy. Although not hypothesized prior to the study, levels of maternal satisfaction were significantly higher for those applying lanolin for their nipple pain versus those who did not (usual care).

Since the use of lanolin is no more effective than usual care for the management of nipple pain, the current widespread use of lanolin is questionable. Further research is required on the role of interventions to prevent nipple pain and damage, and the effect of anticipatory guidance – with respect to nipple pain and damage – on promoting more positive breastfeeding outcomes.

Implications for Research

Although attrition was not a limitation to this trial, it would have been beneficial if measures were employed to gain a better understanding of reasons why participants lost to follow-up may have avoided being contacted. The overall loss to follow-up rates for this trial were 11.3% for the primary outcome at 4 days post-randomization, and 16% for the secondary outcome at 12 week postpartum, with similar rates found between the groups. When compared to other breastfeeding trials, the attrition rates for this trial were good. A Cochrane systematic review evaluating support for breastfeeding mothers found that among the 67 eligible studies, LTF was a particular problem (Renfrew, McCormick, Wade, Quinn, & Dowswell, 2012). Many eligible studies were excluded from the review as a result of high attrition rates, and for many of the included studies, there were still considerable LTF rates, with many having lost greater than 25% of their sample. For this trial it is possible that some women found the four separate follow-up points too onerous a commitment. The early postpartum period is often overwhelming with other children to care for, lack of sleep, and caring for a newborn infant, with little time or

energy to commit to four telephone calls on separate occasions. Another possibility in this trial is that women avoided being contacted because they stopped breastfeeding. A systematic review of mothers' experiences of bottle-feeding found that many who stop breastfeeding worry about what health professionals might say, and perceive a 'breastfeeding culture' which leads to feelings of guilt when one chooses to bottle-feed (Lakshman et al., 2009). Future breastfeeding trials may benefit by utilizing a web-based questionnaire to collect outcome data. This would allow participants to respond without the worry of what an outcome assessor may think of their decisions related to breastfeeding.

Despite not having the benefit of pain reduction, women were more satisfied using lanolin than just receiving standard care. Patient satisfaction with perinatal care is a complex, multifaceted process, influenced by attitudes, and cognitive and affective responses to experiences (Ross, Steward & Sinacore, 1995). Although there are no studies evaluating women's satisfaction with care of nipple pain, a systematic review on pain and satisfaction with childbirth experience demonstrated that the experience of childbirth related pain does not directly relate to dissatisfaction with the birth experience (Hodnett, 2002). It is uncertain if those who used lanolin in this trial were more satisfied because they were doing what they thought was best, or if they enjoyed having some element of controlling the treatment of their nipple pain.

Implications for Practice

It is now understood that applying lanolin does not result in alleviation of pain, nor does it improve breastfeeding outcomes. However, this trial suggests that women are highly satisfied using lanolin. In recent years, the importance of patient satisfaction with care has been emphasized. Several studies have demonstrated a relationship between satisfaction with care and health outcome-related behaviours, such as compliance with treatment (Zapka et al., 1995; Rubin

et al., 1993; Ware & Hayes, 1988). Since this trial did not reveal any benefit of pain reduction or breastfeeding outcomes as a result of using lanolin, the provision of lanolin at the bedside is not warranted for breastfeeding women with nipple pain.

One of the most important findings in this trial was that regardless of the intervention used, for most, nipple pain reduced to mild levels after approximately 7-10 days postpartum. This has significant implications with respect to the information provided to patients about their nipple damage and the management of their pain. Numerous studies support the role of anticipatory guidance as an effective nursing intervention to help mothers cope during the postpartum period (Meleis, 1975; Meleis & Swendsen, 1978; & Swendsen, Meleis & Jones, 1978). In the case of nipple pain and damage, it would be important for nurses to provide anticipatory guidance regarding usual time to pain reduction. Noting that nipple pain peaks at around 3 days postpartum, the provision of health teaching that the pain will subside in a matter of days may help sustain breastfeeding during the most painful period and beyond.

Since there are no known interventions to effectively treat nipple pain, a final consideration for nursing practice is to underscore the importance of preventing nipple damage and pain in the early hours and days postpartum. It is well established that nipple damage often results from improper latch or positioning at the breast (Woolridge, 1986a; & Tait, 2000). To prevent nipple damage and pain it is imperative to provide newly breastfeeding women with education regarding proper positioning and latch, but to also frequently observe breastfeeding in the early postpartum period, to provide hands-on assistance if needed.

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Appendices

**APPENDIX A: STUDIES OF INFANT AND MATERNAL OUTCOMES ASSOCIATED
WITH BREASTFEEDING**

Infant Outcomes

Author	Design	Outcomes	Results	Methodological Critique
Ip (2007)	Meta-analysis of 5 cohort studies and 1 case control study conducted in developed countries among children without co-morbidities	Acute otitis media (AOM)	Ever breastfed (BF) associated with reduced risk of AOM vs. bottle feeding. Pooled adjusted odds ratio (OR) = 0.77 (95% CI 0.64 – 0.91) Significant reduction in risk of AOM with exclusive BF for 3-6 months. OR = 0.50 (95% CI 0.36 – 0.70)	Pooled results taken from cohort studies of good to moderate methodological quality. Cohort studies adjusted for confounders but case control study did not.
Uhari (1996)	Systematic review / meta-analysis of 2 case control and 8 cohort studies in developed countries	AOM	BF for 3 months reduced risk of AOM. Relative risk (RR) = 0.87 (95% CI 0.79 – 0.95) Reduced risk of recurrent AOM when BF for > 6 months compared to those BF for < 6 months. RR = 0.69 (95% CI 0.49 -0.97)	No consideration of possible confounders No restrictions on inclusion criteria
Gdalevich (2001)	Systematic review / meta-analysis of 18 prospective cohort studies in developed countries	Atopic dermatitis (AD)	Reduction in risk of AD (with family history of atopy) when exclusively BF for at least 3 months. Overall OR = 0.68 (95% CI 0.52 -0.88) Restricted to + family history: OR = 0.58 (95% CI 0.41 – 0.92) Restricted to those without family history: OR = 0.84 (95% CI 0.59 – 1.19)	Good quality review with consideration of confounders
Chien (2001)	Systematic review / meta-analysis of 12 prospective cohort, 2 retrospective cohort, and 2 case control studies in developed countries	Gastrointestinal infections (GI)	Conflicting results Not possible to pool measures of association Nine of 16 studies reported significant protective effect of BF on GI	Many studies did not control for detection bias or consider confounders. Many studies did not clearly define feeding practices or outcomes.

Bachrach (2003)	Systematic review / meta-analysis of 5 prospective cohort and 2 retrospective cohort studies in developed countries	Hospitalization secondary to lower respiratory tract diseases (RTD)	72% reduction in hospitalization for infants BF exclusively for ≥ 4 months vs. those bottle fed. Summary RR = 0.28 (95% CI 0.14 – 0.54)	Good quality review with no statistical heterogeneity. Sensitivity analysis performed re: appropriateness of study combinations and found no change to summary risk
Guise (2005)	Systematic review of 10 case control studies in developed countries	Childhood leukemia (CL)	Conflicting results among the higher quality studies	Review included 2 good, 2 fair, and 6 poor quality studies Many studies did not report on BF exclusivity and did not consider potential confounders
Kwan (2004)	Systematic review / meta-analysis of 14 case control studies (2 from developing countries and 12 from developed countries)	CL	Reduced risk of acute lymphocytic leukemia (ALL) with short (< 6 months) and long term (> 6 months) BF. OR = 0.88 (95% CI 0.80 – 0.96), OR = 0.76 (95% CI 0.68 – 0.84), respectively Reduced risk of acute myelogenous leukemia (AML) with long term BF. OR = 0.85 (95% CI 0.73 – 0.98) but not for short term BF	Considered potential confounding No formal assessment of study quality
Ip (2007)	Meta-analysis of 3 case control studies from developed countries	CL (ALL)	Reduced risk of ALL with long term BF OR = 0.80 (95% CI 0.71 – 0.91)	Only included higher quality studies in the review
Ip (2007)	Meta-analysis of 7 case control studies from developed countries	Sudden infant death syndrome (SIDS)	Reduced risk of SIDS with BF OR = 0.64 (95% CI 0.51 – 0.81)	Included studies that confirmed SIDS by autopsy Included studies that adjusted for potential confounders Definition of BF varied across studies
Ip (2007)	Meta-analysis of 4 randomized controlled trials (RCTs) totaling 476 infants	Necrotizing enterocolitis (NEC)	Reduced incidence of NEC among BF infants versus formula fed RR = 0.42 (95% CI 0.18 -0.96)	Only one study was assessed for methodological quality (was rated as fair) Clinical heterogeneity among studies

Maternal Outcomes

Author	Design	Outcomes	Results	Methodological Critique
Stuebe (2005)	Prospective, longitudinal cohort study of 2 large US cohorts from the Nurses' Health Study (NHS) (initiated in 1976) and NHS II (initiated in 1989) including 238,371 women	Type II diabetes (TD)	NHS: Inverse association found between BF duration and risk of TD. Each year of lactation associated with hazard risk (HR) of 0.96 (95% CI 0.92 – 0.99) NHS II: each year of exclusive BF associated with HR of 0.63 (95% CI 0.54 – 0.73) Each year of total BF: HR = 0.76 (95% CI 0.71 – 0.81)	Results only generalizable to those similar to the Nurses Health cohort
Collaborative Group on Hormonal Factors in Breast Cancer (2002)	Meta-analysis of 47 cohort and case control studies from developed and developing countries	Breast cancer (BC)	Reduction in BC among those who ever BF vs. those who did not RR reduction of 4.3% (95% CI 2.9 – 5.8) for every year of BF	Good quality review Stratified for potential confounders Most studies did not distinguish between levels of BF
Bernier (2000)	Meta-analysis of 23 case control studies from developed and developing countries	BC	Reduction in risk of BC when lifetime duration of BF was > 12 months versus those who never BF OR = 0.72 (95% CI 0.65 – 0.80)	Did not distinguish levels of BF
Ip (2007)	Meta-analysis of 6 case control studies from developed countries	Ovarian cancer (OC)	Reduction in risk of OC when lifetime duration of BF was > 12 months versus those who never BF Adjusted OR = 0.72 (95% CI 0.54 – 0.97).	Significant heterogeneity across the studies Results based on retrospective studies Adjusted for possible confounders

APPENDIX B: NIPPLE PAIN STUDIES

Nipple Pain Prevention Experimental Studies

Author Date/Place	Subjects	Interventions	Major Outcome(s) Measurements	Results	Comments
Akkuzu 2000 Turkey	90 primiparous	E(1) = Warm H ² O Compress E(2) = EBM C = No treatment	Nipple pain Nipple trauma	No significant difference between pain scores	
Benbow 2004 UK	E = 30 C = 34	E = Hydrogel C = EBM	Nipple pain Measured with non-validated 5 point VRS	Significant reduction in pain scores for intervention group on day 12 (p=0.017)	Randomization not described Used ITT but 10 participants dropped out No blinding
Buchko 1994 US	73 primiparous	E(1) = Teabag compress E(2) = Warm H ² O Compress E(3) = EBM C = Education	Nipple pain Pain measured with VAS	Significant difference in pain scores with EBM having highest pain; water compress with the lowest (p<0.05)	Randomization not described
Centuori 1999 Italy	E = 123 C = 96	E = Nothing on nipples C = Multi- ingredient ointment	Nipple pain Measured with non-validated VRS Nipple trauma Categorized according to self- report	No significant difference between groups	Randomization not described Outcome assessors blinded
Dodd 2003 US	E = 54 C = 52 with no breastfeeding experience	E = Hydrogel dressing C = EBM, air dry & lanolin	Nipple pain Measured with 5- point VRS Breastfeeding duration Nipple trauma measured by self report with a 5- point VRS	Reduction in pain on day 10 & 12 in hydrogel group No significant difference between groups for breastfeeding duration. Increased infection in lanolin group versus hydrogel P-values not reported	Randomization not described No blinding
Duffy 1997 Australia	E = 35 C = 35 primiparous	E = Usual teaching and additional teaching C = Usual	Nipple pain Measured with VAS BF duration Nipple trauma	Significantly different decrease in nipple pain and trauma in experimental group	Inadequate randomization Outcome assessor blinded

		teaching	measured with Nipple Trauma Index (NTI)	($p < 0.05$)	
Fleming 1984 US	17 women	E = Prenatal nipple conditioning to one nipple C = Nothing done to other nipple	Nipple pain measured with non-validated 3 point VRS	Significant difference in pain in intervention group ($p < 0.025$)	Quasi experimental
Herd 1986 UK	E = 112 C = 114	E = Chlorihexidine & Alcohol spray C = Water	Nipple pain Nipple trauma	Reduction in nipple pain in intervention group ($p < 0.01$)	Double blinded Randomization not described
Henderson 2001 Australia	E = 79 C = 79 primiparous women	E = One-to-one breastfeeding education C = Usual care	Nipple trauma scored as 1 = trauma, 0 = no trauma by investigator Nipple pain Measured with VAS	Significantly different reduction in pain scores on day 2 and 3 for intervention group ($p = 0.004$)	Adequate randomization and concealment methods No blinding
Hewat 1987 Canada	23 women with no breastfeeding experience	E(1) = EBM E(2) = Lanolin	Nipple pain Measured with non-valid 4-point VRS Nipple trauma assessed by investigator	No significant difference found between groups	Quasi-Experimental (used one breast as a control, randomized by coin flip)
Melli 2007 Iran	E = 72 C = 72 primiparous women	E(1) = Lanolin E(2) = Peppermint gel C = Placebo gel	Nipple trauma measured in mm by investigator Nipple pain measured by a 'rating scale' not described	Significantly different increased incidence of nipple cracks with placebo ($p = 0.004$) No difference between groups for pain	Inadequate randomization (by table of random numbers) Blinding unclear
Pugh 1996 US	E(1) = 45 E(2) = 44 E(3) = 44 C = 44 Primiparous	E(1) = Lanolin E(2) = Warm H ₂ O Compress E(3) = EBM C = Education	Nipple pain measured with SF-MPQ Breastfeeding duration	No significant difference for pain or breastfeeding duration	Randomization by computer generated method Outcome assessor blinded
Spangler 1993 US	50 women with no breastfeeding experience	E = Lanolin to one nipple C = nothing to other nipple	Nipple pain measured with 5-point non-valid scale that combined pain and trauma	No significant difference found	Quasi-Experimental 50% loss to follow up
Storr 1987 Country unknown	25 primiparous	E = Nipple conditioning prenatally and breast massage post partum to one breast C = nothing to	Nipple pain measured with 5-point, non-validated VRS Engorgement measured with 5-point non-	Significant difference for nipple pain on experimental side ($p = 0.001$) Significantly different decrease	Quasi-Experimental 31% loss to follow up No ITT

		other breast	validated VRS	of engorgement on experimental side (p = 0.004)	
Vijaylakshmi 2002 Chennai	E = 30 C = 30 primiparous	E = Structured teaching on breastfeeding C = Unknown	Nipple pain measured by a modified VAS	Significant difference between the groups for nipple pain (p < 0.05)	Inadequate randomization method Methods not well described
Ziemer 1995	50 Caucasian women	E = Polyethylene film to one nipple C = Nothing to other nipple	Nipple pain measured with a 6-point VRS Nipple trauma measured by investigator with a 4-point NRS	Significant difference found for reduction of eschar in dressing group (p < 0.001) Significant difference in reduction of pain for intervention side (p < 0.05)	Quasi-experimental 26 women dropped out & replaced

Nipple Pain Treatment Experimental Studies

Author Date/Place	Subjects	Interventions	Major Outcome(s) Measurements	Results	Comments
Clark 1985 New Zealand	114 women	E(1) = As control, but no ointment E(2) = As control but with Vitamin A E(3) = As control but with lanolin C = Education, unspecified ointment	Nipple pain measurement not defined	No differences found	Quasi-Experimental Very little details on methods provided
Gosha 1988 US	20 women	E = Breast shell to one breast C = Nothing to other breast	Nipple pain measured with MPQ PPI	No differences found	Quasi-Experimental Assigned to group by coin toss 25% attrition
Kuscu 2002 Turkey	66 primiparous	E(1) = Collegenase E(2) = Dexpanthanol C = Wash with soap and water	Nipple pain measurement scale not described Nipple trauma measured by scale from 0-3 based on colour/area/ulceration	Significantly different reduction in pain for collegenase group ($p < 0.05$) Significantly less trauma in collegenase group ($p < 0.05$)	Randomization methods not described Outcome assessor blinded
Lavergne 1997 Canada	65 primiparous	E = Tea bag/water compress to one breast C = Water compress to other breast	Nipple pain measured with non-validated 6-point VRS combining pain with trauma	Significant difference for reduction of nipple pain for both compresses versus control ($p = 0.0001$)	Quasi-Experimental
Livingston 1999 Canada	84 women with nipple pain and + s. aureus	E(1) = Mupirocin ointment E(2) = Fusidic acid ointment E(3) = Cloxicillin / erythromycin C = Education on breastfeeding technique	Nipple pain rated as mild/moderate/severe Nipple trauma measured by physician on a scale from 1-3	Study stopped prematurely due to continued nipple pain, delayed healing	

Riordan 1985 US	11 primiparous	E = Lanolin or tea bag to one breast C = Nothing to other breast	Nipple pain measured with non-validated 5- point VRS	No differences found	Quasi- Experimental Assigned to group by coin toss
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**APPENDIX C:
ADMINISTRATIVE DATABASE**

Mother's Code: __ __ __

Date: Day __ __ Month __ __ Year __ __

Please provide the following information so that we can stay in contact with you by phone for the 12-week duration of the study.

NAME: _____

ADDRESS: _____

CITY: _____

POSTAL CODE: _____

PHONE NUMBER: _____

CELLULAR NUMBER: _____

EMAIL ADDRESS: _____

As people sometimes move and can be difficult to reach, could you please provide us with the phone number of two relatives or friends who will know how to reach you if you move or change phone numbers.

1. Name: _____ Phone: _____

2. Name: _____ Phone: _____

NOTE: This page will be removed after the questionnaire is completed and stored separately from all other forms to maintain confidentiality. You will be given a unique numeric code as an identifier, and this code (not your name) will be used on all other documentation.

**APPENDIX D
ASSESSMENT FOR ELIGIBILITY**

Mother's Code:

Date: Day Month Year

Mother's Date of Birth: Day Month Year

- | | | |
|---|--------|-------|
| 1. Is the mother < 72 hours postpartum? | 1. Yes | 2. No |
| 2. Was the infant \geq 37 weeks gestation at birth? | 1. Yes | 2. No |
| 3. Is the mother breastfeeding? | 1. Yes | 2. No |
| 4. Does the mother have nipple pain? | 1. Yes | 2. No |
| 5. Does the mother have any signs of nipple skin trauma? | 1. Yes | 2. No |
| 5. Does the mother speak English? | 1. Yes | 2. No |
| 6. Does the mother have a telephone? | 1. Yes | 2. No |
| 7. Was this a singleton birth? | 1. Yes | 2. No |
| 8. Is it anticipated that the baby will be discharged home with mother? | 1. Yes | 2. No |
| 9. Is the mother free of physical or mental illness that may impact breastfeeding? | 1. Yes | 2. No |
| 10. Is the mother free of any allergies to lanolin? | 1. Yes | 2. No |
| 11. Is the infant free of congenital abnormalities that may interfere with breastfeeding? | 1. Yes | 2. No |

(The mother is ineligible if any of the above questions are circled "no". DO NOT PROCEED)

TRIAL PROCEDURE

STEP 1. Complete the above questions.

STEP 2. If mother is eligible, explain that the PI will be advised. Ask for verbal consent for the PI to speak in more detail regarding participation in the study.

STEP 3. Once verbal consent is obtained, call the PI Kim Allen direct at (289) 456-4564 to advise of a potential recruit.

RANDOMIZATION PROCEDURE

STEP 1: The PI will give further details regarding participation in the study and obtain written consent.

STEP 2: The PI will explain the randomization process to the participant.

STEP 3. The PI will have the participant's RN/RPN select the next sequentially numbered opaque envelope from the box of envelopes. The RN/RPN will open the envelope to reveal the study group allocation to the participant and PI. The study group allocation will be recorded on this form below.

Mother's Hospital ID Number:

Mother's Envelope Number:

Study Group Allocation:

- 1. Lanolin
- 2. Control

**APPENDIX E:
BASELINE QUESTIONNAIRE**

Mother's Code:

Date: Day Month Year

Mother's Date of Birth: Day Month Year

PART 1: MATERNAL DEMOGRAPHICS / CHARACTERISTICS (from medical records)

1. Infant date of birth: Day Month Year
2. Infant birth weight: grams **OR** pounds and ounces
3. Gestational age: completed weeks **OR** weeks and days
4. Infant gender:
 - 1. Male
 - 2. Female
5. Parity:
6. Delivery:
 - 1. Vaginal birth
 - 2. Vaginal birth with vacuum extraction
 - 3. Vaginal birth with forceps
 - 4. Elective caesarean section
 - 5. Caesarean section (emergency or unplanned)
7. Infant admitted to the special care nursery (NICU)?
 - 1. Yes → Date / time admitted:

Day Month Year at hours

Date / time discharged:

Day Month Year at hours
 - 2. No

PART 2: MATERNAL DEMOGRAPHICS / CHARACTERISTICS (from interview)

As most new mothers have different experiences and backgrounds, we would like to know more about you. The following questions are about you, your labour and birth, and your breastfeeding experience thus far. There are no right or wrong answers. If you need me to repeat or clarify any questions, please let me know.

8. How long after your baby was born was he or she first breastfed?
- 1. Less than 30 minutes
 - 2. Thirty minutes to 1 hour
 - 3. One to 2 hours
 - 4. Three to 12 hours
 - 5. More than 12 hours
9. Did you breastfeed any other children?
- 1. Yes → what is the longest duration you breastfed a child? weeks
 - 2. No
10. When did you decide to breastfeed?
- 1. Before pregnancy
 - 2. During pregnancy
 - 3. After the baby was born
11. How long do you intend to breastfeed?
- weeks OR months
12. During this pregnancy did you receive education about breastfeeding?
- 1. Yes
 - 2. No
13. During your labour and delivery, did you receive continuous emotional support and comfort measures from a health-care professional, doula, labour coach, family member or friend?
- 1. Yes
 - 2. No
14. Are you married, or are you living with someone in an intimate relationship?
- 1. Yes
 - 2. No → go to question 16
15. How supportive is your spouse or partner of your decision to breastfeed?
- 1. Very supportive
 - 2. Supportive
 - 3. Neither supportive or unsupportive
 - 4. Unsupportive
 - 5. Very unsupportive

16. How supportive is your family of your decision to breastfeed?
- 1. Very supportive
 - 2. Supportive
 - 3. Neither supportive or unsupportive
 - 4. Unsupportive
 - 5. Very unsupportive
17. How supportive are your friends of your decision to breastfeed?
- 1. Very supportive
 - 2. Supportive
 - 3. Neither supportive or unsupportive
 - 4. Unsupportive
 - 5. Very unsupportive

To get a better understanding about our participants we ask some general demographic questions:

18. What is the highest level of education you have **completed**?

- 1. Elementary school
- 2. High school
- 3. College or trade school
- 4. University undergraduate degree
- 5. University graduate degree

19. Which of the following best describes you?

- 1. White
- 2. First Nations (e.g., North American Indian, Inuit)
- 3. Metis
- 4. Chinese
- 5. South Asian (e.g., East Indian, Pakistani, Punjabi, Sri Lankan)
- 6. Arab / West Asian (e.g., Armenian, Egyptian, Iranian, Lebanese, Moroccan)
- 7. Filipino
- 8. South East Asian (e.g., Cambodian, Indonesian, Laotian, Vietnamese)
- 9. Japanese
- 10. Korean
- 11. Latin American
- 12. African / African American
- 13. Other (*please specify*): _____

20. Were you born in Canada?

- 1. Yes
- 2. No → Where were you born? _____
 → How long have you been in Canada? years

21. What is your annual household income?

- 1. Less than \$20,000
- 2. \$20,000 - \$39,999
- 3. \$40,000 - \$59,999
- 4. \$60,000 - \$89,999
- 5. \$90,000 - \$99,999
- 6. \$100,000 or more

PART 3: SHORT FORM MCGILL PAIN QUESTIONNAIRE

22. Please think about the worst nipple pain you have experienced while breastfeeding your baby in the last 24 hours. If zero represents no pain and ten represents the worst pain imaginable, what number best describes the pain you have?

Score: / 10

23. Please think about the worst nipple pain you have experienced while breastfeeding your baby in the last 24 hours. How would you describe this pain?

- 1. Mild
- 2. Discomforting
- 3. Distressing
- 4. Horrible
- 5. Excruciating

24. I am now going to read another list of words that are used to describe pain. As I read each word, tell me if it describes the nipple pain you have been experiencing while breastfeeding. If the word describes your nipple pain, please tell me if the pain is either “mild”, “moderate” or “severe”.

(Place a check in the boxes corresponding to the level of nipple pain for each descriptor chosen)

	Descriptor	(0) none	(1) mild	(2) moderate	(3) severe
1.	Throbbing				
2.	Shooting				
3.	Stabbing				
4.	Sharp				
5.	Cramping				
6.	Gnawing				
7.	Hot-Burning				
8.	Aching				
9.	Heavy				
10.	Tender				
11.	Splitting				
12.	Tiring-Exhausting				
13.	Sickening				
14.	Fearful				
15.	Punishing-Cruel				

PART 4: MATERNAL NIPPLE PAIN / NIPPLE TRAUMA

25. What skin changes have you noticed to your nipples? (*circle all that apply*)

- 1. Blisters
- 2. Crusting
- 3. Redness
- 4. Bleeding
- 5. Swelling
- 6. Cracking
- 7. White patches
- 8. Peeling
- 9. Dark patches
- 10. Yellow patches
- 11. Fissures
- 12. Other(s): _____

26. Which nipples have changes to the skin?

- 1. Right
- 2. Left
- 3. Both

27. When did you first notice skin changes to your nipples?

- 1. Day 1 of breastfeeding
- 2. Day 2 of breastfeeding
- 3. Day 3 of breastfeeding
- 4. Uncertain

28. When did you first experience nipple pain?

- 1. Day 1 of breastfeeding
- 2. Day 2 of breastfeeding
- 3. Day 3 of breastfeeding
- 4. Uncertain

29. Which nipples are painful?

- 1. Right
- 2. Left
- 3. Both

30. What have you been doing to manage your nipple pain?

(*circle all that apply*)

- 1. Nothing
- 2. Taking pain medication → specify _____
- 3. Applying ice or heat

- 4. Applying expressed breast milk
- 5. Air drying my nipples
- 6. Using proper positioning and latching of the baby at the breast
- 7. Applying cream or ointment → specify _____
- 8. Other → specify _____

31. Aside from nipple pain and nipple skin damage, have you experienced any other problems with breastfeeding? (*circle all that apply*)

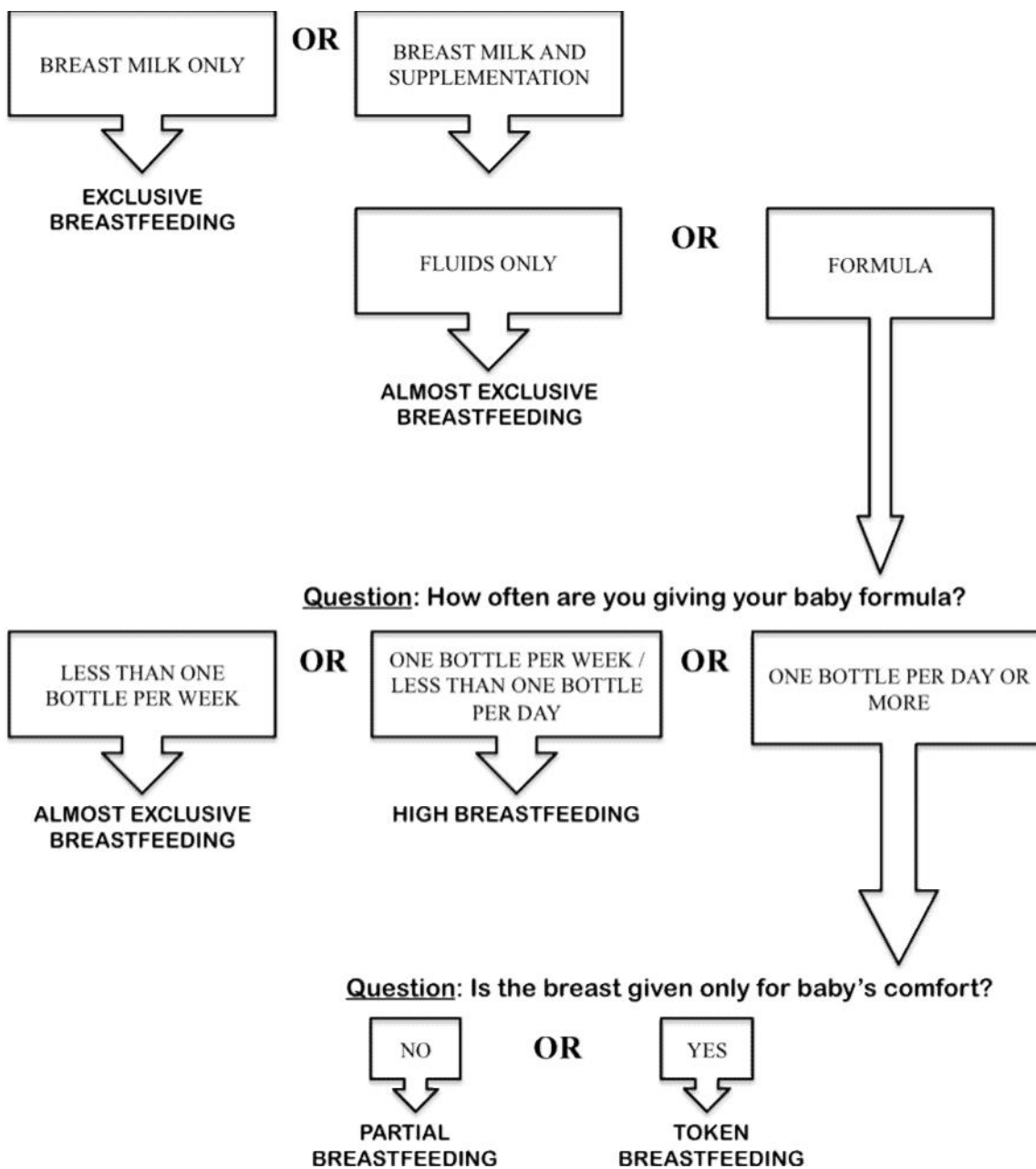
- 1. Engorgement
- 2. Insufficient milk
- 3. Blocked milk duct
- 4. Infection of the breast (mastitis)
- 5. Thrush (candidiasis)
- 6. Blanching of the nipple (vasospasm)
- 7. Other(s): _____
- 8. None

PART 5: INFANT FEEDING CATEGORY

32. Since your baby's birth, how have you been feeding your baby?

- 1. Breastfeeding alone
- 2. Breastfeeding in combination with something else

33. What else besides breast milk has your baby received since he or she was born?



After completing the decision tree, please check the mother's infant feeding category and validate it with her.

Mother's Response	Category of Infant Feeding	Requires that the Infant Receive	Allows the Infant to Receive	Does Not Allow the Infant to Receive
1. <input type="radio"/>	Exclusive Breastfeeding	Breast milk (including milk expressed)	Vitamins, minerals, medicines	Anything else
2. <input type="radio"/>	Almost Exclusive Breastfeeding	Breast milk as the predominant source of infant nourishment	< 1 bottle/week of non-human milk, water, water-based drinks, fruit juice, ORS, ritual fluids	Anything else
3. <input type="radio"/>	High Breastfeeding	Breast milk as the predominant source of infant nourishment	> 1 bottle/week of non-human milk	1 bottle/day of non-human milk
4. <input type="radio"/>	Partial Breastfeeding	Breast milk and any food or liquid	1 bottle/day of non-human milk or any food or liquid	
5. <input type="radio"/>	Token Breastfeeding	Non-human milk or any food or liquid as the predominant source of infant nourishment	Breast is used for comfort or to console the infant with minimal nutritional contribution	
6. <input type="radio"/>	Bottle-feeding	Any food or liquid		

PART 6: BREASTFEEDING SELF-EFFICACY SCALE (SHORT FORM)

34. I am going to read some statements regarding your feelings about breastfeeding. You can respond by choosing anywhere from one to five. If you strongly agree with the statement, you would choose five, and if you strongly disagree with the statement, you would choose one.

1.	I can always determine that my baby is getting enough milk	1	2	3	4	5
2.	I can always successfully cope with breastfeeding like I have with other challenging tasks	1	2	3	4	5
3.	I can always breastfeed my baby without using formula as a supplement	1	2	3	4	5
4.	I can always ensure that my baby is properly latched on for the whole feeding	1	2	3	4	5
5.	I can always manage the breastfeeding situation to my satisfaction	1	2	3	4	5
6.	I can always manage to breastfeed even if my baby is crying	1	2	3	4	5
7.	I can always keep wanting to breastfeed	1	2	3	4	5
8.	I can always comfortably breastfeed with my family members present	1	2	3	4	5
9.	I can always be satisfied with my breastfeeding experience	1	2	3	4	5
10.	I can always deal with the fact that breastfeeding can be time consuming	1	2	3	4	5
11.	I can always finish feeding my baby on one breast before switching to the other breast	1	2	3	4	5
12.	I can always continue to breastfeed my baby for every feeding	1	2	3	4	5
13.	I can always manage to keep up with my baby's breastfeeding demands	1	2	3	4	5
14.	I can always tell when my baby is finished breastfeeding	1	2	3	4	5

**APPENDIX F:
FOLLOW UP INTERVIEW #1 (4 days post-randomization)**

Mother's Code:

Date: Day Month Year

Mother's Date of Birth: Day Month Year

Hello, _____, my name is X. I am the research assistant for the breastfeeding study you agreed to participate in while you were in the hospital. I am calling to ask you a few questions about your experience feeding your baby. It will only take approximately 5 minutes. (If mother not able to talk) When would you like me to call you? Time: _____

PART 1: INFANT FEEDING CATEGORY

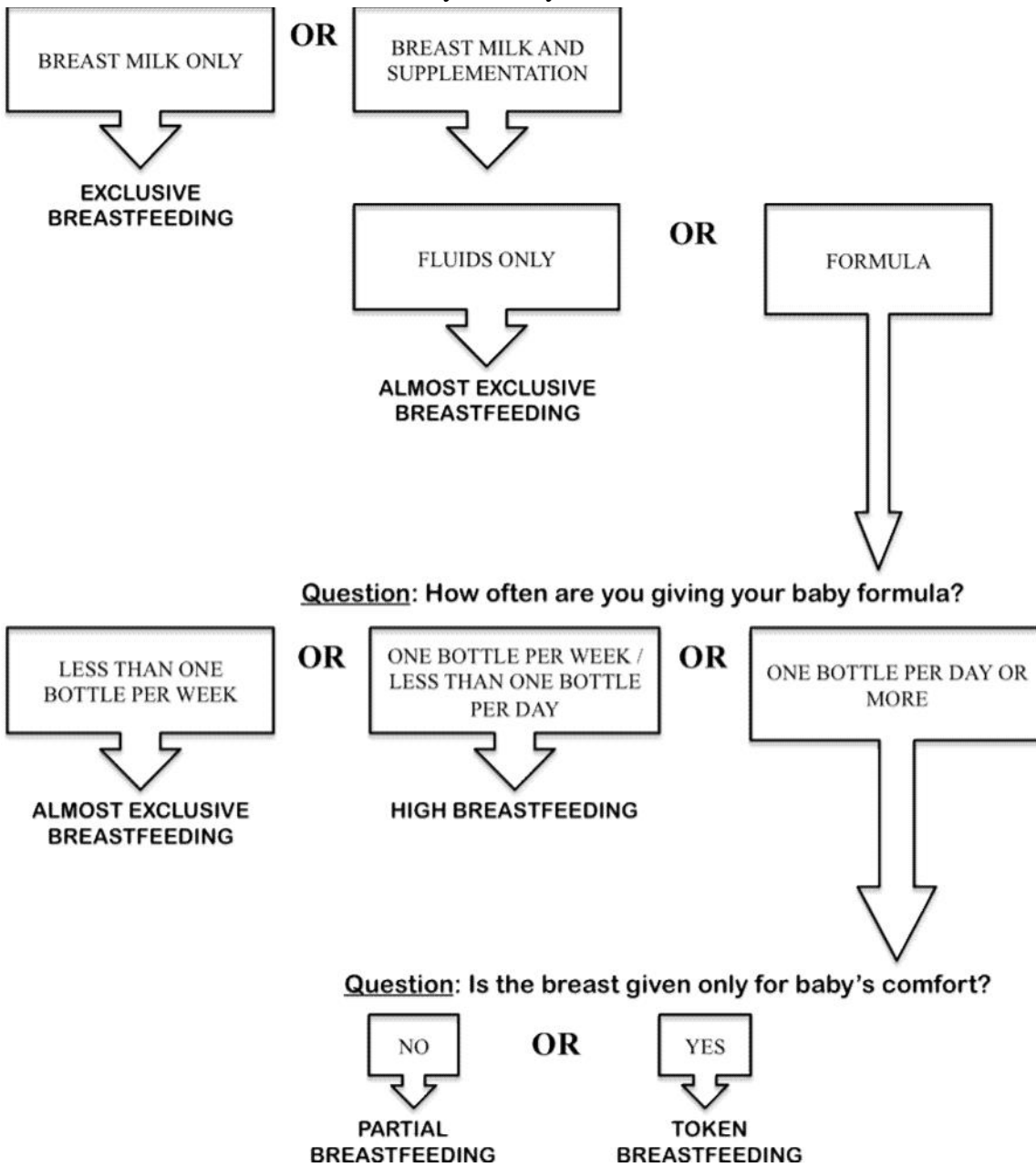
1. Since your baby's birth, how have you been feeding your baby?

1. Breastfeeding alone

2. Breastfeeding in combination with something else

3. Bottle feeding alone → *date stopped breastfeeding*: Day Month Year
→ *skip to question 4*

2. What else besides breast milk has your baby received since he / she was born?



After completing the decision tree, please check the mother's infant feeding category and validate it with her.

Mother's Response	Category of Infant Feeding	Requires that the Infant Receive	Allows the Infant to Receive	Does Not Allow the Infant to Receive
1. <input type="radio"/>	Exclusive Breastfeeding	Breast milk (including milk expressed)	Vitamins, minerals, medicines	Anything else
2. <input type="radio"/>	Almost Exclusive Breastfeeding	Breast milk as the predominant source of infant nourishment	< 1 bottle/week of non-human milk, water, water-based drinks, fruit juice, ORS, ritual fluids	Anything else
3. <input type="radio"/>	High Breastfeeding	Breast milk as the predominant source of infant nourishment	> 1 bottle/week of non-human milk	1 bottle/day of non-human milk
4. <input type="radio"/>	Partial Breastfeeding	Breast milk and any food or liquid	1 bottle/day of non-human milk or any food or liquid	
5. <input type="radio"/>	Token Breastfeeding	Non-human milk or any food or liquid as the predominant source of infant nourishment	Breast is used for comfort or to console the infant with minimal nutritional contribution	
6. <input type="radio"/>	Bottle-feeding	Any food or liquid		

PART 2: BREASTFEEDING SELF-EFFICACY SCALE (SHORT FORM)

3. I am going to read some statements regarding your feelings about breastfeeding. You can respond by choosing anywhere from one to five. If you strongly agree with the statement, you would choose five, and if you strongly disagree with the statement, you would choose one.

1.	I can always determine that my baby is getting enough milk	1	2	3	4	5
2.	I can always successfully cope with breastfeeding like I have with other challenging tasks	1	2	3	4	5
3.	I can always breastfeed my baby without using formula as a supplement	1	2	3	4	5
4.	I can always ensure that my baby is properly latched on for the whole feeding	1	2	3	4	5
5.	I can always manage the breastfeeding situation to my satisfaction	1	2	3	4	5
6.	I can always manage to breastfeed even if my baby is crying	1	2	3	4	5
7.	I can always keep wanting to breastfeed	1	2	3	4	5
8.	I can always comfortably breastfeed with my family members present	1	2	3	4	5
9.	I can always be satisfied with my breastfeeding experience	1	2	3	4	5
10.	I can always deal with the fact that breastfeeding can be time consuming	1	2	3	4	5
11.	I can always finish feeding my baby on one breast before switching to the other breast	1	2	3	4	5
12.	I can always continue to breastfeed my baby for every feeding	1	2	3	4	5
13.	I can always manage to keep up with my baby's breastfeeding demands	1	2	3	4	5
14.	I can always tell when my baby is finished breastfeeding	1	2	3	4	5

PART 3: SHORT FORM MCGILL PAIN QUESTIONNAIRE

4. Please think about the worst nipple pain you have experienced while breastfeeding your baby in the last 24 hours. If zero represents no pain and ten represents the worst pain imaginable, what number best describes the pain you have?

Score: / 10

5. Please think about the worst nipple pain you have experienced while breastfeeding your baby in the last 24 hours. How would you describe this pain?

- 1. Mild
- 2. Discomforting
- 3. Distressing
- 4. Horrible
- 5. Excruciating

6. I am now going to read another list of words that are used to describe pain. As I read each word, tell me if it describes the nipple pain you have been experiencing while breastfeeding. If the word describes your nipple pain, tell me if the pain is either "mild", "moderate" or "severe".

(Place a check in the boxes corresponding to the level of nipple pain for each descriptor chosen)

	Descriptor	(0) none	(1) mild	(2) moderate	(3) severe
1.	Throbbing				
2.	Shooting				
3.	Stabbing				
4.	Sharp				
5.	Cramping				
6.	Gnawing				
7.	Hot-Burning				
8.	Aching				
9.	Heavy				
10.	Tender				
11.	Splitting				
12.	Tiring-Exhausting				
13.	Sickening				
14.	Fearful				
15.	Punishing-Cruel				

PART 4: MATERNAL NIPPLE PAIN

7. What have you been doing to manage your nipple pain?

(circle all that apply)

- 1. Nothing
- 2. Taking pain medication → specify _____
- 3. Applying ice or heat
- 4. Applying expressed breast milk
- 5. Air drying my nipples
- 6. Using proper positioning and latching of the baby at the breast
- 7. Applying cream or ointment → specify _____
- 8. Other → specify _____

8. Aside from nipple pain and nipple skin damage, have you experienced any other problems with breastfeeding? *(circle all that apply)*

- 1. Engorgement
- 2. Insufficient milk
- 3. Blocked milk duct
- 4. Infection of the breast (mastitis)
- 5. Thrush (candidiasis)
- 6. Blanching of the nipple (vasospasm)
- 7. Other(s): _____
- 8. None

9. Have you used any health services to help manage your nipple pain?

(circle all that apply)

- 1. Visit to or from a lactation consultant
- 2. Visit to a breastfeeding clinic
- 3. Call to public health
- 4. Visit from a public health nurse
- 5. Visit to or from a midwife
- 6. Visit to a family doctor
- 7. Visit to an obstetrician
- 8. Visit to a walk-in clinic
- 9. Visit to a hospital emergency department
- 10. Other(s): _____
- 11. None

Thank-you for completing your first follow-up interview with us. We appreciate your participation and your time. Would this be a good time to call you for your next follow-up interview in three days? (If not) When would be a good time to reach you? Time to call: _____ Thanks again, goodbye.

FOLLOW UP INTERVIEW #2 (7 days post-randomization)Mother's Code: Date: Day Month Year Mother's Date of Birth: Day Month Year

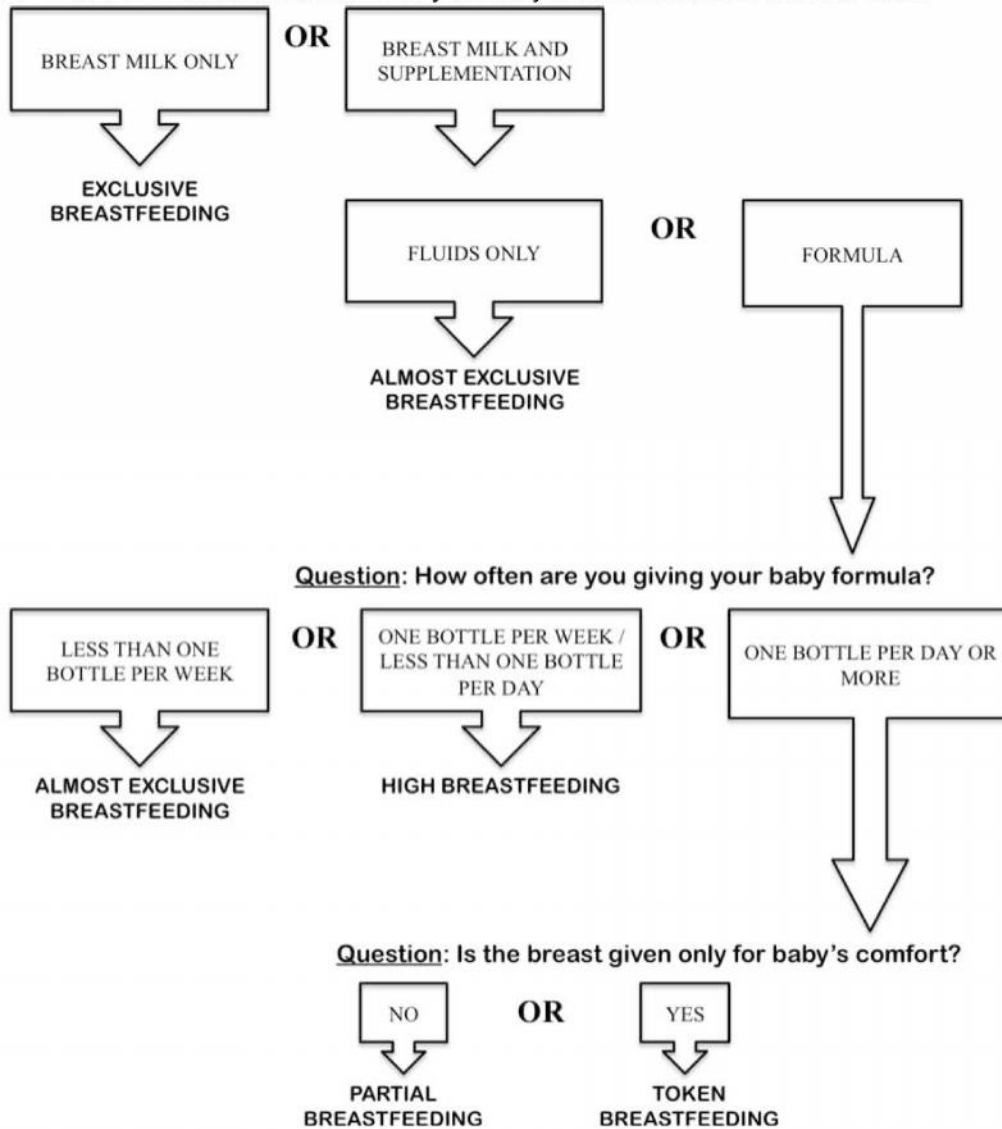
Hello, _____, my name is X. I am the research assistant for the breastfeeding study you agreed to participate in while you were in the hospital. I am calling to ask you a few questions about your experience feeding your baby. It will only take approximately 5 minutes. (If mother not able to talk) When would you like me to call you? Time: _____

PART 1: INFANT FEEDING CATEGORY

1. Since your baby's birth, how have you been feeding your baby?

 1. Breastfeeding alone 2. Breastfeeding in combination with something else
 3. Bottle feeding alone → *date stopped breastfeeding*: Day Month Year
 → *skip to question 4*

2. What else besides breast milk has your baby received since he / she was born?



After completing the decision tree, please check the mother's infant feeding category and validate it with her.

Mother's Response	Category of Infant Feeding	Requires that the Infant Receive	Allows the Infant to Receive	Does Not Allow the Infant to Receive
1. <input type="radio"/>	Exclusive Breastfeeding	Breast milk (including milk expressed)	Vitamins, minerals, medicines	Anything else
2. <input type="radio"/>	Almost Exclusive Breastfeeding	Breast milk as the predominant source of infant nourishment	< 1 bottle/week of non-human milk, water, water-based drinks, fruit juice, ORS, ritual fluids	Anything else
3. <input type="radio"/>	High Breastfeeding	Breast milk as the predominant source of infant nourishment	> 1 bottle/week of non-human milk	1 bottle/day of non-human milk
4. <input type="radio"/>	Partial Breastfeeding	Breast milk and any food or liquid	1 bottle/day of non-human milk or any food or liquid	
5. <input type="radio"/>	Token Breastfeeding	Non-human milk or any food or liquid as the predominant source of infant nourishment	Breast is used for comfort or to console the infant with minimal nutritional contribution	
6. <input type="radio"/>	Bottle-feeding	Any food or liquid		

PART 2: SHORT FORM MCGILL PAIN QUESTIONNAIRE

4. Please think about the worst nipple pain you have experienced while breastfeeding your baby in the last 24 hours. If zero represents no pain and ten represents the worst pain imaginable, what number best describes the pain you have?

Score: / 10

5. Please think about the worst nipple pain you have experienced while breastfeeding your baby in the last 24 hours. How would you describe this pain?

- 1. Mild
- 2. Discomforting
- 3. Distressing
- 4. Horrible
- 5. Excruciating

6. I am now going to read another list of words that are used to describe pain. As I read each word, tell me if it describes the nipple pain you have been experiencing while breastfeeding. If the word describes your nipple pain, tell me if the pain is either "mild", "moderate" or "severe".

(Place a check in the boxes corresponding to the level of nipple pain for each descriptor chosen)

	Descriptor	(0) none	(1) mild	(2) moderate	(3) severe
1.	Throbbing				
2.	Shooting				
3.	Stabbing				
4.	Sharp				
5.	Cramping				
6.	Gnawing				
7.	Hot-Burning				
8.	Aching				
9.	Heavy				
10.	Tender				
11.	Splitting				
12.	Tiring-Exhausting				
13.	Sickening				
14.	Fearful				
15.	Punishing-Cruel				

PART 4: MATERNAL NIPPLE PAIN

7. What have you been doing to manage your nipple pain?

(circle all that apply)

- 1. Nothing
- 2. Taking pain medication → specify _____
- 3. Applying ice or heat
- 4. Applying expressed breast milk
- 5. Air drying my nipples
- 6. Using proper positioning and latching of the baby at the breast
- 7. Applying cream or ointment → specify _____
- 8. Other → specify _____

8. Aside from nipple pain and nipple skin damage, have you experienced any other problems with breastfeeding? *(circle all that apply)*

- 1. Engorgement
- 2. Insufficient milk
- 3. Blocked milk duct
- 4. Infection of the breast (mastitis)
- 5. Thrush (candidiasis)
- 6. Blanching of the nipple (vasospasm)
- 7. Other(s): _____
- 8. None

9. Have you used any health services to help manage your nipple pain?

(circle all that apply)

- 1. Visit to or from a lactation consultant
- 2. Visit to a breastfeeding clinic
- 3. Call to public health
- 4. Visit from a public health nurse
- 5. Visit to or from a midwife
- 6. Visit to a family doctor
- 7. Visit to an obstetrician
- 8. Visit to a walk-in clinic
- 9. Visit to a hospital emergency department
- 10. Other(s): _____
- 11. None

_____*(participant's name)*, at the beginning of the study we provided you a log sheet to record your feedings. Within the next 24 hours can you please place the log sheet in the envelope provided and mail it back to us? Thank you.

Thank-you for completing your second follow-up interview with us. We appreciate your participation and your time. Would this be a good time to call you for your next follow-up interview in three weeks? (If not) When would be a good time to reach you? Time to call: _____

Thanks again, goodbye.

**APPENDIX H:
FOLLOW UP INTERVIEW #3 (4 Weeks Postpartum)**

Mother's Code:

Date: Day Month Year

Mother's Date of Birth: Day Month Year

Hello, _____, my name is X. I am the research assistant for the breastfeeding study you are participating in. I am calling to ask you a few questions about your experience feeding your baby. It will only take approximately 5 minutes. (If mother not able to talk) When would you like me to call you?
Date: _____ Time: _____

PART 1: INFANT FEEDING CATEGORY

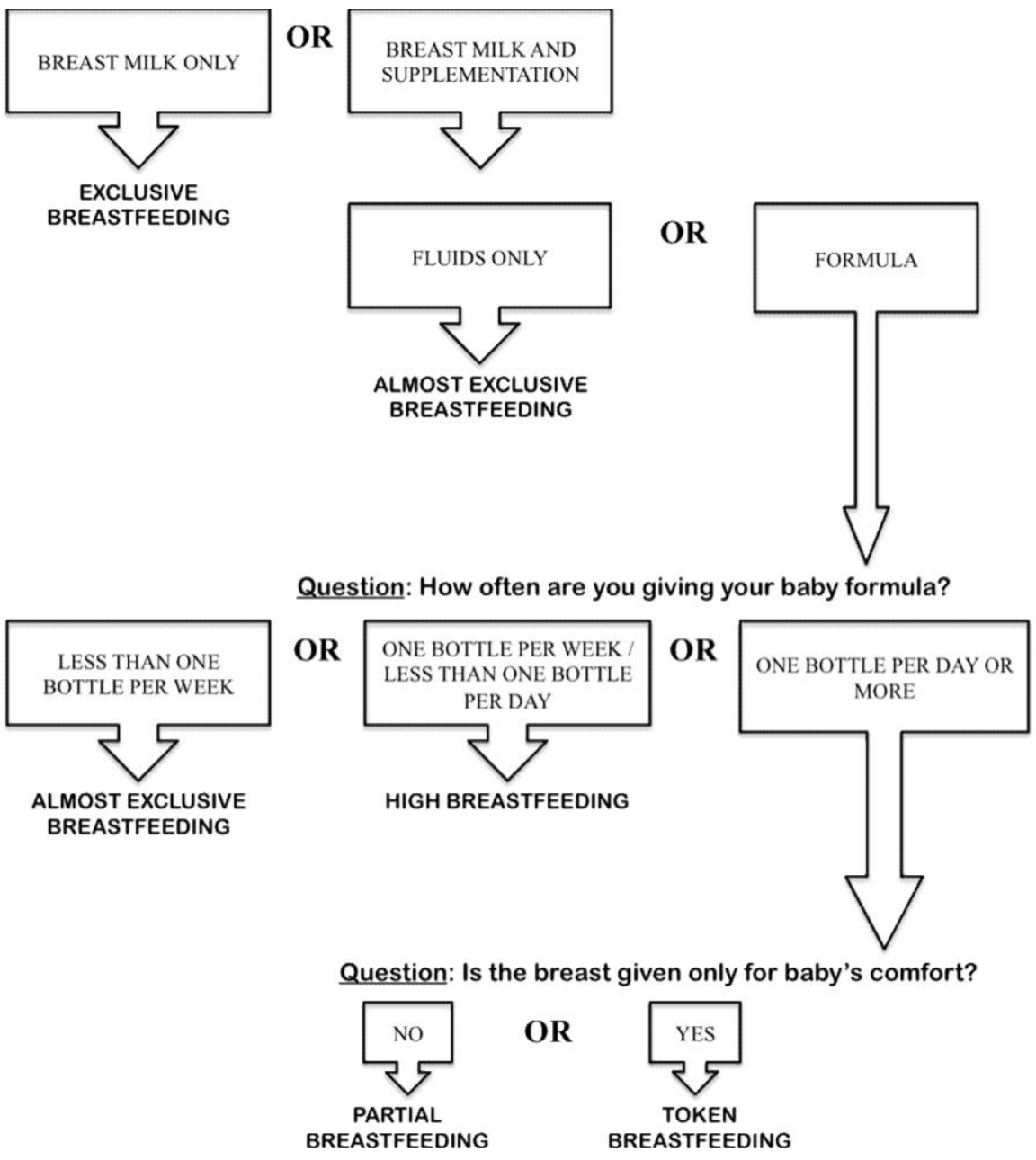
1. Since your baby's birth, how have you been feeding your baby?

1. Breastfeeding alone

2. Breastfeeding in combination with something else

3. Bottle feeding alone → *date stopped breastfeeding*: Day Month Year
 → *skip to question 3*

2. What else besides breast milk has your baby received since he or she was born?



After completing the decision tree, please check the mother's infant feeding category and validate it with her.

Mother's Response	Category of Infant Feeding	Requires that the Infant Receive	Allows the Infant to Receive	Does Not Allow the Infant to Receive
1. <input type="radio"/>	Exclusive Breastfeeding	Breast milk (including milk expressed)	Vitamins, minerals, medicines	Anything else
2. <input type="radio"/>	Almost Exclusive Breastfeeding	Breast milk as the predominant source of infant nourishment	< 1 bottle/week of non-human milk, water, water-based drinks, fruit juice, ORS, ritual fluids	Anything else
3. <input type="radio"/>	High Breastfeeding	Breast milk as the predominant source of infant nourishment	> 1 bottle/week of non-human milk	1 bottle/day of non-human milk
4. <input type="radio"/>	Partial Breastfeeding	Breast milk and any food or liquid	1 bottle/day of non-human milk or any food or liquid	
5. <input type="radio"/>	Token Breastfeeding	Non-human milk or any food or liquid as the predominant source of infant nourishment	Breast is used for comfort or to console the infant with minimal nutritional contribution	
6. <input type="radio"/>	Bottle-feeding	Any food or liquid		

3. Aside from nipple pain and nipple skin damage, have you experienced any other problems with breastfeeding? (*circle all that apply*)

- 1. Engorgement
- 2. Insufficient milk
- 3. Blocked milk duct
- 4. Infection of the breast (mastitis)
- 5. Thrush (candidiasis)
- 6. Blanching of the nipple (vasospasm)
- 7. Other(s): _____
- 8. None

If participant is still breastfeeding → Thank-you for completing your third follow-up interview with us. We appreciate your participation and your time. Is this be a good time and telephone number to reach you for your last follow-up interview in eight weeks? (If not) When would be a good time to reach you? Time to call: _____

If participant has STOPPED breastfeeding → continue on to Maternal Satisfaction Questionnaire.

**APPENDIX I:
FOLLOW UP INTERVIEW #4 (12 Weeks Postpartum)**

Mother's Code:

Date: Day Month Year

Mother's Date of Birth: Day Month Year

Hello, _____, my name is X. I am the research assistant for the breastfeeding study you are participating in. I am calling to ask you a few questions about your experience feeding your baby. It will only take approximately 5 minutes. (If mother not able to talk) When would you like me to call you?
Date: _____ Time: _____

PART 1: INFANT FEEDING CATEGORY

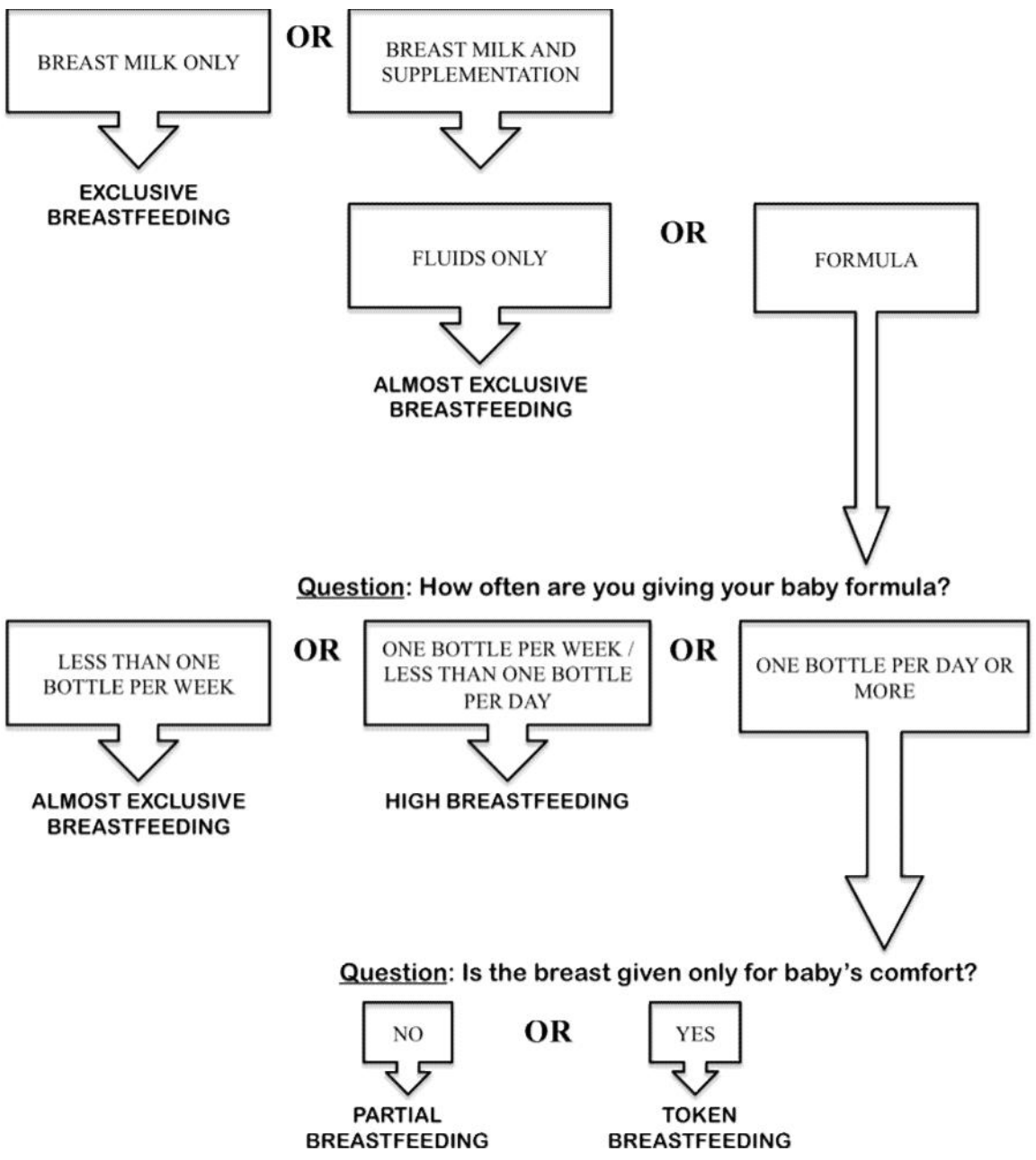
1. Since your baby's birth, how have you been feeding your baby?

1. Breastfeeding alone

2. Breastfeeding in combination with something else

3. Bottle feeding alone → *date stopped breastfeeding:* Day Month Year
 → *skip to question 3*

2. What else besides breast milk has your baby received since he or she was born?



After completing the decision tree, please check the mother's infant feeding category and validate it with her.

Mother's Response	Category of Infant Feeding	Requires that the Infant Receive	Allows the Infant to Receive	Does Not Allow the Infant to Receive
1. <input type="radio"/>	Exclusive Breastfeeding	Breast milk (including milk expressed)	Vitamins, minerals, medicines	Anything else
2. <input type="radio"/>	Almost Exclusive Breastfeeding	Breast milk as the predominant source of infant nourishment	< 1 bottle/week of non-human milk, water, water-based drinks, fruit juice, ORS, ritual fluids	Anything else
3. <input type="radio"/>	High Breastfeeding	Breast milk as the predominant source of infant nourishment	> 1 bottle/week of non-human milk	1 bottle/day of non-human milk
4. <input type="radio"/>	Partial Breastfeeding	Breast milk and any food or liquid	1 bottle/day of non-human milk or any food or liquid	
5. <input type="radio"/>	Token Breastfeeding	Non-human milk or any food or liquid as the predominant source of infant nourishment	Breast is used for comfort or to console the infant with minimal nutritional contribution	
6. <input type="radio"/>	Bottle-feeding	Any food or liquid		

3. Aside from nipple pain and nipple skin damage, have you experienced any other problems with breastfeeding? (*circle all that apply*)

- 1. Engorgement
- 2. Insufficient milk
- 3. Blocked milk duct
- 4. Infection of the breast (mastitis)
- 5. Thrush (candidiasis)
- 6. Blanching of the nipple (vasospasm)
- 7. Other(s): _____
- 8. None

MATERNAL SATISFACTION QUESTIONNAIRE (*outcome assessor now unblinded*)

Please give us your honest opinion on your experience participating in this study:

4. If you stopped breastfeeding, please describe the reason(s) why:

5. Were you assigned to the lanolin group or the standard care group?

1. Lanolin

6. Were you satisfied using lanolin to manage your nipple pain?

- 1. Very satisfied
- 2. Satisfied
- 3. Neither satisfied nor dissatisfied
- 4. Dissatisfied
- 5. Very dissatisfied

7. How often did you use the lanolin while you were still experiencing pain?

- 1. I used it after every feed
- 2. I used it approximately 75% of the time
- 3. I used it approximately 50% of the time
- 4. I used it approximately 25% of the time
- 5. I used it rarely
- 6. I never used it

8. If you used lanolin 50% of the time or less, please indicate why: *(select all that apply)*

- 1. It was uncomfortable to apply
- 2. It was messy
- 3. I did not think it was helping
- 4. I forgot to use it
- 5. Other →

describe _____

9. If you had another baby, how likely would you use lanolin again to treat your nipple pain?

- 1. Definitely would
- 2. Probably would
- 3. Unsure
- 4. Probably not
- 5. Definitely not

10. Would you recommend lanolin to a breastfeeding friend who is experiencing nipple pain?

- 1. Definitely would
- 2. Probably would
- 3. Unsure
- 4. Probably not
- 5. Definitely not

1. Standard Care

11. Were you satisfied having standard postpartum care to manage your nipple pain?

- 1. Very satisfied
- 2. Satisfied
- 3. Neither satisfied nor dissatisfied
- 4. Dissatisfied
- 5. Very dissatisfied

12. Did you use lanolin to manage your nipple pain?

1. Yes → *go to*

question 6

2. No



13. What did you do to manage your nipple pain?

(select all that apply)

- 1. Nothing
- 2. Took pain medication → specify _____
- 3. Applied heat or ice
- 4. Air dried my nipples
- 5. Used proper positioning and / or latching of the baby at the breast
- 6. Applied a cream or ointment → specify _____
- 7. Other → specify _____

14. How satisfied were you with the study group you were assigned to?

- 1. Very satisfied
- 2. Satisfied
- 3. Neither satisfied nor dissatisfied
- 4. Dissatisfied
- 5. Very dissatisfied

This now concludes our interview and your participation in the study. We would like to mail you a thank-you card as a gesture of our appreciation. Can you please confirm your mailing address for us?

Thank you again for your participation.

APPENDIX J:
MATERNAL SATISFACTION QUESTIONNAIRE
(outcome assessor now unblinded)

Mother's Code:

Please give us your honest opinion on your experience participating in this study:

Mother's DOB:

4. If you stopped breastfeeding, please describe the reason(s) why:

5. Were you assigned to the lanolin group or the standard care group?

1. Lanolin

6. Were you satisfied using lanolin to manage your nipple pain?

- 1. Very satisfied
- 2. Satisfied
- 3. Neither satisfied nor dissatisfied
- 4. Dissatisfied
- 5. Very dissatisfied

7. How often did you use the lanolin while you were still experiencing pain?

- 1. I used it after every feed
- 2. I used it approximately 75% of the time
- 3. I used it approximately 50% of the time
- 4. I used it approximately 25% of the time
- 5. I used it rarely
- 6. I never used it

8. If you used lanolin 50% of the time or less, please indicate why: *(select all that apply)*

- 1. It was uncomfortable to apply
- 2. It was messy
- 3. I did not think it was helping
- 4. I forgot to use it
- 5. Other →

describe _____

9. If you had another baby, how likely would you use lanolin again to treat your nipple pain?

- 1. Definitely would
- 2. Probably would
- 3. Unsure
- 4. Probably not
- 5. Definitely not

10. Would you recommend lanolin to a breastfeeding friend who is experiencing nipple pain?

- 1. Definitely would
- 2. Probably would
- 3. Unsure
- 4. Probably not
- 5. Definitely not

2. Standard Care

11. Were you satisfied having standard postpartum care to manage your nipple pain?

- 1. Very satisfied
- 2. Satisfied
- 3. Neither satisfied nor dissatisfied
- 4. Dissatisfied
- 5. Very dissatisfied

12. Did you use lanolin to manage your nipple pain?

1. Yes → *go to*

question 6

2. No



13. What did you do to manage your nipple pain?

(select all that apply)

- 1. Nothing
- 2. Took pain medication → specify _____
- 3. Applied heat or ice
- 4. Applied expressed breast milk
- 5. Air dried my nipples
- 6. Used proper positioning and / or latching of the baby at the breast
- 7. Applied a cream or ointment → specify _____
- 8. Other → specify _____

14. How satisfied were you with the study group you were assigned to?

- 1. Very satisfied
- 2. Satisfied
- 3. Neither satisfied nor dissatisfied
- 4. Dissatisfied
- 5. Very dissatisfied

This now concludes our interview and your participation in the study. We would like to mail you a thank-you card as a gesture of our appreciation. Can you please confirm your mailing address for us?

Thank you again for your participation.

APPENDIX K:

Letter of Explanation

*A Randomized Controlled Trial Evaluating Lanolin for the Treatment of Nipple Pain Among Breastfeeding Women
(LanP Trial)*

Study Principal Investigator: Kimberley Allen, RN, MN, PhD (Candidate), Faculty of Nursing, University of Toronto

Local Principal Investigator: Jacqueline Barrett, Clinical Director, Patient Care Services, St. Joseph's Healthcare Hamilton

Lead Researcher: Dr. Cindy-Lee Dennis, RN, PhD, Faculty of Nursing, University of Toronto

You are being invited to take part in a research study designed to evaluate interventions to treat nipple pain among breastfeeding women. We greatly appreciate you taking the time to consider participating in this study.

About the Study:

Nipple pain and nipple damage are commonly experienced by breastfeeding women. Researchers from the University of Toronto are conducting a study with new mothers to learn more about what best helps mothers manage their nipple pain. The purpose of this study is to better understand the effect of lanolin (a commonly used ointment), versus usual care, so that nurses can provide better care and support to breastfeeding mothers. This study is only being conducted at St. Joseph's Healthcare Hamilton, and will include approximately 190 participants.

What will happen if you participate:

If you are eligible and agree to participate, you will be randomly assigned to receive either usual postpartum care, or usual postpartum care plus lanolin ointment and instructions on its usage. Your group assignment will be revealed when your nurse opens a sequentially numbered, sealed, opaque envelope. Inside the envelope will be a card with a random group assignment. Random assignment means that neither you nor the researchers choose which group you will be assigned to; it is completely by chance.

If you are randomly chosen to receive "usual postpartum care" you will have access to all of the regular hospital and community health services available to all new mothers. You will receive a telephone call from a research assistant at 4 and 7 days post-randomization, and again at 4 and 12 weeks postpartum to ask you questions about your nipple pain and breastfeeding.

If you are randomly chosen to receive lanolin, you will experience the same care as all the other mothers. In addition, you will also receive a tube of lanolin with instructions on its usage. You will also be asked to record each breastfeeding session for 7 days on a log-sheet that will be provided. Recording your breastfeeding sessions on the log-sheet should take no more than one to two minutes per day. A research assistant will telephone you at 4 and 7 days post-randomization, and again at 4 and 12 weeks postpartum to ask you questions about your nipple pain and breastfeeding. These follow up telephone calls should take no longer than five to ten minutes to complete. No matter what group you are in, if you do not feel comfortable answering any questions you can refuse to answer them; this will not impact your participation in the study in any way.

How your privacy and confidentiality will be assured:

To ensure your privacy, you will be assigned a code number so that your name will not appear on any of your questionnaires. In addition, all information will be kept in a locked filing cabinet and no identifying information will be used in any written report of the study. Only Kimberly Allen (PhD(C)) and Dr. Cindy-Lee Dennis (PhD) and the research team members involved in data collection and analysis will have access to the data. Your participation in this study will be kept completely confidential and your questionnaires will be destroyed after 7 years. A summary of the research findings will be made available to you, if requested, at the end of the study.

Your right to refuse:

You may refuse to join in this study with no effect on your (or your baby's) future use of health services. If you agree to participate, you may withdraw from the study at any time. You do not have to answer any questions that you do not feel comfortable with.

Benefits and risks of study participation:

While you may not directly benefit from participating in this study, you will be providing information that will assist us to better understand the effect of lanolin, versus usual care, so that nurses can provide better care and support to breastfeeding mothers. While we don't know if lanolin will benefit breastfeeding women, some women may feel better just by doing something about their pain. There are no known risks to participating in this study. There are no known health risks to women or infants as a result of using lanolin for nipple pain.

If you have questions:

If you have any questions or desire further information with respect to this study, you may contact the Principal Investigator, Kimberley Allen, at (289) 456-4564. You may also contact the Lead Researcher, Dr. Cindy-Lee Dennis, at (416) 946-8608 or the local Principal Investigator, Ms. Jacqueline Barrett, at (905) 522-1155 (extension 33579).

Thank you for considering participation in the LanP Trial.

Sincerely,

Dr. Cindy-Lee Dennis, RN, PhD
Kimberley Allen, RN, PhD(C)

**APPENDIX L:
Participant Consent Form**

***A Randomized Controlled Trial Evaluating Lanolin for the Treatment of Nipple Pain Among Breastfeeding Women
(LanP Trial)***

Study Principal Investigator: Kimberley Allen, RN, MN, PhD (Candidate), Faculty of Nursing, University of Toronto

Local Principal Investigator: Jacqueline Barrett, Clinical Director, Patient Care Services, St. Joseph's Healthcare Hamilton

Lead Researcher: Dr. Cindy-Lee Dennis, RN, PhD, Faculty of Nursing, University of Toronto

PhD Supervisory Committee: Dr. Michael McGillion, RN, PhD, Faculty of Nursing, University of Toronto, Dr. Ellen Hodnett, RN, PhD, Faculty of Nursing, University of Toronto

Funding: Dr. Cindy-Lee Dennis (PhD Supervisor using Canada Research Chair funds)

This study is conducted by Kimberley Allen, RN, MN, PhD(Candidate) in partial fulfillment of the requirements for the PhD in Nursing Science Degree at the University of Toronto. This study is being carried out under the supervision of Dr. Cindy-Lee Dennis, RN, PhD, Associate Professor in the Graduate Department of Nursing Science, Lawrence S. Bloomberg Faculty of Nursing.

Nipple pain and nipple damage is a common problem for breastfeeding women. As such, for this study the researchers hope to better understand the effect of lanolin (a commonly used ointment for nipple damage and pain), versus usual care, so that nurses can provide better care and support to breastfeeding mothers. I understand participation is completely voluntary and I may decide not to join or I may withdraw at any time. I also may refuse to answer any questions.

I understand that I have been asked to participate in this study because:

1. I am breastfeeding my full-term baby.
2. I am experiencing nipple pain as a result of breastfeeding my baby.
3. I have some degree of damage to my nipples.

If I agree to participate in this study, I understand that I will be randomly assigned to receive either usual postpartum care or usual postpartum care plus lanolin. Random assignment means that neither the researchers nor I choose which group I am assigned to, and the group assignment is determined completely by chance. If I am chosen to receive "usual postpartum care", I understand I will have access to all of the regular in-hospital and postpartum community health services. A research assistant will telephone me at 4 and 7 days post-randomization, and again at 4 and 12 weeks postpartum to ask me questions about my nipple pain and breastfeeding. The total amount of time required to participate in this study will be approximately one hour.

If I am chosen to receive lanolin for my nipple pain, I understand I will experience the same postpartum care as all of the other mothers but I will also receive a tube of lanolin with instructions on its usage. I will also be asked to record each breastfeeding session for 7 days on the log-sheet provided. A research assistant will telephone me at 4 and 7 days post-randomization, and again at 4 and 12 weeks postpartum to ask me questions about my nipple pain and breastfeeding. The total amount of time required to participate in this study will be approximately one hour.

I understand that while I may not directly benefit from participating in this study I will be providing information, which will assist the researchers to better understand the effect of lanolin, versus usual care, so that nurses can provide better care and support to breastfeeding mothers. I understand there are no known or anticipated risks to participating in this study. To maintain confidentiality, I will be assigned a code number so that my name will not appear on any of my questionnaires. In addition, all information will be kept in a locked filing cabinet and no identifying information will be used in any written report of the study. My participation in this study will be kept completely confidential and my questionnaires will be destroyed after 7 years. The data records will be kept on a computer hard disk in a secure file and also destroyed after 7 years. A summary of the study findings will be made available to me, if I request it, at the end of the project.

I understand I may refuse to participate in this study with no effect on my future use of health services. If I agree to participate, I may withdraw from the study at any time. If I have any further questions about this study, I can contact the Principal Investigator, Kimberley Allen, at (289) 456-4564. I may also contact the Lead Researcher, Dr. Cindy-Lee Dennis, at (416) 946-8608 or the local Principal Investigator, Ms. Jacqueline Barrett, at (905) 522-1155 ext 33579.

If you have questions about your rights as a research participant, please contact:

Daniel Gyewu, Research Ethics Officer, Health Sciences in the Ethics Review Office, University of Toronto by phone at (416) 946-5606 or by email at d.gyewu@utoronto.ca

OR

The Office of the Chair of Research Ethics Board at St. Joseph's Healthcare Hamilton by telephone at (905) 522-1155 ext 33537.

I understand that participation in this study is completely voluntary and that I may refuse to participate or withdraw from the study at any time without any consequences to my (or my infant's) future use of health care services. I have read the above information and I have had an opportunity to ask questions to help me understand what my participation would involve. I freely consent to participate in this study, and acknowledge receipt of a copy of the consent form.

I consent to participate in this study.

Signature of Participant: _____ Date: _____

Printed Name: _____

Person Obtaining Consent: _____ Date _____

Printed Name: _____

APPENDIX M:
LOG: USE OF LANOLIN WHILE BREASTFEEDING

Participant Instructions: Thank you for your participation in this study! To help us understand how lanolin works to treat nipple pain, we need you to keep track of how often you feed your baby, and how often you apply lanolin after feeds. For the 7 treatment days, please record each time you feed your baby, and place a mark in the check-box when you applied lanolin after feeding. If your pain has resolved completely and you have discontinued using lanolin, please place a check mark beside the day your pain stopped.

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DATE OF BIRTH: DAY __ MONTH __ YEAR __

MOTHER'S CODE: __ __

APPENDIX N:
PARTICIPANT BREASTFEEDING INFORMATION PAMPHLET

Commonly used positions:

1. Side-lying

You and your baby are lying beside each other in bed.



2. Football

You hold your baby's head with your hand and her legs are tucked under your arm.



3. Cradle

Your baby is held across the front of your chest.



How do I know baby is getting enough to eat?

Six to 8 wet diapers in a 24-hour period.

One or more loose, yellowish stools per day (in the first month).

Your baby is gaining weight.

How do I care for my nipples?

Bathe daily, but try to avoid using soap on your nipples. Your nipples have a natural lubricant, and soap may lead to drying or cracking.

You do not need to wash or rinse your nipples before or after feeding.

If your breasts are very full and it is difficult to latch your baby, you may hand express a small amount of milk to soften the nipple.

You may leave some breast milk on the nipple after feeding as it has antibacterial properties.

How do I use lanolin?

Keep your lanolin with you at all times. Apply lanolin to your nipples after **every feed** for **7 full days**, or until your pain is completely gone.

Keep lanolin at room temperature. Lanolin gets harder to use when it is cold.

Ensure that you have washed your hands using soap and water.

After you have finished feeding, apply a small, pea-sized amount of lanolin to your index finger. Soften the lanolin with your fingers if needed.

Gently dab the lanolin onto the erectile and surrounding part of the nipple. You may apply lanolin to the other nipple even if you did not feed on that side.

Record each of your feedings on the **breastfeeding log** provided.

The LanP Trial



1.



What is Colostrum?

Colostrum is the first milk that is produced in the first few days after your baby is born.

Colostrum is yellow or whitish-yellow, and contains important vitamins, minerals, proteins and antibodies (that help protect your baby from infections).

Colostrum gradually turns into mature, white, or blue-white milk around the one-week mark.

When do I feed my baby?

Newborns are best fed on demand, which means whenever she is hungry.

Most newborns will be fed every 2 to 3 hours, or a total of 8 to 12 times in a 24 hour period.

It is best to start feeding your baby when she is awake. Look for cues that your baby is hungry.

Some cues that baby is hungry:

1. awake / looking around
2. moving arms and legs
3. opening and closing her mouth
4. sucking fingers or hand
5. crying (late sign of hunger)

How to stimulate a sleepy baby:

6. undressing her or change her diaper
7. sit her up
8. gently tickle her feet or along her spine
9. gently rub her hair from the neck to forehead
10. pat her back or bottom



Getting ready to feed:

Always wash your hands before you feed your baby.

Choose a bed or chair where you can position yourself and your baby comfortably.

It may be helpful to use a pillow or nursing pillow to help support your arm, or to raise the baby to the level of your breast.

Alternate the breast you start with at each feed.

How to position my baby:

There are several positions that are commonly used for breastfeeding (but you may find other positions that work for you too!).

Your baby's body should be facing your body, with his ear, shoulder and hip in a straight line.

Latching:

If you need to support your breast, keep your fingers away from the areola (the dark part surrounding your nipple). Hold your breast with your hand like a "C" (thumb on top and fingers below).

Tickle your baby's lips gently with your nipple. When the baby opens her mouth wide (like a yawn), quickly but smoothly pull her onto the breast.

Your baby's mouth should be wide open with lips flared outward.



What are signs that my baby is getting milk?

You see rhythmic movement on the top of your areola.

You hear the baby swallowing (a faint "K" or "ca" sound).

Your baby's jaw moves evenly while he sucks.

He seems content after feeding.

How long do I feed my baby?

Keep the baby on one breast until she is finished sucking. Your baby will feed for 10 to 15 minutes, or longer, on one breast.

You may offer the second breast to your baby if you feel she is not done feeding.

If you need to remove the baby from your breast, gently insert a clean small finger into the corner of the baby's mouth to relieve the suction.

Never pull the baby off your breast while the baby is latched - it may cause damage and further pain to your nipples.

APPENDIX O:

The LanP Trial

Are you breastfeeding your newborn baby?
Are you experiencing painful nipples?



Your participation can help us understand how to best help women with nipple pain.

You may be eligible to participate if you:

- Gave birth less than 3 days ago
- Have any damage to your nipples

Study participation involves four short telephone interviews.
A small token of appreciation is provided at study completion.
Confidentiality is assured.

Speak with your nurse for more information, or:

Telephone: (289) 456-4564

Email: kim.allen@utoronto.ca



This project has been approved by the University of Toronto Research Ethics Board

Sore Nipple Study
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