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Promoting Self-Management of Breast and Nipple Pain in Breastfeeding Women: Protocol of a Pilot Randomized Controlled Trial

Ruth Lucas, PhD, RNC, CLS^{1,2}, Katherine Bernier, RN, PhD¹, Mallory Perry, MS, PhD¹, Heather Evans, PhD, RNC-MNN, CLC^{3,4}, Divya Ramesh, PhD¹, Erin Young, PhD^{1,2}, Stephen Walsh, ScD^{1,2}, and Angela Starkweather, PhD, ACNP-BC, FAAN^{1,2}

¹School of Nursing, University of Connecticut, Storrs, Connecticut

²P20 Center for Accelerating Precision Pain Self-Management, University of Connecticut, Storrs, Connecticut

³Manchester Memorial Hospital, Manchester, Connecticut

⁴Department of Nursing, University of Saint Joseph, West Hartford, Connecticut

Abstract

The majority of women experience pain during breastfeeding initiation with few strategies to manage breast and nipple pain. In fact, women cite breast and nipple pain as among the most common reasons for breastfeeding cessation. In order to address this important issue, we developed a Breastfeeding Self-Management (BSM) intervention, based on the Individual and Family Self-Management Theory Framework. In this framework, self-management is conceptualized as a process in which women use knowledge, beliefs, and social facilitation to achieve breastfeeding goals. The purpose of this longitudinal pilot randomized controlled trial was to test the feasibility, acceptability, and preliminary efficacy of the BSM intervention with women initiating breastfeeding. Recruitment of 60 women intending to breastfeed occurred within 48 hours of delivery, and women were randomized to either the intervention or usual care group. The BSM intervention group received breastfeeding SM education modules that included information of how to manage breast and nipple pain and self-management support through bi-weekly texting from the study nurse, and were asked to complete a daily breastfeeding journal. Primary outcomes measured at baseline, 1, 2, and 6 weeks will be used to 1) evaluate feasibility, acceptability, and preliminary efficacy of the BSM intervention, and 2) assess the influence of protective and risk factors of breastfeeding pain (including individual genetic polymorphisms related to pain sensitivity) on process variables for self-management of breastfeeding and breastfeeding pain, and on proximal (breastfeeding pain severity and interference, breastfeeding frequency) and distal outcomes (breastfeeding exclusivity and duration and general well-being).

Corresponding author: ruth.lucas@uconn.edu.

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Keywords

breastfeeding; self-management; pain

Introduction

Breastfeeding is one of the most important early determinants of infant health and development (Pediatrics, 2012; Association of Womens Health Obstretic and Neonatal Nurses, 2015). If 90% of women were breastfeeding exclusively for 6 months, the Healthy People 2020 goal, the United States would save an estimated \$13 billion per year in health care related costs (Bartick & Reinhold, 2010; Koh, Piotrowski, Kumanyika, & Fielding, 2011). Yet, over 35% of all women cease breastfeeding exclusively during the first 6 weeks due to multiple factors, including the significant impact of breast and nipple pain (Kent et al., 2015; Odom, Li, Scanlon, Perrine, & Grummer-Strawn, 2013). Over 90% of women report acute breast and nipple pain during the first week of breastfeeding initiation and, of women with continuing pain, approximately 30% seek professional support for persistent breast and nipple pain (Kent et al., 2015). Half of those women accessing professional services continue to have persistent pain (Kent et al., 2015). Currently, standardized lactation professional approaches do not tailor interventions to the individual-specific factors that place women at risk for acute/persistent breast and nipple pain, like maternal history, genetic, psychological and somatosensory factors, physical and social environmental factors, and individual and family factors (Ryan & Sawin, 2009). In fact, many professionals approach breast and nipple pain during breastfeeding as normal and/or related to the mechanics of breastfeeding (ankyloglossia, infection, or engorgement) (Lucas & McGrath, 2016). The purpose of the pilot randomized controlled trial was to test the feasibility, acceptability, and preliminary efficacy of a Breastfeeding Self-Management (BSM) intervention compared with a usual care (attention control) group. Preliminary efficacy was evaluated by breastfeeding pain severity and interference, breastfeeding frequency, breastfeeding exclusivity and duration, and general well-being.

Individual & Family Self-Management Theory Applied to Breast and Nipple Pain Self-Management

According to the Individual & Family Self-Management Theory (IFSMT), self-management takes place in the context of risk and protective factors specific to the condition, here focused on breast and nipple pain associated with breastfeeding. In addition, breastfeeding pain risk and protective factors, including aspects of the physical and social environment and characteristics of the individual and her family, influence the self-management process of using knowledge and beliefs, self-regulation skills and abilities, and social facilitation to achieve health-related outcomes (Figure 1).

Few researchers have focused on the psychological and molecular mechanisms of breast and nipple pain sensitivity during breastfeeding; therefore, little is known about which women are most vulnerable to acute and/or persistent breast and nipple pain and early cessation of breastfeeding. We have expanded the risk and protective factors of breastfeeding pain to include the genetic makeup of each woman by selecting candidate genetic polymorphisms

within known pain sensitivity genes. Genetic variation within a number of genes is associated with variation in women's interpretation of pain (sensitivity to pain due to ankyloglossia, infection, or engorgement) and can influence pain facilitation or inhibition at the molecular level of pain processing (Berens, Eglash, Malloy, & Steube, 2016; Diatchenko et al., 2005; Kent et al., 2015). Specifically, single-nucleotide polymorphisms (SNPs) of the Catechol-O-methyltransferase (*COMT*) and oxytocin receptor (*OXTR*) genes influence pain sensitivity, the perception of pain and general mental well-being (Diatchenko et al., 2005; Rash, Aguirre-Camacho, & Campbell, 2013; Stuebe, Grewen, & Meltzer-Brody, 2013). Further, we included breastfeeding-specific factors of personal history of breastfeeding, maternal medical history, and pain sensitivity via somatosensory testing (quantitative sensory testing) (Amir, Jones, & Buck, 2015).

Because little attention has been given to addressing breastfeeding pain, women rarely receive adequate knowledge and skills to address SM of their breastfeeding-related pain (Amir, 2014; Amir et al., 2015). Therefore, we designed a BSM intervention to target modifiable process variables, including breastfeeding knowledge and beliefs, self-regulation skills and abilities, and utilization of social resources. The BSM intervention was adapted from cognitive behavioral therapy interventions effective in the chronic pain paradigm (Davis, Zautra, Wolf, Tennen, & Yeung, 2015; Emery, France, Harris, Norman, & VanArsdalen, 2008; Litt & Tennen, 2015). Cognitive behavioral therapy and routine face-to-face counseling have been effective in prolonging breastfeeding in disadvantaged populations but have not been used to support women experiencing breast and nipple pain during breastfeeding (Rahman et al., 2012).

The Breastfeeding Self-Management (BSM) Intervention

The BSM intervention uses educational modules and cognitive restructuring to facilitate pain self-efficacy, breastfeeding self-efficacy, and self-regulation skills, as well as nurse-led real-time support via texting to promote problem-solving of breast and nipple pain. Nurse-led bi-weekly texting provides personalized, time-sensitive, targeted breastfeeding education addressing engorgement, colostrum-to-mature-milk transition, and infant growth. Monitoring of breastfeeding frequency and symptoms is reinforced with a daily breastfeeding journal. The daily journal facilitates women evaluating infant latch and feeding pattern related to breast and nipple pain to identify when pain occurs and identify and implement effective pain-reducing strategies (proximal outcomes) (Bandura, 2005). Lastly, the BSM provides hyperlinks to online breastfeeding resources and general pain management resources adapted from our team's original modular intervention (Starkweather, Acabchuk, Ramesh, & Park, 2018).

A Precision Self-Management Intervention

The goal of the study described in this protocol was to evaluate the effect of the BSM intervention on breastfeeding pain severity and interference, breastfeeding frequency, breastfeeding exclusivity and duration, and general well-being. Using the IFSMT as a framework (Figure 1), we will explore IFSMT factors related to breastfeeding pain for women initiating breastfeeding and modifiable process variables to improve proximal and distal outcomes with the following specific aims:

Specific Aim 1)—Test the feasibility, acceptability, and preliminary efficacy of the BSM intervention designed to effect change in the process variables as measured by proximal and distal outcomes. We will evaluate participant burden (feasibility), retention, and approval of the intervention (acceptability), as well as differences in breast and nipple pain severity and interference, and breastfeeding frequency, between the BSM intervention group and control group at 1, 2, and 6 weeks postpartum (see Figure 1). Breastfeeding exclusivity and duration, and general well-being, will be compared between groups at 6 weeks postpartum.

Specific Aim 2)—Explore potential relationships/interactions among the key IFSMT protective and risk factors, self-management process factors, proximal outcomes and distal outcomes (see Figure 1).

Methods

Study Design and Setting

A multi-site pilot randomized controlled trial was designed to test the feasibility, acceptability, and preliminary efficacy of the BSM intervention among breastfeeding women. The study was conducted at two tertiary care academic hospitals delivering 2,280 infants annually with in-hospital and outpatient lactation support.

Randomization.—Participants were randomized to the BSM or control group based on a randomization schedule created by the study statistician. Two members of the study team performed the randomization, programmed the delivery of educational modules through REDCap links, and provided consultation to participants in the intervention group.

Blinding.—All study team members involved in data collection were blinded to the group assignment of participants. All participants were assigned a study number, which was used to track the study measures and biological samples. Dummy codes were used in the dataset to ensure that study team members were unable to determine the randomization scheme. The master key, which included participants' identifiers was locked and secured, and only accessible to the study team members responsible for scheduling consultations and follow-up visits.

Participants

Enrollment and Retention.—Institutional review board (IRB) approval by the university was obtained prior to enrolling participants. Our clinical partners screened the unit census 2–3 times per week for women who met inclusion/exclusion criteria. If a woman met criteria, a staff member approached her to provide information and inquire about her interest in participating in the study. Once a woman agreed to participate, written informed consent and HIPPA authorization was obtained. All participants completed the first round of data collection prior to discharge from the hospital. The participants received a \$25 gift card after completion of each data collection session for a total of \$100 for completion of all the study time-points. In addition, all participants received a \$25 bonus if they completed all study time-points and, for the intervention group, if they mailed the breastfeeding journal back.

Five women were recruited and initiated the study but were replaced eventually with subsequent participants. These women all discontinued participation (either officially by withdrawing or unofficially by lack of response to communications by members of the study team) within the first week following discharge. To avoid issues related to missing data, we recruited a total of 65 participants to achieve the target sample size of 60 women with complete data.

Inclusion Criteria.—(a) Women 18–45 years of age; (b) gave birth < 48 hours prior to recruitment and enrollment; (c) intention to breastfeed for 6 weeks; (d) daily access to a computer; (e) access to a phone; (f) ability to read and write English; (g) delivered singleton infant born > 37 weeks gestational age without medical complications; and (h) assessed by a Certified Lactation Consultant or International Board Certified Lactation Consultant (IBCLC) before discharge.

Exclusion Criteria.—(a) Teenage mother (< 18 years of age); (b) infant with congenital anomalies; (c) mother with history of significant mental health disorder (i.e. schizophrenia, bipolar disorder); (e) significant health condition not associated with pregnancy as determined by the principal investigator (i.e. sickle cell anemia, HIV+, diabetes, history of seizures, medical conditions that would alter pain sensorium); and (f) skin conditions on non-dominant forearm including eczema, rash, or dermatographism, which could interfere with experimental pain testing.

Sample Size.—Given that this was a feasibility study, there were no plans *a priori* to conduct formal hypothesis testing (Billingham, Whitehead, & Julious, 2013). Additionally, prior studies of the effects of similar interventions on pain severity during breastfeeding were not available to guide sample size calculations. Consequently, sample size was established with the goal of achieving reasonably high precision for estimation of correlation coefficients (relative to Specific Aim 1) and of differences in means between groups (relative to Specific Aim 2).

A sample size of 60 women is sufficient to provide a 97.5% probability that correlation coefficient statistics calculated from data in the study samples will reflect the correct direction of any bivariate association in the broader population as long as the magnitude of those associations is 0.25 or more. Similarly, with 30 women per group, the probability that statistics for the difference in mean pain severity between study samples will reflect the correct direction of any population-level effects will also be 97.5% as long as the magnitude of the standardized effects is 0.50 or more –i.e. a medium or larger effect (Erdfelder, Faul, & Buchner, 1996). The results of the study will inform the effect size for a forthcoming larger study.

Data Collection

Procedures for Both Groups

A member of the study team approached potential participants during hospitalization to screen for eligibility, obtain informed consent, and complete baseline data collection. After informed consent and prior to the start of data collection, the participants were randomized

to the intervention and control group and assigned a unique study identification number. Subsequently, quantitative sensory testing (QST) was performed on the non-dominant forearm and a maternal buccal swab was obtained. All buccal swabs were labeled immediately with participants' identification number and stored in a freezer on the clinical unit at -20 degrees Fahrenheit, until transported to the Center for Accelerating Precision Pain Self-Management biobehavioral lab for processing.

After discharge, a study nurse contacted all participants from the contact information provided during baseline screening. All participants received an email with a link to the study measures in REDCap. Both groups received a text from the study nurse as a reminder to complete the measures at 1, 2, and 6 weeks (Figure 2). The follow-up measures contained questions regarding breast care, problem-solving techniques for breast and nipple pain, use of breastfeeding pain SM interventions, common data elements for the SM of pain, Brief Pain Inventory, Visual Analogue Scale of breast and nipple pain, Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF), Edinburgh Postnatal Depression Scale (EPDS), exclusivity and duration of breastfeeding from the Ongoing Breastfeeding Assessment Survey (OBAS), and Patient-Reported Outcomes Measurement Information System (PROMIS) measures. At the 6-week follow-up, women were also asked to report their positive affect (PROMIS), global health information (PROMIS) and pain (PROMIS). This study protocol followed the University of Connecticut's REDCap recommendations for maintaining de-identified data.

Based on best practices for human subject research, if a concerning health indicator was reported, the study team contacted women from both intervention and control groups via text and, if no response was received, with a follow-up phone call. Concerning health indicators included an EPDS score over 10 (see below for details), indications on the EPDS of harming self or infant, or breastfeeding reported as less than 6 feeding sessions/day, due to the risk of dehydration for the infant. The study nurse identified women experiencing any of these issues and notified the principal investigator (PI). The PI contacted women and referred them immediately for consultation with their attending physician or an IBCLC...

Ten women chosen randomly were contacted by members of the study team after they completed the study for a semi-structured interview regarding the feasibility (participant burden), acceptability of participating (helpful/unhelpful aspects of the study and intervention), and suggestions for improving study procedures. Both Likert-type scale and open-ended questions were given in the interviews. The interviews were 10–15 minutes in length.

SNP Genotyping.—SNP genotyping of pain susceptibility candidate genes: Buccal cell samples were collected at baseline before discharge. Participants were instructed to rinse their mouth twice with water and then roll the sterile buccal brush firmly on the inside of the cheek. Samples transported to the Center's biobehavioral lab were stored at -80°C until subsequent processing in batches. Genomic DNA was extracted from buccal cells using Gentra® Puregene® Buccal Cell Kit according to manufacturer's instructions (Qiagen, #158845). SNP genotyping was completed for six SNPs, four SNPs within *COMT* and two within *OTXR* (Table 1) using Taqman SNP genotyping assays (VIC/FAM) and allelic discrimination analysis according to manufacturer's instructions using an Applied

Biosystems StepOne Plus PCR machine and ABI allelic discrimination software (ThermoFisher Scientific, Waltham, MA).

Breastfeeding Self-Management Intervention

Guided by the IFSMT theory, a cognitive behavioral therapy-based BSM intervention for breast and nipple pain was developed. The BSM intervention involves educational modules; cognitive restructuring facilitating self-regulation, self-efficacy, and breastfeeding self-efficacy; and familial and social support to help patients problem solve breast and nipple pain. The intervention activities include a daily journal of breastfeeding, bi-weekly texting from the study nurse, and hyperlinks to educational modules and online resources.

Breast Feeding Support

Women in the intervention group were given a paper journal to record six breastfeeding sessions per day for weeks 1 and 2 and one breastfeeding session per day for weeks 3, 4, 5, and 6. To facilitate SM of pain or difficulty during each breastfeeding session, women completed the journal prompts, which included the Maternal Assessment of Infant Breastfeeding Behaviors – Revised, and a feeding algorithm. Using the Maternal Assessment of Infant Breastfeeding Behaviors – Revised and the algorithm, women reflected on their pain or difficulty with breastfeeding relative to infant breastfeeding behavior (Bandura, 2005). The daily journaling facilitated women anticipating the trigger of breast and nipple pain, self-regulating the pain, and decreasing negative coping mechanisms such as catastrophizing. Women were given a prepaid mailer to return the journal to the study staff after 6 weeks.

After baseline data collection, a study team member contacted all participants in the intervention group bi-weekly for the entirety of the 6-week study. Following a standardized texting script, participants were given a choice of five words that best summarized their breastfeeding experience: “Happy”, “Average”, “Sore”, “Engorged”, or “Always (feeding)”. Based on the reply given, the study nurse would reply with an educational or supportive standardized text script. The text script content would change each week to address expected changes in lactation and pain issues, i.e. engorgement in the first week, cluster feeding in the second and third week. Each script prompted study team members to provide a number to call if participants had questions or referral to the outpatient IBCLC their hospital provided. The PI, in collaboration with the study IBCLC, developed the targeted educational and supportive text scripts which were adapted from the *MumBubConnect* breastfeeding study (Gallegos, Russell-Bennett, Previte, & Parkinson, 2014). Participants were prompted to contact the study team with concerns or if they required emergent breastfeeding support (Poorman, Gazmararian, Parker, Yang, & Elon, 2015).

Educational Modules and Online Resources—To support self-regulation skills, women were provided with seven 5-minute educational modules on pain and breastfeeding pain SM with additional online resource hyperlinks. The modules included: pain neurophysiology related to breastfeeding, breast and nipple pain non-pharmacological strategies, common breastfeeding issues and interventions, pain catastrophizing, stress

reactivity, deep breathing, guided imagery, and general lactation support and community resources (Table 2).

All educational modules for SM were sent to participants via REDCap email link over the first two weeks of study participation. The study team monitored module completion daily and sent up to 3 reminders via email and text as needed to watch the modules. Completion was assessed via REDCap and the team was notified when patients accessed the hyperlink for each module.

Measurements

After obtaining informed consent and randomization, initial data collection and study sequence was explained by the study team member (Figure 2). Table 3 outlines the self-report measurements obtained at baseline, 1, 2, and 6 weeks. Initial data collection was by paper, but weekly study measurements were collected and managed by the study team using the university REDCap system.

Demographics and general questionnaires.—On entry, women completed the recommended BRICS (biomedical research informatics computing system) Demographics (NINR common data elements). At entry and six weeks, women completed the eight PROMIS® measures: the 6-item measures of fatigue, sleep disturbance, depression, anxiety, pain and applied cognition; the 9-item positive affect measure; and the 10-item global health measure (Available online at: <https://cde.nlm.nih.gov/cde/search?selectedOrg=NINR>). All PROMIS measures are based on the T-score (mean = 50, standard deviation = 10). In most cases 50 equals the mean in the U.S. general population.

Maternal and infant breastfeeding history.—The self-report history form was created by the PI for earlier pilot studies that examined maternal weekly experience of breastfeeding (Lucas et al., 2015; Lucas, Gupton, Holditch-Davis, & Brandon, 2014). Women responded to items related to protective and risk factors grouped under three headings. Breastfeeding-specific factors included height, weight, body mass index, parity, route of delivery, history of breastfeeding, inverted or flat maternal nipples, breast surgery, chronic medical conditions, pregnancy medical conditions, and mental health history. Physical and social environment factors included delivery at a Baby-Friendly Hospital and IBCLC evaluation care (guidance in using artificial milk supplementation, nipple shield use, and pumping). Finally, individual and family factors included familial history of breastfeeding, family capital (income and resources), family structure (family members in the home), and infant characteristics (weight, length, and gender). Women also completed items related to the SM process, including variables related to knowledge and belief (breastfeeding education, which included antenatal knowledge of breast and nipple pain) (American Academy of Pediatrics, 2012; Nommsen-Rivers, Chantry, Pearson, Cohen, & Dewey, 2010).

Coping Strategies Questionnaire- Revised.—Women completed the Coping Strategies Questionnaire – Revised, a 27-item questionnaire to assess participants' six cognitive coping responses to pain (praying, coping self-statement, distancing from the pain, ignoring pain, catastrophizing, and distraction) (Robinson et al., 1997; Riley & Robinson,

1997). Participants rated the frequency of their use of each coping strategy in managing their pain on a 7-point Likert-type scale, from “*never do that*” to “*always do that*” (Robinson et al., 1997; Riley & Robinson, 1997). The range of possible scores (7 – 42) varies by subscale based on the number of subscale items, with higher scores indicating more frequent use of the coping strategy. Published Cronbach’s α values for the subscales range from 0.80 to 0.86.

Kohn’s Reactivity Scale.—Participants’ reactivity to stimulation was assessed using 24 items, each rated on a 5-point scale (“strongly disagree,” “disagree,” “neither disagree nor agree,” “agree,” “strongly agree”) (Dubreuil & Kohn, 1986). Scores range from 24 – 120, with higher reactivity scores indicating increased sensitivity to low-level stimulation and increased distractibility. Cronbach’s α ranged from 0.74 to 0.83 for different samples. Reactivity scores correlate positively with reports of pain and negatively with reports of pain tolerance (Dubreuil & Kohn, 1986; Veldhuijzen, Noordermeer, van Wijck, Snijders, & Geenen, 2013).

Perceived Stress Scale.—Participants’ perception of the degree their life is uncontrollable, unpredictable and stressful was measured by the Perceived Stress Scale (Cohen, Kamarck, & Mermelstein, 1983). The ten items are rated on a 5-point Likert scale ranging from 0 (never) to 4 (very often). Scores range from 0 – 40, with higher scores indicating increased perceived stress. Cronbach’s α values exceed 0.70 across multiple studies (Lee, 2012).

Brief Pain Inventory.—Participants completed the Brief Pain Inventory to measure the domains of pain severity (five items) and pain interference (impact of function) (eight items). Scores range from 0 – 80, with pain severity and interference domain scores calculated using the average of the subscale (0–10) and higher scores indicating increased pain. Cronbach’s α ranges from 0.77 to 0.91 (Cleeland, 2009).

Edinburgh Postnatal Depression Scale (EPDS).—Participants’ risk for depression was screened using the EPDS. The EPDS comprises a 10-item scale with a score range of 0–30 (Cox, Holden, & Sagovsky, 1987). The EPDS’ authors found that any score > 10 indicated risk for possible depression, and women who scored > 13 were likely to be suffering from a depressive illness. The EPDS has 85% sensitivity and 77% specificity in identifying women at high risk for depression. The scale’s split-half reliability was 0.88, and Cronbach’s α was 0.87 (Cox, Holden, & Sagovsky, 1987).

Breastfeeding Self-Efficacy Scale - Short Form (BSES-SF).—Participants’ cognitive choice, effort, and emotional response to breastfeeding initiation, duration and challenges were measured by the BSES-SF (Dennis, 2003). The BSES-SF comprises 14 items, each rated on a 5-point scale. Item scores are summed to produce a total score ranging from 0–70, with higher scores indicating greater maternal breastfeeding confidence. The BSES-SF has been shown to be sensitive to maternal experience with breastfeeding, with breastfeeding self-efficacy at one-week postpartum predicting feeding methods at 4 and 8 weeks. The BSES-SF had Cronbach’s α of 0.94 (Dennis, 2003).

Ongoing breastfeeding assessment survey (OBAS).—The OBAS was originally created by the PI as a semi-structured interview guide for her pilot studies (Lucas et al., 2015, 2014). The interview questions were adapted into Likert-type and multiple choice questions with additional questions added to measure IFSMT protective and risk factors for breastfeeding pain, process variables, and proximal and distal outcomes. Women reported any breastfeeding specific factors that emerged after discharge (engorgement, breast infection, and infant characteristic of ankyloglossia) (Kent et al., 2015; Lucas & McGrath, 2016). They also described any process factors related to their knowledge and belief (perception of breastfeeding experience and milk supply); self-regulation skills (breastfeeding frequency, duration, and strategies to manage breast and nipple pain); and social facilitation (seeking lactation support from family, friends, or social media). Lastly, women reported on the proximal outcomes of self-management behaviors (pharmacological and non-pharmacological interventions; frequency of breastfeeding sessions) and cost of health care services (accessing lactation health professional services) and the distal outcome of breastfeeding exclusivity and duration. (Lucas et al., 2015).

Maternal perception of BF experience.—The PI adapted the LATCH scale into a maternal self-report algorithm (Jensen, Wallance, & Kelsay, 1994). The adaptation was the addition of concrete descriptions of infant latch and sucking behaviors that might cause pain. Using the algorithm, mothers assessed infant awake/sleep state, signs of hunger (hand swipe, rooting, lip smacking), number of attempts to latch, strength of latch, strength of suck, pattern of pauses and sucks, duration of breastfeeding sessions, and, using a visual analogue scale (0–100), breast and nipple pain occurring during breastfeeding.

Maternal Assessment of Infant Breastfeeding Behaviors – Revised.—The Maternal Assessment of Infant Breastfeeding Behaviors – Revised is an adaptation of a maternal self-report measure of five infant latch strength, suck strength, and pause patterns (Barnes, Lethin, Jackson, & Shea, 1953). Based on the results of earlier studies by the PI, the maternal self-report was problematic: 1) the descriptors were adultomorphic and influenced women's choice; 2) 30% of the time women combined patterns to describe infant latch and suck patterns; and 3) none of the patterns described normal milk ejection physiology (Lucas, McGrath, Diallo, & Brandon, 2016). The MAIBB-R measures eight patterns, which include combinations of poor, moderate or vigorous latch, sucking strength, and duration of a feeding. The PI found that women reported increased nipple pain with infants demonstrating a vigorous sucking pattern (Lucas et al., 2015).

Efficacy of the intervention questionnaire.—Participants were interviewed using Likert-type and open-ended questions created by the PI to describe the feasibility (participant burden), acceptability of participating (helpful/unhelpful aspects of the study and intervention), and suggestions for improving the study (Barte, ter Bogt, Beltman, van der Meer, & Bemelmans, 2012; Oakley et al., 2006; Sawin et al., 2017). The interviews on average were 10–15 minutes in length.

Pain sensitivity measures.—Participants' pain sensitivity was measured using standardized stimuli to test both nociceptive and non-nociceptive systems in the peripheral

and central nervous systems (Rolke et al., 2006; Verdugo & Ochoa, 1992). A standardized protocol of administration was performed by all study team members based on previous studies (Starkweather et al., 2016), including instructions provided for the patient and sequence of QST. The QST protocol included a total of seven tests, which quantify functional sensory pathways using mechanical cutaneous pain and pressure pain. The QST protocol was run on participants' non-dominant forearm. A practice run on the dominant forearm was performed in order to verify the participant's understanding of the protocol. The medial side of the non-dominant forearm was utilized for testing purposes. The protocol is described in detail in a previous manuscript by our group (Starkweather et al., 2016).

Data Analysis

Study data were merged by our team into a database using the R statistical package (version 3.4.3). The R package will be used to apply exploratory data analysis techniques to inspect and clean study data, calculate summary statistics and assess distributional characteristics for all study measures, evaluate the reliability of newly developed research instruments used in the study, and perform correlation analysis and longitudinal modeling. In our initial analyses, we will summarize the number of women approached to participate, the proportion of those women who met inclusion criteria, and the proportion who eventually provided informed consent.

To address the specific aims, descriptive statistics will be used to evaluate participant burden, retention, and approval of the study intervention. To obtain preliminary assessments of the efficacy of the BSM intervention, differences between the intervention and control groups in breast and nipple pain and in breastfeeding exclusivity and duration during follow-up (1, 2, and 6 weeks postpartum) will be investigated using longitudinal modeling techniques. Due to varying distributional characteristics of the pain, exclusivity, and duration variables, these techniques will involve both linear mixed models and generalized linear mixed models. Because the current study is a pilot study, the focus of these analyses will be estimation rather than testing of intervention effects. Parameter estimates representing main effects of the BSM intervention and changes in intervention effects over time will be reported with confidence intervals and will provide a basis for identifying and describing the variability of intervention effects among study participants.

To address the exploratory aim, correlation analyses will be conducted to explore associations between protective and risk factors, breast and nipple pain, and breastfeeding exclusivity and duration (while adjusting for study group assignment [intervention vs. control], as necessary). Because these analyses will involve a mix of continuous, ordinal, and dichotomous variables, a combination of Pearson (including phi, point biserial, and point polyserial versions), biserial, polyserial, tetrachoric, and polychoric correlations will be calculated. Matrices of these correlation coefficients will then be used to construct path diagrams that potentially represent the patterns of causal relationships by which protective and risk factors influence pain, and pain, in turn, influences breastfeeding practices. Construction of such path diagrams will guide future, hypothesis-driven studies designed to test and refine our understanding of the factors that promote successful breastfeeding by predicting and managing pain that occurs during its practice.

Additional exploratory analyses will be performed by our team to obtain preliminary evidence of potential relationships/interactions among IFSMT protective and risk factors and process variables and their influence on proximal and distal outcomes. A specific emphasis in these analyses will be evaluation of the roles of baseline pain sensitivity (as measured by QST) and genetic determinants of pain sensitivity (as represented by *COMT* and *OTXR* SNPs) in affecting self-report of breast and nipple pain, the exclusivity and duration of breastfeeding, and the efficacy of the BSM intervention.

Discussion

Progress

Participant recruitment began on April 30, 2017 and a total of 65 women (33 participants in the control group and 32 participants in the intervention group) were recruited by September 2017, which met our target of 60 women. Initial data collection and evaluation of the intervention's acceptability are complete. Five women from the intervention group did not complete the study. Of these, two women did not complete baseline data collection due to time constraints, two discontinued breastfeeding and one was lost to follow-up.

Lessons Learned

The primary lesson we learned was about the burden to the women and the clinical staff posed by collection of the baseline data before participants were discharged. Although women were eager to participate, patient care (self-care, provider rounding, newborn feeding) was a priority. This required the study team to recruit and collect data throughout the day when women and infants were not undergoing procedures, assessments, and self-care. For half of the participants, this resulted in a protracted amount of time required to collect baseline data. To decrease participant burden at baseline data collection, we removed items from the *BRICS NINR SF-36 Affective Well-Being* measure that were duplicated in the other PROMIS measures.

In order to decrease the amount of time the study team spent on the unit and interruptions to patient care, the team switched from electronic to paper data collection. The paper measures allowed women to complete the forms at their own pace and during the evening, and the team picked up the forms the next morning. This required significant communication within the team to ensure the forms were collected before discharge to limit the burden on the clinical staff from managing study data and prevent the data from being included by mistake in patients' chart at discharge. On more than one occasion, maternal discharge was briefly delayed to complete the baseline data, which caused mild tension between the unit staff and the study team.

Another challenge was coordinating with the clinical staff to collect data without disrupting patient care. For our main clinical site, this was the first ongoing research study conducted on the unit, and although the study team deferred to the demands of patient care, the clinical staff sometimes found data collection disruptive. While the study team coordinated data collection and patient care, the team discussed the ongoing status of the study with the clinical staff. To increase staff engagement in the study, the PI introduced the study to staff

nurses at huddles and posted flyers about the study and pictures of the study team in common areas on the unit. The study team also communicated any clinical staff concerns, recruitment status, and ongoing study updates via text and face-to-face meetings 2–3 times a week with our clinical partners.

Another challenge was the study team not having a designated area to work in while participants completed the measurements. The unit common space was limited and needed for the clinical staff to coordinate patient care. The study team avoided waiting in the common working areas on the unit and instead waited in the family lobby or in our clinical partner's office.

Our second site also had data collection challenges. At the first site, data collection occurred on days when our clinical partners were available to screen for participants. The first clinical site had 20–30 deliveries a week, allowing for recruitment of 1–4 women a week. Our second clinical site had a maternal and fetal health specialty clinic with mostly high-risk deliveries and an average of five low-risk deliveries a week. The team texted our clinical partners each week to identify potential participants, but only a few women were eligible for the study. We anticipate that the second site will have more women eligible when we explore SM of pain with women who have underlying medical conditions that would alter pain sensorium.

Another lesson learned was about coordinating Institutional Review Board (IRB) approval between two study sites. The PI obtained IRB approval from her university. However, our main clinical site required approval from their own Institutional Review Committee. Participation of the second clinical site involved a collaborative agreement with the main institution. The study team and study coordinator worked closely with both sites to ensure consistent protocols. Obtaining study approval and adding amendments required time and ensuring communication between study sites.

Another challenge encountered was the location of the two clinical sites, which are 20 and 45 miles away from the university. The team communicated frequently throughout the day via text, email, and phone to address problems at each site and to ensure fidelity of data collection at both sites. The PI and the study coordinator provided weekly updates to the team and clinical partners. Our second site did not receive IRB approval until two months into the study, and the second site clinical partners were initially not part of the regular communication. For this second clinical site, with infrequent low-risk deliveries, the PI found texting twice a week and bi-weekly phone calls to the clinical partners were adequate to ensure ongoing communication.

We also learned the importance of having contact information needed to follow-up with providers of women who reported elevated depression scores. Our protocol was to text these women, and most women responded. However, some women did not respond to text or phone calls. The PI did not ask for women's obstetric health care provider contact information at the baseline data collection and did not have direct access to mothers' medical chart due to HIPPA concerns. To ensure the safety and well-being of the mother and

child, the PI worked with the clinical partners to access a woman's medical chart as needed to identify and contact the woman's provider sooner than the 6-week postpartum visit.

A final lesson learned was the lack of acceptability of keeping a paper daily breastfeeding journal. Many women in the intervention group did not complete the paper daily journal. To improve journal completion rates, the study team emphasized to participants the importance of keeping track of breastfeeding behaviors and also added a monetary incentive for mailing back the journal. The study team added additional text reminders to ensure women were completing and returning their journal. However, many women in the intervention group did not return the paper journals even with the additional reminders and monetary incentives.

Overall, the study design and measures were well received by women. We learned that our baseline data collection protocol was perceived as too extensive by women and clinical staff. In future studies, we will need to prioritize in selecting baseline measures to decrease participant burden. We will also work closely with the clinical staff to coordinate clinical care with data collection to decrease the time burden for participants, clinical staff, and our study team. Women responded well to the nurse lead texting to inquire about their mental health, did not find this invasive, and verbalized that the texting made them feel like "somebody cared and they were not alone." Responses to the paper breastfeeding journal were not as positive. Based on their positive response to texting, in future studies we will convert the paper journal to a text based or mobile app journal. The most important knowledge to be gained from this study is the effect of the BSM intervention on maternal SM of breast and nipple pain and breastfeeding duration. The first three weeks of breastfeeding is the critical window when women choose to continue to breastfeed or cease breastfeeding. The initial positive response to texts/modules suggests that they are an effective means of delivering the SM intervention during this critical window of time without undue participant burden.

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Individual & Family Self-Management Theory Applied to Breast and Nipple Pain Self-Management

Figure 1. Model of Breast and Nipple Pain Self-Management. Adapted from *Individual and Family Self-Management Theory*, by P. A. Ryan and K. J. Sawin retrieved from www.nursing.uwm.edu/smsc. Copyright 2009, 2014 by Ryan and Sawin. Adapted with permission

Figure 2. Data Collection Flow Chart.

Note. BF = Breastfeeding; BSM=Breastfeeding Self-Management; QST = Quantitative Sensory Testing. PROMIS (Patient-Reported Outcomes Measurement Information System) Instruments: Pain Intensity, Anxiety, Sleep Disturbance, Applied Cognition & General Concerns, Depression, Fatigue, Global Health, NeuroQOL Positive Affect & Well Being; Pain Specific Questionnaires (PSQs): Brief Pain Inventory, Coping Strategies, Kohn's Reactivity Scale, Perceived Stress Scale; Breastfeeding Battery (BB): EPDS, BSES-SF, Ongoing Breastfeeding Assessment Survey; BF Log: Maternal Assessment of Infant Breastfeeding Behaviors-Revised, Algorithm of Breastfeeding Experience.

Table 1.*Gene Single-nucleotide Polymorphisms (SNPs) Minor Allele Frequency: COMT and OXR*

SNP	Alleles	Minor Allele Frequency
<i>COMT</i>		
rs6269	<i>G>A</i>	0.36 (Global)
rs4633	<i>C>T</i>	0.37 (Global)
rs4818	<i>G>C</i>	0.30 (Global)
rs4680	<i>A>G</i>	0.37 (Global)
<i>OXR</i>		
rs2254298	<i>A>G</i>	0.2144 (Global)
rs53576	<i>G>A</i>	0.4138 (Global)

Note. *COMT* = Catechol-O-methyltransferase gene; *OXR* = oxytocin receptor gene

Table 2.

Breastfeeding Video Modules

Module Topic	Description
Breastfeeding Pain Neurophysiology	Lactation physiology, infant latch/suction pattern mechanism, neurophysiology of peripheral pain mechanism and strategies to modulate on breast and nipple pain.
Non-Pharmacological Strategies for Nipple and Breast Pain	Explanation of cognitive modulate of pain perception with non-pharmacological analgesic strategies to manage and monitor peripheral and central sensitization.
Common Triggers and Interventions for Breast and Nipple Pain	A checklist approach in identifying breastfeeding issues and simple interventions (i.e. correcting latch, positioning).
Pain Catastrophizing	Explanation of pain catastrophizing and the negative effect catastrophizing has on pain perception and outcomes. Provided in each video are cognitive behavioral therapy exercises to practice prior to each breastfeeding session to reduce breast and nipple pain.
Stress Reactivity	Explanation of how stress and an individual's response to stress, stress reactivity, effects interpersonal relationships, breast and nipple pain management and breastfeeding. Use of cognitive and behavioral exercises will assist in creating a positive breastfeeding experience (i.e. goal-setting, self-monitoring practices).
Deep Breathing	Use of deep breathing as a therapeutic exercise will incite the relaxation response. Relaxation is demonstrated with practice exercises in this video module..
Guided Imagery	To manage anxiety and/or stress using guided imagery throughout breastfeeding initiation and continuation..
Support	Provides resources on breastfeeding intervention and community lactation resources provided; both informational and instrumental.

Table 3.**Study Instruments**

Category and Instrument	Description
Health History and Demographics	
Maternal and Infant Breastfeeding History	Self-report instrument to measure maternal context variables of personal history of breastfeeding, medical/mental history, professional breastfeeding support and interventions during hospitalization. Family context variables of familial history of breastfeeding, capital, structure. Infant Context variables of weight, length, gender. Antenatal breastfeeding preparation, intent and pain perception.
BRICS Demographics: National Institute of Nursing Research Common Data Elements	Self-report instrument which measures demographics.
Emotional and Physical Health	
Patient-Reported Outcomes Measurement Information System	Anxiety, Sleep Disturbance, Depression, Fatigue, Pain, Applied Cognition, Positive Affect, Global Health Form
Pain Specific Questionnaires	
Coping Strategies Questionnaire	Self-report instrument on cognitive coping responses to pain.
Kohn's Reactivity Scale	Self-report instrument measuring sensitivity and distractibility to life situations and painful situations.
Perceived Stress Scale	Self-report instrument that measures perception of one's life being uncontrollable, unpredictable and stressful.
Brief Pain Inventory	Measures two domains of pain severity and impact of pain on function. Process variable measures pain at the moment, the distal outcome measures pain at each data point.
Breastfeeding Battery	
Edinburgh Postnatal Depression Scale	Screening tool for postnatal depression in mothers.
Breastfeeding Self-Efficacy Scale Short Form	Assess and measure maternal breastfeeding self-efficacy.
Ongoing Breastfeeding Assessment Surveys	Semi-structured interview guide, adapted to self-report instrument. Measures familial context variables of paternal/familial support and orofacial anomaly. Process variables of maternal perception of breastfeeding experience. Proximal outcomes of pharmacological and non-pharmacological therapies, maternal management and professional. Distal outcomes of pain interference with breastfeeding and exclusivity of breastfeeding duration.
Breastfeeding Journal	
Maternal Perception of BF Experience	Maternal self-report, breastfeeding algorithm. Assesses infant awake/sleep state, hunger cues, number of attempts to latch, strength of suck, suck/pause pattern, length of breastfeeding session and maternal pain.
Maternal Assessment of Infant Breastfeeding Behaviors Revised	Maternal self-report of eight categories of infant's latch and subsequent sucking pattern.
Evaluation	
Efficacy of the Intervention Questionnaire	Questionnaires that requires mothers to self-report their participation in the study, the study's impact and whether the intervention was helpful.

Note. BRICS = Biomedical Research Informatics Computing System.