# Study Title: Happy, Healthy, Loved: A Mobile-delivered Breastfeeding Self-efficacy Intervention for First Time Parents

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**HAPPY, HEALTHY, LOVED**

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# I. INTRODUCTION

Breastfeeding's health benefits are extensive and well established. For infants, health risks such as sudden infant death syndrome, infections, diabetes, obesity, and asthma(Sung et al., 2016) are lower; for mothers, breastfeeding is associated with lower risks of breast and ovarian cancers(Zhou et al., 2015). Major health organizations recommend exclusive breastfeeding for at least the first six months postpartum (Eidelman, 2012). However, exclusive breastfeeding in the US is reported by only 44.4% of women at three months postpartum (CDC) and even lower in Ohio where this study is proposed (CDC). Improving exclusive breastfeeding rates is among the nation's health priorities outlined in Healthy People 2020 (CDC). We propose a randomized trial of an affordable, scalable intervention to improve rates of exclusive breastfeeding, an important national health priority.

**Theoretical Underpinnings: Targeting Breast Feeding Self-Efficacy, Partner Support and Coping.** Bandura's self-efficacy, originating in social cognitive theory, is defined as confidence in one's ability to effectively perform a specific task or reach a goal (Bandura, 1977). The framework of breastfeeding self-efficacy (BSE) posits that confidence in the ability to breastfeed predicts breastfeeding effort and ability to persevere through common challenges such as latching difficulties, perceived supply concerns, and return to work (Dennis, 1999; McCarter-Spaulding & Dennis, 2010). Four sources of information are central to the development of BSE: performance accomplishments in breastfeeding, exposure to other women's breastfeeding experience, encouragement from influential others, and physiological responses to stress and anxiety (Dennis, 1999).

Multiple studies have established a link between BSE and duration of exclusive breastfeeding, including our own research, which suggests BSE at two days postpartum significantly predicts exclusive breastfeeding rates at 6 months postpartum among primiparous mothers (Henshaw, Fried, Siskind, Newhouse, & Cooper, 2015). Similar findings are reported with outcomes at 4 months postpartum in an Australian sample (Baghurst et al., 2007) and 6 months postpartum in a Canadian sample (Semenic, Loiselle, & Gottlieb, 2008).

A limited number of randomized controlled trials to improve BSE have been conducted, with promising results. A recent systematic review and meta-analysis found that BSE interventions effectively improve exclusive breastfeeding duration (Brockway, Benzies, & Hayden, 2017).The majority of interventions are delivered in one-on-one interventions with between 1-3 contact points (Brockway et al., 2017). Authors of recent BSE interventions suggest that continued contact and engagement with women during the first months postpartum may enhance the impact of BSE interventions (McQueen, Dennis, Stremler, & Norman, 2011; Otsuka et al., 2014). Mobile phone text message delivery, which has been found to be efficacious in altering other health behaviors (Hall, Cole-Lewis, & Bernhardt, 2015), is a cost-effective direction for future BSE interventions. If efficacious, mobile programs can be translated and culturally adapted for women with diverse backgrounds. However, to our knowledge no current BSE programs combine text-message delivery and partner involvement.

*Partner support*. Among partnered women[1], partners are uniquely positioned to be

1 Our proposed study is inclusive of same-sex parent couples; however, most existing literature has studied fathers exclusively. The term father is used when referencing work conducted with fathers; partner is used when referencing our own study design.

sources of support and influential in developing BSE during the postpartum period, yet few breastfeeding programs have attempted to involve partners directly. Developing programs involving partners is a recommended action in the Surgeon General's 2011 report on breastfeeding, due to the important influential role of the partner (McGuire, 2011). Fathers' support of breastfeeding is associated with higher rates of breastfeeding initiation, duration, and exclusivity (Kessler, Gielen, Diener-West, & Paige, 1995; Maycock et al., 2013). Research suggests that fathers feel willing but unprepared to support breastfeeding (Brown & Davies, 2014), suggesting a need for interventions directly equipping them for this role.

Few randomized trials have included partners in breastfeeding education, and even fewer have utilized technology in targeting partners; however, among published intervention trials, promising results have been found when engaging fathers. Prenatal education of fathers in a previous trials resulted in higher rates of breastfeeding initiated and sustained at six weeks when compared with control conditions (Maycock et al., 2013; Wolfberg et al., 2004). Most recently, a randomized controlled trial providing breastfeeding support to couples found significant differences in overall breastfeeding rates at 3 months postpartum, but not exclusive breastfeeding(Abbass-Dick, Stern, Nelson, Watson, & Dennis, 2015; Abbass-Dick et al., 2017). Two recent internet-based interventions involving fathers have been introduced; a website breastfeeding resource targeting fathers and partners in education and a "gamified" breastfeeding support mobile app exclusively for fathers (Abbass-Dick et al., 2017; White et al., 2016). Both have been described in the literature but published randomized trial outcomes are not yet available. To our knowledge, neither technology-based programs nor in-person sessions for fathers have incorporated information for partners that is tailored to the specific challenges, strengths, and support preferences of the couple.

*Positive coping*. The relationship of negative emotional states or stress and breastfeeding has been well established; for example, results of a systematic review suggest early postpartum depressive symptoms are associated with lower BSE and lower breastfeeding duration (Dennis & McQueen, 2009), and recent prospective analysis found 3 month anxiety symptoms predicted reduced odds of exclusive breastfeeding at 6 months(Adedinsewo et al., 2014). Neuroendocrine activity associated with reported stress and anxiety may interfere with production and letdown of milk(Stuebe, Grewen, Pedersen, Propper, & Meltzer-Brody, 2012), while cognitive patterns such as rigid expectations and focus on self-deficiencies may result in less rewarding breastfeeding experiences, ultimately contributing to avoidance and discontinuation(Dennis, 1999).

Positive management of stress and physiological arousal is a key component of BSE theory and therefore is a main behavioral target in the proposed intervention. Aligned with theoretical mechanisms of change in BSE theory, the goals include engaging in constructive internal dialogue and managing emotional reactions to challenges along with enhanced ability to produce calm, relaxed physiological states (Dennis, 1999). Cognitive-behavioral theory is the basis of several efficacious programs to produce positive coping for the prevention of stress and negative emotional states (Barrera, Wickham, & Munoz, 2015; Le, Perry, & Stuart, 2011). Core components include cognitive strategies to foster flexible, self-compassionate, realistic interpretation of one's self and environment, coupled with behavioral strategies to increase rewarding or meaningful activities, increase support networks, and challenge negative self-

beliefs (Beck, 2016). Previous randomized controlled trials suggest that cognitive behavioral coping skills can be effectively taught via internet delivery (Barrera et al., 2015; Milgrom et al., 2016; O'Mahen et al., 2013).

**Improving breast-feeding with a mobile intervention program.** The proposed study will test if the program *Happy, Healthy, Loved (HHL*) can be effectively delivered using a mobile intervention program that includes partner support and actively addressing stress management. Our mobile program is a two-part delivery process that begins with a brief interactive tablet program in the hospital during the postpartum stay. The tablet portion is designed for parents to complete together, and it includes questions for mothers and partners about motivations for breastfeeding, challenges experienced, preferred methods of coping with stress, and preferred support gestures from the partner. This information is then used to provide brief tailored text-message prompts to mothers and partners during the first 6 weeks postpartum, with follow up outcome at 6 weeks and 6 months postpartum. Internet based interventions have been demonstrated to be efficacious in influencing a wide range of health behaviors (Wantland, Portillo, Holzemer, Slaughter, & McGhee, 2004).

Offering HHL as an in-hospital program followed by small, continuous-dosage mobile-based materials that do not require a large block of time for reading or exercises can reduce patient burden and increase engagement. Mobile-based HHL addresses partners directly to improve support behavior, but tandem text-message delivery, unlike in-person or telephone delivery, ensures that dual-parent scheduling is not a barrier to treatment. Preliminary pilot data suggests that the content and method of delivery are both highly acceptable to mothers and partners, and preliminary pilot data suggest positive outcome trends when mother and partner both receive the mobile intervention.

The intervention emphasizes three behavioral targets: a) providing resources to support breastfeeding through modeling, information, and feedback (tailored to maternal reported breastfeeding challenges and motivations); b) providing prompts to mother and partner to communicate about support strategies (tailored to parents' preferred support behaviors); and c) providing prompts for positive evidence-based coping strategies (tailored to parents' preferred coping activities). Exclusive breastfeeding as well as breastfeeding self-efficacy will be measured at 6 weeks and 6 months as primary outcomes. Secondary outcomes of coping behaviors and perceived partner support are the behavioral targets that are hypothesized to influence the primary outcomes of BSE and exclusive breast feeding and will also be measured at 6 weeks and 6 months. Because the intervention emphasizes coping strategies for managing stress, we hypothesize that baseline cortisol will act as a moderator for the intervention, with mothers experiencing elevated cortisol benefitting the most from the intervention.

In 2017, we conducted a small pilot study to test the feasibility of our HHL program. We enrolled 17 mothers and 10 partners to complete the baseline assessments and then randomly assigned them to the HHL group (n=8 mothers) or usual care (n= 8 mothers). Follow-up rates at 6-weeks postpartum were 94% for mothers and 90% for partners. Mothers and partners who completed the HHL intervention (n=12) rated the acceptability of the program on a five-point agreement scale. The majority of parents agreed or strongly agreed that the program was beneficial (83%) and that participating was manageable (91.7%). No parents opted to stop receiving messages during the six-week delivery.

**Investigating individual variability in intervention effectiveness.** In the final aim of the proposal, we explore the extent by which subjective reports of stress and a biological indicator, namely hair cortisol levels, at baseline, and post intervention is associated with the mechanisms of change, as well as breast feeding rates. We hypothesized that higher levels of cortisol will be associated with lower levels of baseline positive coping, BSE, and partner support. Importantly, we also explore both self-reported stress, and hair cortisol levels as moderators of the effects of the intervention. The effects of any behavioral intervention vary significantly, and precision medicine approaches advocate that prevention and treatment strategies take seriously this variability (Insel, 2014). While the majority of this approach has been applicable in the context of oncology, it has important implications for psychological and behavioral research. Consistent with past studies, suggesting that interventions may be particularly useful for those with higher vulnerability at baseline(Blow et al., 2009; Snider et al., 2018), we hypothesized that the intervention would have the biggest impact on mothers with the highest levels of perceived stress and cortisol levels.

We look specifically at subjective reports of stress and hair cortisol due to a large body of research demonstrating intriguing relations between neuroendocrine mechanisms and failed lactation, as well as perinatal mood disorders (Stuebe et al., 2012). Elevated cortisol in the perinatal period is associated with the development of mood disorders (Magiakou et al., 1996; Nierop, Bratsikas, Zimmermann, & Ehlert, 2006a; Nierop, Bratsikas, Zimmermann, & Ehlert, 2006b). In addition, stress is associated with non-responsive feeding styles (Hurley, Black, Papas, & Caulfield, 2008) and undesired weaning (Sjolin, Hofvander, & Hillervik, 1977). Causal evidence demonstrating that chronic stress exposure leads to deficits in maternal care and increases in anxiety and impaired lactation were found in rodent models (Murgatroyd et al., 2015).

Traditional methods of assessing cortisol levels via saliva, urine or plasma are cumbersome, requiring multiple assessments in order to ascertain long term exposure, thus increasing participant burden, attrition and limiting its application during the post-partum period. Hair cortisol provides longer retrospective calendar of exposure to stress, thus has the potential to be a non-invasive biological variable that can be collected with ease, making it an excellent candidate for assessing chronic stress in new mothers. Hair cortisol level is associated with traditional salivary cortisol levels throughout pregnancy (D'Anna-Hernandez, Ross, Natvig, & Laudenslager, 2011; Kirschbaum, Tietze, Skoluda, & Dettenborn, 2009a), and is related to self-report levels of stress among pregnant women (Kalra, Einarson, Karaskov, Van Uum, & Koren, 2007). At the same time, a significant body of research demonstrates that self-reports of stress do not always correlate with biological indicators such as cortisol(Kalra et al., 2007; McLennan, Ihle, Steudte-Schmiedgen, Kirschbaum, & Kliegel, 2016; Milam, Slaughter, Verma, & McConnell, 2014), thus begging the question of which measure may be best for assessing stress in new mothers. By using both self-report measures of stress, as well as hair cortisol as a biological marker, we are able to examine their relations to one another as well as their role in moderating the effects of the intervention. Thus, findings from the current study has the ability to both provide further evidence for hair cortisol as a biomarker of exposure to stressful life events during the prenatal period, as well as its feasibility in predicting the efficacy of interventions.

# II. METHODS

## A. *Study Population*

Primiparous, breastfeeding women living with a partner will be recruited directly on the maternity floors of three OhioHealth hospitals, Riverside Methodist Hospital (RMH), Grant Medical Center (GMC), and Doctors Hospital. Based on our pilot data, we plan to enroll up to 200 mother-partner pairs over a 24-month period. Based on Cohen's standard power functions, 80% power to detect a medium-large effect in outcomes (alpha = .05) should be achieved with 64 participants per arm, leading to the proposed plan of a minimum of 60 couples per arm (Cohen, 1992). Assuming a conservative 25% attrition rate to achieve a final number of 128 couples, as well as the possibility that one member of a couple ends participation while the other continues, we estimate needing to enroll between 160-200 couples. Therefore, we will enroll up to 200 mother-partner pairs during the study period of September 1, 2020 and September 1, 2022.

1. Inclusion criteria includes primiparous mothers:
    a. over the age of 18 years old,
    b. living with a partner or spouse
    c. have an intention to breastfeed their infant for at least 6-weeks postpartum;
    d. whose infant is not in the Neonatal Intensive Care Unit,
    e. have a mobile phone with text message capability,
    f. have no current self-reported depressive episode, and;
    g. English as a primary language
2. Exclusion criteria include mothers who:
    a. have other biological children (past breast-feeding experience),
    b. have infants in the Neonatal Intensive Care Unit,
    c. do not have a mobile phone with text message capabilities,
    d. report current episodes of depression, or are receiving antidepressant treatment or psychotherapy for depression,
    e. have initial study survey that indicates suicide risks (participants who are identified as suicidal ideation at 6 weeks or 6 months will receive further assessment and referral but not be excluded from the program because it may be more harmful and penalizing to remove them from the program if they find it helpful. We will remind the participant that continuing is voluntary and there is no penalty if they wish to discontinue participation)
    f. do not speak, read and write English

## B. A*ims and Hypotheses:*

Aim 1: Investigate the efficacy of mobile-delivered breastfeeding self-efficacy program on

breastfeeding rates and breastfeeding self-efficacy, as compared to care as usual.

Hypothesis 1: Participants randomly assigned to the intervention will report higher breastfeeding self-efficacy and exclusive breastfeeding at six weeks and six months postpartum compared to those assigned to usual care.

Aim 2: Assess whether improved coping with stress (as measured by self-reports), and partner support (as measured by partner and self-report) are mechanisms for the intervention.

Hypothesis 2: Participants randomly assigned to the intervention will report increased positive coping behaviors and higher perceived partner support at six weeks and six months postpartum compared to participants assigned to usual care.

Aim 3: Investigate relationships among levels of hair cortisol, stress (e.g. as indexed by subjective reports of stress) and resilience (social support and positive coping) factors.

Hypothesis 3: Hair cortisol levels measured immediately postpartum will be positively associated with symptoms of depression, anxiety, and stress, and negatively associated with perceived partner support and effective coping.

Aim 4: Investigate hair cortisol levels as a biological indicator of susceptibility (e.g. moderator) to intervention effects.

Hypothesis 4: Mothers who have moderate-high hair cortisol levels will benefit most from HHL.

### C. *Study Variables*

A summary of the measures proposed is provided in the table below.

| **Construct** | **Measure** | **0-2 days postpartum** | | **6 weeks postpartum** | | **6 months postpartum** | |
|---|---|---|---|---|---|---|---|
| | | mom | partner | mom | partner | mom | partner |
| Breastfeeding | Index of breastfeeding status | x | | x | | x | |
| Self-efficacy | Breastfeeding self-efficacy scale short form | x | x | x | x | x | x |
| Coping Behavior | brief COPE | x | x | x | x | x | x |
| Partner Support | Postpartum Partner Support Scale | x | x | x | x | x | x |
| | Social provisions checklist | x | x | x | x | x | x |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Mood/Stress | Edinburgh Postnatal Depression Scale | x | x | x | x | x | x |
| | Depression, Anxiety, and Stress Scale | x | x | x | x | x | x |
| | Maternal Mood Screener | x | x | x | x | x | x |
| Sleep Quality (cortisol covariate) | Pittsburgh Sleep Quality Index | x | | | | | |
| Acceptability & Adherence | HHL acceptability scale<br>Participant adherence | | | x | x | x | x |
| Demographics | Demographics and cortisol covariates. Demographic information includes: Ethnic and racial identity (self-report), Study role, Relationship status, Income, Education, Age, Gender, Sexual preference, Primary Language, Number of persons in household (not counting new infant), Relationship to people living in the household, Employment, Plans to return to work, Timing of planned return to work, Email address, Phone number, Cell phone type, Cell phone use, Frequency of text messages, Opinion on importance of cell phone, Presence of a pregnancy or parenting app on the cell phone and type, medical record number | x | x | | | | |
| Delivery info | Infant weight and Apgar score, delivery method, maternal weight & height in pregnancy/delivery.<br><br>Collected from records and entered in REDCap by the research coordinator | | | | | | |
| Cortisol[2] | Hair habits interview | x | | | | | |
| | Maternal hair sample<br><br>Collected by research coordinator | x | | | | | |

2 Only for mother's with at least 3 cm of hair who opt to participate in this portion of the study

1. Measures

The following validated outcomes and proposed mechanism measures will be used at one or more of the three data collection time points: pre-intervention and six weeks as well as six months postpartum. The schedule of measures administered at each timepoint is indicated in the data collection schedule table above. The survey will be administered through an online link using an ID code to identify participants in the REDcap survey. The follow up survey will be administered through a REDCap link sent via email with text-message reminders. The six week follow up survey is designed to measure immediate outcomes following the intervention content. The six-month follow up is designed to measure whether the six week intervention produces lasting differences in proposed outcomes.

*Demographics and cortisol covariates*. In addition, we will also assess at baseline basic demographics and established covariates of hair cortisol levels. These will include relationship status, birth method (vaginal or caesarean), body mass index, maternal education level, hair characteristics, and number of individuals in the household (Dettenborn, Tietze, Bruckner, & Kirschbaum, 2010)

*Edinburgh Postnatal Depression Scale* (Cox, Holden, & Sagovsky, 1987). The EPDS is a well-validated 10-item self-report depression screening tool, in which endorsement of each item is based on how women feel during the previous 7 days. Possible scores range from 0 to 30, with high scores reflecting more depressive symptoms. The EPDS has shown high sensitivity, specificity, and positive predictive power for postpartum depression when using the 10+ score cutoff (Dennis & Ross, 2006; Zelkowitz & Milet, 1995). Across a variety of studies with women, consistency has been at acceptable levels (Cronbach's alpha .73--.87, test-retest .53--.74; (Boyd, Le, & Somberg, 2005). The EPDS has also been validated as an acceptable screening tool for men in the postpartum period (Edmondson, Psychogiou, Vlachos, Netsi, & Ramchandani, 2010; Matthey, Barnett, Kavanagh, & Howie, 2001).

*Maternal Mood Screener* (Munoz, 1998). The mood screener questions were adapted from the Diagnostic Interview Schedule (Robins, Helzer, Croughan, & Ratcliff, 1981) and assesses lifetime and current major depressive episode. Positive endorsement of 5 out of 9 depression symptoms present for at least two weeks screens positive for possible major depressive episode. The screener is a self-report checklist using DSM-IV criteria that has shown high (kappa = .76) concordance with the SCID-CV, the gold standard diagnostic interview for depression (Vázquez, Muñoz, Blanco, & López, 2008). The assessment for lifetime and current major depressive episodes will be administered at 0-2 days post-partum and only the assessment for current episodes will be administered at the 6 week and 6 month follow-up time points.

*Depression Anxiety and Stress Scales* (DASS-21). The DASS-21 will be used to measure the unique symptoms of each state. There is normative data for the scale, and the depression and anxiety subscales have shown high convergent validity with the Beck Depression Inventory and Beck Anxiety Inventory (Antony, Bieling, Cox, Enns, & Swinson, 1998).

*Index of Breastfeeding Status*. Rather than conceptualizing breastfeeding as a dichotomous outcome, participants' level of breastfeeding exclusivity will be measured as a continuous variable differentiating among exclusive, partial, and token breastfeeding as suggested by previous authors (Labbok & Coffin, 1997) Women will be asked to identify the

level that accurately described their breastfeeding behaviors within the previous 24 hours. Four levels will be reported: exclusive breastfeeding (breast milk only), partial breastfeeding (breast milk and at least 1 bottle of formula per day), token breastfeeding (breast given to comfort baby not for nutrition), and no breastfeeding. Higher values represent more exclusive breastfeeding. This measure has been successfully used at RMH in previous research (Henshaw et al, 2015).

*Breastfeeding Self-Efficacy Scale-Short Form* (McCarter-Spaulding & Dennis, 2010). The BSES-SF has demonstrated strong reliability and validity and will be used to measure BSE. Higher scores indicate greater self-efficacy related to breastfeeding. High internal consistency has been demonstrated in previous samples (Cronbach's α=.91; (Henshaw et al., 2015). A wording change to measure self-efficacy in the supportive partner role has also been validated (Dennis, Brennenstuhl, & Abbass-Dick, 2018) and will be used for the partner survey.

*Brief COPE*. This 28-item validated scale derived from a previously published measure showing reliability (Cronbach's α=..62--.85, test-retest r = .46--.89) and convergent validity with several established coping measures (Carver, Scheier, & Weintraub, 1989) will be used to identify coping strategies consistent with cognitive-behavioral skills, such as positive reframing, and absence of avoidance (Carver, 1997).

*Pittsburgh Sleep Quality Index* (PSQI)**.** The PSQI assesses sleep quality, which is a critically important covariate of hair cortisol and mood. The PSQI is well-established questionnaire for assessing sleep quality, duration and disturbances. The PSQI shows good internal consistency Cronbach's α=.83, test-retest reliability (r = .85) and predicted clinically determined poor sleepers at sensitivity of 89.6% and specificity of 86.5% (Buysse, Reynolds, Monk, Berman & Kupfer, 1989). The PSQI reliability and validity has been established with a pregnant sample as well (Skouteris, Wertheim, Germano, Paxton & Milgrom 2009). Unlike the other outcome measures, the Pittsburgh Sleep Quality Index is only measured at baseline.

*Postpartum Partner Support Scale*, (Dennis & Ross, 2006). The PPSS is a 24-item self-report instrument to assess partner postpartum-specific support. Items are rated on a 4-point Likert-type scale (responses from 1—4) to produce a total score ranging from 24 to 96, with higher scores indicating higher levels of postpartum partner support. This scale demonstrated reliability with mothers during the postpartum period (Cronbach alpha = .96) and significantly distinguished between women with and without depressive symptoms at 8 weeks postpartum (Dennis & Ross, 2006).

*Social Provisions Checklist* (Davis, Morris, & Kraus, 1998). This is a 30-item measure of perceived support from the co-parent, specifically. The scale covers six provisions of support: guidance, reliable alliance, reassurance of worth, attachment, social integration, and opportunity for nurturance. These provisions are influenced by the theoretical work of Weiss (1974; the provisions of social relationships). All items are rated on a 5-point scale for a total score of between 30—120, with higher scores indicating higher levels of support. This measure has been used in the early postpartum period (4 weeks) showing good reliability (Cronbach's alpha = .82) and predictive validity, successfully distinguishing between women with and without depressive symptoms at 8 weeks postpartum (Dennis & Ross, 2006).

*HHL Acceptability Scale*. The investigators developed a list of 11 questions designed to assess participant satisfaction with the program on a scale of 1 (strongly disagree) to 5 (strongly agree). Open ended responses for participants to suggest alterations to the program are

included as well. As this measure has been designed specifically for the current study, psychometric data are not available. Acceptability will be measured at six weeks and six months postpartum

*Participant adherence*. Adherence will be measured by the percentage of text messages recorded as opened (available through 3C Institute program delivery) by participants, as well as the percentage of weekly breastfeeding check-in texts participants respond to with a yes, or no response.

*Hair cortisol*. To provide convergent validity of the DASS-21 and other stress scales, we are collaborating with Dr. Stacey Doan of Claremont McKenna College to analyze hair samples and the correlation of this known biomarker of cortisol to the mother's stated stress levels. We will share study ID number, deidentified hair samples, hair histories, and scores on coping behavior, partner support, mood/stress, and sleep quality index scales with Dr. Doan for comparative analysis with hair cortisol levels. Hair cortisol measurement procedures will follow validated methods (Dettenborn et al., 2010; Stalder & Kirschbaum, 2012). Hair cortisol collection is not required for participation in this study. All mother's with at least 3 cm of hair who enroll in "Happy, Healthy, Loved" may opt to contribute a hair sample. The study staff member who explains the study and obtains the informed consent will collect the hair sample at the time the baseline questionnaires are obtained. At baseline, a small amount (15-30 mg) of hair from the posterior vertex of the head will be collected. Hair strands will then be cut into 3 cm segments, which based on human scalp hair grows at approximately 1 cm per month (Kirschbaum, Tietze, Skoluda, & Dettenborn, 2009b), so each of the 3 cm sample will indexed cortisol output during the three trimesters of pregnancy (D'Anna-Hernandez et al., 2011; Kirschbaum et al., 2009). If hair is less than 9 cm long, the analysis will include only the number of 3 cm segments available. The wash procedure and steroid extraction will be undertaken using high performance liquid chromatography–mass spectrometry (Gow, Thomson, Rieder, Van Uum, & Koren, 2010). Additionally, because washing, hair straightening or dying, and styling products may affect HCC (Gow et al., 2010), mothers will be asked about their hair histories to use as covariates in analysis along with hair sample. Hair histories include questions related to hair color, salon treatments, sunlight exposure, use of hair products, medications, creams, and hair pieces, style and indoor tanning habits. The samples will be sent to Dr. Stacey Doan of Claremont McKenna College for analysis.

*Pasero-Opioid Induced Sedation Scale (POSS)*. All participants who have had opioids for comfort within 6-hours of consenting will be assessed using the POSS scale. The POSS scale is used to determine a patient's level of sedation before subsequent doses of pain medication. The scale ranges in S for "sleep, easy to arouse" to 4 which indicates somnolence. A score of 1-2 indicates that the patient is awake or slightly drowsy but easily awakened. Only patients with scores of S, 1, or 2 will be consented for the study.

**D. *Study Design***

2. Recruitment Procedures:

We plan to hire a study nurse to assist other study staff to recruit eligible participants at the postpartum unit of Riverside Methodist Hospital, Grant Medical Center, and Doctors Hospital during the mother's 2-3 day postpartum hospital stay during the study period. The

OhioHealth Institutional Review Board (IRB) will approve all study staff. Participant recruitment will follow procedures previously used in research with first time mothers at RMH (Henshaw et al., 2015) and the initial feasibility pilot trial for this proposed study. A daily census of patients will be reviewed by nursing staff to ensure that mothers with infants in the NICU and mothers who experienced infant loss will not be contacted. Using a standardized study recruitment script the study staff will introduce the study to the potential participant. If the patient shows interest, study staff will begin the informed consent process. The study staff will check the patient's electronic record to determine when or if pain medication has been given within the last 6-hours. If pain medication was taken the study staff member will assess the patient using the POSS scale and document the results in the medical record. Only patients with a POSS score of "S", 1 or 2 may be consented. If the patient does not have a score of "S", 1 or 2 on the POSS assessment, the study staff can return later to reassess.

If the participant meets eligibility, the study staff will describe the study, and interested mothers will identify if they would like to participate together with their partner. If the co-parent is in the room, a study description and consent will occur immediately. If not, the study staff will leave study materials for the mother and co-parent to discuss, and will set a time to return to the room. Only couples in which a partner is able to consent in person and visit the hospital will be included. The study staff member will bring an iPad for the participants to use for completing pre-intervention surveys. All pre-intervention and study surveys will be completed by accessing the REDcap online survey link on the iPad. No survey data will be stored on the iPad or other computer hard-drive. Survey data entered into REDCap via the iPad will be stored in the REDcap's password-encrypted server.

Participants will complete two mood questionnaires: the EPDS and the Mood Screener. Participants whose survey responses suggest they meet criteria for a current depressive episode will be provided with education and treatment resources for area providers. An automatic pop-up message is coded to appear on the iPad survey when a mother or partner's survey indicates anything other than no risk for suicide. The initial surveys are completed on iPad before being randomized to the intervention or usual care group. The research team member who consented the patient will review the completed questionnaire before continuing to introduce the intervention or usual care instructions. The study nurse will collect the initial surveys and check for the coded message as soon as the participant completes the surveys. If a survey shows depression or suicide risks, the study staff will use the following standard OhioHealth protocol. A patient (included or excluded from study) who reports suicidal ideation (a 1, 2, or 3 on question #10 of the EPDS or yes to the suicide items on Mood Screener), an in-hospital behavioral health consult will be arranged by the assigned clinical nurse for further evaluation of suicide risk and treatment need. As mentioned, these policies are consistent with OhioHealth's approach to depression screening (currently using the SAD Persons; scale-Appendix B). Additionally, their primary care physicians will be notified of the patient's condition in order for follow up to occur post discharge.

Partners will also complete a baseline EPDS and Mood Screener, as part of the baseline survey (not eligibility screening). If partners report suicidal ideation, the level of risk will be assessed by the study staff at the time of survey completion. All cases with low/moderate risk will result in referral to a suicide hotline and immediate mental health referral. High risk

(potential immediate threat) cases will result in an emergency mental health referral (911) made with the participant's knowledge. The details of this risk protocol are attached. If the partner's survey results suggest they meet the criteria for current depressive episode, we will ask them for their primary care provider's contact information so that we can notify them for follow-up. If the patient or partner do not have a primary care provider, we will refer them to the emergency department for evaluation and referral to the appropriate level of care.

The six week and six month surveys will have an automatic message appear at the end of the survey for the mother or partner to read if the suicidal ideation or depression score is elevated. The message states the following: "If your survey results show an elevated depression score you should contact your primary healthcare provider. If your survey suggest you are at risks for suicide or this is an emergency you should contact 911 or the suicide hotline phone number **1-800-SUICIDE 1-800-784-2433.** Survey responses will be reviewed by the research team daily and phone contact will be attempted within 24 hours of the survey receipt. Three attempts to reach the participant will be tried within 24-48 hours. The consent form will remind patients and partners that referrals and physician notification may occur to ensure optimal care. Patients will be informed that failure to accept the notification of a health care provider clause will render them ineligible for the study.

3. Randomization and Bias Reduction:

The study statistician will provide a randomization table. Before beginning the recruitment process we will upload the table into the REDCap software. We set the randomization for two groups; one for patients receiving the intervention of mobile text messaging and prompts to partners about ways they can support the mother, and one group to serve as a control. Following the participant's agreement and consent to participate in the study, the member of the study staff who obtained the consent will provide an iPad to the patient and open the REDCap link so that the participant can begin their surveys. When the patient has finished the surveys, the study staff will log back into REDCap to verify the surveys are complete, following verification, the study staff member will click on the randomization tool to determine the patient's treatment group.

Study staff will inform the intervention participants that they will receive text messaging information for 6 weeks postpartum (4 per week), mapping closely with the tablet content that will provide reminders, resources, and encouragement associated with the three areas of education. Based on participants' responses in the tablet program, the messages will be personalized to the motivations, preferences, and concerns that parents indicate in the tablet program. All program delivery will be managed through contracted partnership with 3C Institute, specializing in behavioral health platforms using HIPAA-compliant procedures. Development of the initial tablet-based prototype was designed in consultation with an instructional technologist at Denison University who contributed to a user-friendly tool. The control group activities consist of usual care at RMH, GMC, and DH along with non-breastfeeding text messages reporting infant developmental milestones over the first 6 weeks postpartum. All patients receive access to a lactation consultant during the hospital stay along with optional in-person class, instructional video, and information packet about breastfeeding. The remaining surveys will be pushed out through email automatically through REDCap six-

weeks and six months after the first message treatment.

After the participants complete the initial education modules and pre-surveys have finished, the study staff will set up the automated, one-way text program. Mothers and their participating partners will receive a $25 pre-paid gift card following the initial survey completion, a second $25 gift card following the 6-week follow up survey completion, and a third $25 gift card following the 6-months follow up survey completion. Therefore, each participant is eligible for a total of $75 in gift cards if they complete all surveys ($150 total per couple).

4. Intervention:

**Happy Health Loved (Experimental Condition).** The HHL program is comprised of the three topical areas described in Table 2. This information will be delivered via tablet to both parents during the postpartum hospital stay. For the next 6 weeks text messages (4 per week) mapping closely with the tablet content will provide reminders, resources, and encouragement associated with the three areas of education. Based on participants' responses in the tablet program, the messages will be personalized to the motivations, preferences, and concerns that parents indicate in the tablet program. Example content is provided in Figure 2. All program delivery will be managed through contracted partnership with 3C Institute (OhioHealth approved), specializing in behavioral health platforms using HIPAA-compliant procedures. 3C Institute is an award-winning research and development company founded in 2001 that brings research to practice to improve the health and well-being of people. The Institute creates, test and disseminates evidence-based programs and has received the Tibbetts Award from the Small Business Administration for technological excellence in 2014. 3C provides the platform for the tailored, automated text messaging for the study.

*Table 2:* Outline of HHL goals and activities

| | Goals | Example Activities |
|---|---|---|
| modeling & feedback | Viewing breastfeeding as learned skill | Other mothers' modeling of challenge management |
| | Reflecting on successes and growth | Accomplishment feedback on breastfeeding success |
| partner support | Increase perceived support | Prompt partner to show active support |
| | Mutual support of self-care | Prompts to both partners to mutually support self-care |
| stress coping | Behavioral activation | Prompt mother's preferred rewarding activity |
| | Realistic expectations of self | Strategies for challenging negative thoughts |

Participants will be asked one yes/no question each week ("still breastfeeding? Text Y for yes, N for no"). Once a "no" response has been received from a participant, all remaining text messages will emphasize coping and partner support only rather than breastfeeding, in order to minimize any guilt or distress a mother may feel for discontinuing breastfeeding. This will occur automatically within the program.

Data security. Participants assigned to the intervention condition will complete questions and activities within the online platform of Happy Healthy Loved, delivered on the HIPAA compliant, secure, encrypted platform delivered by 3C Institute (see support letter for details).

We will obtain survey data from mothers and their partners via online questionnaires completed using OhioHealth approved REDCcap software (https://www.project-redcap.org/). Participants will complete the surveys using iPads provided by the research team.
Only the Principal Investigator (PI) and certain members of the research staff (e.g., study coordinator) will know of or have access to the participants' identities. Privacy and confidentiality will be maintained by assigning a study number to each participating mother-partner dyad. HIPAA compliant, password protected REDCap database will be used to store participant survey information. Only approved study personnel will have access to study data and individually identifiable private information about human subjects. All study personnel with access to study data will be certified to conduct research with human subjects, and will be aware of the importance of maintaining strict confidentiality. REDCap and 3C Institute intervention data will not be linked online; rather, the four-digit participant ID number will be the only link between the two sources of information. REDCap and the 3C Institute platform will be password protected, and accessing the iPad without the correct password would not allow an unauthorized person to access participant data.

The content and delivery of the text-message follow up will map closely with the content provided in the tablet-based materials. The intention is to provide reminders, resources, and encouragement associated with the three areas of education. Texts will be matched to mothers' response to questions in the educational module designed to identify her strengths and preferred coping strategies. For example, a mother who identified during the initial module that walking has been a positive coping strategy for managing stress and mood in the past would get a text specifically encouraging her to make time for a walk, with or without baby. The partner would receive a corresponding text suggesting that walking is helpful for the mother, and encouraging the partner to provide support for this activity in one of two ways: offer to watch the baby while mother walks or go for a walk with the mother and baby. Messages will be sent four times per week.

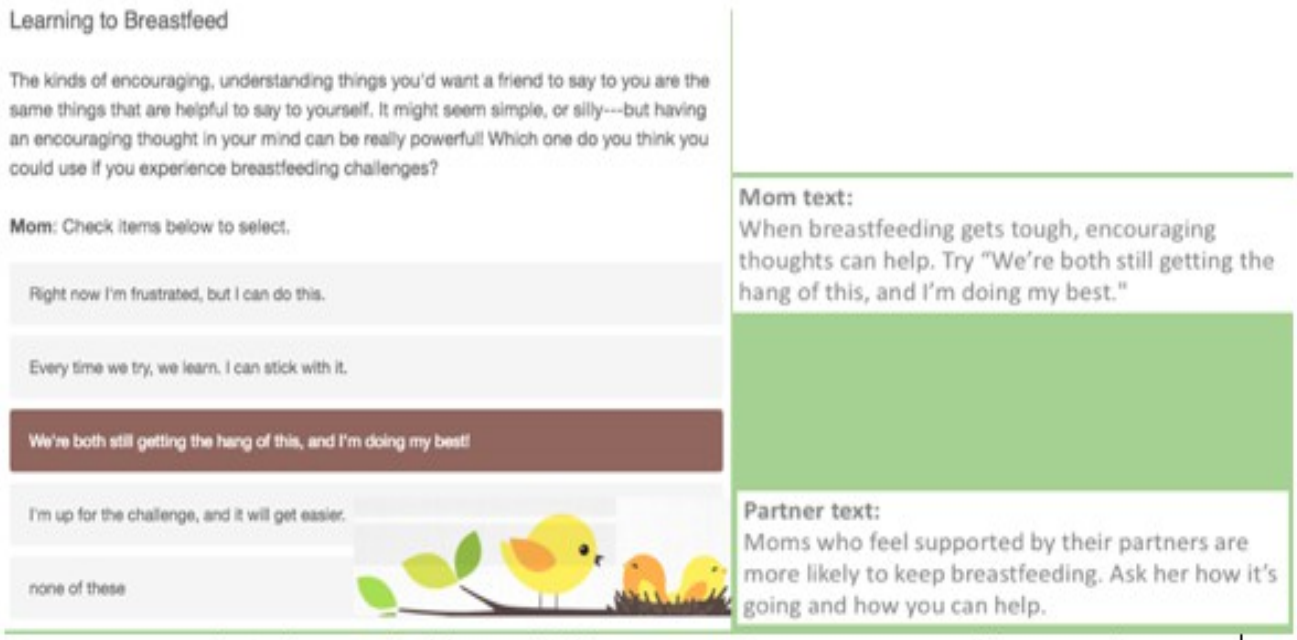


*Figure 2.* Example in-hospital tablet and follow-up text from Happy, Healthy, Loved program

Participants will be instructed on how to unsubscribe from the program at any time using a text response of "unsubscribe." Participants who unsubscribe will still receive the 6 week survey and will be contacted by the research team to learn whether they would like to withdraw from the study entirely or simply unsubscribe from the messages.

Control group activities. The control group activities consist of usual care at the RMH, GMC, and DH care sites. The videos are part of the subscription program The Newborn Channel, and parents can choose videos on demand to watch on topics covering a variety of topics from postpartum depression to safely bathing a newborn and recovery steps post-cesarean section. Control group participants will document with a signature after they have watched Newborn Channel videos on breastfeeding, infant care basics, and postpartum depression (currently required of mothers before hospital discharge). The control group participants will be sent four text messages per week for the first six weeks as well, but the content of the texts will be non-breastfeeding related. The content will instead summarize infant development facts. The text messages will be sent in order to separate the effect of receiving text messages from the effect of the active intervention content.

5. Confidentiality and Data Management:

3C Institute privacy protections are included as an appendix detailing specific technology safeguards. All study personnel will be trained in ethical conduct of research and data will be protected in the REDCap and 3C Institute platforms. Participants would be informed immediately if such a breach were to occur and we would take every effort to recover and protect the information. 3C Institute specializes in mental health education and support applications, and has a history of creating secure platforms for individual use that are HIPAA compliant. OhioHealth Information Security (IS) is reviewing the 3C contract and platform to ensure privacy protections meet OhioHealth strict IS security mandates.

All paper informed consent documents and study log book materials will be stored in a locked file cabinet at each hospital location within a secured room in the maternity floor. The approved study staff will hold the key to the file cabinet.

### *E. Statistical Analysis*

The intervention's impact on the study's primary outcomes will be evaluated using intent-to-treat analysis with multiple imputation for missing follow up cases. Outcomes, adjusting for baseline variables, will be analyzed using ANCOVA for continuous variables (self-efficacy, partner support, and coping) and logistic regression for categorical variables (exclusive breastfeeding). To examine the extent in which increased partner support, and lower levels of stress would explain the effects of the intervention, two criteria will be used to establish whether there is statistically significant mediation in the model(MacKinnon, Lockwood, Hoffman, West, & Sheets, 2002; MacKinnon, Fairchild, & Fritz, 2007) including the joint significance of paths *a* ( i.e., the path from predictor to mediator) and *b* (i.e., the path from mediator to outcome variable) and the asymmetric distribution of the product confidence interval test for the product (a*b) of the coefficients a and *b*, which have both shown the best combination of power and avoidance of type 1 error compared to 12 alternative tests of mediation(MacKinnon et al., 2002; MacKinnon et al., 2007).

We will use the regression-based approach described by Hayes to develop models that allow us to evaluate mediation (Hayes, 2008). The bootstrapping resampling method available in this approach provides an opportunity to run analyses that will approximate the sampling distribution to obtain confidence intervals (CIs) when variables are not normally distributed. With regards to aims 3 and 4, regression (logistic regression for dichotomous outcome variables) analyses controlling for relevant covariates will be used to examine relations between hair cortisol levels and partner support, coping, self-efficacy, and breastfeeding rates. Because both high and low levels of cortisol have been indicated as signs of dysregulation (Miller, Chen, & Zhou, 2007) , a quadratic term will be added to the model to examine non-linear relationships. In addition, to these analyses, we will also use the mediation approach described above to explore the extent to which maternal mood may mediate the relations between cortisol and breastfeeding behaviors.

## III. REFERENCES

Abbass-Dick, J., Stern, S. B., Nelson, L. E., Watson, W., & Dennis, C. L. (2015). Coparenting breastfeeding support and exclusive breastfeeding: A randomized controlled trial. *Pediatrics*, *135*(1), 102-110. doi:10.1542/peds.2014-1416 [doi]

Abbass-Dick, J., Xie, F., Koroluk, J., Alcock Brillinger, S., Huizinga, J., Newport, A., . . . Dennis, C. L. (2017). The development and piloting of an eHealth breastfeeding resource targeting fathers and partners as co-parents. *Midwifery*, *50*, 139-147. doi:S0266-6138(16)30248-0 [pii]

Adedinsewo, D. A., Fleming, A. S., Steiner, M., Meaney, M. J., Girard, A. W., & MAVAN team. (2014). Maternal anxiety and breastfeeding: Findings from the MAVAN (maternal adversity, vulnerability and neurodevelopment) study. *Journal of Human Lactation : Official Journal of International Lactation Consultant Association*, *30*(1), 102-109. doi:10.1177/0890334413504244 [doi]

Antony, M. M., Bieling, P. J., Cox, B. J., Enns, M. W., & Swinson, R. P. (1998). Psychometric properties of the 42-item and 21-item versions of the depression anxiety stress scales in clinical groups and a. *Psychological Assessment*, *10*(2), 176-181. doi:10.1037/1040-3590.10.2.176

Baghurst, P., Pincombe, J., Peat, B., Henderson, A., Reddin, E., & Antoniou, G. (2007). Breast feeding self-efficacy and other determinants of the duration of breast feeding in a cohort of first-time mothers in adelaide, australia. *Midwifery*, *23*(4), 382-391. doi:S0266-6138(06)00059-3 [pii]

Bandura, A. (1977). Self-efficacy: Toward a unifying theory of behavioral change. *Psychological Review*, *84*(2), 191-215.

Barrera, A. Z., Wickham, R. E., & Munoz, R. F. (2015). Online prevention of postpartum depression for spanish- and english-speaking pregnant women: A pilot randomized controlled trial. *Internet Interventions*, *2*(3), 257-265. doi:10.1016/j.invent.2015.06.002 [doi]

Beck, A. T. (2016). Cognitive therapy: Nature and relation to behavior therapy - republished article. *Behavior Therapy*, *47*(6), 776-784. doi:S0005-7894(16)30091-0 [pii]

Blow, F. C., Ilgen, M. A., Walton, M. A., Czyz, E. K., McCammon, R., Chermack, S. T., . . . Barry, K. L. (2009). Severity of baseline alcohol use as a moderator of brief interventions in the emergency department. *Alcohol and Alcoholism (Oxford, Oxfordshire)*, *44*(5), 486-490. doi:10.1093/alcalc/agp031 [doi]

Boyd, R. C., Le, H. N., & Somberg, R. (2005). Review of screening instruments for postpartum depression. *Archives of Women's Mental Health*, *8*(3), 141-153. doi:10.1007/s00737-005-0096-6 [doi]

Brockway, M., Benzies, K., & Hayden, K. A. (2017). Interventions to improve breastfeeding self-efficacy and resultant breastfeeding rates: A systematic review and meta-analysis. *Journal of Human Lactation : Official Journal of International Lactation Consultant Association*, *33*(3), 486-499. doi:10.1177/0890334417707957 [doi]

Brown, A., & Davies, R. (2014). Fathers' experiences of supporting breastfeeding: Challenges for breastfeeding promotion and education. *Maternal & Child Nutrition*, *10*(4), 510-526. doi:10.1111/mcn.12129 [doi]

Carver, C. S. (1997). You want to measure coping but your protocol's too long: Consider the brief COPE. *International Journal of Behavioral Medicine*, *4*(1), 92-100. doi:10.1207/s15327558ijbm0401_6 [doi]

Carver, C. S., Scheier, M. F., & Weintraub, J. K. (1989). Assessing coping strategies: A theoretically based approach. *Journal of Personality and Social Psychology*, *56*(2), 267-283.

CDC.CDC 2016 breastfeeding report card. Retrieved from https://www.cdc.gov/breastfeeding/pdf/2014breastfeedingreportcard.pdf

Cohen, J. (1992). A power primer. *Psychological Bulletin*, *112*(1), 155-159.

Cox, J. L., Holden, J. M., & Sagovsky, R. (1987). Detection of postnatal depression. development of the 10-item edinburgh postnatal depression scale. *The British Journal of Psychiatry : The Journal of Mental Science*, *150*, 782-786. doi:S0007125000214712 [pii]

D'Anna-Hernandez, K. L., Ross, R. G., Natvig, C. L., & Laudenslager, M. L. (2011). Hair cortisol levels as a retrospective marker of hypothalamic-pituitary axis activity throughout pregnancy: Comparison to salivary cortisol. *Physiology & Behavior*, *104*(2), 348-353. doi:10.1016/j.physbeh.2011.02.041 [doi]

Dennis, C. L. (1999). Theoretical underpinnings of breastfeeding confidence: A self-efficacy framework. *Journal of Human Lactation : Official Journal of International Lactation Consultant Association*, *15*(3), 195-201. doi:10.1177/089033449901500303 [doi]

Dennis, C. L., Brennenstuhl, S., & Abbass-Dick, J. (2018). Measuring paternal breastfeeding self-efficacy: A psychometric evaluation of the breastfeeding self-efficacy scale-short form among fathers. *Midwifery*, *64*, 17-22. doi:S0266-6138(18)30138-4 [pii]

Dennis, C. L., & McQueen, K. (2009). The relationship between infant-feeding outcomes and postpartum depression: A qualitative systematic review. *Pediatrics*, *123*(4), 736. doi:10.1542/peds.2008-1629 [doi]

Dennis, C. L., & Ross, L. E. (2006). The clinical utility of maternal self-reported personal and familial psychiatric history in identifying women at risk for postpartum depression. *Acta Obstetricia Et Gynecologica Scandinavica*, *85*(10), 1179-1185. doi:757967013 [pii]

Dettenborn, L., Tietze, A., Bruckner, F., & Kirschbaum, C. (2010). Higher cortisol content in hair among long-term unemployed individuals compared to controls. *Psychoneuroendocrinology*, *35*(9), 1404-1409. doi:10.1016/j.psyneuen.2010.04.006 [doi]

Edmondson, O. J., Psychogiou, L., Vlachos, H., Netsi, E., & Ramchandani, P. G. (2010). Depression in fathers in the postnatal period: Assessment of the edinburgh postnatal depression scale as a screening measure. *Journal of Affective Disorders*, *125*(1-3), 365-368. doi:10.1016/j.jad.2010.01.069 [doi]

Eidelman, A. I. (2012). Breastfeeding and the use of human milk: An analysis of the american academy of pediatrics 2012 breastfeeding policy statement. *Breastfeeding Medicine : The Official Journal of the Academy of Breastfeeding Medicine*, *7*(5), 323-324. doi:10.1089/bfm.2012.0067 [doi]

Gow, R., Thomson, S., Rieder, M., Van Uum, S., & Koren, G. (2010). An assessment of cortisol analysis in hair and its clinical applications. *Forensic Science International*, *196*(1-3), 32-37. doi:10.1016/j.forsciint.2009.12.040 [doi]

Hall, A. K., Cole-Lewis, H., & Bernhardt, J. M. (2015). Mobile text messaging for health: A systematic review of reviews. *Annual Review of Public Health*, *36*, 393-415. doi:10.1146/annurev-publhealth-031914-122855 [doi]

Hayes, A. F. (2008). *Introduction to mediation, moderation, and conditional process analysis: A regression-based approach* Routledge.

Henshaw, E. J., Fried, R., Siskind, E., Newhouse, L., & Cooper, M. (2015). Breastfeeding self-efficacy, mood, and breastfeeding outcomes among primiparous women. *Journal of Human Lactation : Official Journal of International Lactation Consultant Association*, *31*(3), 511-518. doi:10.1177/0890334415579654 [doi]

Hurley, K. M., Black, M. M., Papas, M. A., & Caulfield, L. E. (2008). Maternal symptoms of stress, depression, and anxiety are related to nonresponsive feeding styles in a statewide sample of WIC participants. *The Journal of Nutrition*, *138*(4), 799-805. doi:138/4/799 [pii]

Insel, T. R. (2014). The NIMH research domain criteria (RDoC) project: Precision medicine for psychiatry. *The American Journal of Psychiatry*, *171*(4), 395-397. doi:10.1176/appi.ajp.2014.14020138 [doi]

Kalra, S., Einarson, A., Karaskov, T., Van Uum, S., & Koren, G. (2007). The relationship between stress and hair cortisol in healthy pregnant women. *Clinical and Investigative Medicine.Medecine Clinique Et Experimentale*, *30*(2), 103.

Kessler, L. A., Gielen, A. C., Diener-West, M., & Paige, D. M. (1995). The effect of a woman's significant other on her breastfeeding decision. *Journal of Human Lactation : Official Journal of International Lactation Consultant Association*, *11*(2), 103-109. doi:10.1177/089033449501100214 [doi]

Kirschbaum, C., Tietze, A., Skoluda, N., & Dettenborn, L. (2009a). Hair as a retrospective calendar of cortisol production-increased cortisol incorporation into hair in the third trimester of pregnancy. *Psychoneuroendocrinology*, *34*(1), 32-37. doi:10.1016/j.psyneuen.2008.08.024 [doi]

Kirschbaum, C., Tietze, A., Skoluda, N., & Dettenborn, L. (2009b). Hair as a retrospective calendar of cortisol production-increased cortisol incorporation into hair in the third trimester of pregnancy. *Psychoneuroendocrinology*, *34*(1), 32-37. doi:10.1016/j.psyneuen.2008.08.024 [doi]

Labbok, M. H., & Coffin, C. J. (1997). A call for consistency in definition of breastfeeding behaviors. *Social Science & Medicine (1982)*, *44*(12), 1931-1932. doi:S0277953697000130 [pii]

Le, H. N., Perry, D. F., & Stuart, E. A. (2011). Randomized controlled trial of a preventive intervention for perinatal depression in high-risk latinas. *Journal of Consulting and Clinical Psychology*, *79*(2), 135-141. doi:10.1037/a0022492 [doi]

MacKinnon, D. P., Fairchild, A. J., & Fritz, M. S. (2007). Mediation analysis. *Annual Review of Psychology*, *58*, 593-614. doi:10.1146/annurev.psych.58.110405.085542 [doi]

MacKinnon, D. P., Lockwood, C. M., Hoffman, J. M., West, S. G., & Sheets, V. (2002). A comparison of methods to test mediation and other intervening variable effects. *Psychological Methods*, *7*(1), 83-104.

Magiakou, M. A., Mastorakos, G., Rabin, D., Dubbert, B., Gold, P. W., & Chrousos, G. P. (1996). Hypothalamic corticotropin-releasing hormone suppression during the postpartum period: Implications for the increase in psychiatric manifestations at this time. *The Journal of Clinical Endocrinology and Metabolism*, *81*(5), 1912-1917. doi:10.1210/jcem.81.5.8626857 [doi]

Matthey, S., Barnett, B., Kavanagh, D. J., & Howie, P. (2001). Validation of the edinburgh postnatal depression scale for men, and comparison of item endorsement with their partners. *Journal of Affective Disorders*, *64*(2-3), 175-184. doi:S0165032700002366 [pii]

Maycock, B., Binns, C. W., Dhaliwal, S., Tohotoa, J., Hauck, Y., Burns, S., & Howat, P. (2013). Education and support for fathers improves breastfeeding rates: A randomized controlled trial. *Journal of Human Lactation : Official Journal of International Lactation Consultant Association*, *29*(4), 484-490. doi:10.1177/0890334413484387 [doi]

McCarter-Spaulding, D. E., & Dennis, C. L. (2010). Psychometric testing of the breastfeeding self-efficacy scale-short form in a sample of black women in the united states. *Research in Nursing & Health*, *33*(2), 111-119. doi:10.1002/nur.20368 [doi]

McGuire, S. (2011). U.S. dept. of health and human services. the surgeon general's call to action to support breastfeeding. U.S. dept. of health and human services, office of the surgeon general. 2011. *Advances in Nutrition (Bethesda, Md.)*, *2*(6), 523-524. doi:10.3945/an.111.000968 [doi]

McLennan, S. N., Ihle, A., Steudte-Schmiedgen, S., Kirschbaum, C., & Kliegel, M. (2016). Hair cortisol and cognitive performance in working age adults. *Psychoneuroendocrinology*, *67*, 100-103. doi:10.1016/j.psyneuen.2016.01.029 [doi]

McQueen, K. A., Dennis, C. L., Stremler, R., & Norman, C. D. (2011). A pilot randomized controlled trial of a breastfeeding self-efficacy intervention with primiparous mothers.

*Journal of Obstetric, Gynecologic, and Neonatal Nursing : JOGNN*, *40*(1), 35-46. doi:10.1111/j.1552-6909.2010.01210.x [doi]

Milam, J., Slaughter, R., Verma, G., & McConnell, R. (2014). Hair cortisol, perceived stress and dispositional optimism: A pilot study among adolescents. *Journal of Traumatic Stress Disorders & Treatment*, *3*(3), 1000126. doi:10.4172/2324-8947.1000126 [doi]

Milgrom, J., Danaher, B. G., Gemmill, A. W., Holt, C., Holt, C. J., Seeley, J. R., . . . Ericksen, J. (2016). Internet cognitive behavioral therapy for women with postnatal depression: A randomized controlled trial of MumMoodBooster. *Journal of Medical Internet Research*, *18*(3), e54. doi:10.2196/jmir.4993 [doi]

Miller, G. E., Chen, E., & Zhou, E. S. (2007). If it goes up, must it come down? chronic stress and the hypothalamic-pituitary-adrenocortical axis in humans. *Psychological Bulletin*, *133*(1), 25-45. doi:2006-23058-002 [pii]

Murgatroyd, C. A., Taliefar, M., Bradburn, S., Carini, L. M., Babb, J. A., & Nephew, B. C. (2015). Social stress during lactation, depressed maternal care, and neuropeptidergic gene expression. *Behavioural Pharmacology*, *26*(7 Spec No), 642-653. doi:10.1097/FBP.0000000000000147 [doi]

Nierop, A., Bratsikas, A., Zimmermann, R., & Ehlert, U. (2006a). Are stress-induced cortisol changes during pregnancy associated with postpartum depressive symptoms? *Psychosomatic Medicine*, *68*(6), 931-937. doi:68/6/931 [pii]

Nierop, A., Bratsikas, A., Zimmermann, R., & Ehlert, U. (2006b). Are stress-induced cortisol changes during pregnancy associated with postpartum depressive symptoms? *Psychosomatic Medicine*, *68*(6), 931-937. doi:68/6/931 [pii]

O'Mahen, H. A., Woodford, J., McGinley, J., Warren, F. C., Richards, D. A., Lynch, T. R., & Taylor, R. S. (2013). Internet-based behavioral activation--treatment for postnatal depression (netmums): A randomized controlled trial. *Journal of Affective Disorders*, *150*(3), 814-822. doi:10.1016/j.jad.2013.03.005 [doi]

Otsuka, K., Taguri, M., Dennis, C. L., Wakutani, K., Awano, M., Yamaguchi, T., & Jimba, M. (2014). Effectiveness of a breastfeeding self-efficacy intervention: Do hospital practices make a difference? *Maternal and Child Health Journal*, *18*(1), 296-306. doi:10.1007/s10995-013-1265-2 [doi]

Robins, L. N., Helzer, J. E., Croughan, J., & Ratcliff, K. S. (1981). National institute of mental health diagnostic interview schedule. its history, characteristics, and validity. *Archives of General Psychiatry*, *38*(4), 381-389.

Semenic, S., Loiselle, C., & Gottlieb, L. (2008). Predictors of the duration of exclusive breastfeeding among first-time mothers. *Research in Nursing & Health*, *31*(5), 428-441. doi:10.1002/nur.20275 [doi]

Sjolin, S., Hofvander, Y., & Hillervik, C. (1977). Factors related to early termination of breast feeding. A retrospective study in sweden. *Acta Paediatrica Scandinavica*, *66*(4), 505-511.

Snider, S. E., Deshpande, H. U., Lisinski, J. M., Koffarnus, M. N., LaConte, S. M., & Bickel, W. K. (2018). Working memory training improves alcohol users' episodic future thinking: A rate-dependent analysis. *Biological Psychiatry.Cognitive Neuroscience and Neuroimaging*, *3*(2), 160-167. doi:S2451-9022(17)30201-X [pii]

Stalder, T., & Kirschbaum, C. (2012). Analysis of cortisol in hair--state of the art and future directions. *Brain, Behavior, and Immunity, 26*(7), 1019-1029. doi:10.1016/j.bbi.2012.02.002 [doi]

Stuebe, A. M., Grewen, K., Pedersen, C. A., Propper, C., & Meltzer-Brody, S. (2012). Failed lactation and perinatal depression: Common problems with shared neuroendocrine mechanisms? *Journal of Women's Health (2002), 21*(3), 264-272. doi:10.1089/jwh.2011.3083 [doi]

Sung, H. K., Ma, S. H., Choi, J. Y., Hwang, Y., Ahn, C., Kim, B. G., . . . Park, S. (2016). The effect of breastfeeding duration and parity on the risk of epithelial ovarian cancer: A systematic review and meta-analysis. *Journal of Preventive Medicine and Public Health = Yebang Uihakhoe Chi, 49*(6), 349-366. doi:10.3961/jpmph.16.066 [doi]

Vázquez, F. L., Muñoz, R. F., Blanco, V., & López, M. (2008). Validation of muñoz's mood screener in a nonclinical spanish population. *European Journal of Psychological Assessment, 24*(1), 57-64. doi:10.1027/1015-5759.24.1.57

Wantland, D. J., Portillo, C. J., Holzemer, W. L., Slaughter, R., & McGhee, E. M. (2004). The effectiveness of web-based vs. non-web-based interventions: A meta-analysis of behavioral change outcomes. *Journal of Medical Internet Research, 6*(4), e40. doi:v6e40 [pii]

White, B. K., Martin, A., White, J. A., Burns, S. K., Maycock, B. R., Giglia, R. C., & Scott, J. A. (2016). Theory-based design and development of a socially connected, gamified mobile app for men about breastfeeding (milk man). *JMIR mHealth and uHealth, 4*(2), e81. doi:10.2196/mhealth.5652 [doi]

Wolfberg, A. J., Michels, K. B., Shields, W., O'Campo, P., Bronner, Y., & Bienstock, J. (2004). Dads as breastfeeding advocates: Results from a randomized controlled trial of an educational intervention. *American Journal of Obstetrics and Gynecology, 191*(3), 708-712. doi:S0002937804004880 [pii]

Zelkowitz, P., & Milet, T. H. (1995). Screening for post-partum depression in a community sample. *Canadian Journal of Psychiatry.Revue Canadienne De Psychiatrie, 40*(2), 80-86.

Zhou, Y., Chen, J., Li, Q., Huang, W., Lan, H., & Jiang, H. (2015). Association between breastfeeding and breast cancer risk: Evidence from a meta-analysis. *Breastfeeding Medicine : The Official Journal of the Academy of Breastfeeding Medicine, 10*(3), 175-182. doi:10.1089/bfm.2014.0141 [doi]