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Development And Evaluation Of An Instrument To Measure Mother-infant Togetherness After Childbirth

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DEVELOPMENT AND EVALUATION OF AN INSTRUMENT TO MEASURE MOTHER-INFANT TOGETHERNESS AFTER CHILDBIRTH

by

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ABSTRACT

No existing measure to date captures mother-infant togetherness. A valid measure of togetherness is essential to engage in evidence-based practice, evaluate obstetric delivery models and nursing interventions, and measure the level of togetherness which promotes optimal maternal-infant outcomes. When together and in close proximity, a women and her infant have access to one another to allow for mutual caregiving or caregiving on cue. A new measure entitled the Mother-Infant Togetherness Scale (MITS) was developed based on a review of the literature and conceptual framework of Mother-Newborn Mutual Caregiving. The MITS is a 35-item instrument composed of four subscales that measures the timing, duration, and intensity of togetherness of the mother-infant dyad during entire hospitalization. The purpose of this multiphase study was to obtain support for the validity of the MITS.

Phase 1 determined the content validity at the scale (S-CVI), subscale, and item level (I-CVI) with a panel of expert judges. The final sample for the content validation consisted of 7 judges from medicine (n = 2), maternal-child nursing (n = 1), nursing research (n = 3), and social work (n = 1). Judges were instructed to use a 4-point Likert scale to rate the relevance of each item (I-CVI) to the construct of togetherness. The S-CVI was calculated from the mean I-CVI scores. The CVI-S of .88 was just slightly below the desired CVI-S (> .90). Of the four subscales, all had adequate CVI (> .90) at the subscale level except the delivery affective subscale (CVI = .74) and postpartum affective subscale (CVI = .89). The delivery events and postpartum events subscales had satisfactory CVI scores (CVI $\geq$ .90), 1.00 and .94, respectively. The CVI-I results identified a total of seven items on the affective subscales that did not meet the desired I-CVI ($\geq$ .78).

Phase 2 pre-tested the readability and understandability of the MITS among eight postpartum women. During the interviews, the women were asked to complete the MITS and provide opinions about the readability and understandability of the directions and items. The audiotapes were transcribed word for word, reviewed for thematic content, and revisions made to the study instrument accordingly. This same sample of postpartum women participated in the content validation of the delivery affective subscale (items #4a-j) and postpartum affective subscale (items #17a-j). The I-CVI results identified that a total of six items on the affective subscales had a CVI-I of .75, just slightly below the desired I-CVI ($\geq$ .78). Scale items were deleted or revised and the instrument retested until the desirable CVI at the scale and subscale level was achieved.

Phase 3 used a descriptive study design to examine women's ability to accurately self-report birth events on the MITS delivery events subscale at 4 weeks postpartum, as compared to observer-collected data obtained at delivery to determine the most valid mode of administration. A purposive sample consisted of 45 women having delivered at a community hospital in southwest Florida. The research team completed the MITS delivery events subscale immediately after delivery. Women were sent the MITS for completion 4 weeks after delivery. McNemar Chi-Squares were (χ) were calculated from the self-reported MITS delivery events subscale scores and the observer-collected MITS delivery events subscale scores. No significant difference ($p < .05$) was found supporting self-reported mode of administration for the MITS.

Phase 4 is in-progress and evaluates the reliability and validity of the MITS subscale and total scale scores. The interim analysis was performed on a sample of 113 postpartum participants (composed of the final sample of 31 participants from Phase 3 and the first 82 participants from Phase 4) having delivered at three of the four participating hospital study sites.

Adequate internal consistency reliability was found at the scale level with Cronbach's alpha (α = .89) and split-half reliability results (α = .79 – 81, r = .83 - .88). Of the 35 MITS items, 10 items (28.6%) were found to have item-total correlations less than .30, arguing against treating MITS items as a single total scale measure. Good internal consistency was found at the delivery events subscale level (α = .78). Exploratory factor analysis (EFA) identified a two-factor solution. The two factors were named *Taking In* and *Taking Control* and had internal consistency reliability.79 and .65, respectively. Additional work needs to be done to improve the internal consistency of the *Taking Control* factor. The postpartum events subscale also had low internal consistency (α = .58). This subscale was not factor analyzed because the item response data did not meet the criteria for factor analysis. The items on the postpartum events subscale were assessed to be unique, singular, heterogeneous items that did not correlate well with other items. These results are conceptually logical given the nature of what the items are measuring (occurrence/intensity of specific events in time). The delivery affective subscale had good internal consistency reliability (α = .85) and a two factor solution. The two factors, named *Feelings At Delivery* and *Delivery Concerns,* had adequate internal constancy (α = .81 and α = .80, respectively). The postpartum affective subscale had good internal consistency reliability (α = .92) and a one factor solution.

Results for known groups testing based on feeding type and mode of delivery found all group differences were in the predicted direction. Higher scores were found for mother-infant dyads who breastfed than for mother-infant dyads who bottle fed. However, only group differences for the events subscales were substantive and statistically significant (p < 001.). Higher scores were found for mother-infant dyads who experiencing a vaginal delivery than for mother-infant dyads who experienced a cesarean delivery. Group differences were substantive

and statistically significant ($p < .01$) for three of the four subscale scores. A post hoc power analysis on the means and standard deviations from the interim analysis and the between-groups comparison effect size observed for feeding type (d = .50) found a sample of 45 adequate to have statistical power at the recommended beta of .80 and alpha of .05. The post hoc power analysis on the effect size for mode of delivery (d = .75), found a sample of 156 are needed to obtain statistical power at the recommended beta of .80 and alpha of .05. Therefore, the desired sample size of 200 women for the final analysis is adequate to obtain statistical power. A third known group testing for the variable of central nursery availability could not be performed with the interim analysis data because no participants in the interim analysis sample reported this experience. However, this analysis will be performed with the final data set.

This is the first study to operationalize togetherness during the entire hospitalization and to include all dimensions of the construct. The findings from this multi-phase study provide initial support for the reliability and validity of the MITS. Although the results from Phase 4 are interim and therefore tentative, they provide preliminary psychometric evidence for construct validity.

I lovingly dedicate this dissertation to my wonderful family.

Particularly to my patient and supportive husband, Rob, who has put up with me every step of this journey and has motivated me to pursue my dream;

my parents who instilled in me a desire for academic excellence; and

my awesome children, Robbie and Anthony, who inspire me every day.

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LIST OF ABBREVIATIONS

CVI	Content validity index
CVI-I	Content validity at the item level
CVI-S	Content validity at the scale level
EFA	Exploratory factor analysis
LDR	Labor-delivery-recovery
LDRP	Labor-delivery-recovery-postpartum
MITS	Mother-Infant Togetherness Scale
MNMC	Mother-newborn mutual caregiving
PI	Principal investigator

CHAPTER ONE: THE PROBLEM

Introduction

Keeping mothers and infants together after birth is foundational to normal, physiological childbirth (Zwelling, 2008). Mother-infant togetherness promotes improved physiological (Bergman, Linley, & Fawcus, 2004; Bystrova et al., 2003), psychological (Erlandsson & Fagerberg, 2005; Hughes & McCollum, 1994), and developmental outcomes (Ferber & Makhoul, 2004; Field, 1994; Greenberg, Rosenberg, & Lind, 1973; O'Connor, Vietze, Sherrod, Sandler, & Altemeier, 1980; Sostek, Scanlon, & Abramson, 1982). Evidence supports keeping mothers and infants together, yet this evidence is not being used in practice. Mothers and infants are frequently separated after childbirth (Declercq, Sakala, Corry, & Applebaum, 2007; Declercq, Sakala, Corry, Applebaum, & Risher, 2002).

A review of the literature identifies several interventions to minimize mother-infant separation and to facilitate mother-infant togetherness, such as early physical contact, skin-to-skin, and rooming-in, hereinafter referred to as togetherness interventions. The literature also identifies many benefits to keeping mothers and infants together. However, there is a lack of consistency in the operationalization of togetherness across studies. This study proposes a new measure of mother-infant togetherness.

Background

Recommendations and Current Practice

Obstetrical practices that promote togetherness are recommended by the World Health Organization ([WHO] 1998; [UNICEF/WHO], 2006); Academy of Breastfeeding Medicine (Chantry, Howard, & McCoy, 2003); American Academy of Pediatrics (Gartner et al., 2005);

and Association of Women's Health, Obstetrical, and Neonatal Nurses ([AWHONN] 2004). Recommendations from these organizations include promoting early, undisturbed skin-to-skin contact after birth, avoiding routine separation of mother and infant, maintaining mothers in close proximity to their infants, and implementing a policy of continuous rooming-in. The "2020 Vision for a High-Quality, High-Value Maternity Care System" report issued by the Transforming Maternity Care Vision Team specifies that "mothers and babies routinely stay together, skin to skin, receiving evidence-based care, support, and minimal disruption in the minutes and hours after birth to promote early attachment and the initiation of breastfeeding" (Carter et al., 2010, p. S12).

Despite recommendations to keep mothers and infants together after birth, separation remains prevalent. The Listening to Mothers I and II surveys (Declercq et al., 2007; Declercq et al., 2002) have been the largest research studies describing the childbearing experience in U.S. hospitals. In the first survey, Declercq et al. (2002) obtained information on women's childbearing experience in the United States and included interviews from 1,583 women who delivered within the previous 24 months. Mothers reported that during the first hour after birth, 40% had their infants in their arms and an additional 13% of the mothers reported the infants were in their partner's arms. Of the infants who were not being held by the mother or her partner, 69% were being cared for by hospital staff to provide routine infant care (Declercq et al., 2002). The survey was subsequently repeated in 2006 and found similar results (Declercq et al., 2007). The Listening to Mothers Survey and other studies have also found that infants are often separated unnecessarily for examinations, transitional care, and to promote maternal sleep (Bajo, Hager, & Smith, 1998; Declercq et al., 2002; Declercq et al., 2007).

Rooming-in is an underutilized obstetrical practice to promote togetherness and is described as the policy of keeping mothers and their infants together during the hospitalization (Bajo, 1998; LaFrance, 2003). Rooming-in engages the mother in the infant caregiving. DiGirolamo, Grummer-Strawn, and Fein (2001) from the 1993/1994 Baby Feeding Practices Survey conducted by the U.S. Food and Drug Administration found that of the 1,132 women who delivered with the prenatal intent to breastfeed, only 55% reported rooming-in with their infants. LaFrance (2003) described women's experience with rooming-in practices on four obstetrical units in Canada. Of the 552 postpartum women in the study, 33.9% (n = 187) experienced rooming-in and 95.8% (n = 529) reported being separated from their infants during the hospital stay. Most recently, the Listening to Mothers I & II surveys (Declercq et al., 2007; Declercq et al., 2002) assessed rooming-in practices in the United States. Both surveys found only 62-63% of women who delivered infants not requiring neonatal intensive care experienced continuous rooming-in.

There is a paucity of literature regarding the frequency of rooming-in practices based on race, ethnicity, socioeconomic status, and maternal age. According to Anderson (1989), rooming-in is "a white, middle to upper class phenomena [*sic*]" (p. 198). In the Listening to Mothers II survey (Declercq et al., 2007), a subgroup analysis was performed on the three main racial/ethnic groups and no statistical difference ($p > .01$) was found in rooming-in practices: Black non-Hispanic (59%), White non-Hispanic (56%), and Hispanics (62%). However, a statistical difference ($p < 0.01$) was noted in the location of the infant during the first hour after birth (in the parent's arms): Black non-Hispanic (33%), White non-Hispanic (48%), and Hispanics (60%) (Declercq et al., 2007).

Implications for Patient Safety

Interventions and practices that promote togetherness can have implications for patient safety. Although rare, infant abductions are a catastrophic event and often occur in the hospital immediately after childbirth. From 1983 to 2004, 116 infants were abducted from healthcare facilities (Rabun, 2005). A common trend in hospital-based infant abductions is persons presenting in scrubs requesting to take the newborn from the mother. In two infant abductions from two different hospitals in Lubbock, Texas, persons dressed in scrubs removed infants from their mother's rooms with the excuse of routine testing (Freeman, 2007). These abductions might have been avoided if the standard of practice was to keep mothers and infants together, even during routine testing. Infant abductions translate to huge litigious and financial implication for hospitals when they occur; labor and delivery admissions have been shown to decrease up to half immediately after abduction (Butler, 2003).

As of 2012, there is an absence of any heath policy regulation addressing togetherness of mothers and infants after childbirth. The Joint Commission ([TJC], 2010) does not address the issue. The only related measure addressed by the Joint Commission includes sentinel events involving patient abductions ([TJC], 2010; Rabun, 2005). A valid measure of togetherness can help drive health policy regulation by quantifying togetherness in the evaluation of obstetric delivery models and actual practice. The measure can also be used to assess for vulnerabilities as part of comprehensive infant abduction program. Regardless, the benefits of togetherness as discussed in the following section are considerable.

Implications for Patient Outcomes

Positive Effects of Togetherness

There is a plethora of research investigating the positive effects of togetherness for mother-infant dyads. A seminal study conducted by Klaus, Kennell, Plumb, and Zuehlke (1970) identified the first hour of birth as a critical and sensitive period for the mother-infant dyad. Klaus et al. (1970) described a species-specific behavior between mothers and infants who were left undisturbed in the first minutes to hours after the birth. Since 1970, Klaus and colleagues have identified short-term, long-term, and transient physiological, developmental, psychosocial, and attachment consequences when mothers are separated from their newborns (Kennell & Klaus, 1979, 1984; Kennell, Trause, & Klaus, 1975; Klaus & Kennell, 1970, 1976a, 1977, 2001; Klaus et al., 1972; Klaus, Kennell, & Hamilton, 1983; Newman, Kennell, Klaus, & Schreiber, 1976).

The design of most of the outcomes research on togetherness has used togetherness interventions and practices, such as skin-to-skin and rooming-in, as the independent variable. A multitude of dependent variables have identified positive effects of togetherness. A summary of positive effects that have been associated with togetherness is presented in Table 1. The supporting evidence associated with each positive effect is presented in Appendix B.

Table 1. Positive Effects Associated with Togetherness

Mother	**Infant**	**Both Mother and Infant**
• Affectional behaviors • Decreased anxiety/stress (improved hypothalamic-pituitary adrenal regulation) • Decreased engorgement • Decreased negative emotional responses: distress, guilt, powerlessness, sadness, alienation • Earlier recognition of infant cues/increased sensitivity/increased responsiveness • Elevated mood/decreased depression • Hormonal regulation • Involutional stability • Lactogenesis • Maternal competence • Maternal confidence • Maternal identity (maternal role attainment) • Satisfaction with birth experience	• Awake-sleep state organization • Cardiopulmonary stability • Decreased cortisol levels • Decreased crying • Decreased nosocomial infections/ complications • Decreased rehospitalization and illness • Less responsiveness to pain • Neurobehavioral and emotional development • Sucking behaviors (response/strength) • Thermoregulation • Weight gain (earlier/improved)	• Attachment/bonding • Breastfeeding (duration, latch, number of feedings) • Cohesive family relationships • Decreased abandonment/rejection • Decreased abuse/neglect • Verbal and nonverbal communication behaviors and language

Breastfeeding

Of the positive effects of togetherness listed in Table 1, breastfeeding duration is highly supported in the literature. In 2012, a Cochrane systematic review of 34 intervention studies evaluated the effects of early skin-to-skin contact on breastfeeding and found significant positive effect of skin-to-skin contact on breastfeeding at 1 to 4 months postpartum (Moore, Anderson, Bergman, & Dowswell, 2012). In a 1989 meta-analysis of nine studies, early contact of at least 15 minutes during the first hour was found to have a significant positive effect on breastfeeding duration (Bernard-Bonnin, Stachtchenko, Girard, & Rousseau, 1989). Pérez-Escamilla, Pollitt,

Lönnerdal, and Dewey (1994) conducted a meta-analysis on rooming-in practices in conjunction with breastfeeding instruction on lactation outcomes and found rooming-in was associated with higher breastfeeding rates in primiparous women only but had no effects in multiparous women. The togetherness interventions vary from skin-to-skin, early contact, and rooming-in and despite this, there is consistent support that togetherness has a positive effect on breastfeeding (Lindenberg, Cabrera Artola, & Jimenez, 1990; Pérez-Escamilla, Segura-Millán, Pollitt, & Dewey, 1992).

Infant Physiologic Adaptation and Crying

Intervention studies provide considerable support for the positive effect of togetherness on infant physiologic adaptation and crying. The 2012 Cochrane Review of the effect of skin-to-skin contact found improved infant physiological stability (heart rate, respiratory rate, oxygen saturation, glucose levels), improved infant thermoregulation, and decreased infant crying. However, the difference was not statistically different ($p < .05$) (Moore et al., 2012). Additional evidence supports the positive effect of togetherness on thermoregulation. Infants become cold-stressed when their body temperature is not maintained in the neutral thermal zone. When cold stress is left untreated, a potentially fatal cascade of events can occur which includes increased oxygen consumption, increased glucose use, acidemia, hypoxemia, and shock (London, Ladewig, Ball, & Bindler, 2007). Research has shown that effective temperature regulation occurs when infants are in skin-to-skin contact with their mother's body (Britton, 1980; Ludington-Hoe, 2011) and is often superior to technological interventions such as radiant warmers and incubators (Bergman et al., 2004; Lambesis, Vidyasagar, & Anderson, 1979). Skin-to-skin contact has been found to be as effective (Galligan, 2006) or more effective than

technological interventions for the treatment of hypothermia (Christensson, Bhat, Amadi, Eriksson, & Höjer, 1998). Separation by removing cesarean born infants from the operating room after delivery is also not necessary to maintain thermoregulation in the cool intraoperative environment (Gouchon et al., 2010; Nolan & Lawrence, 2009).

Togetherness has a positive effect on crying. Infants that remain together with their mothers cry less frequently and for shorter durations (Anderson, Chang, Behnke, Conlon, & Eyler, 1995; Anderson, Chang, & Wood, 1997; Anderson, Moore, Hepworth, & Bergman, 2003; Christensson, Cabrera, Christensson, Uvnäs-Moberg, & Winberg, 1995; De Chateau & Wiberg, 1977; Keshavarz, Haghighi, & Bolboli, 2010; Kostandy et al., 2008; Lambesis et al., 1979; Ludington-Hoe, 2011; McBryde, 1951; Michelsson, Christensson, Rothgänger, & Winberg, 1996; Salk, 1973). Crying causes decreased cerebral blood flow (Brazy, 1988; Burroughs, Asonye, Anderson-Shanklin, & Vidyasagar, 1978) and places infants at risk for hypoxic brain injury and intraventricular hemorrhage (Anderson, 1988), right to left shunting through the foramen ovale (Anderson, 1988), elevated salivary cortisol levels (Anderson et al., 1995; Anderson et al., 1997), and slower weight gain (Bystrova, Matthiesen, Widström et al., 2007; Salk, 1973).

Negative Effects of Togetherness

There is a paucity of outcomes research investigating the negative effects of togetherness for the mother-infant dyads. A systematic review of the effect of skin-to-skin contact on physiological adaptation and breastfeeding found no negative effects of skin-to-skin contact (Moore et al., 2012). Early program reports identified possible concerns regarding decreased maternal sleep and associated fatigue with rooming-in (Cox, 1974; Durand, 1960; Gonzales,

1990), but these possible concerns were not supported by research (Greenberg et al., 1973; Keefe, 1988; Waldenstrom & Swenson, 1991). However, a few studies have identified potential negative effects for rooming-in. Only two studies identified cultural concerns with rooming-in, one with Hmong women living in Australia (Rice, 2000) and another study with Italian women (Cuttini et al., 1995).

Rice (2000) performed a qualitative study with Hmong (Asian-descent) women living in Australia and found that rooming-in was in conflict with this group's cultural beliefs. In Hmong culture, women are to rest and regain strength for the first 30 days while the family assumes responsibility for most of infant caregiving. The women in the study experienced some emotional distress with rooming-in. Similar findings were noted when Cuttini et al. (1995) administered a questionnaire to Italian women after delivery ($N = 54$). Although 86.8% of Italian mothers were satisfied with rooming-in, 16.7% reported difficultly sleeping as a drawback to rooming-in. Higher education was associated with an increased awareness of the role rooming-in had in helping the mothers get to know their infants. Both studies highlighted the importance of cultural assessment with rooming-in practices and identified a cultural domain of togetherness.

Implications for Research

A lack of operationalization and fidelity of the delivery of interventions to promote togetherness is found in the literature. Operationalization of togetherness interventions are varied and described as the location of the infant in reference to the mother, such as central nursery or intensive care nursery (Ksykiewicz-Dorota & Karauda, 2004), radiant warmers or cribs (Durand et al., 1997), rooming-in (Bajo et al., 1998; Bystrova, Matthiesen, Widström et al., 2007), or in reference to being in physical contact or skin-to-skin contact (Britton, 1980). Failure to deliver

togetherness interventions reliably and lack of consistent controls are also common (Cuttini et al., 1995; Greenberg et al., 1973; Keefe, 1987, 1988; Norr, Roberts, & Freese, 1989).

Problems with operationalization limit the ability to feasibly capture togetherness. Two instruments have been developed that quantify specific components of togetherness: the Index of Mother Infant Separation (Anderson, Radjenovic, Chiu, Conlon, & Lane, 2004) and the First Contact Index (FCI) (Rowe-Murray & Fisher, 2002). Although these instruments have contributed to an increased understanding of the construct of togetherness, they fail to capture togetherness essential for comparative effectiveness and outcomes research, as called for in the "2020 Vision" report (Carter et al., 2010). A valid measure of togetherness is essential to engage in evidence-based practice, evaluate obstetric delivery models, nursing interventions, and measure levels of togetherness which promotes optimal maternal-infant outcomes.

Purpose

The purpose of this multiphase study is to obtain support for the validity of the new measure of mother-infant togetherness during hospitalization. This new measure, the Mother-Infant Togetherness Scale (MITS), was developed by this researcher based on a review of the literature and from a conceptual framework from Anderson (Anderson, 1977, 1988, 1989, 2007) The MITS is provided in Appendix A.

Assumptions

The underlying assumptions of the study were as follows:

1. The phenomenon of togetherness is amenable to quantitative measurement and operationalization.
2. Mothers have an innate desire to be close to their infants immediately after childbirth.

3. The study samples were representative of term, low-risk mothers.
4. Specially trained labor nurses who assisted in data collection followed the study procedures.

Research Questions

This multiphase study addressed the following research questions.

Phase 1– Content Validity Testing

Is there support for the content validity of the MITS?

Phase 2– Understandability, Readability, and Content Validity Testing

Do postpartum women find the MITS and demographic data collection form understandable and readable?

Is there support for the content validity of the MITS delivery affective subscale and postpartum affective subscale among a panel of postpartum women?

Phase 3– Feasibility Testing of Self-Reported Data

Is there psychometric evidence to support women's ability to accurately self-report birth events on the MITS delivery events subscale at 4 weeks postpartum as compared to observer-collected observational data obtained at delivery?

Phase 4—Reliability Testing

Research Question I. Pending the establishment of accuracy of a self-reported MITS, is there support for the internal consistency reliability of the MITS at the scale level?

Research Question II. Is there support for the internal consistency reliability of each MITS subscale in a sample of women 4 weeks postpartum?

Phase 4—Factor Analysis

Research Question III: What is the factor structure for each MCI subscale?

Phase 4—Known Groups Testing

Research Question VI. Is there a significant difference in mean subscale scores by infant feeding type (breast and bottle)?

Research Question V. Is there a significant difference in mean subscale scores by mode of delivery (vaginal and cesarean)?

Research Question VI. Is there a significant difference in mean subscale scores by central nursery availability?

Summary

This study is the critical first step in developing psychometric evidence for the MITS and provides the foundation for comparative effectiveness and outcomes research on interventions supporting physiological childbirth. The research study is presented in the remainder of this document. Definition of terms is provided in Table 2. A discussion of the conceptual framework and literature on measurement of togetherness is presented in chapter 2. A description of the research methodology and supporting science to address the research questions are presented in chapter 3. The results are presented in chapter 4. Chapter 5 discusses the findings from the study and implications for research, practice, policy, and theory.

Table 2. Definition of Terms

Term	**Definition**
LDR delivery model	A model of obstetrical care where labor, delivery, and recovery (LDP) care takes place prior to transfer to a postpartum unit.
LDRP delivery model	A model of obstetrical care where labor, delivery, recovery (LDP), and postpartum (LDRP) care takes place without transfer.
Mutual Caregiving	Auditory, emotional, olfactory, tactile, and visual interaction which supports caregiving on cue (Anderson, 2007).
Rooming-in	The policy of keeping mothers and their infants together and engaging the mother in infant caregiving during the hospitalization in which the birth occurred.
Physiological childbirth	Childbirth is recognized a hormonally driven process driven by the mother-infant dyad, which begins with the onset of labor and ends with the establishment of breastfeeding and attachment. The mother-infant dyad should be supported through this process with avoidance of external inferences (Sakala & Corry, 2008).
Togetherness	Cultural, emotional, environmental, olfactory, spatial, temporal, or visual facilitators that promote mutual caregiving.
Separation	Cultural, emotional, environmental, olfactory, spatial, temporal, or visual barriers that prevent mutual caregiving.
Skin-to-skin contact	Placement of a naked infant or shirtless infant on a mother's bare chest.

CHAPTER TWO:
THEORETICAL FRAMEWORK AND LITERATURE REVIEW

Introduction

Keeping mothers and infants together after childbirth is a priority for obstetrical nursing practice (Crenshaw, 2007; Simpson, Creehan, & [AWHONN], 2008). Unfortunately, the concept of mother-infant togetherness is not consistently operationalized in the literature. This lack of consistent operationalization is due at least in part to a lack of sound theoretical definition of mother-infant togetherness. It also contributes to a problem with instrumentation. Currently, no current instrument practically captures togetherness during the hospitalization in which the birth occurs. This chapter presents Anderson's (1977, 1988, 1989, 2007) conceptual framework and uses it to derive a theoretical definition and guide development of a new measure entitled The Mother-Infant Togetherness Scale (MITS) (See Appendix A). The chapter begins by using this framework to articulate the importance of mother-infant togetherness to maternal and infant health.

Mother-Newborn Mutual Caregiving Theoretical Framework and its Importance to Maternal and Infant Health

The conceptual framework guiding instrument development for this new measure is an adaptation of Anderson's Mother-Newborn Mutual Caregiving (MNMC) (1977, 1988, 1989, 2007). Anderson's MNMC conceptual framework argues for the importance of mother-infant togetherness to facilitate physiological mutual caregiving. This mutual caregiving is how infant and mother work together to manage the physiological stressors they each are experiencing as part of the birth and postpartum period to achieve or maintain stability. Mutual caregiving can only take place when the mother and infant are together. Unfortunately, the framework itself

does not include the construct of togetherness or its anti-thesis, separation. Both togetherness and separation are essential to defining the conditions under which mutual caregiving with its ensuing benefits can occur. Using these constructs to define these conditions is essential for assessing the outcomes of interventions designed to increase togetherness and decrease separation. Hence, the MNMC framework was adapted in consultation with Anderson to include these concepts. The revised framework is presented in Figure 1. In this study, the operational definition of mother-infant togetherness is the cultural, emotional, environmental, olfactory, spatial, temporal, or visual facilitators that promote mutual caregiving. A map of how the constructs might be applied to the dimensions and study variables to guide empirical testing of study variables is offered in Table 3.

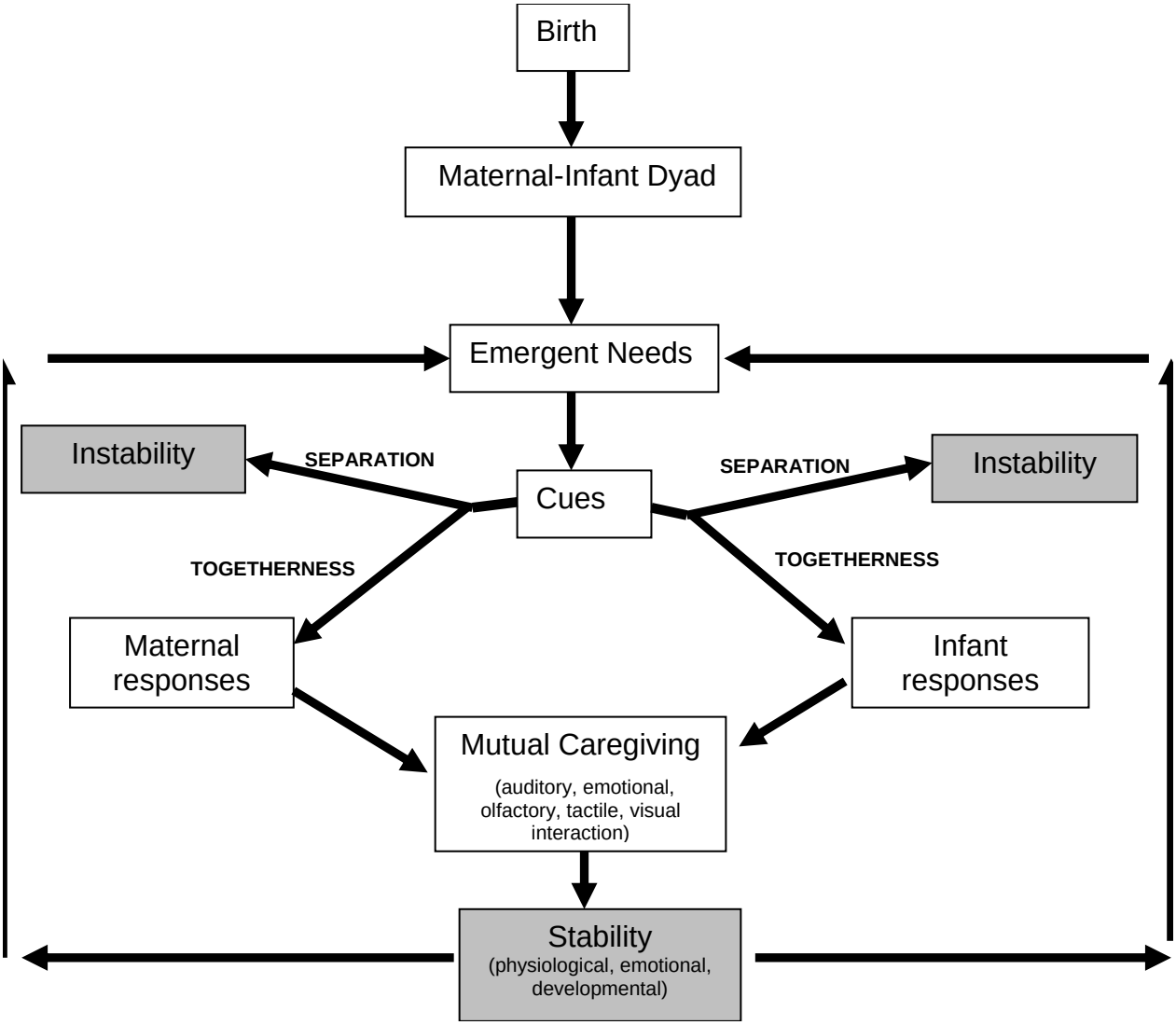


Figure 1.Revised Mother-Newborn Mutual Caregiving Conceptual Framework. Adapted with permission from Anderson (2004).

Table 3. Mother-Newborn Mutual Caregiving Constructs, Dimensions, and Potential Study Variables

Construct	**Dimensions**	**Potential Study Variables**
Togetherness	Auditory	Maternal ability/proximity to hear infant cry
	Emotional	Maternal attachment/bonding
	Olfactory	Sucking- strength, latch, timing, frequency
	Tactile	Physical contact, holding, skin-to-skin contact
	Temporal	Time, timing, duration, and/or frequency of contact, feeding, and/or skin-to-skin
	Visual	Maternal eye contact, undisturbed visual eye contact
Separation	Cultural barriers	Cultural beliefs and practices
	Emotional barriers	Depression, mental illness, fear of maternal transmission of infectious disease, substance abuse
	Environmental barriers	Institutional policies and rituals, practitioner preferences, obstetrical unit environment
	Olfactory barriers	Delayed breastfeeding, denial of breastfeeding initiation, delayed holding
	Physical/spatial barriers	Infant clothing/swaddling, lack of proximity, technology (cribs, radiant warmers)
	Visual barriers	Inability of mother to visualize infant
Facilitators	Cultural facilitators	Cultural beliefs and practices
	Emotional facilitators	Positive affective state, adequate pain control, psychosocial and family support
	Environmental facilitators	Institutional policies and rituals, practitioner preferences, obstetrical unit environment
	Physical/spatial	Institutional policies and rituals, practitioner preferences, obstetrical unit environment

This operationalization of togetherness is distinctly different from LaFrance's (2003) construct of *mother-baby togetherness*. LaFrance operationalization is limited to the first contact, proximity during the first few hours, post-delivery transfer, rooming-in, and combined mother-infant care (in which the same nurse provides postpartum care to both the mother and her infant).

LaFrance's operationalization focuses on the environmental facilitators of togetherness whereas togetherness as operationalized within the MNMC conceptual framework is inclusive of the all types of facilitators- physical/spatial, emotional, cultural, and environmental. Another distinct difference is that LaFrance's operationalization is limited to one tactile dimension at one time point, the first contact, which is not representative of the other dimensions of togetherness during the entire hospitalization. The MNMC conceptual framework operationalization encompasses all types of tactile facilitators throughout the entire hospital stay, such as skin-to-skin contact, breastfeeding, and holding. For these reasons, the operationalization of togetherness within the MNMC conceptual framework provides a more comprehensive operational definition more amenable to research on assessing the outcomes of interventions designed to increase togetherness and decrease separation.

Literature Review

Operationalization and Fidelity

In the literature, there is a lack of consistency in the operationalization across studies and a failure to deliver togetherness interventions reliably. Operationalizations varied and included environmental, spatial (physical), tactile, or temporal domains and less commonly in visual, olfactory, cultural, and emotional domains. Spatial operationalizations were diverse and included the location of the infant in reference to the mother, such as central nursery or intensive care nursery (Ksykiewicz-Dorota & Karauda, 2004), radiant warmers or cribs (Durand et al., 1997), rooming-in (Bajo et al., 1998; Bystrova, Widström, Matthiesen et al., 2007), or in reference to being in skin-to-skin contact (Britton, 1980). Tactile, visual, and olfactory operationalizations were assorted and included the first time mothers visualized, touched, or held their infants

(Nolan & Lawrence, 2009; Rowe-Murray & Fisher, 2002). Temporal operationalizations lacked consistency and included the time or timing of contact and administration of togetherness interventions in minutes, hours, or days (Chang, Thompson, & Fisch, 1982; Keefe, 1987; Nolan & Lawrence, 2009). Environmental operationalizations identified a lack of consistency of hospital policies and rituals (Spear, 2006) and lack of standardization of practitioner practices that facilitate togetherness (Nolan & Lawrence, 2009). The emotional domain of togetherness is scarcely described in the literature. Mothers can be physically together with their infants yet emotionally unavailable because of current depressive symptoms (Field, 1994), current substance abuse (Mundal, VanDerWeele, Berger, & Fitsimmons, 1991), or past emotional trauma (Madrid, Skolek, & Shapiro, 2006). Cultural operationalizations, such as any belief or practice to facilitate or hinder togetherness, were rarely disclosed in the literature (Cuttini et al., 1995; Rice, 2000).

Campbell and Taylor (1979) and others (Myers, 1984; Thomson & Kramer, 1984) challenged the critical-sensitive period identified by Klaus, Kennel et al. (1970) on the basis of methodological failures. These failures include: fidelity in delivery and operationalization of togetherness interventions, small sample sizes, overemphasis on short-term consequences and under emphasis on long-term consequences of separation, and overreliance on maternal behaviors and the meaning of those behaviors. Additional concern was raised regarding how interventions to facilitate togetherness are often evaluated simultaneously with other interventions, thus hindering the ability to draw a cause-effect and dose conclusion for the togetherness intervention.

These inconsistencies and methodological failures of togetherness are also reflected in the interventions to support togetherness. There is a lack of consistent operationalization and control of rooming-in as a togetherness intervention. For example, multiple variations in the

operationalization of rooming-in have been used: continuous throughout the hospitalization (Prodromidis et al., 1995), continuous rooming-in during the first 1-2 hours (Bajo et al., 1998), continuous rooming-in initiated after 2-36 hours (Greenberg et al., 1973), daytime rooming-in (Greenberg et al., 1973; Norr, Roberts, & Freese, 1989), and nighttime rooming-in (Keefe, 1987, 1988). Togetherness interventions were often interrupted as infants were often removed unnecessarily and unpredictably for examinations, transitional care, and to promote maternal sleep interrupting togetherness (Bajo et al., 1998; Cuttini et al., 1995; Declercq et al., 2007; Declercq et al., 2002).

There is a lack of consistent operationalization of skin-to-skin contact as a togetherness intervention and lack of standardization of care in control groups. The frequency, timing, and duration of skin-to-skin contact varied tremendously. Some infants experienced one 20-minute skin-to-skin intervention (Gray, Watt, Blass, 2000; Nolan & Lawrence, 2009) and others experienced early, frequent skin-to-skin contact throughout the hospitalization (Dombrowski, Anderson, Santori, & Burkhammer, 2001). The lack of standardization of care to infants in the control groups included infants being held while swaddled/dressed (Bystrova et al., 2003), removed to a central nursery (Anderson et al., 1997), and placed in a radiant warmer or crib (Christensson et al., 1995; Durand et al., 1997). Often usual or standard care provided to the control group is inadequately described (Anderson et al., 1997).

Existing Instrumentation

The two instruments that have been developed that quantify specific components of togetherness are the Index of Mother Infant Separation (Anderson et al., 2004) and the First Contact Index (Rowe-Murray & Fisher, 2002). The Index of Mother Infant Separation (Anderson

et al., 2004) is an observational instrument that measures the quality, timing, and quantity of the early separation. The Index of Mother Infant Separation captures three conceptual dimensions: location of infant, who provided the care, and the observed contact behavior (holding, feeding, or other caregiving). The Index of Mother Infant Separation contains 37 items recorded at predefined intervals to determine behavior frequency. Adequate content validity at the item level (77-100%) was obtained among a panel of nine expert judges. Interrater reliability of 86-90% was established with the trained raters (Anderson et al., 2004). Construct validity with known groups testing was conducted with 224 mothers randomized to a control group or an intervention group. The mothers in the invention group received an intervention of self-regulatory care administered by the research team in the mother's room from the time of the birth to one to six hours after delivery. The infants born to mothers in the control group were taken at one hour of age to a central nursery for routine care. Construct validity was supported ($p < .0001$) in the expected direction for five of the six hypotheses tested.

Index of Mother Infant Separation is an incomplete measure for the construct of togetherness. The Index of Mother Infant Separation is limited to spatial, tactile, olfactory, and temporal elements of togetherness and is an incomplete measure of togetherness because it does contain the emotional domain of togetherness. Furthermore, the Index of Mother Infant Separation is extremely labor-intensive to administer because it contains 37 items recorded at predefined intervals, rendering it impractical for most research and clinical applications (Anderson et al., 2004).

The First Contact Index (Rowe-Murray & Fisher, 2002) measures a mother's self-reported quality, quantity, and subjective experience of contact with her infant immediately after birth. The First Contact Index contains three main items: the time of first holding, the duration of

first holding, and the mother's subjective experience at the time of the first holding. No reliability or validity evidence has been reported by the instrument developers. The First Contact Index is an incomplete measure for the construct of togetherness because it only includes the initial contact experience of holding, and it does not assess many of the other critical events and domains of togetherness, such as the quality and quantity of feeding, skin-to-skin contact, and location of the infant in reference to the mother that occur throughout the hospitalization. The First Contact Index fails to capture togetherness during the remainder of the hospitalization. However, the First Contact Index is unique in that that it collects the mother's subjective experience at first holding, including 10 semantic differential scale questions which address the emotional domain of togetherness (Rowe-Murray & Fisher, 2001).

Although the First Contact Index and Index of Mother Infant Separation have contributed to an increased understanding of the phenomenon of togetherness, they are an insufficient measure for the construct of togetherness. A new measure must capture all the domains of togetherness and is needed is needed to determine the timing, duration, and intensity of togetherness of the mother-infant dyad during the entire hospitalization. This measure is critical to engage in evidence-based practice, evaluate obstetric delivery models, nursing interventions, and measure levels of togetherness to promote optimal mother-infant outcomes.

Development of a New Measure

A new measure entitled the Mother-Infant Togetherness Scale (MITS) was developed by this researcher based on a review of the literature and operational definition of togetherness as described in the MNMC conceptual framework. The MITS was developed to measure the timing, duration, and intensity of togetherness of the mother-infant dyad during entire

hospitalization. The MITS is a self-administered 35-item instrument composed of four subscales: the delivery events subscale, delivery affective subscale, the postpartum events subscale, and the postpartum affective subscale. The MITS is presented in Appendix A.

Organization of the MITS items into the delivery events subscale (items #1-3, 5-9) and postpartum events subscale (items #10 – 16) permits measurement of the temporal domain of togetherness events. The delivery events subscale focuses on events and behaviors immediately after the birth and the postpartum events subscale focuses on the events and behaviors that occurred from approximately one hour after the birth until hospital discharge. Critical togetherness events and behaviors are contained in the delivery events subscale item stems and include the first time the mother saw (item #1), touched (item #2), held (item #3), and fed her infant (item #5). The response options for these items measure the specific timing of the togetherness event and behaviors (*immediately, within 10 minutes of the birth, 10-59 minutes of the birth, 1-4 hours after the birth,* and *more than 4 hours after the birth*). The infant's first feeding type, breast or bottle, and the caregiver who administered the feeding is measured in item #6. Administration and duration of skin-to-skin (item #8) and rooming-in (item #9) during the first hour is also assessed. Table 4 provides a complete mapping of MITS items, togetherness behaviors/events, and domains of togetherness. The cultural domain of togetherness is not mapped to a specific item on the MITS. The MITS items were developed based on the assumption that the presence of any cultural beliefs which facilitate or hinder togetherness are manifested in the togetherness behaviors included in the existing MITS items.

Table 4. Mother-Infant Togetherness Scale Items, Togetherness Behavior Event, and Domains

Item Number	**Togetherness Behavior/Event**	**Domains of Togetherness**
1	First time mother saw infant	Spatial, temporal, visual
2	First time mother touched infant	Spatial, tactile, temporal
3	First time mother held infant	Auditory, olfactory, spatial, tactile, temporal, visual
4	Mother's affective state at first holding	Auditory, emotional, olfactory, spatial, tactile, temporal, visual
5	First time mother fed infant	Olfactory, spatial, tactile, temporal, visual
6	First feeding type	Olfactory, spatial, tactile, temporal. visual
7	Infant holding in first hour	Auditory, olfactory, spatial, tactile, temporal, visual
8	Skin-to-skin contact in first hour	Auditory, olfactory, spatial, tactile, temporal, visual
9	Rooming-in during first hour	Auditory, spatial, tactile, temporal, visual
10	Continuous rooming-in from 1 hour until discharge	Auditory, spatial, tactile, temporal, visual
11	Day time rooming-in from 1 hour until discharge	Auditory, spatial, tactile, temporal, visual
12	Night time rooming-in from 1 hour until discharge	Auditory, spatial, tactile, temporal, visual
13	Location of infant during medical procedures	Auditory, spatial, tactile, temporal, visual
14	Feeding type from 1 hour until discharge	Olfactory, spatial, tactile, temporal, visual
15	Skin-to-skin contact from 1 hour until discharge	Auditory, olfactory, spatial, tactile, temporal, visual
16	Infant holding in first hour	Auditory, olfactory, spatial, tactile, temporal, visual
17	Mother's affective state regarding interaction with infant from 1 hour until discharge	Auditory, emotional, olfactory, spatial, tactile, temporal, visual

The postpartum events subscale permits measurement of key togetherness events and behaviors identified in the literature from approximately one hour after the birth until hospital discharge. The presence and intensity of continuous rooming-in, daytime rooming-in, and night time rooming-in (items #10, #11, and #12, respectively) are included in the subscale. The

location of the infant during medical procedures (item #13) and the intensity of skin-to-skin (item #15) are assessed. The intensity of the infant holding and the caregiver responsible for the holding are contained in item #16.

The delivery affective subscale (items #4a - j) and the postpartum affective subscale (items #17a - j) capture the emotional domain of togetherness. Each affective subscale includes ten semantic differential scales that include happy/sad, good/bad, relaxed/tense, positive/negative, comfortable/painful, dissatisfied/satisfied, confused/clear, attached/detached, frightened/safe, and overwhelmed/calm. Of the ten semantic differential scale items, seven items were obtained from the publically available First Contact Index (Rowe-Murray & Fisher, 2001). Revisions were made from mixed bipolar and unipolar adjective pairs to exclusively bipolar adjective pairs for two items to allow for summed scoring. One item was revised to improve readability (*elated* was revised to *happy*).

Psychometric evaluation of the English version of the MITS is presented in this multiphase study. In anticipation of translation and evaluation of the MITS into Spanish and Creole, the researcher consulted with one bicultural translator from each language. The two translators independently reviewed the MITS items and did not identify any potentially problematic words or concepts. Input was also obtained from the translators about the preferred format of the semantic differential scale items response options (placing an "X" on one of five lines, placing an "X" in one of five boxes, or fill-in one of five circles). The preferred format of filling-in one of five circles was identified.

The purpose of this study is to obtain support for the validity of the new measures. A multiphase approach is necessary to modify, refine, test, and evaluate the new measure. Measurement considerations and challenges are presented in the following section.

Measurement Considerations

Multiple strategies are necessary to develop and evaluate a new measure. Assessing for adequate content validity, readability and understandability are important first steps. Consideration to the establishment of adequate internal consistency reliability is of critical importance in the evaluation of a new measure. Construct validity is approached using factor analysis and known groups testing. A review of the literature supports that togetherness varies based on central nursery availability, delivery type, feeding type and provides the foundation for known groups testing for this study.

Content Validity

A two-step process as recommended by Lynn (1986) was used for the assessment of content validity. The first step of content validity was the developmental stage and began with domain identification. Once the domains of the measure were identified, specific items were generated. The items were then assembled and organized into an appropriate sequence and format. These steps have been previously described and completed by this researcher for the MITS. The second step was the judgment-quantification stage of content validity. A panel of expert judges was selected and invited to quantify the content validation of the items in the instrument. The index of content validation (CVI) is the most common quantification method and includes each judge rating the relevance of each item on an ordinal rating scale. The judgment-quantification stage of content validity was completed in Phase 1 of this multiphase study.

Readability and Understandability

Preliminary evaluation of new measure should include an evaluation of readability and understandability. The two approaches to evaluate readability and understandability as presented by Polit and Beck (2008) include assessment of reading level and input from the target audience. These approaches were used in this multi-phase study. The baseline readability of the MITS as calculated from Microsoft Word® was Flesch reading ease 62.3 (0-100 scale with higher score indicating greater ease) and Flesch-Kincaid grade level of 8.0. The readability was repeated throughout the study as revisions are made to the study instrument. The final readability was Flesh reading ease 60.1 and Flesch-Kincaid grade level of 8.2. Postpartum women were asked to provide input to the understandability and readability of the MITS in Phase 2 of this multiphase study.

Internal Consistency Reliability

Internal consistency reliability is the degree to which parts or items on an instrument are all measuring the same dimension (Polit & Beck, 2008). High internal consistency reliability provides support that the items fit well together and that the items are strongly correlated with one another (Pett, Lackey, & Sullivan, 2003). The MITS contains distinctly different types of items on the subscales. Therefore, the internal consistency reliability was assessed for each MITS subscale and at the scale level.

Construct Validity

Construct validity is how well an instrument measures the phenomena of interest (Goodwin & Goodwin, 1981; Polit & Beck, 2008). This study used the statistical procedures of factor analysis and known groups testing and to evaluate construct validity. The three study

variables used for known groups testing were central nursery availability, delivery type, and mode of delivery. The rationale for their selection is presented.

Factor Analysis

Evidence for construct validity can be obtained using factor analysis. Factor analysis are statistical procedures used in this multiphase study to evaluate the different factors (dimensions, traits, variables) that make up the structure of an instrument (Goodwin & Goodwin, 1991; Polit & Beck, 2008). As described by Polit and Beck (2008, p. 487), "Factor analysis disentangles complex interrelationships among items and identifies that 'go together' as unified concepts." Each subscale measure very specific togetherness behaviors in time so it would be expected that that the items would not correlate well with one another. Therefore, factor analysis methods were used to assess construct validity for each subscale and not performed on the total scale.

Known Groups Testing – Central Nursery Availability

If the MITS truly measures the concept of togetherness, then it would be expected to be sensitive to differences between infants that received care in a central nursery and those infants that did not. When infants are cared for in a central nursery, they are obviously not together with their mothers. The geographical and physical barrier of a central nursery provides a significant barrier to togetherness. The literature is unequivocal in that mothers are less engaged in infant caregiving when infants are separated from their mothers to receive care in a central nursery (Anderson, 1977; Anderson et al.1995; Bajo et al., 1998; Barnett, 1947; Bystrova et al., 2007; Carter et al., 2010, Cox, 1974; Crenshaw, 2007; de Chateau, 1979; DiGirolamo et al., 2001; Gonzales, 1990; Janssen, Klein, Harris, Soolsma, & Seymour, 2000; Keefe, 1987; Klatskin,

Lethin, & Jackson, 1950; Noor et al., 1989). Therefore, central nursery availability can assist in the establishment of adequate construct validity of the MITS using known groups testing.

Known-Groups Testing – Delivery Type

If the MITS truly measures the concept of togetherness, then it would be expected to be sensitive to differences between mother-infant dyads having experienced a cesarean birth and mother-infant dyads that experienced a vaginal birth. The literature supports that women who have a cesarean delivery have a different togetherness experience from women that delivered vaginally. Women who have a cesarean are more likely to be separated from their infants and less likely to receive rooming-in as compared to women who deliver vaginally (Declercq et al., 2007; Declercq et al., 2002; Gathwala & Narayanan, 1991; LaFrance, 2003). LaFrance (2003) found that women who had a cesarean were less likely to be physically close to their infant and less likely to hold or touch their infant immediately after birth as postoperative cesarean care is often provided to women in a different room or location from their infant (Declercq et al., 2007; Declercq et al., 2002; Spear, 2006). The invasive nature of a cesarean birth often results in women having experienced higher levels of pain and anesthesia/analgesia intervention (Declercq et al., 2007; Declercq et al., 2002; McGrath & Phillips, 2009; Redshaw & Hockley, 2010) placing them at risk to be more reliant upon others to provide caregiving to their infants (Redshaw & Hockley, 2010). In addition, breastfeeding initiation can be delayed after cesarean birth. Spear (2006) conducted a descriptive study of 154 obstetric nurse managers from southeastern U.S. hospitals, and 69.0% (n = 106) of the nurse managers reported that breastfeeding was not allowed in the operating room and 21.4% (n = 33) reported that breastfeeding was not allowed in the recovery room.

Recent commentary in the literature has included a description of a "gentle or natural" cesarean to promote family-centered approach to cesarean delivery, which includes early, undisrupted contact, skin-to-skin, and breastfeeding (Smith, Plaat, Fisk, 2008; Young, 2011). Despite this increasing trend to naturalize cesarean birth, no studies have been published which evaluate this approach to cesarean birth. Therefore, delivery type was used to assist in the establishment of adequate construct validity of the MITS using known groups testing. If the MITS truly measures the concept of togetherness, then it should also be expected to be sensitive to differences between mother-infant dyads that experienced a "non-natural" cesarean birth and mother-infant dyads that experienced a vaginal birth.

Known Groups Testing – Feeding Type

Breastfeeding provides the opportunity for more mother-infant togetherness so if the MITS truly measures the concept of togetherness, then it would be expected to be sensitive to differences between mother-infant dyads that engage in breastfeeding and mother-infant dyads that engage in exclusive bottle feeding. Women who decide to breastfeed their infants are more engaged in infant caregiving given the exclusive nature of the feeding method. Infants are more likely to be held and in skin-to-skin contact when the mother is the caregiver exclusively responsible for the feedings (Anderson, 1977).

Measurement Challenges

The MITS has been developed to be a self-administered instrument presenting a unique measurement challenge. Self-administration is a preferred mode of administration because of accuracy and feasibility concerns with observational data. Even though it is common practice to administer instruments to women 4 to 6 weeks postpartum before mothers reenter the work force

(Hodnett et al., 2002; Hodnett et al., 2008), a review of the literature identified there is a paucity of the research investigating maternal recall of birth events. Prior research has demonstrated that women generally have vivid long-term memories of their birth experience (Lundgren, Karlsdottir, & Bondas, 2009; Simkin, 1991, 1992), but their ability to specifically recall the timing and occurrence of togetherness practices is not known.

Several studies provide evidence of women's ability to recall specific aspects of their infant's birth, such as birth weight and gestational age (Adegboye & Heitmann, 2008; Catov et al., 2006) and labor and delivery procedures (Bennett, 1985; Hewson & Bennett, 1987). Even so, mothers' ability to recall exclusive breastfeeding practices, specifically when exclusive breastfeeding practices were stopped was poor (Bland, Rollins, Solarsh, Van den Broeck, & Coovadia, 2003). Therefore, an important aspect in the development of a new measure of togetherness was to investigate women's ability to accurately self-report the timing and occurrence of togetherness practices during the first few hours of birth.

One last methodological concern for this study was to acknowledge a cautious interpretation of any validity testing is warranted. Goodwin and Goodwin (1991) asserts that there are multitude of statistical techniques to evaluate construct validity but only a collective and comprehensive evaluation of all the findings should be used to make the final determination of adequate construct validity. Dr. Gene Anderson (personal communication, March 5, 2010) adds that instrument development and evaluation is a life long journey of obtaining support for construct validity. Therefore, the methods presented in this study only represent the beginning and foundation for the construct validity for a new measure.

Summary

A revision of Anderson's MNMC conceptual framework provided the framework for the research. Togetherness as defined within the MNMC conceptual framework is cultural, emotional, environmental, olfactory, spatial, temporal, or visual facilitators for mutual caregiving. Concerns with current operationalization and fidelity of togetherness were identified. No current instrument provides a practical means for capturing togetherness during the hospitalization which the birth occurred. Development of a new measure was proposed and described. Methodological approaches and challenges to develop and evaluate the new measure were presented.

CHAPTER THREE: METHODS

This chapter presents the qualitative and quantitative methods used in this multi-phase study to obtain the initial psychometric evidence for the MITS instrument. First, the Mother-Infant Togetherness Scale (MITS) is described. Then, the study design, sample, study procedures, data collection, and data analysis are provided for each phase of the study. Ethical considerations are also described.

The MITS was developed based on a review of the literature and from the researcher's experience with childbearing women. Consistent with MNMC conceptual framework, the MITS measures the mother-infant togetherness experience. MITS items were developed to detect togetherness, defined as cultural, emotional, environmental, olfactory, spatial, temporal, or visual facilitators of mutual caregiving. High scores are the MITS will indicate togetherness and low scores will indicate mother-infant separation. See Chapter two for a full description of the development of the measure.

The MITS is a 35-item instrument composed of four subscales: the delivery events subscale, delivery affective subscale, the postpartum events subscale, and the postpartum affective subscale. The delivery events subscale measures togetherness events during the first hour after birth (items #1-3, 5-9) and the postpartum events subscale measures togetherness events during the remainder of the hospitalization (items #10 – 16). The delivery affective subscale (items #4a - j) and the postpartum affective subscale (items #17a - j) each include ten semantic differential scales that were revised from the publically available First Contact Index (Rowe-Murray & Fisher, 2001) that capture women's delivery and postpartum affective experiences of togetherness.

Phase 1

Overview

Initial psychometric testing of a new measure of the MITS was conducted to examine the content validity at the scale (S-CVI) and item level (I-CVI) with a panel of expert judges. The following research question was addressed in Phase 1: Is there support for the content validity of the MITS?

Sample

Purposive sampling was used to recruit the panel of expert judges. The PI initially recruited 12 expert judges who had a strong conceptualization of togetherness. The following 12 expert judges were invited to participate: medicine (n = 2), nursing research (n = 4), maternal child nursing (n = 3, 1 each from a free-standing birth center, low risk inpatient setting, and high risk inpatient setting), psychology (n = 2), and social work (n = 1). Adequate representation from each specialty was desired as follows: medicine (n = 1), maternal-child nurse (n=1), nursing researcher (n = 2), psychology (n = 1), and social work (n = 1) resulting in a minimum final sample size of at least 6 judges. A second round of recruitment occurred with 8 individuals with expertise in psychology in an effort to recruit 1 to 2 more psychologists to the panel of judges, but none responded.

Procedure

Each judge was sent an initial email invitation to participate in the content validation of the MITS. If no response was received by the PI 10 days after the initial notification, a reminder email notification was sent. Judges that agreed to participate within 20 days of the initial notification were sent the instructions to complete the content validation.

Materials

Each judge was sent a packet that included the background and description of the constructs of mutual caregiving, togetherness and separation, instructions, and the content validation tool. To avoid neutral responses, judges were instructed to use a 4-point Likert scale (1 = not *relevant*, 2 = *somewhat relevant*, 3 = *quite relevant*, and 4 = *highly relevant*) to rate the relevance of each item (I-CVI) (Polit & Beck, 2008).

Data Collection and Analysis

Preliminary analysis was performed and included exploring MITS responses for missing data and outliers. Responses were dichotomized into relevant (3's and 4's) and not relevant (1's and 2's). I-CVI was computed for each item by totaling the number of judges that answered relevant (3's and 4's) divided by the total number of judges. The desirable I-CVI was greater than .78. The desirable subscale content validity and S-CVI (calculated from the mean I-CVI scores) was S-CVI greater than or equal to .90 (Polit & Beck, 2008).

Phase 2

Overview

A descriptive qualitative study design was used to pretest the readability and understanding of the MITS and demographic data collection form with the target audience. A qualitative methodology was necessary in order to generate narrative data (Creswell, 2007) to best address the following research question: Do postpartum women find the MITS and demographic data collection form understandable and readable? The second research question was: Is there support for the content validity of the MITS delivery affective subscale (item #4a - j) and postpartum affective subscale (item #17a - j) among a panel of postpartum women?

Results from this study help clarify the content validity of the affective subscales with the target audience who has recent direct experience with the construct of togetherness.

Sample

A purposive sample of 8 diverse postpartum women was recruited to participate in a 60-minute interview. The sample was diverse with respect to age, parity, educational level and race/ethnicity. Inclusion criteria for this phase were English-speaking women having delivered a live, singleton, term (36 weeks completed gestation) infant within the last 4-6 weeks. The following women were excluded: women having no memory of their delivery experience (general anesthesia or deep sedation), women who were employees of the research site, women who delivered at home, and women that placed their infants for adoption.

Procedures

Recruitment flyers were placed in three community hospitals that are part of a large health care system in Southwest Florida. Hospital A performed approximately 1,500 deliveries per year, Hospital B performed approximately 3,800 deliveries per year, and Hospital C performed approximately 2,500 deliveries per year. The flyers instructed interested women to contact the PI directly.

The PI visited women who expressed interest while hospitalized (when feasible) or spoke to them by phone to explain the study and screen for inclusion/exclusion criteria. Each woman was then sent the written consent by mail and instructed to review the consent and to contact the PI with any questions. The PI placed a follow-up phone call to each woman, answered any study-related questions, and scheduled an interview. Women determined the time, place, and location

of the interview. Women were instructed to bring the signed consent to the interview and received an incentive for their participation ($20 gas gift card or Visa gift card).

Data Collection and Analysis

The interviews were conducted by the PI and audio taped. If a woman did not want to be audio taped, the PI or research assistant was prepared to take field notes. However, all women consented to be audio taped. Women were asked to complete the MITS and the demographic data collection form (See Appendix C) and then asked their opinions about the readability and understandability of the items. Appendix D provides the interview guide. The audiotapes were transcribed word-for-word, reviewed for thematic content (themes, viewpoints, suggestions), and revisions made to the study instrument accordingly. Trustworthiness of the interpretation of the data was managed by the PI as any necessary revisions to improve readability and understanding were explored. When a participant identified potential concerns with the study instrument, the concerns and possible solutions were explored with the participant. During subsequent interviews, concerns were re-explored until an acceptable resolution was identified. Each participant was asked to participate in the content validation for the affective subscales (items #4a - j and #17a - j). Participants were provided with the background of the study instrument and asked to rate the relevance of each item. A visual scale 4-point scale (1 = *not relevant/important to ask*, 2 = somewhat relevant/important to ask, 3 = *quite relevant/import to ask*, 4 = *highly relevant/important to ask*) was provided to assist participants. Means with standard deviations (*sd*) were used to describe normally-distributed study variable. Medians with ranges were used to describe skewed study variable ($\left| skew > 1.0 \right|$).

Phase 3

Overview

A descriptive study design was used to examine if there was psychometric evidence to support the ability of women to accurately self-report birth events on the MITS delivery events subscale at 4 weeks postpartum as compared to observer-collected observational data obtained at delivery. Results from this study help clarify the feasibility of using self-reported data to measure togetherness.

Sample

The purposive sample consisted of 45 women delivering at a Hospital A, a community hospital in Southwest Florida that performed approximately 1,500 deliveries per year (also used in Phase 2). Assuming an attrition rate of 40%, this would provide a sample of 27 for analysis which is sufficient to detect a moderate Pearson's product-moment correlation coefficient ($r \geq .49$), assuming an alpha of .05 and beta of .80. Estimated attrition was based on prior obstetrical research studies at this hospital in which the PI has been involved and which utilized scheduled phone reminders to participants to complete questionnaires 6-8 weeks after discharge (Hodnett et al., 2008, Nolan & Lawrence, 2009). The attrition rate here was conservative to ensure that sample size estimates were reasonable and provided sufficient power for statistical analysis. The inclusion criteria for this phase included English-speaking women who delivered a term (36 weeks completed gestation), live, singleton birth at a time during which a research assistant was available for data collection for the first 4 hours after birth. Women having no memory of their delivery experience (general or deep sedation), women who were employees of the research site, and women who placed their infants for adoption were excluded from participation.

Procedures

Women admitted for childbirth were given a study flyer instructing them to inform their labor nurse if they were interested in participation. When a woman expressed interest in participation, the labor nurse screened for inclusion/exclusion criteria and enrolled the woman by obtaining informed written consent. If the woman had any additional questions about the study, the labor nurse immediately notified the PI to address these questions and obtain informed written consent. Labor nurses at this hospital had participated in several obstetrical research trials and had experience with screening and enrolling subjects in research studies (Hodnett et al., 2008, Nolan & Lawrence, 2009). Each labor nurse assisting in enrollment and data collection received an incentive of one free meal ticket at the hospital's cafeteria for their assistance.

Data Collection and Analysis

The PI and research assistant used the train-the-trainer model to establish inter-rater reliability for data collection on the delivery events subscale (items #1-3, 5-9). The PI and research assistant independently and simultaneously completed the delivery events subscale on participants until adequate inter-rater reliability coefficient ($\geq$ 1.00) was achieved. Then eight labor nurses working in the labor and delivery unit at the participating hospital were trained in data collection procedures by attending a 120-minute training session given by the PI on study procedures, data collection, and conduct of research involving human subjects. During the first four hours after delivery, the research assistant, trained labor nurse, or PI were responsible for completing the delivery events subscale of the MITS and the demographic data collection form (see Appendix E). Inter-rater reliability was established by the PI or research assistant by observing each trained labor nurse's data collection until adequate inter-rater reliability coefficient ($\geq$ 0.86) was achieved.

At 4 weeks after delivery, the PI called each woman, verified her mailing address, and informed her to anticipate receipt of the MITS along with a self-addressed stamped envelope. Two reminder calls were made at 6 and 8 weeks for unreturned MITS. Upon receipt of the completed MITS, the study incentive ($20 gas card or Visa card) was sent to the participant by mail.

Preliminary analysis included exploring demographic data and MITS responses for outliers and missing data. Exploratory and descriptive statistics (mean, standard deviations, percents) were calculated to describe participant demographic characteristics and summarize MITS responses on the self-reported and observer collected scores. Means with standard deviations (*sd*) were used to describe normally-distributed study variable. Medians with ranges were used to describe skewed study variable ($\left| skew > 1.0 \right|$). The MITS responses were found to be skewed ($> \left| 1.0 \right|$). Hence, they were dichotomized as summarized in Table 5. McNemar Chi-Squares (χ) were calculated to evaluate group differences on the dichotomized self-reported and observer collected scores because these scores were not independent.

Table 5. Dichotomized Responses from the Delivery Events Subscale

Item Number	**Dichotomized Responses**
When was the first time you saw your baby? (1)	< 10 minutes; ≥ 10 minutes
When was the first time you touched him/her after the birth? (2)	< 10 minutes; ≥ 10 minutes
How old was your baby the first time you held him/her in your arms? (3)	< 10 minutes; ≥ 10 minutes
When was the first time you fed your baby? (5)	< 1 hour; ≥ 1 hour
Which statement best reflects your baby's first feeding? (6)	Breast; bottle
Which statement best reflects what your baby was doing during the first hour after the birth? (7)	With mother; Not with mother
Which statement best reflects the amount of time you held your naked or shirtless baby next to your bare chest (skin-to-skin) during the first hour after the birth? (8)	Provided skin-to-skin: Did not provide skin-to-skin
During the first hour after the birth, where was your baby? (9)	In the same room as the mother all or most of the time; Some or none of the time.

Phase 4

Overview

Phase 4 is in-progress and evaluates the reliability and validity of the MITS subscale and total scale scores. An interim data analysis was performed with a combined sample of participants from Phase 3 and Phase 4 of this multiphase study. The Phase 4 final analysis will be completed once adequate recruitment is complete. Internal consistency reliability is being assessed using the split-half technique and Cronbach's alpha. Construct validity is being assessed using factor analysis and known groups testing. Known groups testing are being performed on three variables (feeding type, mode of delivery, and central nursery availability). The following research questions are addressed (see also Table 6).

Phase 4—Reliability Testing

Research Question I. Is there support for the internal consistency reliability of the MITS at the *scale* level among a sample of women 4 weeks postpartum?

Research Question II. Is there support for the internal consistency reliability of *each* MITS subscale?

Phase 4—Exploratory Factor Analysis (EFA)

Research Question III. What is the factor structure of *each* MITS subscale?

Phase 4—Known Groups Testing

Research Question IV. Is there a significant difference in mean subscale scores by infant feeding type (breast and bottle)?

Research Question V. Is there a significant difference in mean subscale scores by mode of delivery (vaginal and cesarean)?

Research Question VI. Is there a significant difference in mean subscale scores by central nursery availability?

Table 6. Phase 4 Research Questions

Psychometric Evidence	**Question**
Reliability	Is there support for the internal consistency reliability of each of the MITS subscale and total scores as measured by split-half reliability techniques and Cronbach's alpha?
EFA	What is the factor structure for each MITS subscale?
Known groups testing	Is there a significant difference in mean subscale scores by infant feeding type (breast and bottle) as measured by independent-samples *t* tests? Is there a significant difference in mean subscale scores by mode of delivery (vaginal and cesarean) as measured by independent-samples *t* tests? Is there a significant difference in mean subscale scores central nursery availability as measured by independent-samples *t* tests?

Study Sites

Subjects were recruited from four hospitals to obtain a large, diverse sample of postpartum women. A heterogeneous sample was desired with respect to subject's demographic characteristics and childbirth experiences to fully examine the reliability and validity of the MITS and MITS subscales.

Hospital A

Hospital A (a participating site for Phase 2 and Phase 3) was a low-risk birthing center that performed approximately 1,500 deliveries per year and provided a LDRP delivery model. Labor, delivery, recovery and postpartum care were provided in one room. Transitional infant care was provided in the mother-infant dyad's room. No central nursery existed. Infant separation at night at maternal request was rare and dependent upon adequate staffing to observe infants at the nurse's station.

Hospital B

Hospital B (a participating site for Phase 2) performed approximately 3,800 deliveries per year and provided an LDR model of care. Labor, delivery, and recovery care were provided prior to transfer to a postpartum unit. Hospital B provided low and high risk obstetrical services. Transitional infant care was provided in the mother-infant dyad's room. Similar to Hospital A, no central nursery was available. Infant separation at night at maternal request was rare and dependent upon adequate staffing to observe infants at the nurse's station.

Hospital C

Hospital C was a low risk obstetrical center that performed approximately 2,500 deliveries per year. An LDR model of care was provided. Labor, delivery, and recovery care

were provided prior to transfer to a postpartum unit. Transitional infant care was provided in the mother's presence in the mother-infant dyad's room after vaginal delivery. After cesarean delivery, infant transitional care was completed in the mother-infant dyad room while the mother was in the post anesthesia care unit. No central nursery was available and there were no accommodations to remove the infants during the night to accommodate maternal request.

Hospital D

Hospital D performed approximately 13,000 deliveries per year and provided a LDR delivery model. Labor, delivery, and recovery care was provided prior to transfer to a postpartum unit. A central nursery was used for transitional care, post cesarean care, medical procedures, pediatrician examinations, and during the night to promote maternal sleep.

Phase 4 is still in-progress. A sample of approximately 400 postpartum women who are agreeable to receive the MITS at four week postpartum are being recruited from four different hospitals. The recommended minimal sample size for Cronbach's alpha is 10 subjects per item and the recommended sample size for factor analysis is 10-15 subjects per item or a total sample size of at least 200 subjects (Pett et al., 2003). Given that there are a total of 35 items on the MITS at least 170 subjects were needed for the final analysis to compute a Cronbach's alpha at the scale level and 200 subjects were need for factor analysis. Applying the attrition projections (50%), a total of 400 interested women were needed to obtain a final sample size of 200. The inclusion criteria for this phase included English-speaking women who delivered a live, singleton infant after 36 weeks completed gestation. Women who had no memory of their delivery experience (general or deep sedation), women who were employees at the research site, and women who placed their infants for adoption were excluded.

Procedures

Postpartum women were recruited from the participating hospitals through use of advertisement flyers posted on the unit and informational flyers given to eligible woman. Interested women provided their name and address on the information flyer and returned to the hospital staff permitting receipt of the MITS at 4 weeks after delivery. The informational flyer instructed interested women to contact the PI directly with any questions. The flyer also instructed interested women that they were under no obligation to participate but by providing their name and address they were giving permission to receive the MITS at their mailing address. Interested women were mailed a cover letter describing the study purpose (that served as the consent), the MITS instrument (Appendix F), demographic data collection form (See Appendix E), a self-addressed stamped envelope, and a coupon for a free cookie at Perkin's® Restaurant & Bakery. The cover letter instructed women who wanted to proceed with participation to complete and return the MITS and the demographic data collection form. Completion of the MITS implied informed consent.

Data Collection and Analysis

An interim data analysis was performed on a sample of 113 postpartum women (composed of the final sample of 31 participants from Phase 3 and the first 82 participants from Phase 4) having delivered at three of the four participating hospitals (Hospital A, B, & C). The final data analysis for Phase 4 will be completed once adequate recruitment is complete at Hospital D. Preliminary analysis included exploring demographic data and MITS responses for outliers and missing data. Descriptive statistics (mean, standard deviations, percents) were calculated to describe participant's demographic characteristics. The issue of data transformation was considered before proceeding with Cronbach's alpha because historically the assumption of

normality must be met. However, Norris and Aroian (2004) and Enders and Bandalos (1999) have challenged this assumption and found Cronbach's alpha to be robust. The appropriate reverse scoring of MITS items were performed using a computer. All items were then converted into z-scores given that the subscales have items with four and five response options permitting data analysis at the scale level. Descriptive statistics were calculated to describe MITS responses.

For Research Question I and II, split-half technique and/or Cronbach's alpha were used to assess internal consistency reliability for the each of the four MITS subscale scores and total MITS scores. For the split-half reliability, items in the analysis were randomly split in half and the resulting alpha coefficients on the two halves correlated. Correlations between the two halves greater than .70 and Cronbach's alpha greater than .70 was used to determine adequate internal consistency reliability (DeVellis, 2003).

Research Question III, data analysis included exploring data to determine if the assumptions for factor analysis were met for each MITS subscale scores. The first step in conducting factor analysis was to determine if factor analysis was indicated and appropriate, that is, to determine if there were an adequate number of significant correlations among the items as determined by a significant Bartlett's test of sphericity and Kaiser-Meyer-Olkim greater than .60. Exploratory factor analysis was conducted and the scree plots, Eigen values, residual communalities, and factor loadings were explored to examine the factor structure to identify like items and groupings. Concerning items were identified during the interim data analysis and may be dropped in the final data analysis if doing so improves the factor loadings, makes conceptual sense, and maintains an acceptable Cronbach's alpha (Pett et al., 2003).

For Research Questions IV-VI, independent samples *t* tests ($p \leq .05$) were used in the interim analysis to detect if there was a significant difference for each of the subscale scores

among each study variable (infant feeding type, mode of delivery). Significant findings in the interim analysis for infant feeding type and mode of delivery provided preliminary evidence for the validity and sensitivity of the MITS to detect group differences. A post hoc power analysis on the effect size for mode of delivery and feeding type was conducted to determine the final sample size needed to obtain statistical power at the recommended alpha of .05 and beta of .80. A third known group testing for the variable of central nursery availability will be performed in the final analysis.

Ethical Considerations

Each phase of this study involved minimal risk. Approval was obtained from the University of Central Florida's Institutional Review Board and from each participating site's Institutional Review Board (Appendixes H, I, and J). The procedures to obtain consent were provided in this chapter in the procedural details for each phase of the study. In summary, informed written consent was obtained from subjects prior to participation by the PI or research team for Phase 2 and Phase 3. The consent procedures for Phase 1 and Phase 4 included providing the potential subject with an informative email or traditional mailing providing instructions to complete and return the study instrument if they consented to participate. Completion of the MITS implied informed consent.

Summary

This chapter has provided the study design, methods, the sample, procedures, and data analysis for this multi-phase study. An interim analysis was presented for Phase 4 of the study. The ethical considerations were also identified.

CHAPTER 4: RESULTS

Participant characteristics and results from each phase of the study are described in this chapter. Data for each phase were examined for outliers, missing data, and the assumptions for the statistical analysis performed. The SPSS Statistical Package Graduate Pac™ 20.0 and Microsoft Excel ™ were used to conduct the analysis, generate tables, and construct graphs.

Phase 1

The research question for Phase 1 was to evaluate if there was support for the content validity of MITS scale and subscales as directed by CVI at the scale, subscale, and item level using rating provided by a panel of expert judges. The sample of expert judges (n = 7) consisted of judges from medicine (n = 2), maternal-child nursing (n = 1), nursing research (n = 3), and social work (n = 1).

The CVI at the scale level (CVI-S) of .88 was just slightly below the desired CVI-S ($\geq$ .90). The subscale and item CVI results are presented in Table 7. Of the four subscales, all had adequate CVI at the subscale level except the delivery affective subscale (CVI = .74) and postpartum affective subscale (CVI = .89). The delivery events and postpartum events subscales had satisfactory CVI scores (CVI > .90), 1.00 and .94, respectively.

Table 7. Phase 1 Expert Judges (n = 7) Content Validity Index Ratings at Subscale and Item Levels

Subscale or Item Label and Wording (Item no.)	**CVI N=7**
Delivery Events Subscale	**1.00**
When was the first time you saw your baby after the birth? (1)	1.00
When was the first time you touched him/her after the birth? (2)	1.00

Subscale or Item Label and Wording (Item no.)	CVI N=7
How old was your baby the first time you held him/her in your arms? (3)	1.00
When was the first time you fed your baby? (5)	1.00
Which statement best reflects your first feeding? (6)	1.00
Which statement best reflects what your baby was doing during the first hour after the birth? (7)	1.00
Which statement best reflects the amount of time you held your naked or shirtless baby next to your bare chest (skin-to-skin) during the first hour after the birth? (8)	1.00
During the first hour after the birth, where was your baby? (9)	1.00
Delivery Affective Subscale	**.74****
Comfortable/Painful (4a)	.71*
Positive/Negative (4b)	1.00
Happy/Sad (4c)	.86
Good./Bad (4d)	.57*
Relaxed/Tense (4e)	.71*
Dissatisfied/Satisfied (4f)	.71*
Confused/Clear (4g)	.57*
Attached/Detached (4h)	.86
Frightened/Safe (4i)	.57*
Overwhelmed/Calm (4j)	.86
Postpartum Events Subscale	**.94**
Which statement best reflects the general location of your baby while hospitalized? (10)	1.00
Which statement best reflects the general location of your baby during the daytime? (11)	1.00
Which statement best reflects the general location of your baby during the night time? (12)	1.00
Which statement best reflects the general location of your baby during medical procedures, for example, when the nurses or pediatricians (baby doctor) examined your baby? (13)	.86
Which statement best reflects how your baby was fed while hospitalized? (14)	.86
Which statement best reflects the amount of time you held your baby naked or shirtless next to your bare chest (skin-to-skin) while hospitalized? (15)	1.00
Which statement best reflects your baby's activity while hospitalized? (16)	.86
Postpartum Affective Subscale	**.89****
Comfortable/Painful (4a)	.86

Subscale or Item Label and Wording (Item no.)	CVI N=7
Positive/Negative (4b)	1.00
Happy/Sad (4c)	1.00
Good./Bad (4d)	.57*
Relaxed/Tense (4e)	1.00
Dissatisfied/Satisfied (4f)	.86
Confused/Clear (4g)	.86
Attached/Detached (4h)	1.00
Frightened/Safe (4i)	.86
Overwhelmed/Calm (4j)	.86

* Below the desired CVI-I > .78; **Below the desired CVI-S > .90

The CVI-I results identified a total of seven items on the affective subscales that did not meet the desired I-CVI (≤ .78). These findings appeared conceptually inconsistent with the literature review and the conceptual framework. Upon further reflection, the study design might have been susceptible to actor-observer bias, in which there is bias when one group (the experts or observers) are asked to provide insight on the affective state of another group (postpartum women or actors). Observers can have a distorted reality especially with events involving pain and suffering (Nisbett, Caputo, Legant, & Marecek, 1973; Pronin, 2008). Hence, no items were removed from the MITS until additional content validation was completed using a sample of postpartum women as judges. This additional validation work was built into Phase 2 interviews.

Phase 2

Phase 2 examined the understandability and readability of the MITS and demographic data collection form among a sample of postpartum women and provided additional data regarding the content validation of the delivery affective and postpartum affective subscales. A

total of 8 postpartum women were enrolled in this phase of the study. The sample for Phase 2 had a median age of 20.50 (*range* 17-37) with exactly half of the participants reported married or in a committed relationship. The sample was diverse with respect to parity (62.5% primiparous, 37.5% multiparous). The majority of the patients had experienced a vaginal birth (87.5%). Of the eight participants, four were Hispanic (50.0%) and three participants (37.5%) were born outside of the United States. Half (50%) of the sample had completed high school or earned a GED. See also Table 8 for additional demographic information.

Understandability and Readability

The mean time for participants to complete the demographic data collection form and MITS was 10.0 minutes (*sd* = 4.11). However, participants identified several readability and understandability issues to improve the MITS and demographic form. Tables 9 and 10 provide the results of the directions and items that were revised based in participant input.

Table 8. Phase 2 Descriptive Statistics and Obstetric Variables

Demographic Data	**Statistic**
Age (years)	(n-8)
Median	20 - 50
Range	17 - 37
Marital status	(n=8)
Single	37.5% (3)
Married	25.0% (2)
Committed relationship	25.0% (2)
Divorced	12.5% (1)
Racial/ethnic group	(n=8)
Caucasian/white	50.0% (4)
Hispanic	50.0% (4)
Country of origin	(n=8)
United States	62.5% (5)

Demographic Data	**Statistic**
Cuba	12.5% (1)
Mexico	12.5% (1)
Greece	12.5% (1)
Education level (highest level completed)	(n=8)
Less than high school	25.0% (2)
High school	25.0% (2)
GED	25.0% (2)
Some college	25.0% (2)
College degree	0.0% (0)
Para	(n=8)
Primipara	62.5% (5)
Multipara	37.5% (3)
Delivery type	(n=8)
Vaginal	87.5% (7)
Cesarean	12.5% (1)
Number of days postpartum	(n=8)
Mean	29.63
(sd)	5.35
Infant's gender	(n=8)
Female	62.5% (5)
Male	37.5% (3)
Infant's gestational age	(n=8)
Mean	38.61
(sd)	.61
Breastfed during hospital stay	(n=8)
Yes	62.5% (5)
No	37.5% (3)
Breastfed at four weeks postpartum	(n=8)
Yes	25.0% (2)
No	75.0% (6)

Table 9. Phase 2 Revisions to the Demographic Data Collection Form

Item	Revision
What is the name of the country where you were born? (please specify)	What is the name of the country where you were born (such as the United States, Mexico, etc?) (please specify)
What is the highest grade of school you completed (check one): • ☐ Less than high school	What is the highest grade of school you completed (check one): ☐ Have not completed high school ☐ GED
Due Date: __/__/___ (month/day/year)	*(Re-ordered this item to appear after baby's birth date)*
During your hospitalization, did your baby receive any of his/her feedings with breast milk?	During your hospitalization, did your baby receive ***any*** of his/her feedings with breast milk?
At 4 weeks of age, was your baby receiving any of his/her feedings with breast milk?	At 4 weeks of age, was your baby receiving ***any*** of his/her feedings with breast milk?

Additional Content Validation

The I-CVI results for this phase identified that a total of six items on the affective subscales had a CVI-I = .75, just slightly below the desired I-CVI of $\geq$.78. The CVI-I and CVI at the subscale level results are provided in Table 11. These findings were discussed the PI's dissertation chair and each item was examined for conceptual congruency with the literature review and conceptual framework. The decision was made to only drop two of the six items from the study instrument, "dissatisfied/satisfied" from the delivery affective scale and "confused/clear" from the postpartum affective scale. The remaining four items with CVI of .75 were retained until additional psychometric testing can be performed because they appeared to be conceptually consistent with the literature and conceptual framework. Retention of the four items still maintained the desired subscale and scale CVI greater than .90. See Table 12 for the final subscale and scale CVI results.

Table 10. Phase 2 Revisions to the Mother-Infant Togetherness Scale

Item (Item No.)	**Revision**
Please rate how you were feeling the first time you held your baby by filling-in the circle between each pair of words. (4) Comfortable/Painful Positive/Negative Happy/Sad Good/Bad Relaxed/Tense Dissatisfied/Satisfied Confused/Clear Attached/Detached Frightened/Safe Overwhelmed/Calm	Please rate how you were feeling **the first time you held your baby** by filling-in the circle between each pair of words. Positive/Negative Happy/Sad Confused/Clear Relaxed/Tense Dissatisfied/Satisfied Good/Bad Comfortable/Painful Attached/Detached Frightened/Safe Overwhelmed/Calm Worried/Relieved *(Re-ordered the items and added Worried/Relieved)*
When was the first time you fed your baby? (5)	When was the first time you **fed** your baby? □ I don't know *(Added new response option)*
Which statement best reflects what your baby was doing during the first hour after the birth? (7)	Which statement best reflects what your baby was doing **during the first hour after the birth**?
Which statement best reflects the amount of time you held your infant naked or shirtless next to your bare chest (skin-to-skin) during the first hour after the birth? (8)	Which statement best reflects the amount of time you held your baby naked or shirtless next to your bare chest (skin-to-skin) **during the first hour after the birth?**
During the first hour after the birth, where was your baby? (9)	**During the first hour after the birth,** where was your baby?
Please answer the remaining questions that best described your hospitalization from approximately 1 hour after the birth until you were discharged from the hospital. Do NOT include events that occurred during the first hour after your baby was born.	**DIRECTIONS: Please answer the remaining questions that best describes your hospitalization from approximately 1 hour after the birth until you were discharged from the hospital. Do NOT include events that occurred during the first hour.** *(also increased font size)*
Which statement best reflects the general location of your baby while hospitalized? (10)	Which statement best reflects the general location of your baby **while hospitalized?**

Item (Item No.)	Revision
Which statement best reflects how your baby was fed while hospitalized? (14) □ At my request, my baby received both breast and bottle (formula) feedings □ At the staff's request, my baby received both breast and bottle (formula) feedings	Which statement best reflects how your baby was fed while hospitalized? □ My baby received both breast and bottle (formula) feedings because it was what I wanted □ My baby received both breast and bottle (formula) feedings because the hospital staff recommended this
Which statement best reflects the amount of time you held your baby naked or shirtless next to your bare chest (sin-to-skin) while hospitalized? (15)	Which statement best reflects the amount of time you held your baby naked or shirtless next to your bare chest (skin-to-skin) while hospitalized?
Please rate how you were feeling the first time you held your baby by filling-in the circle between each pair of words. (17) Comfortable/Painful Positive/Negative Happy/Sad Good/Bad Relaxed/Tense Dissatisfied/Satisfied Confused/Clear Attached/Detached Frightened/Safe Overwhelmed/Calm	Please rate how you were feeling **the first time you held your baby** by filling-in the circle between each pair of words. Positive/Negative Happy/Sad Confused/Clear Relaxed/Tense Dissatisfied/Satisfied Good/Bad Comfortable/Painful Attached/Detached Frightened/Safe Overwhelmed/Calm Worried/Relieved *(Re-ordered the items and added Worried/Relieved)*

Table 11. Phase 2 Postpartum Women (n = 8) Content Validity Index Ratings for Delivery Affective and Postpartum Affective Subscales and Items

Subscale or Item Number	**CVI (n=8)**
Delivery Affective Subscale	**.90**
Positive/Negative (4a)	.88
Happy/Sad (4b)	.75*
Confused/Clear (4c)	.75*
Relaxed/Tense (4d)	1.00
Dissatisfied/Satisfied (4e)	.74*
Good/Bad (4f)	.88
Comfortable/Painful (4g)	1.00
Attached/Detached (4h)	1.00
Frightened/Safe (4i)	1.00
Overwhelmed/Calm (4j)	.88
Worried/Relieved (4k)	1.00
Postpartum Affective Subscale	**.90**
Positive/Negative (4a)	1.00
Happy/Sad (4b)	1.00
Confused/Clear (4c)	.75*
Relaxed/Tense (4d)	.75*
Dissatisfied/Satisfied (4e)	.88
Good/Bad (4f)	.88
Comfortable/Painful (4g)	1.00
Attached/Detached (4h)	1.00
Frightened/Safe (4i)	1.00
Overwhelmed/Calm (4j)	.75*
Worried/Relieved (4k)	.86

* Below the desired CVI-I > .78.

Table 12. Final Content Validation Results at the Subscale and Scale Level

Subscale or Item (Item No.)	**CVI**
Delivery Affective Subscale	.91
Postpartum Affective Subscale	.91
Delivery Event Subscale	1.00*
Postpartum Event Subscale	.94*
Total Scale	.94

*As reported in Phase 1

Phase 3

Phase 3 of the study used a descriptive study design to examine women's ability to accurately self-report birth events on the delivery events subscale as compared to observer-collected observational data obtained at delivery. A purposive sample of 45 English-speaking/reading women who delivered a live, term, singleton infant at community hospital (Hospital A) in Southwest Florida were enrolled into the study. Of the 45 women enrolled into the study, 31 completed the MITS at 4 weeks resulting in a 68.9% response rate.

The participants demographic and obstetrical data were explored for outliers and missing data. Country of origin was the only variable with missing data greater than 10% (12.9%). Participants with missing data did not significantly differ ($p > .05$) from participants without missing data on country of origin by age ($t(43) = -.57$, $p = .57$), marital status ($p = .52$, for married/committed and not married/committed relationship comparison), race ($p = .31$, for White and non-White comparison), and education ($p = 1.00$, for $\leq$ high school/GED and > high school comparison). However, a Fisher's exact test found a significant difference ($p = .02$) based on delivery type. Women who delivered vaginally had no missing data, whereas 4 (25.0%) women who delivered by cesarean had missing data on country of origin.

The final sample did not statistically differ from participants lost to follow-up by missing data, age, marital status, race/ethnicity, country of origin, parity, delivery type, gestational age, receipt of labor or postpartum medications potentially altering memory, and labor and postpartum medication type ($p > .05$). Table 13 summarizes demographic and obstetric variables for the final sample (n = 31) and participants lost to follow-up (n = 14). The final sample had a mean age of 26.52 (*sd =6.01*) with 87.1% of the participants reported being married or in a committed relationship. The final sample was diverse in respect to parity (45.2% primiparous,

54.8% multiparous) and education (6.5% less than high school, 32.3% high school graduate/GED, 61.3% college).

Table 13. Phase 3 Demographic and Obstetric Variables of Participants

Demographic Data	**Final Sample**	**Lost to Follow-up**	**Results**
Age (years)	(*n*=31)	(*n*=14)	*t*(43) = 1.33, *p* = .19
Mean	26.52	24.14	
SD	6.01	4.24	
Marital Status	(*n* = 31)	(*n* = 14)	*p* = .66^ (for married/committed and non-married/committed comparison)
Single	12.9% (4)	21.4% (3)	
Married	48.4% (15)	35.7% (5)	
Committed Relationship	38.7% (12)	42.9% (6)	
Divorced	0.00%	0.0% (0)	
Racial/Ethnic Group	(*n* = 31)	(*n* = 14)	*p* = .27^ (for white and non-white comparison
White/Caucasian	77.4% (24)	57.1% (8)	
Hispanic	12.9%(4)	28.6% (4)	
Black/African American	6.5% (2)	7.1% (1)	
Other (>1 ethnic group)	3.2% (1)	7.1% (1)	
Country of Origin	(*n* = 27)	(*n* = 14)	*p* = .54^
United States	88.9% (24)	100.0% (14)	
Outside United States	11.1% (3)	0.0% (0)	
Country of Origin Name	(*n* = 27)	(*n* = 14)	*p* = .54^ (for US and non-US comparison)
United States	88.9% (24)	100.0% (14)	
Cuba	3.70 %	0.0% (0)	
Germany	3.70 %	0.0% (0)	
Columbia	3.70 %	0.0% (0)	
Education Level	(*n* = 31)	(*n* = 14)	*p* = .20^ (for $\leq$ high school/GED and > high school comparison)
Less than high school	6.5% (2)	21.4% (3)	
High school	25.8% (8)	35.7% (5)	
GED	6.5% (2)	7.1% (1)	
Some college	35.5% (11)	21.4% (3)	
College degree	25.8% (8)	14.3% (2)	
Para	(*n* = 31)	(*n* = 14)	$\chi(1) = .35$, *p* = .55
Primipara	45.2% (14)	35.7% (5)	
Multipara	54.8% (17)	64.3% (9)	
Delivery Type	(*n* = 31)	(*n* = 14)	$\chi(1) = .47$, *p* = .49

Demographic Data	Final Sample	Lost to Follow-up	Results
Vaginal	67.7% (21)	57.1% (8)	
Cesarean	32.3% (10)	42.9% (6)	
Infant's Gestational Age	(n = 31)	(*n* = 14)	*t*(43) = -1.60, *p* = .17
Mean	39.2	39.60	
SD	.78	.76	
Labor Medication Altering Memory	(n = 31)	(*n* = 14)	$\chi(1) = 1.93$, *p* = .17
Yes	58.1% (18)	35.7% (5)	
No	41.9% (13)	64.3% (9)	
Labor Medication Type	(n = 31)	(*n* = 14)	*p* = 1.0^ (for received medication and did not receive medication comparison)
IV (only)	22.6% (7)	7.1% (1)	
Epidural (only)	6.5% (2)	35.7% (5)	
IV and epidural	35.5% (11)	28.6% (4)	
Spinal	22.6% (7)	21.4% (3)	
None	12.9% (4)	7.1% (1)	
Postpartum Medication Impact Memory	(n = 31)	(*n* = 14)	$\chi(1) = .90$, *p* > .05
Yes	41.9% (13)	57.1% (8)	
No	58.1% (18)	42.9% (6)	
Postpartum Medication Type	(n = 31)	(*n* = 14)	*p* = .75^ (for received medication and did not receive medication comparison)
Oral	3.2% (1)	0.0% (0)	
IV (only)	35.5% (11)	42.9% (6)	
Epidural (only)	6.5% (2)	0.0% (0)	
IV and epidural	3.2% (1)	14.3% (2)	
Spinal	0.0% (0)	0.0% (0)	
None	51.6% (16)	42.9% (6)	
Labor or Postpartum Medication Impact Memory	(n = 31)	(*n* = 14)	*p* = .52^
Yes	83.9% (26)	71.4% (10)	
No	16.1% (5)	26.8% (4)	

^Fisher's Exact Test results

The observer collected data and self-reported MITS responses for delivery events subscale items were explored and found no outliers or missing data. MITS responses were dichotomized as described in Table 5 and then analyzed using McNemar Chi-Square. Results are

summarized in Table 14 and 15. No statistical difference ($p < .05$) was found between observer collected data and self-reported data supporting women's ability to accurately self-report data on the delivery events subscale. The results did not vary by delivery type (See Table 15; $p \geq .13$).

Table 14. Phase 3 Results of Observed and Self-Reported Score

Item (No.)	**Observed Score (n=31) % (*n*)**	**Reported Score (n=31) % (*n*)**	**McNemar Chi-Square**
When was the first time you saw your baby after the birth? (1)			χ= 1.00 ($p > .05$)
< 10 min	100.0% (31)	100.0% (31)	
When was the first time you touched him/her after the birth? (2)			χ= .50 ($p > .05$)
< 10 min	9.7 (3)	3.2 (1)	
$\geq$ 10 min	90.3 (28)	96.8 (30)	
How old was your baby the first time you held him/her in your arms? (3)			χ=.38 ($p > .05$)
< 10 min	25.8 (8)	16.1 (5)	
$\geq$ 10 min	74.2 (23)	83.9 (26)	
When was the first time you fed your baby? (5)			χ=.75
< 1hour	25.8 (8)	19.4 (6)	($p > .05$)
$\geq$ 1 hour	74.2 (23)	80.6 (25)	
Which statement best reflects your baby's first feeding? (6)			χ= 1.00 ($p >. 05$)
Breast	80.6 (25)	80.6 (25)	
Bottle	19.4 (6)	19.4(6)	
Which statement best reflects what your baby was doing during the first hour after the birth? (7)			χ=.35 ($p > .05$)
With mom	51.6 (16)	61.3 (19)	
Not with mom	48.4 (15)	38.7 (12)	
Which statement best reflects the amount of times you held your naked or shirtless baby next to your bare chest (skin-to-skin) during the first hour after the birth? (8)			χ=.38 ($p > .05$)
Provided skin-to-skin	64.5 (20)	74.2 (23)	
Did not provide skin-to-skin	35.5 (11)	25.2 (8)	
During the first hour after the birth, where was your baby? (9)			χ= 1.0 ($p >. 05$)
In mom's room all/most of the time	73.5 (29)	96.8 (30)	
In mom's room some of the time	6.5 (2)	3.2 (1)	

Table 15. Phase 3 Results of Observed and Self-Reported Scores by Delivery Type

Item (No.)	**Vaginal Observed Score (n = 21) % (*n*)**	**Vaginal Reported Score (n = 21) % (*n*)**	**McNemar Chi-Square**	**Cesarean Observed Score (n = 10) % (*n*)**	**Cesarean Reported Score (n = 10) % (*n*)**	**McNemar Chi-Square**
When was the first time you saw your baby after the birth? (1)			$\chi = 1.00$ (p>.05)			$\chi = 1.00$ (p >.05)
<10 min	100.0 (21)	100.0 (21)		100.0 (10)	100.0 (10)	
When was the first time you touched him/her after the birth? (2)			$\chi = .50$ (p>.05)			$\chi = 1.00$ (p > .05)
< 10 min	90.5 (19)	100.0 (21)		90.0 (9)	90.0 (9)	
≥ 10 min	9.5 (2)	0 (0)		10.0 (1)	10.0 (1)	
How old was your baby the first time you held him/her in your arms? (3)			$\chi = .50$ (p>.05)			$\chi = 1.00$ (p > .05)
< 10 min	85.7 (18)	95.2 (20)		50.0 (5)	60.0 (6)	
≥ 10 min	14.3 (3)	4.8 (1)		50.0 (5)	40.0 (4)	
When was the first time you fed your baby? (5)			$\chi = .29$ (p>.05)			$\chi = .50$ (p > .05)
< 1 h	66.7(14)	85.7 (18)		90.0 (9)	70.0 (7)	
≥ 1 h	33.3 (7)	14.3 (3)		10.0 (1)	30.0 (3)	
Which statement best reflects your baby's first feeding? (6)			$\chi = 1.00$ (p>.05)			$\chi = 1.00$ (p > .05)
Breast	71.4 (15)	71.4 (15)		100.0 (10)	100.0 (10)	
Bottle	28.6 (6)	28.6 (6)		0 (0)	0(0)	
Which statement best reflects what your baby was doing during the first hour after the birth? (7)			$\chi = 1.00$ (p>.05)			$\chi = .13$ (p > .05)
With mom	57.1 (12)	57.1 (12)		30.0 (3)	70.0 (7)	
Not with mom	42.9 (9)	42.9 (9)		70.0 (7)	30.0 (3)	

Item (No.)	Vaginal Observed Score (n = 21) % (*n*)	Vaginal Reported Score (n = 21) % (*n*)	McNemar Chi-Square	Cesarean Observed Score (n = 10) % (*n*)	Cesarean Reported Score (n = 10) % (*n*)	McNemar Chi-Square
Which statement best reflects the amount of times you held your naked or shirtless baby next to your bare chest (skin-to-skin) during the first hour after the birth? (8)			χ =.38 (p>.05)			χ= 1.00 (p > .05)
Provided skin-to-skin	57.1 (12)	71.4 (15)		80.0 (8)	80.0 (8)	
Did not provide skin-to-skin	42.9 (9)	28.6 (6)		20.0 (2)	20.0 (2)	
During the first hour after the birth, where was your baby? (9)			χ = 1.0 (p > .5)			χ= 1.00 (p >.05)
In mom's room all/most of the time	100.0 (21)	100.0 (21)		80.0 (8)	90.0 (9)	
In mom's room some of the time	0 (0)	0 (0)		20.0 (2)	10.0 (1)	

Phase 4

Phase 4 evaluates the reliability and validity of the MITS. Data collection is on-going with results from an interim data analysis reported here.

The sample for the interim analysis described here uses data from two sources to create a combined sample for analysis of 113 women. The first source are the 82 women who delivered at one of the three hospital study sites, expressed an interest in participating, and returned the MITS four weeks postpartum. These women are from an on-going study with an anticipated total enrollment of approximately 200 women. This study was designed to address Phase 4 aims and

currently there are 316 women who expressed interest in participating. The 82 women represent 31.1% of the 264 women eligible for participation at this point in time. It is expected that approximately 155 women will be available for the final analysis from this first source as more women become eligible and respond, assuming the current response rate is maintained. The second source is the 31 women who delivered at one of the three hospital study sites and returned the MITS four weeks postpartum. These women were recruited during Phase 3 of this multiphase study.

Demographic characteristics for the sample used in these analyses are presented in Table16. This sample had a mean age of 27.7 (*sd* = 6.11) years. The sample was diverse with respect to parity (50.4 % primiparus, 49.6 % multiparous), delivery type (66.4% vaginal, 33.6% cesarean, and education (56.6% high school graduate or less, 43.4% college graduate). The sample was predominately White (75.2% White, 24.8% non-White). Of the 113 women, 79.6% of the women breastfed during the hospital stay. See also Table 16 for additional demographic information.

Table 16. Phase 4 Demographic and Obstetric Variables of Participants

Demographic	**Variable**
Age (years)	(*n* = 111)
Mean	27.7
SD	6.11
Marital Status	(*n* = 113)
Single	10.6% (12)
Separated	0.9% (1)
Married	62.8% (71)
Committed Relationship	25.7% (29)
Divorced	0.0% (0)
Racial/Ethnic Group	(*n* = 113)

Demographic	**Variable**
White/Caucasian	75.2% (85)
Hispanic	15.0% (17)
Black/African American	6.2% (7)
Haitian	0.9% (1)
American Indian	0.9% (1)
Other (>1 ethnic group)	1.8% (2)
Country of Origin	(*n* = 108)
United States	88.9% (96)
Outside United States	11.1% (12)
Country of Origin Name	(*n* = 108)
United States	88.9% (96)
Canada	1.2% (1)
Columbia	0.9% (1)
Cuba	0.9% (1)
Dominican Republic	0.9% (1)
Jamaica	0.9% (1)
Germany	0.9% (1)
Guatemala	0.9% (1)
Lebanon	0.9% (1)
Puerto Rico	2.8% (3)
Spain	0.9% (1)
Education Level	(*n* = 113)
Less than high school	5.3% (6)
High school	15.0% (17)
GED	7.1% (8)
Some college	29.2% (33)
College degree	43.3% (49)
Para	(*n* = 113)
Primipara	50.4% (57)
Multipara	49.6% (56)
Psychiatric Disorder in Past Year	(*n* = 113)
Yes	4.4% (5)
No	68.1% (77)
Unknown *(Phase 3 participants)*	27.4% (31)
Postpartum Depression History	(*n* = 113)
Yes	2.7% (3)
No	70.0% (79)
Unknown *(Phase 3 participants)*	27.4% (31)

Demographic	**Variable**
Psychiatric Disorder in Past Year OR Postpartum Depression History	(*n* = 113)
Yes	5.3% (6)
No	67.3% (76)
Unknown *(Phase 3 participants)*	27.4% (31)
Delivery Type	(*n* = 113)
Vaginal	66.4% (75)
Cesarean	33.6% (38)
Infant's Gestational Age	(*n* = 111)
Mean	39.42
SD	.79
Infant's Gender	(*n* = 113)
Male	47.8% (54)
Female	52.2% (59)
Breastfeeding at Hospital	(*n* = 113)
Yes	79.6% (90)
No	20.4% (23)
Breastfeeding at 4 Weeks	(*n* = 111)
Yes	41.4% (46)
No	30.6% (34)
Unknown *(Phase 3 participants)*	37.9 (31)

Total MITS Scale Results

Item level descriptive statistics are presented in Appendix G. Of the 35 MITS items, 27 were skewed (skew >|1 .0|). Note: Consistent with the recommendations of Norris and Aroian (2004) and Enders and Bandalos (1999), these items were not transformed.

Adequate internal consistency was found at the scale level (α= .89). The mean item-total correlation was .41 (range .04-.63). Of the 35 MITS items, 4 (11.4%) did not correlated with at least three other items and 11 items (34.4%) were found to have item-total correlations less than .30, arguing against treating MITS items as a single total scale measure.

Three separate analyses were conducted with random sampling of items to create halves (parts) for a split-half reliability approach to analyzing internal consistency as recommended by Pett et al. (2003) when the sample for analysis does not provide a minimum of 10 participants per item. Results using this approach argued for internal consistency at the total scale level. See the estimates of internal consistency reliability (α = .79-81) and simple split-half correlations (*r* = .83 - .88) provided in Table 17.

Table 17. Phase 4 Split-Half Internal Consistency Reliability Results at the MITS Total Scale Level

Analysis Number	**Part 1 α (n = 18)[1]**	**Part 1 α (n = 17)**	**Mean α for Parts**	**Correlation Between Parts (*r*)**
Analysis 1	.80	.81	.81	.83
Analysis 2	.75	.84	.80	.83
Analysis 3	.81	.77	.79	.88

[1] Part halves are not equivalent in size due to the total pool of scale items being an odd number (35 items).

Delivery Events Subscale Results

Item Characteristics and Internal Consistency Reliability

Item level descriptive statistics are presented in Table 18. 0f the 8 delivery events subscale items, 5 were skewed (> |1.0|). Adequate internal consistency was found at the delivery events subscale level (α = .78). The mean item-correlation was .39 (range .15 -.66). Two items did not correlate at greater than .30 with at least three other items, suggesting these items may be problematic in the factor analysis.

Only one of the 8 items was found to have an item-total correlation of less than .40. This item (item #6) measured how the infant was fed the first time (method and caregiver). However, this item correlated with item #8 (skin-to-skin contact; *r* = .35), and item #5 (time the mother

first fed her infant; $r = 20$), suggesting the item may be capturing some aspects of the infant feeding experience. Hence, this item #6 was retained in the subscale until additional construct validity was completed in the factor analysis.

Table 18. Phase 4 Descriptive Statistics for the Items on the Delivery Events Subscale

Item Description (No.)	**n**	**Mean (sd)**	**Median (range)**	**Skew**	**Item-total correlation**	**Number of items that correlate with this item >|.30|**	**α if item deleted**
When was the first time you saw your baby after the birth? (1)	113	3.89 (.39)	4 (2-4)	-3.87	.46	2	.78
When was the first time you touched him/her after the birth? (2)	113	3.74 (.50)	4 (2-4)	-1.78	.66	6	.72
How old was your baby the first time you held him/her in your arms? (3)	113	3.54 (.67)	4 (1-4)	-1.36	.62	5	.73
When was the first time you fed your baby? (5)	110	2.65 (.75)	3 (1-4)	-.11	.47	4	.76
Which statement best reflects your first feeding? (6)	112	3.57 (.81)	4 (1-4)	-1.82	.15	1	.80
Which statement best reflects what your baby was doing during the first hour after the birth? (7)	111	3.28 (.82)	4 (1-4)	-.66	.53	5	.74
Which statement best reflects the amount of times you held your naked or shirtless infant next to your bare chest (skin-to-skin) during the first hour after the birth? (8)	113	1.95 (.99)	2 (1-4)	.73	.48	5	.75
During the first hour after the birth, where was your baby? (9)	113	3.76 (.59)	4 (1-4)	-2.60	.48	4	.74

Factor Analysis

Bartlett's test of sphericity was significant ($p < .001$) and the Kaiser-Meyer-Olkin measure of sampling adequacy (> .78) supported use of factor analysis. Scree plots were obtained and suggested a one or two factor solution. The minimum desired threshold for factor loadings was set at greater than or equal to the absolute value of .30 to support the factor structure (Pett et al., 2003).

Multiple exploratory factor analyses (EFA) methods were conducted using various extraction and rotation methods to explore a one or two factor solution with and without item #6 (*how the infant was first fed).* The most conceptually logical factor structure that emerged was a two factor solution using a principal component extraction and varimax rotation. This analysis, which included item #6 (*how the infant was first fed*), produced factor loadings with minimal cross loadings and explained 59.29% of the total variance. The two factors identified were named *Taking In* and *Taking Control* with Cronbach's' alpha values .79 and .65, respectively. Two items (items #5 and #9) cross loaded on both factors. As recommended by Pett et al. (2003), items that load on multiple factors were evaluated for the strength of which they loaded on each factor but the ultimate decision on which factor to place the item was conceptual. Table 19 presents the two-factor solution and reflects these decisions.

Table 19. Phase 4 Factor Loadings from the Rotated Factor Structure Matrix for the Delivery Events Subscale: Principal Component Factoring with Varimax Rotation

Delivery Events Subscale Item	**Factors**	
	1	**2**
When was the first time you touched him/her after the birth? (2)	**.90**	.16
When was the first time you saw your baby after the birth? (1)	**.81**	.23
How old was your baby the first time you held him/her in your arms? (3)	**.81**	-.02
During the first hour after the birth, where was your baby? (9)	**.49**	.40
Which statement best reflects your first feeding? (6)	-.27	**.74**
Which statement best reflects the amount of times you held your naked or shirtless infant next to your bare chest (skin-to-skin) during the first hour after the birth? (8)	.20	**.71**
Which statement best reflects what your baby was doing during the first hour after the birth? (7)	.29	**.69**
When was the first time you fed your baby? (5)	.35	**.54**

Note: Underlined values indicate a double loading on two factors. Loadings highlighted in bold indicate the factor on which the item was placed.

Postpartum Events Subscale Results

Item level descriptive statistics are presented in Table 20. 0f the 7 postpartum events subscale items, 2 items were skewed (> |1.0|). The mean item-correlation was .21 (range .19 - .50). Only one item (10%) correlated with at least three other items at greater than .30 and only one item (14.2%) had an item-total correlation greater than .40 suggesting that the items within the subscale are measuring distinctly different events. Cronbach's alpha for these items as a group was low ($\alpha = .58$) which is consistent with this pattern of findings. The lack of subgroups of postpartum events subscale items correlating with three or more other items argues against factor analysis because it indicates a lack of shared covariation among subsets of scale items. Consistent with this observation, the Kaiser-Meyer-Olkin measure of sampling adequacy was low (.55) and did not support use of factor analysis.

Table 19. Phase 4 Descriptive Statistics for the Items on the Postpartum Events Subscale

Item Description (No.)	**n**	**Mean (sd)**	**Median (range)**	**Skew**	**Item-total correlation**	**Number of items that correlate with this item >|.30|**	**α if item deleted**
Which statement best reflects the general location of your baby while hospitalized? (10)	113	3.65 (.50)	4 (2-4)	-.88	.50	3	.46
Which statement best reflects the general location of your baby during the day?(11)	113	3.87 (.34)	4 (3-4)	-2.19	.35	1	.52
Which statement best reflects the general location of your baby during the night time?(12)	113	3.73 (.45)	4 (3-4)	-1.03	.27	1	.55
Which statement best reflects the general location of your baby during medical procedures?(13)	113	3.37 (.66)	4 (1-4)	-.95	.19	1	.57
Which statement best reflects how your infant was fed while hospitalized?(14)	112	2.97 (1.18)	3 (1-4)	-.74	.29	2	.54
Which statement best reflects the amount of time you held your infant naked or shirtless next to your bare chest (skin-to-skin) while hospitalized(15)	113	2.56 (1.10)	3 (1-4)	-.21	.34	2	.52
Which statement best reflects your baby's activity while hospitalized(16)	112	2.82 (.74)	3 (1-4)	-.25	.14	1	.59

Delivery Affective Subscale Results

Item Characteristics and Internal Consistency Reliability

Item level descriptive statistics are presented in Table 21. 0f the 10 delivery affective subscale items, 8 items were skewed (> |1.0|). Internal consistency for the delivery affective subscale level was high ($\alpha = .85$). Of the 10 items, 8 items (80%) were found to have an item-total correlation of at least .40 and the mean item-total correlation was .56 (range .35 -.70). All 10 items correlated at greater than .30 with at least three other items, but no pairs of items had intercorrelations consistent with multicollinearity ($r > .80$) arguing for retaining all items (Pett et al, 2003).

Table 20. Phase 4 Descriptive Statistics for the Items on the Delivery Affective Subscale

Item Description (No.)	**n**	**Mean (sd)**	**Median (range)**	**Skew**	**Item-total correlation**	**Number of items that correlate with this item >|.30|**	**α if item deleted**
Positive/Negative (4a)	111	4.82 (.45)	5 (3-5)	-2.54	.65	6	.83
Happy/Sad (4b)	110	4.87 (.41)	5 (3-5)	-3.39	.62	7	.84
Clear/Confused (4c)	110	4.43 (.91)	5 (1-5)	-1.84	.35	3	.86
Relaxed/tense (4d)	109	4.02 (1.04)	4 (1-5)	-1.00	.67	9	.83
Good/Bad(4e)	109	4.69 (.63)	4 (2-5)	-2.08	.61	8	.84
Comfortable/Painful (4f)	110	4.08 (.97)	3 (1-5)	-.78	.36	3	.86
Attached/Detached (4g)	110	4.67 (.67)	3 (2-5)	-2.00	.47	4	.85
Safe/Frightened (4h)	110	4.61 (.74)	5 (2-5)	-1.81	.59	7	.84
Calm/Overwhelmed (4i)	109	3.96 (1.15)	4 (1-5)	-.74	.59	6	.84
Relieved/Worried (4k)	110	4.50 (.88)	5 (1-5)	-1.84	.70	7	.83

Factor Analysis

Bartlett's test of sphericity was significant ($p < .001$) and the Kaiser-Meyer-Olkin measure of sampling adequacy (.89) supported use of factor analysis. Scree plots were obtained and suggested a one to three factor solution. Multiple EFA methods were conducted using various extraction and rotation methods to explore a one, two, and three factor solution. The most conceptually logical factor structure that emerged was a two factor solution using a principal component extraction and varimax rotation with minimal cross loadings. This explained 57.93% of the variance. The two factors identified, *Feelings At Delivery* and *Delivery Concerns,* were found to have good Cronbach's alpha values .81 and .80, respectively. Table 22 presents the two-factor solution.

Table 21. Phase 4 Factor Loadings from the Rotated Factor Structure Matrix for the Delivery Affective Subscale: Principal Component Factoring with Varimax Rotation

Delivery Affective Subscale Item	**Factors**	
	1	**2**
Positive/Negative (4a)	**.79**	.23
Attached/Detached (4g)	**.74**	.03
Happy/Sad (4b)	**.73**	.26
Good/Bad (4e)	**.73**	.23
Relaxed/Tense (4d)	**.63**	.41
Comfortable/Painful (4f)	**.48**	.13
Safe/Frightened (4h)	.17	**.87**
Relieved/Worried (4j)	.37	**.77**
Calm/Overwhelmed (41)	.31	**.70**
Clear/Confused (4c)	.02	**.67**

Note: Underlined values indicate a double loading on two factors. Loadings highlighted in bold indicate the factor on which the item was placed.

Postpartum Affective Results

Item Characteristics and Internal Consistency Reliability

Item level descriptive statistics are presented in Table 23. 0f the 10 postpartum affective subscale items, all 10 items were skewed (> |1.0|). Internal consistency for the postpartum affective subscale level was good (α = .92).The mean item-total correlation was .69 (range .55 - .78). All 10 items had an item-total correlation of at least than .40. All 10 items correlated at greater than .30 with at least three other items, but no pairs of items had intercorrelations consistent with multicollinearity (r > .80) arguing for retaining all items (Pett et al, 2003).

Table 22. Phase 4 Descriptive Statistics for Delivery Affective Subscale

Item Description (No.)	**n**	**Mean (sd)**	**Median (range)**	**Skew**	**Item-total correlation**	**Number of items that correlate with this item >|.30|**	**α if item deleted**
Positive/Negative (17a)	112	4.89 (.36)	5 (3-5)	-3.64	.76	9	.91
Happy/Sad (17b)	112	4.88 (.40)	5 (3-5)	-3.63	.75	9	.91
Relaxed/tense (17c)	111	4.82 (.71)	5 (2-5)	-2.54	.75	9	.91
Satisfied/Dissatisfied (17d)	111	4.81 (.45)	5 (3-5)	-2.54	.73	9	.91
Good/Bad(17e)	110	4.83 (.47)	5 (3-5)	-2.76	.77	9	.91
Comfortable/Painful (17f)	111	4.48 (.82)	5 (2-5)	-1.40	.57	8	.92
Attached/Detached (17g)	111	4.86 (.38)	5 (3-5)	-2.56	.55	7	.92
Safe/Frightened (17h)	111	4.76 (.62)	5 (2-5)	-3.03	.78	9	.90
Calm/Overwhelmed (17i)	111	4.32 (.91)	5 (1-5)	-1.34	.58	8	.92
Relieved/Worried (17j)	111	4.50 (.83)	5 (2-5)	-1.54	.70	9	.91

Factor Analysis

Bartlett's test of sphericity was significant ($p < .001$) and the Kaiser-Meyer-Olkin measure of sampling adequacy (.89) supported use of factor analysis. Scree plots were obtained and suggested a one or two factor solution. Multiple EFA methods were conducted using various extraction and rotation methods to explore a one or two factor solution. The most conceptually logical factor structure that emerged, a one factor solution using maximum likelihood extraction, had a significant solution ($\chi(35) = 109.9$, $p < .001$). This explained 58.09% of the variance. Table 24 presents the one-factor solution.

Table 23. Phase 4 Factor Loadings from the Factor Matrix for the Postpartum Affective Subscale: Maximum Likelihood Extraction

Postpartum Affective Subscale Item	**Factors**
Good/Bad(17e)	.82
Happy/Sad (17b)	.82
Safe/Frightened (17h)	.81
Positive/Negative (17a)	.81
Satisfied/Dissatisfied (17d)	.78
Relaxed/Tense (17c)	.76
Relieved/Worried (17j)	.72
Attached/Detached (17g)	.59
Calm/Overwhelmed (17i)	.57
Comfortable/Painful (17f)	.57

Known Groups Testing Results

The interim data analysis presented here includes the results from known groups testing performed on the two variables of feeding type and mode of delivery. A post hoc power analysis was also performed to determine the minimum sample size needed for the analyses addressing

the feeding type and mode of delivery known groups testing. Known groups testing could not be performed for the third variable, central nursery availability, because no participants in the interim analysis sample reported this experience.

Results are reported for known groups testing conducted at the subscale or factor level depending on the number of factors previously identified for a given subscale. The only exception is the postpartum events subscale. Previous results argued for treating these items as single item measures. However, concerns about Type I error argued for using the sum of responses on this measure as a subscale score. Hence, this subscale was treated as if it had a single factor structure in the known groups testing.

Feeding Type

Results for known group testing based on feeding type are reported in Table 25. All group differences were in the predicted direction with higher scores for mother-infant dyads who breastfed than for mother-infant dyads who bottle fed. However, only group differences for the events subscales were substantive and statistically significant ($p <$ 001). A post hoc power analysis on the means and standard deviations from the interim analysis and the between-groups comparison effect size observed for feeding type (d = .50) indicated a sample size of 45 adequate to have statistical power at the recommended alpha of .05 and beta of .80.

Table 24. Phase 4 Results of the Known Groups Hypotheses by Feeding Type

	Breast Fed		**Bottle Fed**		
Scale/Subscale	**n**	**Mean (sd)**	**n**	**Mean (sd)**	**Test**
Delivery Events	90	3.38 (.41)	23	2 99 (.33)	(t(111) = 4.15, p < 001)*
Postpartum Events	90	3.40 (.32)	23	2.81 (.31)	(t(111) = 8.08, p < 001)*
Delivery Affective	90	4.47 (.51)	21	4.41 (.53)	(t(109) = .47, p = .64)
Postpartum Affective	90	4.47 (.51)	23	4.41 (.54)	(t(111) = -1.04, p = .30)

*Denotes $p < .05$

Mode of Delivery

Results for known groups testing based on mode of delivery are reported in Table 26. All group differences were in the predicted direction with higher scores for mother-infant dyads who experienced a vaginal birth than for mother-infant dyads who experienced a cesarean birth. Group differences were substantive and statistically significant ($p < .01$) for three of the four subscale scores. The post hoc power analysis on the effect size for mode of delivery (d = .75), indicated a sample size of 156 are needed to obtain statistical power at the recommended alpha of .05 and beta of.80. Therefore, the sample size of approximately 200 women anticipated for the final analysis will be adequate to obtain statistical power.

Table 25. Phase 4 Results of Known Groups Hypotheses Testing by Mode of Delivery

	Vaginal		**Cesarean**		
Scale/Subscale	**n**	**Mean (sd)**	**n**	**Mean (sd)**	**Test**
Delivery Events	75	3.41 (.33)	38	3.07 (.49)	($t(111) = 4.10$, $p < 001$)
Postpartum Events	75	3.30 (.32)	38	2.25 (.34)	($t(111) = 8.08$, p .67)
Delivery Affective	75	3.41 (.33)	38	3.07 (.49)	($t(111) = 4.04$, $p < .001$)*
Postpartum Affective	75	4.47 (.33)	38	4.53 (.59)	($t(111) = 2.73$, $p = .01$)*

*Denotes $p < .05$

CHAPTER 5: DISCUSSION

This multiphase study provided the foundation for establishing the reliability and validity of the MITS. The rigorous content validation and readability testing resulted in enhancements to the study instrument. The content validation among expert judges in Phase 1 was essential to validate the core set of items identified by the PI as important to the construct of mother-infant togetherness. Phase 2 allowed expansion of the panel to include postpartum women resulting in retention of items that the previous panel had identified as having borderline relevance to the construct of mother-infant togetherness. Phase 3 substantiated women's ability to recall the timing and occurrence of togetherness interventions in the often chaotic and often medicated childbirth experience, arguing for women's ability to self-report their experience of togetherness which is essential to evaluate interventions to promote togetherness.

Although the results from Phase 4 are interim and therefore tentative, they provide preliminary psychometric evidence for construct validity. Adequate internal consistency was found at delivery events, delivery affective, and postpartum affective subscale level. The items on the delivery affective subscale were highly intercorrelated in this sample. However, the issue of redundancy was explored during the Phase 2 interviews with postpartum women. Participants were asked to provide input regarding the conceptual differences of the adjective pairs as several appeared to be measuring similar affective states, particularly the items of *good/bad, happy/sad,* and *positive/negative*. During the interviews, the theme emerged that the negative adjective (*bad, negative, sad)* of the bipolar pair were measuring distinctly aspects of the affective experience. The negative adjective of the bipolar pairs are less common in this sample and removal would result in the inability to measure them when they do occur in a future sample.

Factor analysis identified two-factor solutions for the delivery events and delivery affective subscale supporting multiple dimensions of the construct of mother-baby togetherness immediately after delivery. The delivery affective subscale factor analyses provided additional evidence regarding retention of two of the items (item 4b- *happy/sad*, item #4d *clear/confused*) which had marginal content validity (CVI = .75) in Phase 2 analyses. These items had factor loadings on their respective factor greater than .66 in Phase 4 analyses. This supported retention of these items.

Factor analysis identified a one-factor solution for the postpartum affective subscale. This analysis provided additional evidence regarding retention of two the items (item #4d *relaxed/tense*, item #4j *calm/overwhelmed*) which had marginal content validity (CVI = .75) in Phase 2 analyses. These items had factor loadings ($\geq$.63) supporting retention of these items.

The results from the factor analysis on the postpartum events subscale assessed the items on this subscale to be unique, singular, heterogeneous items that did not correlate well with other items, and was supported by the lack of internal consistency reliability (α = .58). This presents measurement challenges for traditional statistical methods to establish adequate construct validity at the scale level using methods based on item homogeneity (Ferketich, 1991). Nevertheless, the results are conceptually logical given the nature of what the items are measuring (occurrence/intensity of specific events in time). These findings argue that each item on the postpartum events subscale should be treated as a separate and distinct item. However, the final analysis needs to replicate this lack of consistency before a final determination of how to best treat these items can be made.

The results from the interim known group testing provided preliminary support for construct validity. All group differences were in the predicted direction based on feeding type

and mode of delivery. The events subscales were more sensitive to differences in feeding type as compared to the affective subscales. This is conceptually logical given that the events subscales contain several items assessing the infant feeding experience. The affective subscales and delivery events subscale were more sensitive to the mode of delivery. The postpartum events subscale was not sensitive to group differences to the mode of delivery. However, this lack of sensitivity is due to the low-risk nature of the childbirth experience and the consistency in nursing practice at the participating hospitals.

Several issues warrant discussion regarding these findings. Only one women delivering by cesarean delivery participated in the Phase 2 content validation of the affective subscales. Although the emphasis was on selecting a purposive sample of women based on education level and parity, this sampling approach may have overlooked the unique experience of women delivering by cesarean. Another issue with this multi-phase study is the implication of selecting a low-risk postpartum population of women for each phase of the study. By the very nature of the low risk experience, there are fewer variations in intrapartum and postpartum care and fewer negative experiences resulting in less variability of response options by participants. This has implications when statistical techniques rely on adequate variability and continuous level of measurement (Ferketich, 1991; Pett et al., 2003) and may have contributed to the skew observed in many of the MITS items or the failure of participants to use all of the available response options in 23 of the 35 MITS items. For example, the original data analysis plan for Phase 3 using a correlation coefficient had to be replaced with the less rigorous, nonparametric McNemar chi-square test because several items only had one, two, or three response options selected by participants. Having an instrument development and validation sample comprised primarily of women who had positive childbirth experiences did dictate caution in item deletion. Consistent

with Pett et al (2003), items were retained, despite marginal CVIs or low factor loadings due to the possibility that these items reflected rare but important events or experiences with respect to the construct being measured. This rationale justified the retention of items in this study, whereas in other studies they would have been dropped.

Limitations

This research is limited to predominately White and Hispanic women delivering low-risk infants in Southwest Florida. Women from African –American, Creole and Asian racial/ethnic groups were not adequately represented in this multi-phase study. The study also lacked diversity as it related to the childbirth experience and was limited to hospitals providing LDR/LDRP models of care. Therefore, the findings may not be generalizeable to all postpartum women.

Phase 4 interim analyses were underpowered to detect group differences based on mode of delivery. The findings from these analyses are tentative and not generalizeable. The post hoc power analysis on the observed effect size for mode of delivery (d = .75) found that sample of 156 woman are needed to obtain statistical power at the recommended alpha of .05 and beta of.80. This argues that the final analysis involving a sample of approximately 200 women will be adequately powered.

Factor analysis involves multiple techniques and decisions to obtain a parsimonious factor structure. The techniques used in this analysis are those recommended by Pett et al (2003). However, factor analysis is not a precise method of analysis. Rather, it is a sequence of analyses and decisions made by a researcher which ultimately affects the final factor solution Additionally, the factor structure in the final sample may differ from what was reported here with the addition of Hospital D because of differences in obstetrical practices. Therefore it is

important to replicate these factor analysis results with the final sample as well as with additional samples, and to involve other researchers in this attempt.

Implications of Findings

Implications for Future Instrument Development

This study identified several implications for further instrument development. The *Taking Control* factor in the delivery events subscale and the post-partum events subscale were found to have a less than desirable internal consistency, so additional work needs to be done if these finding holds true in the final data analysis. The focus of this work should be on item #6 (*how the infant was first fed)* regarding the infant feeding experience. Given that the *Taking Control* factor remained below the targeted alpha of .70, additional conceptual work needs to be done to explore other dimensions of the factor and infant feeding experience, such as the mother's preference or desire for feeding method. Item # 14 (*how the infant was fed during the remainder of the hospitalization*) in the postpartum events subscale does measure this dimension of the infant feeding experience and warrants consideration for inclusion as an additional item in the delivery events subscale or possible revision of item #6.

Additional work should focus on the postpartum subscales. The interim factor analysis identified a two-factor solution for delivery subscales. However, similar two factor solutions were not found in the in the postpartum subscales. Therefore, it is important to replicate these factor analysis results with the final sample as well as with additional diverse samples. Although factor analysis was not supported for the postpartum events subscale, item #10 (*rooming-in during entire hospitalization*) did correlate with three other items (item #11 *daytime rooming in*, item #*12 night time rooming in*, and item #13 (*location of infant during medical procedures*) at

greater than .30. Item #10 (*rooming in during entire hospitalization*) correlated with item #11 (*daytime rooming in*) and item #12 (*night time rooming in*) at .52 and .57, respectively. This warrants further investigation in the final analysis with possible consideration of dropping item #10 if high correlations remain with items #11 and #12.

The final factor analysis should include control of the variable of preexisting affective disorders. The results of the factor analysis reported here in this sample included women with and without a positive history of postpartum depression and other mental health disorders. Although only 5.5% of the women had a positive history, the final factor analysis should include an additional factor analysis of a sample excluding women with a positive history to control for the impact of preexisting affective disorders on the affective subscales. This analysis should reveal the most clear final factor structure.

Implications for Research

The multiphase study provided the preliminary psychometric evidence for the MITS, a measure which is critical to assessing and altering the levels of togetherness that are essential to promoting optimal infant outcomes. Additionally, findings from Phase 3 demonstrated that women who have received potentially memory altering drugs can accurately recall the timing and occurrence of their togetherness experience. Both the psychometric evidence and findings regarding women's ability to self-report have implications for research regarding the quality of labor and postpartum patient care. For example, women often experience variations in care within the same hospital based on practitioner preferences so obtaining data directly from women is necessary to accurately assess their experience (Nolan & Lawrence, 2009). Phase 3

also provided the methods and procedures other researchers can use to investigate mother's ability to accurately recall other aspects of their childbirth experience.

Completion of Phase 4 is necessary to complete the construct validity testing as proposed in Phase 4 and will provide the foundation for future psychometric testing. This foundation is critical to identify gaps and future research opportunities necessary to continue to develop adequate support for construct validity for the MITS. Additional research should focus on larger, more ethnically/racially diverse samples of women.Women who experienced more negative or high risk childbirth experiences as well as women who have experienced cesarean birth without full sedation will assist in the psychometric evaluation of the MITS, especially with respect to the factor structure and internal consistency reliability. Ultimately, confirmatory factor analysis is needed to validate the factor structure. Confirmatory factor analysis is also needed to explore and detect group differences among ethnic/racial groups.

Implications for Practice

The preliminary results from Phase 4 of this study described the frequency and intensity of togetherness interventions at three different hospitals. The preliminary results from Phase 4 fall short of the recommendations for undisturbed skin-to-skin contact, continuous rooming in, and keeping mothers and infants together as called for in the "2020 Vision" report (Carter et al., 2010). Of the 113 mother-infant dyads in Phase 4 of the study, 103 (92.0%) of the infants were held by their mothers within the first hour of the birth. However, only 49.6% (n = 56) of infants were predominately held by their mothers during the first hour, 27.9% (n = 23) were predominately held by the family, and 20.7% (n = 23) were predominately with the hospital staff for routine care. Continuous rooming in was only experienced by 66.4% (n = 75) of the mother-

infant dyads. These findings are consistent with the Listening to Mothers I and II surveys (Declercq et al., 2002; Declercq et al., 2007). Skin-to-skin contact was identified as an underutilized togetherness intervention. Only 41.6% (n = 47) of the mother-infant dyads experienced skin-to-skin contact during the first hour of the birth and only 23.0% (n = 26) of the mothers reported they frequently provided skin-to-skin contact during the remainder of the hospital stay. This was a sample of predominately breastfeeding dyads (79.6%). These results suggest that skin-to-skin contact is not occurring consistently during breastfeeding and identify the need for staff and patient education on skin-to-skin breastfeeding.

There is paucity of research describing togetherness practices by race/ethnicity (Cuttini et al., 1995, Declercq et al, 2007, Rice, 2000). The MITS has additional implications for practice in that it provides for the assessment of group differences in togetherness practices by race/ethnicity. The MITS can guide future practice by offering a feasible measure of togetherness for which to assess and identify health disparities, so that appropriate action can be taken.

Implications for Policy

This multi-phase study has implications for policy in that it provides preliminary psychometric evidence for a feasible measure of togetherness to evaluate obstetrical delivery care. A feasible measure of togetherness can be used by hospital leadership to evaluate togetherness within their organization and assess vulnerabilities as part of a comprehensive infant abduction program. A feasible measure can also be used to influence The Joint Commission to add mother-infant togetherness as a national hospital performance measure, which would trigger togetherness education for hospital staff. Additionally, national policy can mandate the inclusion of mother-infant togetherness education as part of the comprehensive

prenatal education offered to all pregnant women prior to delivery. Collaborating with the Association of Women's Health, Obstetric, and Neonatal Nurses Association and expert panels of the American Academy of Nursing may be strategic to address policy issues.

Implications for Theory

This multi-phase study offered a new operationalization of the construct of mother-infant togetherness from which to guide theory. This is the first study to operationalize togetherness during the entire hospitalization and to include all known dimensions of the construct. The construct has become less abstract and is now operationalized with the MNMC conceptual framework. Operationalization is necessary to provide the theoretical definitions to guide research and empirical testing on study variables.

This study has made a positive contribution in support of the MNMC conceptual framework as a middle range theory. The revised framework is less abstract and more concrete. The revised framework now includes and describes the relationships between additional constructs. This study has advanced the understanding of the MNMC conceptual framework as a practical, useable theoretical framework for obstetrical research and practice (Smith & Liehr, 2003).

Summary

The findings from this multi-phase study provide preliminary support for the reliability and validity of the MITS and indicate its potential utility for comparative effectiveness and outcomes research on different obstetrical delivery models and interventions supporting mother-infant togetherness. Additional research is needed, particularly research involving larger samples of women and women who have experienced more negative childbirth experiences as

well as women who have experienced Cesarean deliveries without full sedation. Nevertheless, these study findings are promising and address a critical gap in the methodology available for studying obstetrical care delivery models and interventions. Often in obstetrical research, women are sent surveys in the postpartum period without validation of their accuracy (Hodnett et al, 2002; Hodnett et al, 2008; Nolan & Lawrence, 2009). Moreover, prior to this study, no valid, reliable, feasible measures of maternal-infant togetherness exist, despite the centrality of this togetherness to healthy mother-infant transition through the birth and postpartum period.

APPENDIX A: MOTHER-INFANT TOGETHERNESS SCALE (MITS) - FIRST DRAFT

Mother-Infant Togetherness Survey (MITS)

Please check only one answer that best reflects your childbirth experience.

1. When was the first time you **saw** your baby after the birth?

   - ☐ Immediately- within 10 minutes of the birth
   - ☐ 10-59 minutes after the birth
   - ☐ 1-4 hours after the birth
   - ☐ More than 4 hours after the birth

2. When was the first time you **touched** him/her after the birth?

   - ☐ Immediately- within 10 minutes of the birth
   - ☐ 10-59 minutes after the birth
   - ☐ 1-4 hours after the birth
   - ☐ More than 4 hours after the birth

3. How old was your baby the first time you **held** him/her in your arms?

   - ☐ Immediately- within 10 minutes of the birth
   - ☐ 10-59 minutes of the birth
   - ☐ 1-4 hours after the birth
   - ☐ More than 4 hours after the birth

4. Please rate how you were feeling the first time you held your infant by filling-in the circle between each pair of words. You can select one of the five circles.

   Here are a few examples.

   If you were feeling very distracted and could not focus at all on what was happening, you would fill-in the following circle:

   Focused ○ ○ ○ ○ ● Distracted

   If you were feeling somewhat relieved, you would fill-in the following circle:

   Relieved ○ ● ○ ○ ○ Anxious

a. Comfortable	○	○	○	○	○	Painful
b. Positive	○	○	○	○	○	Negative
c. Happy	○	○	○	○	○	Sad
d. Good	○	○	○	○	○	Bad
e. Relaxed	○	○	○	○	○	Tense
f. Dissatisfied	○	○	○	○	○	Satisfied
g. Confused	○	○	○	○	○	Clear
h. Attached	○	○	○	○	○	Detached
i. Frightened	○	○	○	○	○	Safe
j. Overwhelmed	○	○	○	○	○	Calm

5. When was the first time you **fed** your baby?

- ☐ Immediately- within 10 minutes of the birth
- ☐ 10-60 minutes of the birth
- ☐ 1-4 hours after the birth
- ☐ More than 4 hours after the birth

6. Which statement best reflects your infant's first feeding?

- ☐ I offered the breast for my baby's first feeding
- ☐ I provided a bottle for my baby's first feeding
- ☐ My partner or another family member provided a bottle for my baby's first feeding
- ☐ The hospital staff provided the first feeding

7. Which statement best reflects what your baby was doing during the first hour after the birth?

- ☐ My baby was mostly in my arms
- ☐ My baby was mostly in my partner's or family member's arms
- ☐ My baby was mostly with the hospital staff for routine care
- ☐ My baby was mostly with the hospital staff because my baby needed special medical attention

8. Which statement best reflects the amount of times you held your infant naked or shirtless next to your bare chest (skin-to-skin) during the **first hour after the birth**?

- ☐ I held my baby next to my bare chest all the of time
- ☐ I held my baby next to my bare chest most the time
- ☐ I held my baby next to my bare chest some of the time
- ☐ I did not hold my baby next to my bare chest

9. **During the first hour after birth**, where was your baby?

- ☐ My baby was always with me in my room all of the time
- ☐ My baby was with me in my room most of the time
- ☐ My baby was with me in my room some of the time
- ☐ My baby was in the nursery most of the time

Please answer the remaining questions that best describes your hospitalization from approximately 1 hour after the birth until you were discharged from the hospital. Do NOT include events that occurred during first hour after your baby was born.

10. Which statement best reflects the general location of your baby while hospitalized?

- ☐ My baby was with me in my room all of the time
- ☐ My baby was with me in my room most of the time
- ☐ My baby was with me in my room some of the time
- ☐ My baby was in the nursery most of the time

11. Which statement best reflects the general location of your baby **during the daytime**?

- ☐ My baby was with me in my room all of the time
- ☐ My baby was with me in my room most of the time
- ☐ My baby was with me in my room some of the time
- ☐ My baby was in the nursery most of the time

12. Which statement best reflects the general location of your baby **during the night time**?

- ☐ My baby was with me in my room all of the time
- ☐ My baby was with me in my room most of the time
- ☐ My baby was with me in my room some of the time
- ☐ My baby was in the nursery most of the time

13. Which statement best reflects the general location of your baby **during medical procedures,** for example, when the nurses or pediatrician (baby doctor) examined your baby?

- ☐ Medical procedures were performed on my baby in front of me (or a family member) all of the time
- ☐ Medical procedures were performed on my baby in front of me (or a family member) most of the time
- ☐ Medical procedures were performed on my baby in front of me (or a family member) some of the time
- ☐ Medical procedures were NOT performed on my baby in front of me or a family member).
- ☐ I don't know

14. Which statement best reflects how your infant was fed while hospitalized?

- ☐ My baby received only breast milk
- ☐ At my request, my baby received both breast and bottle (formula)feedings
- ☐ At the staff's request, my baby received both breast and bottle (formula) feedings
- ☐ My baby received only bottle feedings (formula)

15. Which statement best reflects the amount of time you held your infant naked or shirtless next to your bare chest (skin-to-skin) while hospitalized?

- ☐ I frequently held my baby next to my bare chest
- ☐ I sometimes held next to my bare chest
- ☐ I rarely held my baby next to my bare chest
- ☐ I did not hold my baby next to my bare chest

16. Which statement best reflects your baby's activity while hospitalized?

- ☐ My baby was mostly in my arms
- ☐ My baby was mostly in my arms or my partner/ family member's arms
- ☐ My baby was in their crib as much as they were being held
- ☐ My baby was mostly with in his/her crib

17. Please rate how you were felt about the interaction you had with your infant while hospitalized by placing an "X" between each pair of words. You can place an "X" on any of the five lines.

a. Comfortable	○	○	○	○	○	Painful
b. Positive	○	○	○	○	○	Negative
c. Happy	○	○	○	○	○	Sad
d. Good	○	○	○	○	○	Bad
e. Relaxed	○	○	○	○	○	Tense
f. Dissatisfied	○	○	○	○	○	Satisfied
g. Confused	○	○	○	○	○	Clear
h. Attached	○	○	○	○	○	Detached
i. Frightened	○	○	○	○	○	Safe
j. Overwhelmed	○	○	○	○	○	Calm

APPENDIX B: POSITIVE EFFECTS OF TOGETHERNESS WITH SUPPORTING EVIDENCE

Positive Effect	Evidence
Maternal	
Anxiety/stress (HPA dysregulation)	(Shiau, 1997; Sostek et al., 1982)
Decreased affectional behaviors	(Bystrova et al., 2009; De Chateau, 1979; De Chateau & Wiberg, 1977; Feldman, Weller, Sirota, & Eidelman, 2003; Field, 1977, 1987; Gathwala & Narayanan, 1991; Grossmann, Thane, & Grossmann, 1981; Hales, Lozoff, Sosa, & Kennell, 1977; Kennell & Klaus, 1979; Klaus & Kennell, 1970; Klaus et al., 1970; Leiderman & Seashore, 1975; Moore et al., 2012; Prodromidis et al., 1995; Sostek et al., 1982)
Decreased lactogenesis	(Bystrova, Widström, Matthiesen et al., 2007; Greenberg et al., 1973; Syafruddin, Djauhariah, & Dasril, 1988)
Delayed recognition of infant cues/sensitivity/responsiveness	(Bystrova et al., 2009; Feldman et al., 2003; Keefe, 1988; McBryde, 1951; Salk, 1970)
Depression/less elevated mood	(Dombrowski et al., 2001; Ludington-Hoe, 2011; McLaren, Kuh, Hardy, & Mishra, 2007; Righetti-Veltema, Conne-Perréard, Bousquet, & Manzano, 1998)
Dissatisfaction with birth experience	(Barnett, 1947; Cottrell & Grubbs, 1994; Cuttini et al., 1995; Greenberg et al., 1973; Jackson, 1948; Janssen et al., , 2000)
Engorgement	(Bystrova, Widström, Matthiesen et al., 2007; Shiau, 1997)
Hormonal regulation	(Buckley, 2004)
Impaired maternal identity (maternal role attainment)	(Flacking, Ewald, Nyqvist, & Starrin, 2006; Gardner & Deatrick, 2006; Mercer & Walker, 2006)
Involutional difficulties	(Gonzales, 1990; Ludington-Hoe, 2011)
Lower maternal competence	(Greenberg et al., 1973; Grossmann et al., 1981; Leiderman & Seashore, 1975; O'Connor et al., 1980)
Lower maternal confidence	(Barnett, 1947; Seashore, Leifer, Barnett, & Leiderman, 1973; Shea, Klatskin, & Jackson, 1952)
Negative emotional responses-distress, guilt, powerlessness, sadness, alienation	(Bialoskurski, Cox, & Hayes, 1999; Erlandsson & Fagerberg, 2005; Hughes & McCollum, 1994; Roller, 2000; Shea et al., 1952)

Consequences	Evidence
Infant	
Awake-sleep state organization	(Ferber & Makhoul, 2004; Keefe, 1988; Ludington, 1990; Ludington-Hoe, 201l)
Cardiopulmonary instability	(Bergman et al., 2004; Burroughs et al., 1978; Lambesis et al., 1979; Ludington-Hoe, 2011; Moore et al., 2012; Nolan & Lawrence, 2009)
Compromised thermoregulation	(Anderson, Lane et al., 1995; Bergman et al., 2004; Britton, 1980; Bystrova et al., 2003; Bystrova, Matthiesen, Vorontsov et al., 2007; Chiu, Anderson, and Burkhammer., 2005; Christensson et al., 1998; Durand et al., 1997; Galligan, 2006; Kennell & McGrath, 2003; Lambesis et al., 1979; Ludington-Hoe, 2011; Nolan & Lawrence, 2009)
Delayed weight gain	(Bystrova, Matthiesen, Widström et al., 2007; Ludington-Hoe, 2011; Salk, 1973; Syafruddin et al., 1988)
Elevated cortisol levels	(Anderson et al., 1997; Anderson, Chang et al, 1995)
Heightened response to pain	(Gray et al., 2000; Kostandy et al., 2008; Ludington-Hoe, 201l)
Impaired neurobehavioral and emotional development	(Ferber & Makhoul, 2004; Field, 1994; Feldman, 2004); Leiderman, Leifer, Seashore, Barnett, & Grobstein, 1973; Ludington-Hoe, 201l; Sostek et al., 1982)
Increased crying duration and frequency	(Christensson et al., 1995; De Chateau & Wiberg, 1977; Keshavarz, Haghighi, & Bolbol, 2010; Kostandy et al., 2008; Lambesis et al., 1979; Ludington-Hoe, 201l; McBryde, 1951; Michelsson et al., 1996; Salk, 1973)
Nosocomial Infections/complications	(Barnett, 1947; Bishop, Cameron, Veenstra, & Barnes, 1979; Flacking et al., 2006; Martin, 1975; McBryde, 1951; Montomgery & Shenk,1949)
Re-hospitalization and illness	(Ludington-Hoe, 201l; Madrid, 2006; O'Connor et al., 1980; Suradi, 1988; Syafruddin et al., 1988)
Sucking (response, strength)	(Anderson, McBride, Dahm, Ellis, & Vidyasagar, 1982; Lambesis et al., 1979; Moore & Anderson, 2007; Righard & Alade, 1990)
Both maternal and infant	
Abandonment/rejection	(Collingwood & Alberman, 1979)
Abuse/neglect	(O'Connor et al., 1980)

Consequences	Evidence
Breastfeeding difficulties (duration, difficulties, number of feedings)	(Bernard-Bonnin et al., 1989; Bystrova, Widström, Matthiesen et al., 2007; Chiu et al., 2005; Chiu, Anderson, & Burkhammer, 2008); DiGirolamo et al., 2001; Elander & Lindberg, 1984; Flacking et al., 2006; Lindenberg et al., 1990; Ludington-Hoe, 201l; Meyer & Anderson, 1999; Mikiel-Kostyra, Mazur, & Boltruszko, 2002; Mizuno, Mizuno, Shinohara, & Noda, 2004; Moore & Anderson, 2007; Moore et al., 2012; Pérez-Escamilla et al., 1994; Pichaipat et al., 1992; Procianoy, Fernandes-Filho, Lazaro, Sartori, & Drebes, 1983; Righard & Alade, 1990; Roller, Meyer, & Anderson, 1999; Shiau, 1997; Suradi, 1988; Waldenstrom & Swenson, 1991; Wright, Rice, & Wells, 1996)
Impaired Attachment/bonding	(Bretherton, Biringen, Ridgeway, Maslin, & Sherman, 1989; Dickerson, 1981; Gathwala & Narayanan, 1991; Kennell & Klaus, 1979; Kennell et al., 1975; Klaus & Kennell, 1970, 1976a, 1976b, 1982; Klaus et al., 1983; Klaus, Kennell, & Klaus, 1995; Leiderman et al., 1973; Leifer, Leiderman, Barnett, & Williams, 1972; Norr et al., 1989; Peterson & Mehl, 1978)
Less verbal and nonverbal communication behaviors	(De Chateau, 1979: Velandia, Mattisen, Uvnäs-Moberg, & Nissen, 2010)
Noncohesive family relationships	(Feldman et al., 2003)

APPENDIX C: DEMOGRAPHIC DATA COLLECTION FORM - FIRST DRAFT

Name: _____ Secondary Contact: _____

Address: _____ Address:_____

_____ _____

Phone (h):_____ Phone (h):_____

Phone (c):_____ Phone (c):_____

[This top section was only included in Phase 3 only]

Mother's Information

1. Your date of birth: ____ / ____ / _____ (month/day/year). Age_____(years)

2. Marital Status (check one):
   - ☐ Divorced
   - ☐ Committed relationship
   - ☐ Married
   - ☐ Separated
   - ☐ Single
   - ☐ Widow

3. What racial/ethnic groups do you belong to (check all that apply)?
   - ☐ African American
   - ☐ American Indian
   - ☐ Asian
   - ☐ Black
   - ☐ Caucasian
   - ☐ Haitian
   - ☐ Pacific Islander
   - ☐ White
   - ☐ Other (please specify):_____
   - ☐ I don't know

4. What is the name of the country where you were born? (please specify)

   _____

5. What is the highest grade of school you completed? (check one)
   - ☐ Less than high school
   - ☐ High school
   - ☐ Some college or associate's degree
   - ☐ Bachelor's degree
   - ☐ Graduate degree

Obstetrical Information

1. Due date: ____ / ____ / _____ (month/day/year)
2. Date of the baby's birth: ____ / ____ / _____ (month/day/year)
3. Delivery type (check one):
   - ☐ Vaginal
   - ☐ Cesarean (surgically through a cut on my abdomen)
4. Baby's gender (check all that apply):
   - ☐ Boy
   - ☐ Girl
5. How do you intend to fed your baby?*
   - ☐ Breast
   - ☐ Bottle (Formula)
   - ☐ Both Breast and Bottle

[*For Phase 2 and Phase 4, the following questions were used to replace Question 5].

5. During your hospitalization, did your baby receive any of his/her feeding with breast milk?
   - ☐ Yes
   - ☐ No
6. At 4 weeks of age, was your baby receiving any of his/her feedings with breast milk?
   - ☐ Yes
   - ☐ No

7. How many times have you been pregnant? _____
8. How many living children do you have? _____

APPENDIX D: INTERVIEW GUIDE

1. Where the instructions easy to understand?
2. What was good about these questions?
3. Are there any questions that you really liked?
4. What was bad about these questions?
5. Are there any questions that you did not like?
6. Are there questions that confused you?
7. Did you understand the meaning of each question?
8. Were there any questions or words you had to read twice or that made you pause? Specifically, medical procedures, skin-to-skin, bottle feedings, formula, heritage.
9. Were the answers appropriate for the questions?
10. What changes can you recommend to make the questions or answers more understandable?
11. Do you think there are any questions I should add?
12. I have been asking a lot of questions, what questions do you have for me?

APPENDIX E: DEMOGRAPHIC DATA COLLECTION FORM - FINAL DRAFT

1. Your Age_____*(years)*

2. Your Date of Birth _____/_____/_____ *(month/day/year)*

[Question 2 was removed from Phase 4 to maintain patient anonymity]

2. Marital Status (check one):

- ☐ Divorced
- ☐ Committed relationship
- ☐ Married
- ☐ Separated
- ☐ Single
- ☐ Widow

2. What racial / ethnic groups do you belong to (check all that apply)?

- ☐ African American
- ☐ American Indian
- ☐ Asian
- ☐ Black
- ☐ Caucasian
- ☐ Haitian
- ☐ Hispanic
- ☐ Pacific Islander
- ☐ White
- ☐ Other (please specify):_____
- ☐ I don't know

4. What is the name of the **country** where you were **born** (such as United States, Mexico, etc)?

*(please specify)*_____

5. What is the highest grade of school you **completed** (check one):

- ☐ Have not completed high school
- ☐ GED
- ☐ High school
- ☐ Some college
- ☐ Associate degree
- ☐ Bachelor's Degree
- ☐ Graduate degree

Medical Information

1. Date of the baby's birth: ____ / ____ / _____ *(month/day/year)*

2. Due date: ____ / ____ / _____ *(month/day/year)*

3. Delivery type (check one):

- ☐ Vaginal
- ☐ Cesarean (surgically through a cut on my abdomen)

4. Baby's gender (sex):

- ☐ Boy
- ☐ Girl

5. During your hospitalization, did your baby receive ***any*** of his/her feeding with breast milk?

- ☐ Yes
- ☐ No

6. At 4 weeks of age, was your baby receiving ***any*** of his/her feedings with breast milk?

- ☐ Yes
- ☐ No

7. How many times have you been pregnant? _____

8. How many living children do you have? _____

9. In the last year, have you been treated or diagnosed with a mental health disorder, such as depression, anxiety disorder, etc? *[added for Phase 4]*

- ☐ Yes
- ☐ No
- ☐ I do not wish to answer

10. Have you ever been treated or diagnosed with postpartum depression? *[added for Phase 4]*

- ☐ Yes
- ☐ No
- ☐ I do not wish to answer

APPENDIX F: MOTHER-INFANT TOGETHERNESS SCALE – FINAL DRAFT

Mother-Infant Togetherness Survey (MITS)

Please check only one answer that best reflects your childbirth experience.

1. When was the first time you **saw** your baby after the birth?

   - ☐ Immediately- within 10 minutes of the birth
   - ☐ 10-59 minutes after the birth
   - ☐ 1-4 hours after the birth
   - ☐ More than 4 hours after the birth

2. When was the first time you **touched** him/her after the birth?

   - ☐ Immediately- within 10 minutes of the birth
   - ☐ 10-59 minutes after the birth
   - ☐ 1-4 hours after the birth
   - ☐ More than 4 hours after the birth

3. How old was your baby the first time you **held** him/her in your arms?

   - ☐ Immediately- within 10 minutes of the birth
   - ☐ 10-59 minutes of the birth
   - ☐ 1-4 hours after the birth
   - ☐ More than 4 hours after the birth

4. Please rate how you were feeling the **first time you held your baby** by filling-in the circle between each pair of words. You can select one of the five circles.

Here are a few examples.

If you were feeling very distracted and could not focus at all on what was happening, you would fill-in the following circle:

Focused ○ ○ ○ ○ ● Distracted

If you were feeling somewhat relieved, you would fill-in the following circle:

Relieved ○ ● ○ ○ ○ Anxious

a. Positive	○	○	○	○	○	Negative
b. Happy	○	○	○	○	○	Sad
c. Confused	○	○	○	○	○	Clear
d. Relaxed	○	○	○	○	○	Tense
e. Good	○	○	○	○	○	Bad
f. Comfortable	○	○	○	○	○	Painful
g. Attached	○	○	○	○	○	Detached
h. Frightened	○	○	○	○	○	Safe
i. Overwhelmed	○	○	○	○	○	Calm
j. Worried	○	○	○	○	○	Relieved

5. When was the first time YOU **fed** your baby?

- ☐ Immediately- within 10 minutes of the birth
- ☐ 10-59 minutes of the birth
- ☐ 1-4 hours after the birth
- ☐ More than 4 hours after the birth
- ☐ I don't know

6. Which statement best reflects your baby's first feeding?

- ☐ I offered the breast for my baby's first feeding
- ☐ I provided a bottle for my baby's first feeding
- ☐ My partner or another family member provided a bottle for my baby's first feeding
- ☐ The hospital staff provided the first feeding

7. Which statement best reflects what your baby was doing **during the first hour after the birth**?

- ☐ My baby was mostly in my arms
- ☐ My baby was mostly in my partner's or family member's arms
- ☐ My baby was mostly with the hospital staff for routine care
- ☐ My baby was mostly with the hospital staff because my baby needed special medical attention

8. Which statement best reflects the amount of time you held your baby naked or shirtless next to your bare chest (skin-to-skin) during the **first hour after the birth**?

- ☐ I held my baby next to my bare chest all the of time
- ☐ I held my baby next to my bare chest most the time
- ☐ I held my baby next to my bare chest some of the time
- ☐ I did not hold my baby next to my bare chest

9. **During the first hour after birth**, where was your baby?

- ☐ My baby was always in the same room as me
- ☐ My baby was in the same room as me most of the time
- ☐ My baby was in the same room as me some of the time
- ☐ My baby was in the nursery most of the time

DIRECTIONS: Please answer the <u>remaining</u> questions that best describes your hospitalization from approximately 1 hour after the birth until you were discharged from the hospital. Do NOT include events that occurred during first hour.

10. Which statement best reflects the general location of your baby **while hospitalized?**

- ☐ My baby was with me in my room all of the time
- ☐ My baby was with me in my room most of the time
- ☐ My baby was with me in my room some of the time
- ☐ My baby was in the nursery most of the time

11. Which statement best reflects the general location of your baby **during the daytime?**

- ☐ My baby was with me in my room all of the time
- ☐ My baby was with me in my room most of the time
- ☐ My baby was with me in my room some of the time
- ☐ My baby was in the nursery most of the time

12. Which statement best reflects the general location of your baby **during the night time?**

- ☐ My baby was with me in my room all of the time
- ☐ My baby was with me in my room most of the time
- ☐ My baby was with me in my room some of the time
- ☐ My baby was in the nursery most of the time

13. Which statement best reflects the general location of your baby **during medical procedures,** for example, when the nurses or pediatrician (baby doctor) examined your baby?

- ☐ Medical procedures were performed on my baby in front of me (or a family member) all of the time
- ☐ Medical procedures were performed on my baby in front of me (or a family member) most of the time
- ☐ Medical procedures were performed on my baby in front of me (or a family member) some of the time
- ☐ Medical procedures were NOT performed on my baby in front of me or a family member.
- ☐ I don't know

14. Which statement best reflects how your baby was fed while hospitalized?

- ☐ My baby received only breast milk
- ☐ My baby received both breast and bottle (formula)feedings because it was what I wanted
- ☐ My baby received both breast and bottle (formula) feedings because the hospital staff recommended this
- ☐ My baby received only bottle feedings (formula)

15. Which statement best reflects the amount of time you held your baby naked or shirtless next to your bare chest (skin-to-skin) while hospitalized?

- ☐ I frequently held my baby next to my bare chest
- ☐ I sometimes held next to my bare chest
- ☐ I rarely held my baby next to my bare chest
- ☐ I did not hold my baby next to my bare chest

16. Which statement best reflects your baby's activity while hospitalized?

- ☐ My baby was mostly in my arms
- ☐ My baby was mostly in my arms or my partner/ family member's arms
- ☐ My baby was in their crib as much as they were being held
- ☐ My baby was mostly with in his/her crib

17. Please rate how you felt about the **involvement (interaction) you had with your baby while hospitalized** by filling-in the circle between each pair of words. You can select one of the five circles.

a. Positive	○	○	○	○	○	Negative
b. Happy	○	○	○	○	○	Sad
c. Relaxed	○	○	○	○	○	Tense
d. Dissatisfied	○	○	○	○	○	Satisfied
e. Good	○	○	○	○	○	Bad
f. Comfortable	○	○	○	○	○	Painful
g. Attached	○	○	○	○	○	Detached
h. Frightened	○	○	○	○	○	Safe
i. Overwhelmed	○	○	○	○	○	Calm
j. Worried	○	○	○	○	○	Relieved

Please feel free to add any comments here:

APPENDIX G: PHASE 4 DESCRIPTIVE STATISTICS FOR SCALE ITEMS IN TOTAL SCALE ANALYSIS

Item Description (No.)	n	Mean (sd)	Median (range)	Skew	Item-total correlation	Number of items that correlate with this item >|.30|	α if item deleted
When was the first time you saw your baby after the birth? (1)	113	3.89 (.39)	4 (2-4)	-3.87	.38	8	87
When was the first time you touched him/her after the birth? (2)	113	3.74 (.50)	4 (2-4)	-1.78	.51	12	.87
How old was your baby the first time you held him/her in your arms? (3)	113	3.54 (.67)	4 (1-4)	-1.36	.40	9	.87
Positive/negative at first holding (4a)	111	4.89 (.36)	5 (3-5)	-3.64	.60	15	.87
Happy/sad at first holding (4b)	110	4.88 (.40)	5 (3-5)	-3.63	.49	15	.81
Clear/confused at first holding (4c)	110	4.82 (.71)	5 (2-5)	-2.54	.24	3	.88
Relaxed/tense at first holding (4d)	109	4.81 (.45)	5 (3-5)	-2.54	.51	15	.87
Good/bad at first holding (4e)	109	4.83 (.47)	5 (3-5)	-2.76	.58	21	.87
Comfortable/painful at first holding (4f)	110	4.48 (.82)	5 (2-5)	-1.40	.32	5	.87
Attached/detached at first holding (4g)	110	4.86 (.38)	5 (3-5)	-2.56	.45	7	.87
Safe/frightened at first holding (4h)	110	4.76 (.62)	5 (2-5)	-3.03	.54	10	.87
Calm/overwhelmed at first holding (4i)	109	4.32 (.91)	5 (1-5)	-1.34	.56	12	.87
Relieved/worried at first holding (4j)	110	4.50 (.83)	5 (2-5)	-1.54	.55	13	.87
When was the first time you fed your baby? (5)	110	2.65 (.75)	3 (1-4)	-.11	.24	4	.88
Which statement best reflects your first feeding? (6)	112	3.57 (.81)	4 (1-4)	-1.82	.19	3	.88
Which statement best reflects what your baby was doing during the first hour after the birth?(7)	111	3.28 (.82)	4 (1-4)	-.66	.23	5	.88
Which statement best reflects the amount of times you held your naked or shirtless infant next to your bare chest (skin-to-skin) during the first hour after the birth? (8)	113	1.95 (.99)	2 (1-4)	.73	.49	8	.87
During the first hour after the birth, where was your baby? (9)	113	3.76 (.59)	4 (1-4)	-2.60	.49	6	.88

Item Description (No.)	n	Mean (sd)	Median (range)	Skew	Item-total correlation	Number of items that correlate with this item >|.30|	α if item deleted
Which statement best reflects the general location of your baby while hospitalized? (10)	113	3.65 (.50)	4 (2-4)	-.88	.14	3	.88
Which statement best reflects the general location of your baby during the day?(11)	113	3.87 (.34)	4 (3-4)	-2.19	.14	1	.88
Which statement best reflects the general location of your baby during the night time?(12)	113	3.73 (.45)	4 (3-4)	-1.03	.04	1	.88
Which statement best reflects the general location of your baby during medical procedures?(13)	113	3.37 (.66)	4 (1-4)	-.95	.14	1	.88
Which statement best reflects how your infant was fed while hospitalized?(14)	112	2.97 (1.18)	3 (1-4)	-.74	.19	3	.88
Which statement best reflects the amount of time you held your infant naked or shirtless next to your bare chest (skin-to-skin) while hospitalized(15)	113	2.56 (1.10)	3 (1-4)	-.21	.44	5	.87
Which statement best reflects your baby's activity while hospitalized(16)	112	2.82 (.74)	3 (1-4)	-.25	.13	2	.88
Positive/negative for remainder of hospitalization (17a)	112	4.89 (.36)	5 (3-5)	-3.64	.50	12	.87
Happy/sad for remainder of hospitalization (17b)	112	4.88 (.40)	5 (3-5)	-3.63	.51	17	.87
Relaxed/tense for remainder of hospitalization (17c)	111	4.82 (.71)	5 (2-5)	-2.54	.61	17	.87
Satisfied/dissatisfied for remainder of hospitalization (17d)	111	4.81 (.45)	5 (3-5)	-2.54	.56	17	.87
Good/bad for remainder of hospitalization (17e)	110	4.83 (.47)	5 (3-5)	-2.76	.56	17	.87
Comfortable/painful for remainder of hospitalization (17f)	111	4.48 (.82)	5 (2-5)	-1.40	.49	13	.87
Attached/detached for remainder of hospitalization (17g)	111	4.86 (.38)	5 (3-5)	-2.56	.48	13	.87
Safe/frightened for remainder of hospitalization (17h)	111	4.76 (.62)	5 (2-5)	-3.03	.63	18	.87
Calm/overwhelmed for remainder of hospitalization (17i)	111	4.32 (.91)	5 (1-5)	-1.34	.48	11	.87
Relieved/worried for remainder of hospitalization (17j)	111	4.50 (.83)	5 (2-5)	-1.54	.63	16	.87

[1] *To clarify: Item-total correlations refer to the correlations for each item to the total scale*

APPENDIX H: UNIVERSITY OF CENTRAL FLORIDA INSTITUTIONAL REVIEW BOARD APPROVAL LETTERS

University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Approval of Exempt Human Research

From: **UCF Institutional Review Board #1**
FWA00000351, IRB00001138

To: **Carol L. Lawrence**

Date: **March 15, 2011**

Dear Researcher:

On 3/15/2011, the IRB approved the following activity as human participant research that is exempt from regulation:

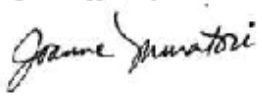
Type of Review:	Exempt Determination
Project Title:	Development of an Instrument to Measure Early Mother-Infant Separation After Childbirth- Phase 1 & 2.
Investigator:	Carol L Lawrence
IRB Number:	SBE-11-07506
Funding Agency:	
Grant Title:	
Research ID:	n/a

This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these changes affect the exempt status of the human research, please contact the IRB. When you have completed your research, please submit a Study Closure request in iRIS so that IRB records will be accurate.

In the conduct of this research, you are responsible to follow the requirements of the Investigator Manual.

On behalf of Joseph Bielitzki, DVM, UCF IRB Chair, this letter is signed by:

Signature applied by Joanne Muratori on 03/15/2011 01:29:35 PM EST



IRB Coordinator

University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Approval of Human Research

From: **UCF Institutional Review Board #1**
FWA00000351, IRB00001138

To: **Carol L Lawrence**

Date: **December 13, 2011**

Dear Researcher:

On December 13, 2011, the IRB approved the following human participant research until 12/12/2012 inclusive:

Type of Review:	UCF Initial Review Submission Form Expedited Review Category #7
Project Title:	Development of an Instrument to Measure Early Mother-Infant Separation after Childbirth-Phase 3
Investigator:	Carol L Lawrence
IRB Number:	SBE-11-08047
Funding Agency:	Assoication of Women's Health, Obstetric, and Neonatal Nursing(AWHONN)

The Continuing Review Application must be submitted 30days prior to the expiration date for studies that were previously expedited, and 60 days prior to the expiration date for research that was previously reviewed at a convened meeting. Do not make changes to the study (i.e., protocol, methodology, consent form, personnel, site, etc.) before obtaining IRB approval. A Modification Form **cannot** be used to extend the approval period of a study. All forms may be completed and submitted online at https://iris.research.ucf.edu .

If continuing review approval is not granted before the expiration date of 12/12/2012, approval of this research expires on that date. When you have completed your research, please submit a Study Closure request in iRIS so that IRB records will be accurate.

Use of the approved, stamped consent document(s) is required. The new form supersedes all previous versions, which are now invalid for further use. Only approved investigators (or other approved key study personnel) may solicit consent for research participation. Participants or their representatives must receive a signed and dated copy of the consent form(s).

In the conduct of this research, you are responsible to follow the requirements of the Investigator Manual.

On behalf of Sophia Dziegielewski, Ph.D., L.C.S.W., CF IRB Chair, this letter is signed by:

Signature applied by Janice Turchin on 12/13/2011 04:03:03 PM EST

Janice M Turchin

IRB Coordinator

University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Approval of Human Research

From: **UCF Institutional Review Board #1**
FWA00000351, IRB00001138

To: **Carol L. Lawrence**

Date: **June 15, 2012**

Dear Researcher:

On 6/15/2012, the IRB approved the following human participant research until 6/14/2013 inclusive:

Type of Review:	UCF Initial Review Submission Form
Project Title:	Psychometric Evaluation of the Mutual Caregiving Index
Investigator:	Carol L Lawrence
IRB Number:	SBE-12-08490
Funding Agency:	Association of Women's Health, Obstetric, and Neonatal Nurses(AWHONN)
Grant Title:	Hill-Rom Celeste Phillips Maternity Centered Care Research Award ($5,000)
Research ID:	n/a

The Continuing Review Application must be submitted 30days prior to the expiration date for studies that were previously expedited, and 60 days prior to the expiration date for research that was previously reviewed at a convened meeting. Do not make changes to the study (i.e., protocol, methodology, consent form, personnel, site, etc.) before obtaining IRB approval. A Modification Form **cannot** be used to extend the approval period of a study. All forms may be completed and submitted online at https://iris.research.ucf.edu .

If continuing review approval is not granted before the expiration date of 6/14/2013, approval of this research expires on that date. When you have completed your research, please submit a Study Closure request in iRIS so that IRB records will be accurate.

Use of the approved, stamped consent document(s) is required. The new form supersedes all previous versions, which are now invalid for further use. Only approved investigators (or other approved key study personnel) may solicit consent for research participation. Participants or their representatives must receive a copy of the consent form(s).

In the conduct of this research, you are responsible to follow the requirements of the Investigator Manual.

On behalf of Sophia Dziegielewski, Ph.D., L.C.S.W., UCF IRB Chair, this letter is signed by:

IRB Coordinator

APPENDIX I: LEE MEMORIAL HEALTH SYSTEM INSTITUTIONAL REVIEW BOARD APPROVAL LETTERS

LEE MEMORIAL
HEALTH SYSTEM
Cape Coral Hospital
Gulf Coast Medical Center
HealthPark Care Center
HealthPark Medical Center
Lee Convenient Care
Lee Memorial Hospital
Lee Physician Group
Regional Cancer Center
The Children's Hospital
The Rehabilitation Hospital

Institutional Review Committee
636 Del Prado Boulevard
Cape Coral, Florida 33990

Phone: 239-772-6383
Fax: 239-772-6388
Email: pam.fowler@leememorial.org

March 8, 2011 VIA EMAIL

Carol Lawrence, MS, BSN, RNC-OB
Lee Memorial Health System

RE: **Development of an Instrument to Measure Early Mother-Infant Separation after Childbirth**

Dear Ms. Lawrence:

The Lee Memorial Health System Institutional Review Committee met on March 2, 2011, at that meeting the Committee reviewed your request for approval of the above-referenced protocol dated 1-2011, Recruitment Flyer, Nursing Research Council approval letter and the associated informed consent form dated 2-2011. After review and consideration of the information provided, the Committee has voted to approve this protocol for a period of one year from 3-2-2011 through 3-1-2012. If this protocol is to be continued for more than one year, please remember to request yearly reapproval from this committee. Enclosed you will find your approved informed consent form with the stamp that states "Approved by LMHS IRC". Please make copies of the original, stamped informed consent form and use these copies for subjects you enroll into this protocol. The original approved consent form should be placed in your study binder and may be used to make additional copies as needed.

This study is to be conducted within a Lee Memorial Health System facility. As a condition of approval, Lee Memorial Health System requires that a copy of the signed and dated subject consent form be placed in the subject's hospital medical record. This consent should be placed in the subject's medical record prior to any registry enrollment, device/ implant surgery, before any experimental medication is given to the subject (if applicable) or prior to any study related participation from the patient.

The Lee Memorial Health System Institutional Review Committee policy requires reporting of any serious or unexpected adverse event within five days of discovery. This Committee must approve any protocol, informed consent, or research activity changes prior to their implementation. Please be reminded that study renewal is due annually and a final report is required upon study completion. While investigators are sent notices regarding continuing review, it is ultimately the responsibility of the investigator to submit the required information to the committee in sufficient time for review before approval expiration.

The Principal Investigator (PI) is ultimately responsible for the conduct of the research, including ensuring that an investigation is conducted according to the approved protocol and the applicable regulations. The PI is also responsible for protecting the rights, safety, and welfare of the subjects under the investigator's care.

Sincerely,

Pam Fowler, R.N., B.S., CIM
Administrator
Lee Memorial Health System, Institutional Review Committee

LEE MEMORIAL
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Gulf Coast Hospital
HealthPark Care Center
HealthPark Medical Center
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Lee Memorial Hospital
Lee Physician Group
Southwest Florida Regional
Medical Center
The Children's Hospital
The Rehabilitation Hospital

Institutional Review Committee
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Phone: 239-424-3383
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Email: pam.fowler@leememorial.org

December 8, 2011

Ms. Carol Lawrence, MS, BSN, RNC-OB

RE: – Development of an Instrument to Measure Early Mother-Infant Separation after Childbirth – Phase 3

Dear Ms. Lawrence:

The Lee Memorial Health System Institutional Review Committee met on December 7, 2011, at that meeting the Committee reviewed your request for approval of the above-referenced protocol dated 11-8-2011, associated recruitment flyer, mutual caregiving Index, enrollment and data collection forms, NRC approval letter and associated Informed consent form dated 11-2011 After review and consideration of the information provided, the Committee has voted to approve Phase 3 of this protocol for a period of one year, from 12-7-2011 through 12-6-2012. If this protocol is to be continued for more than one year, please remember to request yearly reapproval from this committee. Enclosed you will find your approved informed consent form with the stamp that states "Approved by LMHS IRB". Please make copies of the original, stamped informed consent form and use these copies for subjects you enroll into this protocol. The original approved consent form should be placed in your study binder and may be used to make additional copies as needed.

The Lee Memorial Health System Institutional Review Committee policy requires reporting of any serious or unexpected adverse event within five days of discovery. This Committee must approve any protocol, informed consent, or research activity changes prior to their implementation. Please be reminded that study renewal is due annually and a final report is required upon study completion. While investigators are sent notices regarding continuing review, it is ultimately the responsibility of the investigator to submit the required information to the committee in sufficient time for review before approval expiration.

The Principal Investigator (PI) is ultimately responsible for the conduct of the research, including ensuring that an investigation is conducted according to the approved protocol and the applicable regulations. The PI is also responsible for protecting the rights, safety, and welfare of the subjects under the investigator's care.

Sincerely,

Pam Fowler, RN

Pam Fowler, R.N., B.S., CIM
Administrator
Lee Memorial Health System
Institutional Review Committee

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June 15, 2012

Carol Lawrence MS, BSN, RNC-OB
Nursing Practice Specialist
Project Manager- Interdisciplinary Plans of Care
Interdisciplinary Practice and Documentation
Lee Memorial Health System

RE: Psychometric Evaluation of the Mutual Caregiving Index

Dear Ms. Lawrence:

The Lee Memorial Health System Institutional Review Committee has received your request for review and approval of the revised patient letter and participant demographic form for the above -mentioned protocol.

FDA/DHHS regulations state an expedited review procedure may be used if the item to be reviewed meets the following criteria:

56.110 (b) (2)-minor changes in previously approved research during the period (of one year or less) for which approval is authorized

The Lee Memorial Health System Institutional Review Committee has determined that the revisions requested have met this criterion and are eligible for expedited review. Therefore, after careful consideration of the information provided, approval of the revised patient letter and participant demographic form has been granted.

The Lee Memorial Health System Institutional Review Committee policy requires reporting of any serious or unexpected adverse event within five days of discovery. This Committee must approve any protocol, informed consent, or research activity changes prior to implementation. Please be reminded that study renewal is due annually and a final report is required upon study completion.

Sincerely,

Pam Fowler, R.N., B.S., CIM
Administrator

APPENDIX J: ARNOLD PALMER MEDICAL CENTER INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

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MDACCO FWA # 00000131
ORMC/APMC FWA # 00000384

DATE:	August 29, 2012
TO:	Carol Lawrence, MS
FROM:	Arnold Palmer Medical Center (APMC) IRB
PROJECT TITLE:	[364957-1] Psychometric Evaluation of the Mutual Caregiving Index
REFERENCE #:	12.096.08
SUBMISSION TYPE:	New Project
ACTION:	APPROVED
APPROVAL DATE:	August 29, 2012
EXPIRATION DATE:	August 28, 2013
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category #7

Thank you for your submission of New Project materials for this project. The following items were received:

- Advertisement - Approval Request for Advertisement and/or Study Materials (UPDATED: 08/16/2012)
- Application Form - APMC Expedited- Lawrence signature page (UPDATED: 08/2/2012)
- Application Form - APMC Expedited - Apple signature page (UPDATED: 08/2/2012)
- Conflict of Interest - Declaration - OH Human Research Financial Disclosure Form - Wright (UPDATED: 08/23/2012)
- Conflict of Interest - Declaration - Financial Disclosure Lawrence (UPDATED: 08/23/2012)
- Conflict of Interest - Declaration - OH Human Research Financial Disclosure Form - Lawrence (UPDATED: 08/18/2012)
- Conflict of Interest - Declaration - OH Human Research Financial Disclosure Form - Parsons signature page (UPDATED: 08/16/2012)
- Conflict of Interest - Declaration - OH Human Research Financial Disclosure Parsons (UPDATED: 08/16/2012)
- Conflict of Interest - Declaration - OH Human Research Financial Disclosure Form Lawrence (UPDATED: 08/16/2012)
- Consent Waiver - Waiver of Documentation of Informed Consent - signature page (UPDATED: 08/2/2012)
- Consent Waiver - Waiver of Documentation of Informed Consent (UPDATED: 08/16/2012)
- CV/Resume - Appendix R Wright CV (UPDATED: 08/2/2012)
- CV/Resume - Appendix R Parsons CV (UPDATED: 08/2/2012)

- CV/Resume - Lawrence-CV (UPDATED: 08/2/2012)
- Orlando Health - IRB Application - Orlando Health - IRB Application (UPDATED: 08/2/2012)
- Protocol - Study Protocol dated 7/15/2012 (UPDATED: 08/21/2012)
- Protocol - Appendix P Supervising Faculty's Letter of Support (Norris) (UPDATED: 08/2/2012)
- Protocol - Appendix Q Supervising Faculty's CV (Norris) (UPDATED: 08/2/2012)
- Protocol - Appendix M Reminder Post Card (UPDATED: 08/2/2012)
- Protocol - Appendix L Demographic Form (UPDATED: 08/2/2012)
- Protocol - Appendix K Cover Letter (to serve as consent) (UPDATED: 08/2/2012)
- Protocol - Appendix H UCF IRB Approval Letter for Hospitals A, B, & C (UPDATED: 08/2/2012)
- Protocol - Appendix A Mutual Caregiving Index (UPDATED: 08/2/2012)
- Protocol - Appendix J Advertisement Flyer (UPDATED: 08/21/2012)
- Protocol - Appendix I Advertisement poster (UPDATED: 08/2/2012)
- Training/Certification - Wright NIH Training (UPDATED: 08/23/2012)
- Training/Certification - Wright Citi Training (UPDATED: 08/23/2012)
- Training/Certification - Wright Citi Modules (UPDATED: 08/23/2012)
- Training/Certification - CITI HIPS Training Lawrence (UPDATED: 08/16/2012)
- Training/Certification - Lawrence CITI Research Staff Basic (UPDATED: 08/16/2012)
- Training/Certification - Lawrence CITI training (UPDATED: 08/2/2012)
- Training/Certification - Parsons NIH training (UPDATED: 08/2/2012)

The Arnold Palmer Medical Center (APMC) IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation. The Arnold Palmer Medical Center (APMC) IRB is organized and operates in compliance with DHHS regulations as described in 45 CFR part 46, i.e. The Common Rule, FDA regulations as described in 21 CFR Parts 50 and 56, and guidelines resulting from the International Conference on Harmonisation (ICH) E-6 Good Clinical Practice guidelines as appropriate.

In addition, the Arnold Palmer Medical Center (APMC) IRB operates in compliance with portions of the Health Insurance of Portability Act of 1996 (HIPAA Privacy Rule) that apply to research, as described in 45 CFR Parts 160 and 164 as appropriate.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document. The waiver of the documentation of informed consent is approved under 45CFR 46.117(C) for this project.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others (UPIRSOs) and SERIOUS and UNEXPECTED adverse events must be reported promptly to this committee. Please use the appropriate reporting forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this committee.

This project has been determined to be a Minimal Risk project. Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this

procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of August 28, 2013.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

If you have any questions, please contact Jonathan Lin at 321-841-5895 or jonathan.lin@orlandohealth.com. Please include your project title and reference number in all correspondence with this committee.

Sincerely,

David G. Nykanen, M.D., *Co-Chairman of the APMC IRB*

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Arnold Palmer Medical Center (APMC) IRB's records.

LIST OF REFERENCES

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