Helping Mothers Defend their Decision to Breastfeed

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HELPING MOTHERS DEFEND THEIR DECISION TO BREASTFEED

by

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ABSTRACT

The United States has established breastfeeding as an important health indicator within the Healthy People agenda. Healthy People target goals for breastfeeding initiation, duration, and exclusivity remain unmet. The US Surgeon General's Office reports that lack of knowledge and widespread misinformation about breastfeeding are barriers to meeting Healthy People goals. Breastfeeding mothers are vulnerable to messages that cast doubt on their ability to breastfeed. Very little research has examined specific approaches to help people resist negative messages about health beliefs and behaviors. The objective of this quasi-experimental study was to test an intervention designed to help mothers defend their breastfeeding decisions and resist influences that attempted to persuade them to give formula to their babies. Women attending prenatal breastfeeding classes were recruited and assigned to comparison and intervention groups. The intervention was a board game based on McGuire's inoculation theory of resistance to influence. Controlling for intention to breastfed, intervention and comparison groups were examined for differences in maternal self-efficacy to resist persuasion to give formula and breastfeeding rates for initiation, duration, and exclusivity. Data analyses consisted of analysis of covariance and logistic regression. There was no significant difference between comparison and intervention groups, both groups had high self-efficacy to resist giving formula to their babies; nor were there significant differences regarding breastfeeding initiation, duration and exclusivity. The lack of significant differences may have been influenced by ceiling effects in all of the breastfeeding variables, possibly due to the high socioeconomic level of the sample. The intervention may have worked better in women who were more prone to dissuasive influence, such as those with lower education.

To my husband John, and my children Karen, Jacob, and Scooter.

To all the young mothers who participated in this research.

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CHAPTER ONE: INTRODUCTION

Increasing breastfeeding rates to meet Healthy People 2020 goals has the potential to improve the health and well-being of mothers and babies in the United States. Although breastfeeding initiation rates are high, duration and exclusivity rates remain far below recommended guidelines from the World Health Organization and the American Academy of Pediatrics. The US Surgeon General's Office reports that lack of accurate knowledge and widespread misinformation about breastfeeding are barriers to meeting Healthy People goals. Additionally, individuals who want to follow the guidelines may be unprepared to cope with persuasive oppositional messages about infant feeding from their social network and the infant food industry. Interventions that increase mothers' ability to resist messages that try to persuade them to use formula may increase breastfeeding rates. However, very little research has examined specific approaches to help women resist dissuasive messages and succeed in their infant feeding goals. The inoculation theory of resistance to influence has been used to guide interventions to help people resist persuasive/ dissuasive influences in other contexts and may be a viable approach for increasing breastfeeding behaviors by helping mothers preserve their attitude to avoid formula.

The Inoculation Theory of Resistance to Influence (IT) served as the theoretical framework for the development of a resistance strategy for infant feeding. The aim of this dissertation was to evaluate the efficacy of an IT intervention designed to help women defend their decision to breastfeed and resist persuasion to give formula to their infants. The primary aim of was to evaluate the efficacy of an IT intervention designed to help women defend their decision to breastfeed and resist persuasion to give formula to their infants. The three manuscripts included: 1) The Use of Inoculation Theory to Preserve Positive Health Beliefs; 2)

Helping Mothers Defend their Decision to Breastfeed: An Intervention Study; and 3) Myths and Misinformation about Breastfeeding.

Manuscript number one, The Use of Inoculation Theory to Preserve Positive Health Beliefs, is a both an introduction to the theory and a state of the science review of the use of the theory in a health context. Nursing has not previously applied this well established theory and this article proposes that IT is suitable for nursing to use as a strategy for health promotion and disease prevention efforts. Thus, an analysis of the theory's constructs and applications as well as a systematic appraisal of health-related studies from disciplines other than nursing are presented.

Manuscript number two, Helping Mothers Defend their Decision to Breastfeed: An Intervention Study, reports the results of a controlled trial designed to improve breastfeeding rates. The intervention, based on IT was administered as a game board activity to pregnant women during a prenatal breastfeeding class. It was hypothesized that the intervention would help women cope with influences that would attempt to persuade them to give formula to their infants.

Manuscript number three, Myths and Misinformation about Breastfeeding, reports the findings of a survey administered to determine the prevalence of myths and misinformation about breastfeeding. The study was conducted because there was no comprehensive, empirically-based source to consult regarding commonly misrepresented breastfeeding information. The results of this study were used to develop the intervention administered in manuscript number two.

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CHAPTER TWO: THE USE OF INOCULATION THEORY TO PRESERVE POSITIVE HEALTH BELIEFS

Abstract

Very little research has examined specific approaches to help people resist negative messages about health beliefs and behaviors. One approach to helping people resist persuasion and adhere to therapeutic regimens and health guidelines is the Inoculation Theory of Resistance to Influence (IT). This paper presents an overview of the theory and reviews studies that have applied an inoculation treatment in a health context. Primary research reports of intervention studies based on inoculation theory were identified using electronic database searches, bibliographic mining, and citation searches. Studies from 1992 to 2014 were included in the review. A number of so-called IT studies were excluded from the review because the intervention did not contain the essential constructs of an inoculation treatment - forewarning of impending attack on attitude and individual susceptibility to attitude change, followed by presentation of a weak persuasive argument that is promptly refuted. Only five studies met the selection criteria. The studies were in the following categories: smoking, alcohol, risky sexual behavior, and nutritional advertisements. Across these studies, IT was found to preserve health beliefs but the studies were limited to client populations who are more easily dissuaded, such as adolescents and young adults. Findings suggest that IT holds promise for improving health behavior but more research is needed to determine its impact with other study populations.

The Use of Inoculation Treatment to Preserve Positive Health Beliefs

Maintaining positive health beliefs can help individuals adhere to health guidelines for health promotion or therapeutic regimens for disease prevention and management. Health beliefs are affected by gender, age, ethnicity, agency, values, and other circumstances of individuals.

Health beliefs are also affected by societal influences. People who have positive beliefs about health guidelines and therapeutic regimens may be unprepared for persuasive oppositional arguments by other people in their social network. For example, a pregnant woman may have a positive attitude toward breastfeeding, but may receive advice from individuals in her social network to "Give the baby formula at night and you will get more sleep." This kind of statement may contribute to slippage in the woman's positive attitude toward breastfeeding, and she may then give formula to her baby. Very little research has examined specific approaches to help people resist negative messages about health and health behaviors. One approach to helping people resist persuasion and adhere to therapeutic regimens and health guidelines is the Inoculation Theory of Resistance to Influence (IT). This paper presents an overview of the theory and reviews studies that have applied IT in a health context.

The Inoculation Theory of Resistance to Influence

The Inoculation Theory of Resistance to Influence (IT) was developed in mid-20th century in response to a call to action within the US Department of Defense for scientists to devise a method of training that could foil persuasive harmful influence (Zweiback, 1998). American prisoners of war had been subjected to a rigorous ideological-warfare program of thought reform (brainwashing) developed by Chinese and Korean communists. Many soldiers had had difficulty defending their ideological beliefs, and as their mental defenses were breached, they yielded and cooperated with their captors (Columbia Law Review, 1956; Wubben, 1970). Subsequently, researchers began to explore techniques to help people hold their beliefs more strongly and resist persuasive counter-attitudinal arguments.

Seminal Research

William McGuire developed a theory of resistance to persuasive influence based on recognition that individuals are attracted to information that agrees with their beliefs and they avoid information that disagrees with their beliefs. As a result, individuals are not experienced in defending their beliefs, and their inexperience can mean that individuals are at risk for attitude change if they are confronted with a strong persuasive message. According to IT (McGuire, 1964), individuals can be taught to adhere more strongly to their beliefs and to resist persuasion. Table 1 summarizes the underlying assumptions of IT noted by McGuire.

McGuire's method for guiding individuals to defend their beliefs is called an *inoculation treatment.* The core constructs of inoculation treatment were identified in McGuire's early research as *threat* and *refutational defense.* First, the individual is exposed to a threat. The threat includes a *forewarning* and then a weak *counter-attitudinal argument*. The individual is warned that his or her belief may come under attack and he or she is at risk for attitude change as a result. Following the forewarning, the individual is confronted with a weak counter-attitudinal argument *(*C-AA), which puts forward an attitude in opposition to the person's current attitude or belief. Next comes a *refutational defense* or rebuttal of the C-AA that includes supporting information and evidence to defend the person's original attitude or claim. In the literature, refutational defense is labeled as refutational treatment, refutational pre-treatment, or refutational preemption. Figure 1 portrays a proposed model of IT developed by Natoli (2012) to help women resist persuasion to use formula.

The inoculation treatment provides information and models cognitive behaviors that the individual can use when confronted with a future C-AA. The process is analogous to inoculating against a virus by preexposure to a weakened dose of the virus:

> In the biological situation, the person is typically made resistant to some attacking virus by pre-exposure to a weakened dose of the virus. This mild dose stimulates his defenses to that he will be better able to overcome any massive viral attack to which he is later exposed, but it not so strong that this pre-exposure will itself cause the disease (McGuire, 1964, p. 202).

In a series of experiments, McGuire showed that IT was a viable method to preserve attitude. Findings from these experiments suggest that the inoculation treatment is not only effective when the person is later confronted with the exact same C-AA, but also confers resistance against multiple types of C-AAs (Papageorgis & McGuire, 1961). Findings from the experiments also suggest that a person will be resistant to persuasion if he or she receives the inoculation passively, for example by reading an essay containing the inoculation treatment, or if the person actively participates in developing a defensive refutation. However, actively conferred resistance has greater duration and is more effective against new C-AAs than passive inoculation (McGuire, 1961).

Further Development of the Theory

With 50 years of research using IT, the theory has been refined and expanded by researchers in marketing, communications, psychology, and education. These studies have investigated whether effectiveness varies according to characteristics of the three elements of Aristotle's Model of Communication as described by Ball & Byrnes (1960, p.17): source – message - receiver. The *message* is the information being exchanged between the *source*, who is the originator of the information, and the *receiver* who is the recipient of the information.

Source credibility affects resistance to influence, with participants demonstrating greater effects when the message source is highly credible (An, 2003; Compton, 2005 p. 109). Eroding the credibility of the source of the counter-attitudinal message is thus a useful tactic suggested by Parker, Ivanov and Compton (2011). However, using a peer to as opposed to an authoritative person to deliver the message has not been found to produce significantly different results (Pfau, Van Bockern & Kang, 1992).

An important message characteristic is the strength of the threat. It is generally accepted that the threat needs to be of sufficient strength to motivate participants to protect their beliefs (Compton, 2013 p. 227; McGuire, 1964 p. 210-215). Threat arouses anxiety, which increases retention in a learning situation (Yerkes, 1908; Palethorpe, 2011). However, with too much anxiety there is less learning. Also, too high a level of threat, with weak refutation, may lead to incubation of the counter-attitudinal stance instead of inoculation (McGuire, 1964, p.202). More recently researchers have concluded that forewarning (explicit threat) appears to be more effective than the weak C-AA component (implied threat) (Compton & Ivanov, 2012).

Receiver characteristics that have been shown to moderate the inoculation treatment include attitude valence, gender, affect, ethnicity, self-esteem, and self-efficacy (Pfau, et. al., 2001). Attitude valence is considered a crucial covariate in the analysis of the efficacy of the inoculation treatment (Compton, 2012). Generally, IT bolsters existing attitude, but it was also shown to have a persuasive effect in a study by Wood (2007). Gender, affect, self-esteem and self-efficacy have been inconsistent moderators; age has not been explored. Only one study has examined the effect of an inoculation treatment on ethnicity and that study found that participants from a South Asian American culture responded similarly to participants from mainstream American culture. (Ivanov, Parker, Miller, & Pfau, 2012).

Literature Search

To identify studies that applied IT within a health context, a search of the scholarly literature was conducted using electronic databases and other techniques such as bibliographic mining. Search terms included 'inoculation theory' and variations and truncations of 'health'. Abstracts of the retrieved articles were screened using the following: (1) the phenomenon of study was a health issue, (2) the inoculation treatment was employed as an intervention, (3) a quantitative measure of the impact of the inoculation treatment was reported and (4) the study met the basic assumptions of inoculation theory and implemented the inoculation treatment as put forth by McGuire.

Thirty-five articles were retrieved; 23 studies were excluded in the abstract screening process. Twelve full-text articles were then reviewed for eligibility. Seven were excluded because of lack of adherence to the assumptions and constructs of IT as put forth by McGuire. Figure 2 is the diagram of the search strategy.

Review of Inoculation Theory in a Health Context

Five studies used IT as described by McGuire and met the criteria for review. The health topics investigated included smoking, alcohol, and nutritional advertisements. Inoculation treatments were administered to preadolescents, adolescents, or young adults, usually in a classroom setting. Mode of delivery of the inoculation treatment included video, or text via computer. All of the studies used at least one attitudinal outcome measure. All five studies found the inoculation treatment to be effective in preserving attitude in all or a subsample of study participants. The studies are described in detail below according to the health behaviors that were the focus of the intervention.

Smoking

Pfau, VanBokern and Kang (1992) used a randomized factorial design (3x2) to test the efficacy of an inoculation treatment regarding attitudes toward cigarette smoking. The investigators also explored mechanisms that might influence the effect of the inoculation treatment, including the authority of the message source, use of a booster message, and the moderation of the treatment by gender or self-esteem. The inoculation treatment modality was video. Key outcome measures included attitude toward smoking, attitude toward smokers, likelihood of smoking, and likelihood of resisting smoking.

Participants were 948 adolescents attending an urban middle school in the Midwest who were assigned to one of three experimental groups or a control group. Students' attitude toward smoking was assessed prior to the intervention. The inoculation treatment was operationalized as one of three videos: (1) attitude inoculation featuring a young adolescent spokesperson (peer led), (2) attitude inoculation featuring an adult spokesperson (adult led), and (3) attitude inoculation featuring both adult and adolescent spokespersons.

Each video began with a forewarning that the students' anti-smoking attitude would come under attack by persuasive influences. Each video then raised and refuted a series of C-AAs such as smoking is cool, smoking won't affect me, and experimental smoking won't lead to regular smoking. Some members of each experimental group also received a 'booster' reinforcement video 1 month after the inoculation treatment. In the final phase of the study, participants were presented with an attack argument and attitude assessment surveys were administered to all groups.

Key findings suggested that the inoculation treatment was effective in preventing attitude slippage, but only in students with low self-esteem (p = .001). Presumably, people with low self-

esteem are most vulnerable to counter-attitudinal influences. There were no differences by gender, by the use of a booster, or by message source (adult or peer). In a follow-up study conducted 2 years later (Pfau & Van Brockern, 1994), the inoculation treatment continued to provide moderate protection against attitude slippage in all students who received the treatment (p = .05).

Szabo (2000) used a randomized factorial design (4x2x2x2 and 3x2x2) to test the efficacy of an inoculation treatment regarding attitudes toward cigarette smoking. The investigator explored mechanisms that might influence the effect of the inoculation treatment including the normative appeal of the message (perception of peer approval/disapproval of the message) and the effect of triggering anger during message delivery. The investigator also sought to determine whether the inoculation treatment was moderated by two message receiver characteristics, self-esteem and self-efficacy. The inoculation treatment modality was video. Key outcome measures included intention to smoke and attitude toward smoking and smokers.

Participants were 420 fifth and sixth grade students attending rural and urban Midwestern middle schools. They were assigned to one of three experimental groups or a control group. Students' attitude toward smoking was assessed prior to the intervention. The inoculation treatment was operationalized as one of three videos using the same spokesperson as the message source but messages differed in content: (1) a cognitive appeal message using health-based factual information (i.e., a traditional inoculation treatment), (2) a normative appeal message (containing peer disapproval) using health-based factual information, and (3) a normative appeal message (containing peer disapproval) using information designed to trigger anger.

In the treatment videos, students were warned that peer pressure could change their minds about smoking. The C-AAs included smoking is cool, smoking won't affect me, and

experimental smoking won't lead to regular smoking. Each C-AA was refuted, with supportive information and evidence. Then in the final phase of the study, participants were presented with an attack argument and attitude assessment surveys were administered to all groups.

Prevention of attitude slippage was found to be inconsistent across groups. Traditional inoculation treatment and inoculation with a normative appeal using an anger message were both effective in preventing attitude slippage in rural sixth grade students. Traditional inoculation treatment and normative appeal using a factual message were effective for urban 5^{th} grade students. Self-efficacy moderated resistance; the effect varied with the type of message; anger messages worked best for students with high self-efficacy and happiness messages worked best for students with low self-efficacy. The effect of self-esteem on resistance to smoking was not statistically significant. A small number of students who had negative attitudes toward the desired behaviors showed an increase in their negativity.

Alcohol

Goldbold and Pfau (2000) used a randomized factorial design (3x2) to test the efficacy of an inoculation treatment regarding attitudes toward alcohol use. The authors also explored mechanisms that might influence the effect of the inoculation treatment, including message type (i.e., normative social influence or a traditional inoculation message) and varying the time between treatment and persuasive attack. The inoculation treatment modality was video. Outcome measures included attitude toward alcohol use, perception of peer acceptance of alcohol use, and intention to use alcohol.

Participants were 417 sixth grade students from urban and small towns in the Midwest. Students' attitude toward drinking was assessed prior to the intervention. They then were

assigned to one of the following four experimental groups or one of two control groups: (1) traditional inoculation message with immediate attack, (2) traditional inoculation message with delayed attack, (3) normative social influence inoculation message (peer disapproval) with immediate attack, (4) normative social influence inoculation message (peer disapproval) with delayed attack, (5) control with immediate attack, and (6) control with delayed attack.

Students in the four inoculation treatment groups viewed one of two public service announcement videos. Both began with a warning that peers would try to persuade them that drinking alcohol was okay. The refutational component of the normative social influence inoculation message refuted an argument about the popularity of drinking by stating that fewer adolescents drink than viewers think and their friends would be more likely to avoid them if they drank. The refutational component of the traditional inoculation message presented statistics about adolescent alcohol use and the consequences of adolescent drinking. The groups were then assigned to receive an immediate or delayed attack. Following the attack message, attitude assessment surveys were administered to all groups.

Immediate attack was more effective at preventing attitude slippage than delayed attack ($p < .005$). The normative social influence inoculation message resulted in significantly greater resistance to attitude change than seen in the control groups ($p < .01$). The traditional inoculation treatment message performed less well. The investigators suggested that the information portrayed in the traditional inoculation video may have been interpreted to suggest that adolescent drinking was widespread and therefore acceptable.

Parker, Ivanov and Compton (2011) used a randomized factorial design (3x2) to test the efficacy of an inoculation treatment on attitudes about unsafe sex. Additionally, the study investigated the ability of the inoculation treatment to extend protective effects from the target

behavior, unsafe sex, to another risky behavior, binge drinking. The inoculation treatment modality was written essays. Key outcome measures included attitude toward condom use and attitude toward drinking. Participants were 121 college students in a large Midwestern university. Students were assigned to an experimental or control group and their attitudes toward drinking and condom use were assessed prior to the intervention.

Students in the experimental group were cautioned that they would receive an attack against their positive attitude toward condom use and that they might be vulnerable to the C-AA. Counter-attitudinal arguments included the unavailability of condoms when needed, decrease in sexual pleasure, and ineffectiveness of condoms to protect against HIV and AIDS. Each C-AA was refuted using supporting statements and evidence. In the final phase of the study, participants were presented with an attack argument that supported unsafe sex and binge drinking. Following the attack, attitude assessment surveys were administered.

Participants who received the inoculation treatment demonstrated significantly less attitude slippage regarding condom use than those who did not receive the inoculation treatment ($p < .01$). Also, the students who received the inoculation treatment were cross protected against attitude slippage regarding binge drinking ($p = .01$), demonstrating that the inoculation treatment was effective to extend protection against attitude slippage in "related but experimentally untreated" risky behaviors.

Nutrition

Mason and Miller (2013) used a 2x2 randomized factorial design to test the efficacy of an inoculation treatment in regards to attitudes about nutrition-related advertising claims. The authors also explored mechanisms to influence the effect of the inoculation treatment messages.

The message orientation was either promotion focused or prevention focused. The depth of the message was either shallow and abstract or detailed and concrete. The promotion and prevention focused messages were each combined with an abstract and then a concrete message. The inoculation treatment modality was text essays via computer. The key outcome measure was attitude toward health and nutrition.

Participants were 145 college students from a Midwestern university, who were assigned to one of four experimental groups: (1) promotion-outcome focus with abstract message (2) promotion-outcome focus with concrete message, (3) prevention-outcome focus with abstract message and (4) prevention-outcome focus with concrete message. Students' attitudes toward health and nutrition were assessed prior to the intervention.

One essay was developed for each treatment condition. Students were cautioned that their perception of healthy foods might in fact be faulty and that they might be vulnerable to commercial food advertising appeals. The essays presented C-AAs about taste, cost, and accessibility. A refutational defense was constructed for each of the four treatment conditions. In the final phase of the experiment, students were presented with an attack message and attitude assessment surveys were administered.

Participants who received the prevention focused messages demonstrated significantly more resistance to persuasive attempts than those who received promotion focused messages. Concrete messages generated more resistance to persuasive attempts than abstract messages. The inoculation treatment with strong supporting evidence (prevention focus with a concrete message) was most effective in promoting resistance ($p < .01$). Authors suggested that this type of evidence helped participants be more vigilant in anticipating a C-AA.

Discussion

The literature search identified only five studies that applied inoculation theory to a health issue according to the following principles put forth by McGuire about how the intervention inoculates against dissuasive influence: The target audience is people who hold a positive attitude toward a target behavior and the inoculation treatment includes three components: forewarning, weak counter-attitudinal argument, and defense of the original attitude. The majority of studies to date have not adhered to these core constructs.

In general, the studies included in this review excluded individuals with negative attitudes. Although Szabo (2002) retained participants with negative attitudes, her research found that the small number of students who did hold a negative attitudes were more likely to evidence an increase in negativity toward the desired behavior.

Forewarning and recognition of vulnerability are motivators to resist later counter-attitudinal arguments. In McGuire's studies, participants were forewarned that they could be vulnerable to persuasive counter-attitudinal argument. All six of the studies reviewed here contained implicit threats in the forewarning component and explicit threats in the C-AA issue message portion.

Weaknesses of the six studies included a lack of description of how the fidelity of the implementation phase was ensured and a lack of behavioral measures of the intervention's effectiveness. No study reported data on behavioral outcomes that demonstrated the effectiveness of IT. While attitude can generally predict behavior, behavioral outcome measures provide stronger evidence of the efficacy of inoculation treatment.

Finally, participants in most of the studies included in the review lacked diversity in age and ethnicity and therefore it is difficult to generalize findings. The studies included only

adolescents or young adults and ethnicity was overwhelmingly white. No study had a heterogeneous sample. Like age groups who are more susceptible to peer pressure, people with less education, or those with a collective cultural orientation, like Hispanics populations, may be more vulnerable to dissuasive influence.

Recommendations for Practice and Research

More research is needed to explore the efficacy of IT in populations less vulnerable to social influence than adolescents and young adults. Efforts to explore the efficacy of the inoculation treatment in populations other than Caucasians would be needed to determine IT's utility among minorities and immigrants. Future research should also consider how to gage the threat level needed to provide inoculation and avoid incubation. Finally, novel modalities, such as a game application for mobile phones or a game at a social networking site, are needed to better reach clients.

Conclusion

The inoculation treatment has the potential to be an inexpensive, efficient, and effective approach, at least for some client populations. IT can be used to potentiate existing interventions or be included in existing curricula of health education programs. However, clear guidance is needed regarding operationalization of the core constructs of threat and refutation. In addition, further research is needed to determine whether IT used in health context is effective with groups who may be less vulnerable to attitude slippage, such mature adults, people with high educational levels, and people with an individual rather than collective orientation.

Tables and Figures

The tables and figures referenced in text are shown below.

Table 1. Assumptions of the inoculation theory of resistance to influence

Individuals have beliefs which are common with their culture or community.
Individuals avoid dissonant information and are attracted to supporting information.
Individuals are unpracticed at defending their beliefs.
Individuals are motivated to defend a belief when the belief is threatened.
Individuals inexperienced in defending their beliefs can be guided in the development a defense.
Individuals who have been guided in the development of a defense of their beliefs can develop defensive material when confronted with future challenges to the belief.

Note: Adapted from McGuire: (1964, p.196)

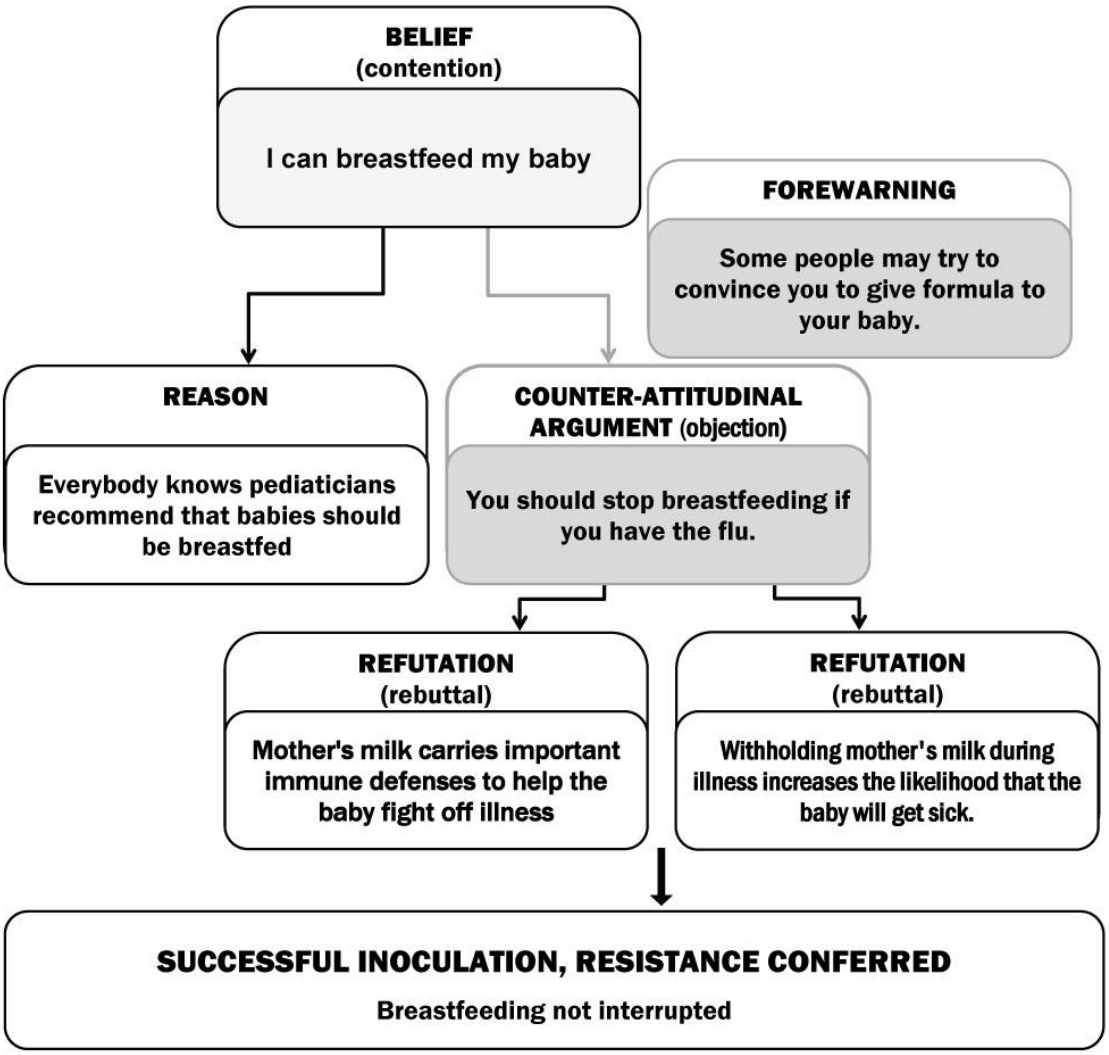

Figure 1. Proposed model of an inoculation treatment applied to breastfeeding beliefs.

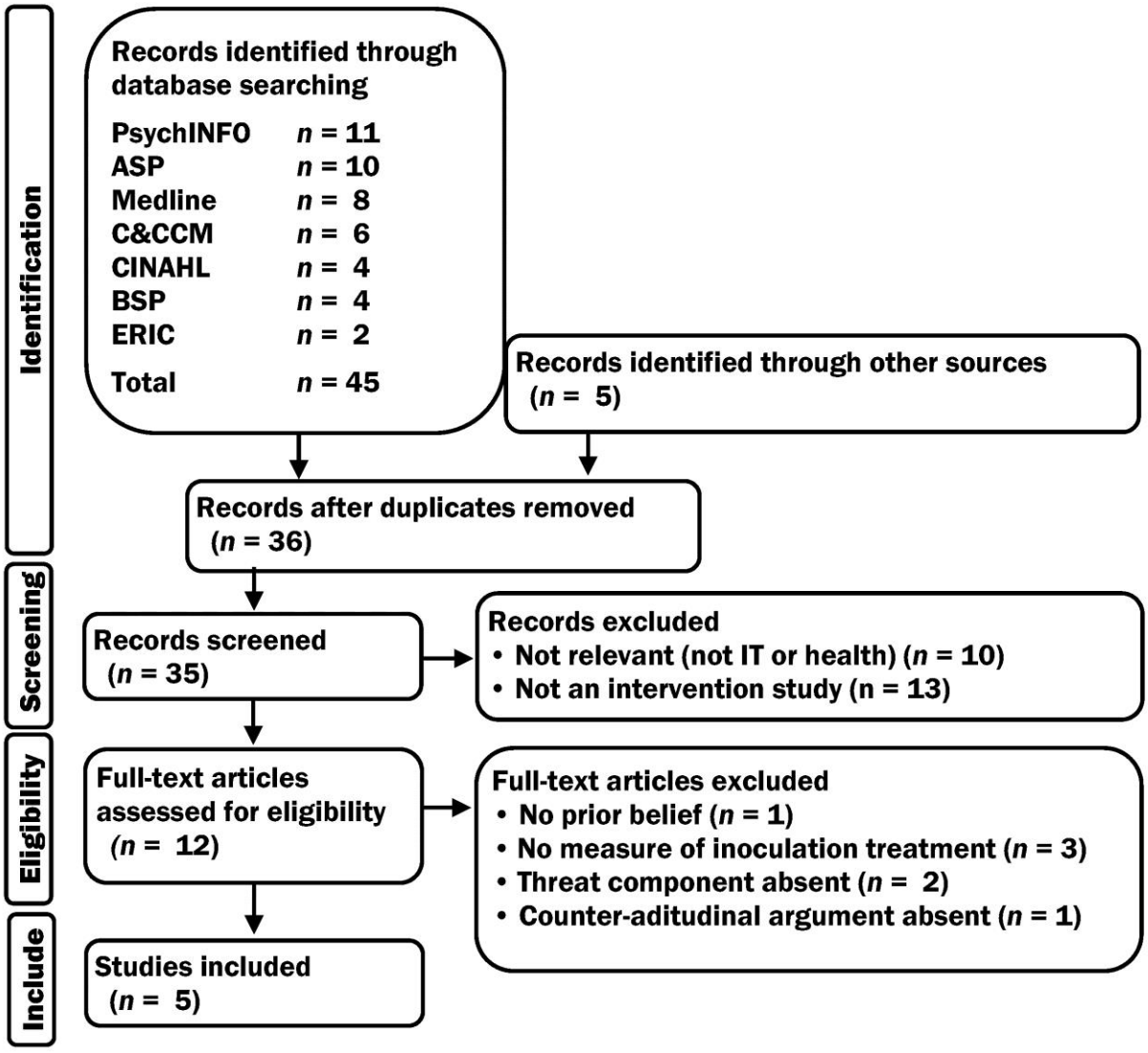

Figure 2. Studies identified, excluded and included in review of inoculation theory in a health context. Flow diagram adapted from the PRISMA statement, (Moher, Liberati, Tetzlaff, & Altman, 2009).

Table 2. Summary of selected studies

Author and date	Research topic, sample and design	Operationalization of inoculation treatment	Key findings
Pfau, 1992,94	Resistance to: smoking Sample: Adolescents (n=1047) Design: Factorial RTC, 2x2	Modality: Video Threat: Forewarning - peer pressure could change their minds about smoking. C-AA issues - smoking is cool, smoking won't affect me, experimental smoking won't lead to regular smoking Refutation: Refutation followed immediately after each C-AA using supportive statements and evidence	No main effect, Interaction effect: Students with low-self-esteem in the inoculation treatment group demonstrated significantly less attitude slippage ($p<.001$) Two year follow-up showed main effects - students receiving the inoculation treatment demonstrated significantly less attitude slippage ($p<.05$)
Szabo, 2000	Resistance to: smoking Sample: Pre-adolescents (n=420) Design: Factorial RCT, 4x2x2x2 and 3x2x2	Modality: Video Threat: Forewarning - students were warned that peer pressure could change their minds about smoking. C-AA issues - smoking is cool, smoking won't affect me, experimental smoking won't lead to regular smoking Refutation: Refutation followed immediately after each C-AA using supportive statements and evidence	Primary; Inoculation can be an effective technique in some populations. Secondary: Self-efficacy was related to resistance to smoking for all students

Author and date	Research topic, sample and design	Operationalization of inoculation treatment	Key findings
Godbold, 2000	Resistance to: alcohol Sample: Adolescents (n=417) Design: Factorial RTC, 3x2	Modality: Video Threat: Forewarning - peers would try to persuade that drinking is okay C-AA: drinking is popular, drinking is okay. Refutation: one actor refuting the drinking message using social influence (drinking is not common among peers) or informational (statistics and information about consequences of adolescent drinking)	Students who received the social influence inoculation message demonstrated significantly less attitude slippage than students in the traditional inoculation or control groups ($p<.01$). Inoculation followed by immediate attack was significantly more effective to prevent attitude slippage than delayed attack occurring at two weeks after inoculation treatment ($p <.005$).
Mason, 2013	Resistance to: Nutrition related advertising claims Sample: College students (n=145) Design: Factorial RTC 2x2	Modality: Text Threat: Forewarning - some foods may not be as healthy as they think , vulnerable to commercial advertisement C-AA: three issues: taste, cost, and accessibility Refutation: Refutation followed immediately after each C-AA using supportive statements and evidence	Prevention outcome focus condition (inoculation) generated more resistance to persuasive attempts ($p<.005$) Concrete linguistic signature generated more resistance to persuasive attempts ($p<.05$) Inoculation treatments using “good fit” fit conditions (prevention focus with concrete appeal) were most successful at countering health and nutrition related advertising claims ($p<.01$).

Author and date	Research topic, sample and design	Operationalization of inoculation treatment	Key findings
Parker, 2013	Resistance to: Unsafe sex, binge drinking Sample: College students (n=121) Design: Factorial RTC, 2x2	Modality: Text essays Threat: Forewarning - challenge of attitude toward condom use; vulnerable to peer pressure. C-AA issues - unavailability of condoms, expense, decreased sexual pleasure, ineffectiveness to protect against HIV and AIDS. Refutation: Refutation followed immediately after each C-AA using supportive statements and evidence	Participants who received the inoculation treatment demonstrated significantly less attitude slippage regarding unsafe sex ($p<.01$), and also were cross protected against attitude slippage regarding binge drinking ($p=.01$)

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CHAPTER THREE: HELPING MOTHERS DEFEND THEIR DECISION TO BREASTFEED: AN INTERVENTION STUDY

Abstract

The objective of this quasi-experimental study was to test an intervention designed to help mothers defend their breastfeeding decisions and resist influences that attempted to persuade them to give formula to their babies.

Women attending prenatal breastfeeding classes from July through December of 2012 at a large urban maternity hospital in the Southeast were recruited and classes were assigned to comparison and intervention groups. The intervention was a board game based on McGuire's inoculation theory of resistance to influence. Controlling for intention to breastfed, intervention and comparison groups were examined for differences in maternal self-efficacy to resist persuasion to give formula and breastfeeding rates for initiation, duration, and exclusivity. Data analyses consisted of analysis of covariance and logistic regression.

There was no significant difference between comparison and intervention groups, both groups had high self-efficacy to resist giving formula to their babies; nor were there significant differences regarding breastfeeding initiation, duration and exclusivity.

The lack of significant differences may have been influenced by ceiling effects in all of the breastfeeding variables, possibly due to the high socioeconomic level of the sample. The intervention may have worked better in women who were more prone to dissuasive influence, such as those with lower education.

Helping Mothers Defend their Decision to Breastfeed: An Intervention Study

Increasing breastfeeding rates to meet Healthy People 2020 goals would result in better health outcomes for mothers and babies (Bartick & Reinhold, 2010; Bartick et. al, 2013; Dieterich, Felice, O'Sullivan, & Rasmussen, 2013; Ip, et al, 2007). Yet, breastfeeding rates of mothers lag behind goals set by the national health-promotion and disease-prevention program, Healthy People 2020 (CDC, 2011). Nearly one quarter of US infants are never breastfed and by the end of the puerperium, about one-third of infants are not receiving any breast milk. Among women who intend to breastfeed, about two-thirds will fail to meet their personal breastfeeding goals (Gregory, Butz, Ghazarian, Gross, & Johnson, 2015; Odom, Li, Scanlon, Perrine & Grummer-Strawn, 2013).

Negative messages about breastfeeding and misconceptions about formula are among the numerous barriers to breastfeeding identified by the US Surgeon General's Call to Action to Support Breastfeeding (2011). Breastfeeding mothers are vulnerable to messages that cast doubt on their ability to breastfeed or lead them to think formula and breast milk are comparable (Larsen, Hall, & Aagaard, 2008; McBride-Henry, 2010). Attitudes from proximal relationships such as supervisors and coworkers, health professionals, friends, and family are key influences that support or discourage breastfeeding (Arora, et al, 2000; Baranowski et. Al, 1983; Clifford & McIntyre, 2007; De Oliveria et al, 2001; Heinig, et al, 2009; Henderson, Kitzinger & Green, 2000; Hong, Callister & Schwart. 2003; Khoury, et al., 2002; Odom, Li, Scanlon, Perrine, & Grummer-Strawn, 2013).

The infant food industry and its sophisticated marketing techniques is another pervasive influence that negatively impacts attitudes towards breastfeeding. Analysis of mass media showed that increases in formula and hand-feeding advertisements lead to declines in

breastfeeding rates (Foss & Southwell, 2006; Frerichs, Andsager, Campo, Aquilino, & Dyer, 2006). Distribution of formula company literature and free samples given out by hospitals and doctor's offices, a key formula marketing strategy, has a significant negative impact on breastfeeding behaviors (Bergevin, Dougherty & Kramer,1983; Donnelly, Snowden, Renfrew, & Woolridge, 2007; US Government Accountability Office (GAO), 2006).

The purpose of this study was to investigate the effect of an intervention to teach women who intend to breastfeed to defend against negative and deceptive messages about breastfeeding. After controlling for intention to breastfeed, the intervention was expected to increase the woman's self-efficacy to resist giving formula to her baby and improve three dimensions of breastfeeding behavior (i.e., initiation, duration, and exclusivity) at two time points (i.e., postpartum while in the hospital and one month later). A secondary objective was to explore women's reasons for supplementing with formula or cessation of breastfeeding. The following hypotheses were tested:

Hypothesis One. Statistically controlling for intention to breastfeed, participants in the intervention group will have higher scores on self-efficacy to resist formula than participants in the comparison group.

Hypothesis Two. Statistically controlling for intention to breastfeed, participants in the intervention group will be more likely than participants in the comparison group to report breastfeeding in the hospital (initiation).

Hypothesis Three. Statistically controlling for intention to breastfeed, participants in the intervention group will be more likely than participants in the comparison group to report breastfeeding at one month (duration).

Hypothesis Four. Statistically controlling for intention to breastfeed, participants in the intervention group will be more likely than participants in the comparison group to report exclusive breastfeeding in the hospital.

Hypothesis Five. Statistically controlling for intention to breastfeed, participants in the intervention group will be more likely than participants in the comparison group to report exclusive breastfeeding at one month.

Theoretical Framework

William McGuire developed the Inoculation Theory of Resistance to Influence (IT) to help individuals learn to adhere more strongly to their existing beliefs and resist dissuasion (McGuire, 1964). IT is an attitude bolstering strategy that assumes individuals may not be practiced in defending beliefs and often do not anticipate that their beliefs will be attacked. However, when individuals are purposefully exposed to mild attacks on their attitudes or beliefs, they develop defenses against subsequent attacks on those attitudes or beliefs. The theory is analogous to inoculating against a virus by pre-exposure to an attenuated dose of the virus.

Specifically, an inoculation treatment is a onetime, two-component intervention that includes both a threat and a refutational defense. The *threat* component has two stages, forewarning and counter-attitudinal argument. During the *forewarning*, individuals are warned that their belief is going to be challenged and that their ability to defend their belief may not be strong enough. During the *counter-attitudinal argument*, the individual's belief is attacked by a dissuasive argument that attempts to change the individual's belief. The threat component arouses anxiety, which prepares individuals for learning and increases attention and retention (Yerkes & Dodson, 1908; Anderson, Revelle, & Lynch, 1989). The *refutational defense*

component repudiates the threat and includes supporting statements. The refutational defense not only provides information, but also models cognitive behavior that the participant can use when confronted with a future dissuasive attack.

A meta-analysis of studies investigating IT found that people who experienced an inoculation treatment were significantly more resistant to future persuasive counterattack messages compared to those who were not inoculated (Banas & Rains, 2010). Researchers have demonstrated the efficacy of IT as a strategy to bolster loyalty to brands (Szybillo & Heslin, 1973), strengthen support for political candidates (Pfau & Burgoon, 1988), protect against attitude change on corporate issues (Burgoon, Pfau, & Birk, 1995), and promote resistance to credit card marketing (Compton & Pfau, 2004). IT has also been applied to health contexts including interventions to discourage alcohol consumption (Duryea, 1982; Godbold & Pfau, 2000; Goldberg, Niedermeier, Bechtel, & Gorn, 2006), discourage cigarette smoking (Pfau & Van Bockern, 1994; Szabo, 2000), discourage risky sexual behavior (Parker, Ivanov, & Compton, 2013) and evaluate nutritional claims made in advertisements (Mason & Miller, 2013). These studies showed that IT has potential to bolster positive health beliefs and help individuals resist dissuasion. However, the health research studies using IT were conducted with adolescents and young adults from primarily European ancestry. Further, published studies have reported impact only on attitudinal outcome measures, not behavioral.

Heretofore, IT has not been used to help women strengthen their determination to breastfeed and resist influences that attempt to persuade them to use formula. This study used a board game activity, based on IT, as an intervention intended to increase breastfeeding initiation, duration, and exclusivity rates as well as enhance the mother's self-efficacy to resist persuasion to give formula to her infant.

Methods

Design and Sample

The study design was quasi-experimental because a randomized design could not rule out the possibility of contamination or diffusion of information about the game board activity from intervention to comparison groups. Additionally, the study took place at a single site, (i.e., Winnie Palmer Hospital for Women and Babies; WPH). The institutional review boards of Arnold Palmer Medical Center (the IRB responsible for research at WPH) and the University of Central Florida both granted permission to conduct the study. Signed informed consent was obtained from participants and they received a debriefing letter explaining the full nature of the study after all data collection was completed. All attendees of the prenatal breastfeeding classes (N = 431) conducted from July through December of 2012 were invited to participate. However, they were included in the data analysis only if they met the following criteria: low-risk, singleton pregnancy, had a telephone, read or spoke English, and they and their infants were free of medical complications before, during, or after birth. The sample size was determined via power analyses using Power Analysis and Sample Size (PASS) software.

Intervention: Breastfeeding Myth Busters Game

The Breastfeeding Myth Busters Game activity, which was the operationalization of the inoculation treatment, was developed in three phases. In Phase I, common myths or misinformation about breastfeeding were identified from the literature. Thirty items of different types of misinformation were developed from themes in literature and included in a survey. In Phase II, professionals (n=81) who work with breastfeeding families were surveyed to assess the prevalence of each type of misinformation item in the survey. The four most common

misinformation issues were as follows: sleep, convenience, milk supply, and regulation of feeding. In Phase III, four refutational *defense cards* and twelve counter-attitudinal argument *myth cards* were developed. The defense and myth cards were assessed for domain clarity, simplicity, and relevance by two human lactation experts. A trial of the game was conducted at a site not affiliated with the study setting to obtain feedback regarding design of the game board as well as ease and length of time for play.

Instruments

Data collection questionnaires and measures were developed for the study. Measures included maternal characteristics and a measure of maternal infant feeding intentions using the Maternal Intention to Breastfeed (MIB) scale. Maternal self-efficacy to resist giving formula to her baby was assessed using the Self-Efficacy to Resist Formula (SERF) scale. Questionnaires about breastfeeding behaviors, reasons for supplementation or cessation of breastfeeding, and screening for inclusion criteria were also developed.

Maternal characteristics included: age, ethnicity, education, family income, closeness with someone who breastfed, previous breastfeeding experience, WIC participation, accompaniment to the prenatal class, and whether the delivery was vaginal or cesarean.

Intention to breastfeed was measured by The Maternal Intention to Breastfeed (MIB) scale. The instrument elicits the strength of participants' intentions regarding breastfeeding and formula use in the hospital, at one month after childbirth, and at five months after childbirth. It is a 6-item, 5-point Likert-type scale with anchors ranging from 1 (*extremely unlikely)* to 5 (*extremely likely)* regarding breastfeeding intention and reverse coded for formula feeding intention. The possible range of scores is from 6 to 30. The Cronbach's alpha coefficient was

0.736 in this study, indicating adequate internal consistency reliability. The MIB is similar to the Infant Feeding Intention (IFI) scale developed by Nommsen-Rivers & Dewey (2009) that measures exclusive breastfeeding and exclusive formula feeding intentions. In psychometric testing of the IFI, the Cronbach's alpha was 0.9.

The Self Efficacy to Resist Formula (SERF) scale was developed specifically for this study and measures the participants' confidence to resist influences that try to persuade to them to give formula to their babies. It is a 6-item, 5-point Likert-type scale with anchors ranging from 1 *(not at all)* sure to 5 *(completely sure).* The possible range of scores is from 6 to 30. The Cronbach's alpha for the SERF tool was 0.64 in this study (n = 267), which is acceptable internal constancy reliability considering the small number of items in the scale (Hair, 2010, p. 91).

Breastfeeding behavior questionnaire. Breastfeeding behaviors were operationalized as follows: initiation was any breastfeeding in the hospital; duration was any breastfeeding at one month; exclusivity was whether the infant received anything other than breastmilk in the hospital and if the infant received anything other than mother's milk in the last 24-hours preceding the one-month postpartum interview. Responses were dichotomous, no or yes.

Reasons for Supplementation or Cessation Breastfeeding was a checklist of the following items: (1) medical indication, baby or mother was sick and couldn't breastfeed (2) perceived milk insufficiency (3) difficulty latching on (4) nipple or breast pain (5) perceived inconvenience such as returning to work or school (6) discouraged by someone, and (7) other, which elicits a write-in response. These options were derived from research that investigated reasons for breastfeeding cessation (Ahluwalia, Morrow, & Hsia, 2005; Li, Fein, Chen & Grummer-Strawn, 2008). If supplementation or cessation of breastfeeding occurred, participants were asked to select as many reasons as were applicable to them.

Screening items asked for information that would disqualify the participant from data analysis according to the inclusion and exclusion criteria of the study.

Research Procedure

All attendees of the prenatal breastfeeding classes completed the maternal characteristic questionnaire and MIB measure immediately before class and received a breastfeeding cape (valued at $12.00) as a thank you gift. Participants attending breastfeeding classes during the first 12 weeks of the recruitment phase were assigned to the comparison group and viewed a breastfeeding video. Participants attending the breastfeeding class during the remaining weeks of the recruitment phase were assigned to the intervention group and played the board game activity. Each activity, watching the video or playing the game, required 20-minutes of class time.

The video viewed by the comparison group repeated standard information that was delivered didactically during class. The intervention group received the following; First, they were given explicit forewarning that more half of women who want to breastfeed would not achieve their desired breastfeeding goals at one month postpartum. It was explained that myths and misinformation about breastfeeding are one type of barrier to women meeting their breastfeeding goals. Next, they were given an example of a myth and a defense against the myth that were different from those included in the game. After giving instruction on how to play the game, intervention participants and the people who accompanied them to class then began to play the board game. Instructions for the game were also posted on an overhead screen.

Each game board allowed for up to six players and up to ten games were played in each class. Each player received a movable game piece marker and a set of defense cards. Players

rolled die and advanced along the colored squares according to the number indicated by the die. Some squares contained directions to draw a myth card. Each group of players then conferred and selected a defense card to refute the myth before the next player's turn. Groups competed to be the first group to have played at least one of each type of defense card, but groups continued to play until all groups had played at least one of each type of defense card.

All participants received two follow-up telephone interviews. The first interview was conducted two-weeks after the breastfeeding class at which time participants completed the SERF measure about their self-efficacy to resist pressure to give formula to their baby. The second interview was conducted about one month after childbirth and three questionnaires were administered: the screening questionnaire which determined eligibility for inclusion in data analysis; the questionnaire about breastfeeding initiation, duration, exclusivity; and the questionnaire that explored reasons for supplementation or cessation of breastfeeding. In addition, participants were asked if their delivery was vaginal or cesarean.

Data Analysis

Data analyses were conducted using SPSS; alpha was set at 0.05 for all tests and significance tests were two-tailed. Maternal characteristics that could potentially affect results (e.g. ethnicity) were analyzed using univariate and bivariate statistics to detect differences between comparison and intervention groups as well as differences between participants who completed and did not complete the study. Missing values comprising less than 5% of the data were imputed using the series mean. SERF scores were strongly negatively skewed and data were transformed using reflect $\log_{10}$ procedure prior to running the ANCOVA (Tabachnick & Fidell, 2007, p.86-87). Analyses of breastfeeding behaviors were conducted using logistic

regressions. The items comprising the list of reasons for supplementation were analyzed using descriptive statistics and write-in responses were coded and summarized.

Results

Sample

The study was conducted from July 2012 through May of 2013. The acceptance rate of attendees (N = 431) was 86%; 306 participants completed the study, and 267 participants met the inclusion criteria for data analysis. Figure 3 is a flow diagram of participant recruitment, allocation to treatment group, and study completion. There were no statistically significant differences regarding participant characteristics between completers and non-completers or between comparison and intervention groups. Table 3 shows the study participant characteristics.

Hypothesis One

Hypothesis one stated that members of the intervention group would have significantly higher mean scores on the SERF measure than members of the comparison group, after controlling for maternal intention to breastfeed. Hypothesis one was not supported; groups did not differ with respect to SERF score $F(1, 241) = 0.001$, $p = 0.975$ when adjusted for MIB. Table 4 presents the ANCOVA results. Homoscedasticity and the linear relationship between SERF $\log_{10}$ and MIB was assessed by visual inspection of a scatter plot; Levine's was used to test homoscedasticity of error variance (p = .508) and it appears these assumptions were met.

Hypothesis Two

Hypothesis two stated that members of the intervention group would have a higher likelihood of breastfeeding in the hospital than members of the comparison group, while controlling for maternal intention to breastfeed. Although a logistic regression was planned for the data analysis, the percentage of participants who breastfed was 100% for both groups. Therefore, no analysis was conducted and the conclusion is that there was no difference between the two groups.

Hypothesis Three

Hypothesis three stated that members of the intervention group would have a higher likelihood of breastfeeding at one month than members of the comparison group. Although a logistic regression was planned for the data analysis, the percentage of participants who breastfed was 96.6% and 94.7% for comparison and intervention groups respectively. Therefore, no analysis was conducted and the conclusion is that there was no difference between the two groups.

Hypothesis Four

Hypothesis four stated that the intervention group would have a higher likelihood of breastfeeding exclusively in the hospital than the members of the comparison group, while controlling for maternal intention to breastfeed. A logistic regression analysis was conducted using maternal intention to breastfeed, treatment group assignment, and the interaction between maternal intention to breastfeed and treatment group assignment as the independent variables. Exclusive breastfeeding in the hospital was the dependent variable. The logistic regression analysis indicated that the hypothesis was not supported; the intervention did not result in

improving exclusive breastfeeding rates in the hospital. These results are displayed in Table 5. Note that the assumptions for logistic regression residual analyses were met, the model was not statistically significant (χ^2 (3, N = 267) = 5.846, p = 0.119), and the area under the ROC curve for the above model was 0.602, which is considered unacceptable.

Hypothesis Five

Hypothesis five stated that the intervention group would have a higher likelihood of breastfeeding exclusively at one month postpartum, while controlling for maternal intention to breastfeed, than the members of the comparison group. A logistic regression analyses was conducted using maternal intention to breastfeed, treatment group, assignment and the interaction between maternal intention to breastfeed and treatment group assignment as the independent variables. Exclusive breastfeeding at one month was the dependent variable. The logistic regression analysis indicated that the hypothesis is not supported; the intervention did not result in improving exclusive breastfeeding rates at one month. These results are displayed in Table 6. Note that the assumptions for logistic regression residual analyses were met, the model was not statistically significant (χ^2 (N = 267) = 5.258, p = 0.154), and the area under the ROC curve for the above model was 0.592, which is considered unacceptable.

Reasons for Supplementation or Cessation of Breastfeeding

Insufficient milk supply was the most frequently reported reason supplementing breastfeeding with formula feeding. Illness in the mother or baby was the second most frequently reported reason for supplementation in the hospital. Difficulty latching the baby was the third most frequently cited reason for supplementation in hospital and the second most frequently reported reason at one month. In addition to the listed items, participants

8Line stated that they were giving formula to help with the baby's digestive process or to help the baby sleep longer at night. Table 7 displays reasons for supplementation and cessation of breastfeeding.

Discussion

Contrary to other studies demonstrating that IT is an effective strategy to help people resist persuasion (Banas & Rains, 2011; Compton & Pfau, 2005), findings from this study did not provide evidence that the inoculation treatment increased self-efficacy to resist formula or increased breastfeeding rates. However, findings from previous studies about reasons for supplementation or cessation of breastfeeding are similar to findings from this study (Ahluwalia, Morrow, & Hsia, 2005; Brand, Kothari, & Stark, 2011; Li, Fein, Chen & Grummer-Strawn, 2008). More specifically, perceived insufficient milk supply, perceived illness, and latch on difficulties were the most frequently reported reasons for supplementation or cessation of breastfeeding.

Several participants told of a reason previously undocumented in the literature, "reflux", in the write-in response section of the Reasons for Supplementation or Cessation of Breastfeeding questionnaire. These participants were supplementing using a "reflux formula", that is, an infant food formulated to treat symptoms of gastroesophageal reflux (GER) such as spitting up. The Internet has commercial sites that discuss GER and many brands of formula claim to help babies' digestive problems. However, GER is a self-limited physiologic phenomenon that occurs in infants irrespective of feeding with breast milk or formula (Lightdale, & Gremse, 2013; Rosen; 2014; Vandenplas, et al., 2009). There is no evidence to support the myth that infant formula is desirable or effective treatment for GER in breastfed infants.

The lack of significant findings in this study may be due to ceiling effects. First, 100% of participants in both the comparison and intervention groups breastfed in the hospital, exceeding HP2020 goals for breastfeeding initiation as well as exceeding state and national rates. The rate of exclusive breastfeeding in the hospital was high as well. In addition, 71% to 72% of the comparison and intervention groups respectively, were exclusively breastfeeding at one month compared to 54% nationally and 45% state-wide (CDC, 2015; Yu, Adams-Thames, & Huang, 2011, p. 153). Second, ceiling effects were observed with SERF scores. Out of a possible score of 30, mean scores were 28.2 for the comparison group and 28.4 for the intervention group.

Sample characteristics, such as age, education, and income, most likely accounted for the high ceiling effects obtained in this study. The mean age was 31 years (SD 4.157), 80% reported a four year college degree or higher, and 75% reported incomes in the fourth quintile or higher (Florida Charts; US Census Bureau). Each of these sample characteristics is associated with higher breastfeeding rates. More specifically, rates of breastfeeding are highest for women over 30-years of age (Brand, Kothari, & Stark, 2011; Jones, J. Kogan, M., Singh, G., Dee, D., & Grummer-Strawn, L., 2011), previous research has shown that college educated women were the only demographic to have reached HP2010 goals, (Forste & Hoffman, 2008), and higher income is associated with increased breastfeeding rates and likelihood of reaching personal breastfeeding goals (Odom, Li, Scanlon, Perrine & Grummer-Strawn, 2013; Thulier & Mercer, 2009).

Additional reasons why IT may not have had the same positive effects in this study as in other studies include differences in the outcome domain and study population and setting. Regarding outcome domain, this study, like other studies, assessed intervention effects on attitude, which in this case was perceived self-efficacy to resist pressure to use formula (i.e., SERF scores). However, this study also investigated behavioral outcomes (i.e. breastfeeding

initiation, duration, and exclusivity). Although attitude was considered to be an adequate outcome measure in many IT studies, Healthy People goals are measured in terms of behaviors, not attitudes**.** It is likely that many intervening variables account for not behaving as intended with regard to breastfeeding.

Regarding study population and study setting, the participants in the study were adults, and behaviors were assessed in real world settings (i.e., hospital and at home). In contrast, previous studies of IT in a health context were conducted among preadolescents, adolescents, and young adults in school settings. The difference in study populations may be particularly relevant. Adults are presumably less influenced by peers or significant others and the majority of the adults in this study reported having a 4-year college degree or higher. Achieving baccalaureate education is the trait that would bestow upon participants an ability to make and defend thoughtful behavioral choices. Historically, the crucial role of the baccalaureate education is to produce graduates who have the ability to think critically, communicate, and solve problems (Miller, 2003).

Another reason IT was not effective in this study may be because dissuasive influence was not the key reason for supplementation or cessation of breastfeeding. More specifically, the item on the questionnaire about reasons for supplementation or cessation of breastfeeding that was designed to elicit dissuasive incidents, "*Others discouraged you from breastfeeding,"* was not frequently selected. It may have been selected if worded differently, such as, "*I was following the advice of someone who told me to give formula*." Some participants did not select the item and but verbally reported that they had been discouraged or told to give formula. For example, a participant reported that a family member repeatedly asked if she was "making

enough milk. This caused her to doubt her ability to make enough milk for her baby and the baby was supplemented with formula.

Limitations

A limitation of the study is that the outcome measures developed for this study have not undergone psychometric evaluation. It may be that the SERF scale would have greater range and not be hampered by ceiling effects if it were used with participants whose breastfeeding rates are similar to the general population. On the other hand, more response options or multiple items may increase the range and variability of the scores. Another limitation is that the study participants were overwhelmingly from the same ethnic and socioeconomic group, therefore generalizability of the study findings is limited.

Recommendations for Clinical Practice

Participant responses about the reasons for supplementation, perceived milk insufficiency, latch-on difficulties, and perceived illness such as an episode of low blood glucose underscore the importance of skilled lactation support for mothers. Healthcare workers who provide care to breastfeeding mothers and infants should have knowledge of recommended protocols for common issues, such as low blood glucose and basic competency to assist mother-baby dyads. Additionally, education should include knowledge of normal infant behavior as regards to feeding, sleep, and consolibility. Continuing education should be mandated to maintain competency and update knowledge. In-hospital assistance from International Board Certified Lactation Consultants (IBCLC) should be readily available for dyads experiencing difficulties such as ineffective latch-on as well as referrals to community based IBCLCs who can continue care after hospital discharge.

Recommendations for Research

Future application of IT in a health context should target lower socioeconomic populations who may have less experience defending their beliefs against dissuasive influences. Myths may be different in other regions of the US or unique to certain groups or populations. As was the case with the myth about reflux, new myths may also emerge and be in need of intervention. Thus, future editions of the game should be updated by including myths that are relevant to the target population. Prior to developing future editions of the game, misinformation and myths about breastfeeding need to be documented by surveying representative samples.

Conclusion

The inoculation theory of resistance to influence was applied in a novel approach as a board game that was administered as an intervention to pregnant women who attended a prenatal breastfeeding class. The intervention activity was intended to equip participants with explicit strategies that could help them resist messages from industry sponsored ads, from staff at primary care offices, from co-workers, or from family members that tempt them to give formula to their babies. There were no significant differences in self-efficacy or breastfeeding behaviors between the comparison and treatment groups. However, ceiling effects were present for both groups and may have precluded finding significant group differences.

Tables and Figures

The tables and figures referenced in text are shown below.

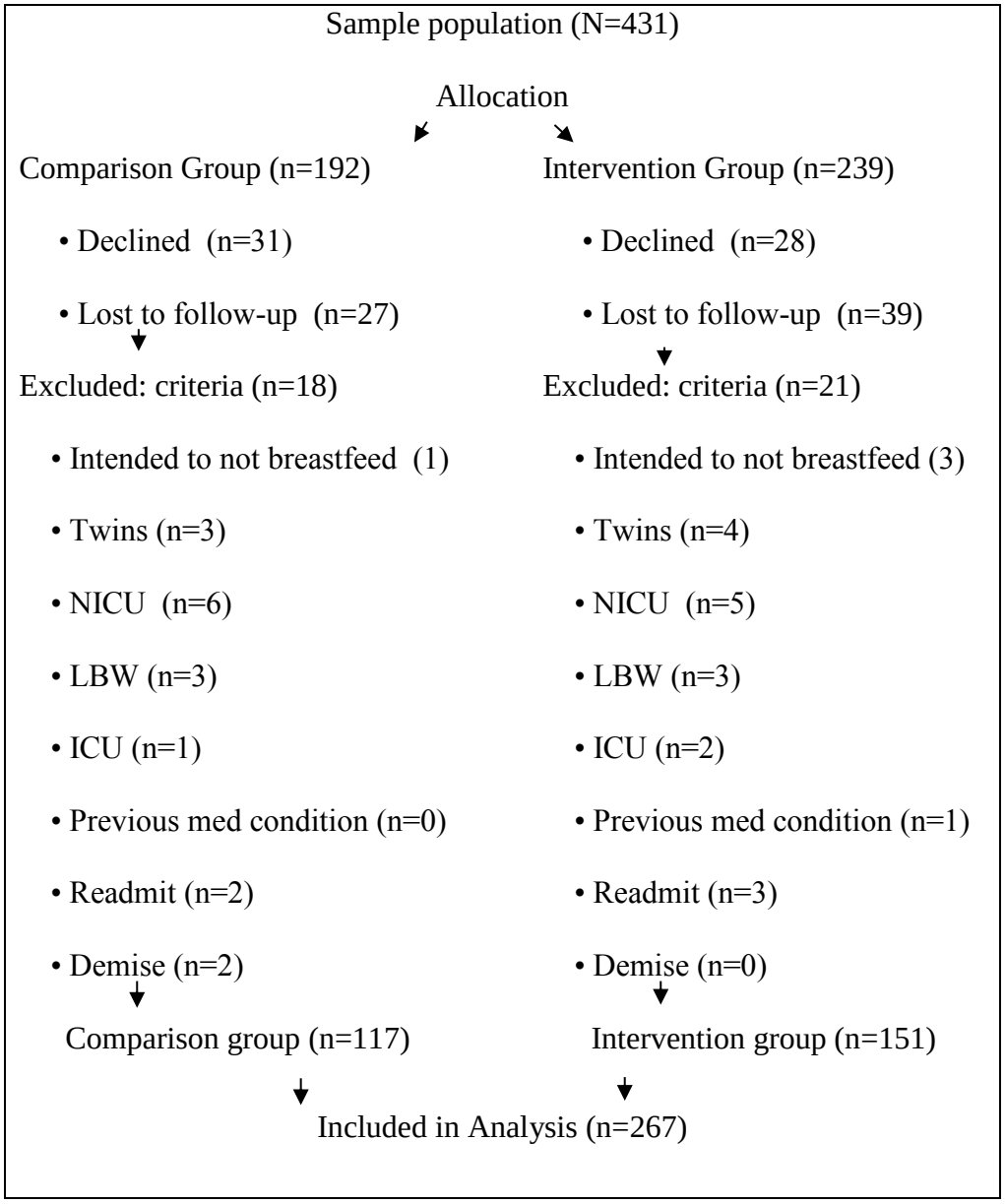

Figure 3. Allocation to treatment group, follow-up, and analysis

Table 3. Sample characteristics by treatment group

	Frequency Distribution	
	Comparison	**Intervention**
Characteristic	**(n = 116)**	**(n = 151)**
Accompanied to class (yes)	74.1%	69.5%
Age	M = 31.4	M = 31.5
	(SD 4.4)	(SD 3.9)
Cesarean delivery rate	34.5%	31.8%
Education $\geq$ 4-year college degree (yes)	75%	84.8%
Ethnicity: White non-Hispanic (yes)	68.1%	63.6%
Family Income $\geq$ $68,000 (yes)	75%	75.5%
Maternal intention to breastfeed score	M= 8.68	M = 8.82
	(SD 2.90)	(SD 2.94)
Previous breastfeeding experience (yes)	4.3%	2%
Someone close breastfed (yes)	92.2%	88.1%
WIC participation (yes)	4.3%	2

Note: Other ethnicities comprised 35.5% as follows: African American 4.9%, Asian 5.2%, Hispanic 19.9%, Undefined 4.5%

Table 4. General linear model analysis of co-variance for self-efficacy to resist formula score by treatment group while controlling for, maternal intention to breastfeed (N = 244)

Variables	Sum of Squares	*df*	Mean of Squares	F-value	p-value
Treatment group	8.345E-5	1	8.345E-5	.001	.975
MIB	2.441	1	2.441	28.535	<.001

Table 5. Logistic regression for exclusively breastfed in hospital while controlling for maternal intention to breastfeed (n = 267)

							95% C.I. for Odds Ratio	
Variables	**B**	**S.E.**	**Wald**	**df**	**Sig.**	**Odds Ratio**	**Lower**	**Upper**
Treatment group	2.162	2.650	0.665	1	0.415	8.865	0.048	1565.019
Maternal intention to breastfeed	0.158	0.078	4.130	1	0.042	1.172	1.006	1.365
Treatment group* Maternal intention to breastfeed	0.091	0.101	0.827	1	0.827	0.913	0.749	1.111
Constant	-2.822	1.375	0.050	1	0.823	0.735		

Table 6. Logistic regression for exclusively breastfed at one month while controlling for maternal intention to breastfeed (n = 267)

							95% C.I. for Odds Ratio	
Variables	**B**	**S.E.**	**Wald**	**df**	**Sig.**	**Odds Ratio**	**Lower**	**Upper**
Treatment group	0.971	2.479	0.154	1	0.695	2.642	0.020	340.745
Maternal intention to breastfeed	0.123	0.093	3.048	1	0.081	1.131	0.985	1.298
Treatment group* Maternal intention to breastfeed	-0.34	0.093	0.136	1	0.712	0.996	0.805	1.160
Constant	-2.378	1.866	1.625	1	0.202	0.093		

Table 7. Reasons for Supplementation or Cessation of Breastfeeding

	Hospital *n* = 61	**At one month *n* = 76**
Mother or baby was sick.	29	10
Not enough milk to satisfy baby.	43	62
Pain in nipples or breasts.	11	10
Prepare to return to work or school.	0	6
Someone discouraged you.	5	4
The baby had difficulty latching on.	24	16
Other	10	7

Note: participants could select more than one item

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CHAPTER FOUR: MYTHS AND MISINFORMATION ABOUT BREASTFEEDING

Abstract

The United States has established breastfeeding as an important health indicator within the Healthy People agenda. Healthy People target goals for breastfeeding initiation, duration, and exclusivity remain unmet. The US Surgeon General's Office (2011), reports that lack of knowledge and widespread misinformation about breastfeeding are barriers to meeting Healthy People goals. This study investigated whether myths and misinformation about breastfeeding that were previously identified as common by lactation experts in three geographical areas are valid in Florida. The myths were compiled into a single survey which was completed by a convenience sample of health care and social service providers who work with pregnant and breastfeeding women in Florida. Findings were that most of the myths previously identified by the lactation experts are still current. The majority of commonly heard myths and misinformation were related to three areas: normal infant behavior, particularly regarding infant sleep and feeding patterns; the adequacy of lactation and abundance of mother's milk supply; and breastfeeding difficulty and convenience. Healthcare and social service providers can use the study findings to develop strategies to refute myths and misinformation and counter them with evidence-based breastfeeding information.

Myths and Misinformation about Breastfeeding

Increasing breastfeeding rates to meet Healthy People 2020 goals has the potential to improve the health and well-being of mothers and babies in the United States. The US Surgeon General's Office reports that lack of accurate knowledge about breastfeeding and widespread misinformation are barriers to meeting Healthy People goals (US Department of Health &

Human Services, 2011). Pregnant and breastfeeding women hear many inaccurate statements about breastfeeding (Hyman & Stanner, 2004; Salud, et al, 2009). Debunking myths and refuting misinformation is an important part of any breastfeeding counseling or education effort (Riordan and Wambach, p.554; Shealy, Li, Benton-Davis, & Grummer-Strawn, 2005).

Healthcare and social service providers need empirical information on which to base their breastfeeding education efforts. There is no comprehensive, empirically-based source to consult about myths and misinformation in need of debunking. Thus, this study investigates common breastfeeding myths and misinformation reported by clients to healthcare and social service providers who work with pregnant or breastfeeding women in Florida.

The survey was undertaken because an exhaustive search of literature about the types and prevalence of negative messages about breastfeeding suggests that there are no research studies focused on breastfeeding myths and misinformation. However, some studies reported misinformation obtained anecdotally when conducting research. Li, Fein, Chen and Grummer-Strawn (2008), reported that women in their study thought they needed to stop breastfeeding when the mother was sick or taking medicine. Grassley, Spencer and Law (2012), noted that some grandmothers in their study believed that most mothers cannot produce enough milk. Myths about who should not breastfeed, such as mothers who smoke, have poor diets, or consume caffeine, were reported in another study (Lucas, et al, 2013).

In addition to anecdotal reports, three different lactation specialists separately published lists of myths and misinformation in the grey literature (Finnigan, 2009; Marasco, 1998, 2009; Newman, 2009). The lists were myths and misinformation they had heard in the course of their practice. Items from these lists were compiled to construct the survey for this study. The purpose

of this study was to identify and to estimate the frequency of myths and misinformation about breastfeeding recounted by providers who care for pregnant and breastfeeding women in Florida.

Methods

The institutional review board of the University of Central Florida and the board of the Florida Lactation Consultant Association granted approval for the study. A convenience sample of 81 healthcare and social service professionals who provide care to pregnant and breastfeeding women was recruited from the attendees of the 2010 Florida Lactation Consultant Association biennial conference. Professionals were used as key informants because they regularly counsel large numbers of pregnant or breastfeeding women.

Development of the Survey

The Knightingale Myths and Misinformation About Breastfeeding survey was developed specifically for use in this study. The items came from the insights and work of three experts in human lactation, Jack Newman of Canada, Lisa Marasco of the United States Southwest; and Valerie Finigan of United Kingdom. The breastfeeding myths from each expert were combined into a single master list. A close reading of the master list identified items with similar content that were worded differently. Collapsing items with similar content resulted in a total of 30 survey items. Each item was rated using a 5-point rating scale, with 1 indicating *never heard* to 5 indicating *very frequently heard*. Write in responses were solicited following the survey items. Demographic items about the practice site and professional credentials were added to the final form of the survey.

Procedure

A table was placed in the lobby area near conference exhibitors and was staffed by the principal investigator. The conference chair gave a general announcement regarding the study and invited attendees to participate in the survey by stopping by the table during scheduled breaks. Respondents completed the survey on-site. No personal identifying information was collected and respondents received no compensation for completing the survey.

Data Analysis

Data were analyzed with IBM SPSS statistics software V21. The mode, mean, and standard deviation were calculated for each survey item. One respondent circled more than one response for two items. The items' mode and mean were calculated first by using the lower number and next by using the higher number from this respondent. There was no difference in the items' mode or mean using either the lower or higher number.

Results

There were 90 respondents, representing a response rate of 85 percent. Eighty one of these respondents fully completed the survey. Most of respondents held one or more lactation specialist credentials (77.8%) including Certified Lactation Consultant (CLC) (16.9%), Internationally Board Certified Lactation Consultant (IBCLC) (59.4%), La Leche League Leader (LLL) (6.7%), or Peer Counselor (PC) 4.4%. Besides lactation consultant credentials, many respondents also held another professional credential. Nearly half the respondents identified themselves as registered nurses (RN) (48.9%). Other respondents identified as one of the following: registered dietician (4.4%), medical doctor (3.3%), childbirth educator (3.3%), doula

(2.2%), accredited registered nurse practitioner (1.1%), or physician's assistant (1.1%). A few respondents (7.8%) did not answer the credential query.

The majority of respondents worked in a birthing hospital (51%) or WIC setting (19%). Other practice settings included free-standing birthing centers, ambulatory care or outpatient centers, private practice, academia, and Healthy Start. Several respondents (13.3%) did not select a practice site. Respondents indicating that they worked in the hospital setting were mostly registered nurses and nearly all of these were IBCLCs.

No item was reported as frequently heard by 100% of respondents. Table 1 reports the frequency of each item. Seventy percent of respondents reported the same six items as heard *very frequently* (1) Bottle fed babies sleep longer than breastfed babies (2) If breastfeeding, you don't know how much milk the baby is getting (3) Breastfeeding is difficult (4) A baby should be fed for a specific number of minutes per breast (5) It is easier and more convenient to bottle feed, and (6) Many women don't produce enough milk.

Nine items were reported as heard *frequently*. Two myths had very low frequency (1) Women who breastfeed should not dye their hair or get permanents (2) Women should not breastfeed after exercise. No item was reported as *never* heard by the respondents. Nine respondents included write-in responses; most of the responses were subsumed into existing categories as they did not yield new information. Three items were new misinformation, "Colostrum is bad milk," "Breastfeeding mom cannot eat sushi," and "Cannot eat chocolate"; these were singular reports.

Discussion

This study empirically examined myths and misinformation circulated about breastfeeding. Study findings confirmed that most of the myths and misinformation about breastfeeding that were compiled from the lists of three experts from different geographic regions (i.e., the US Southwest, the United Kingdom, and Canada) are mostly current and operative in the state of Florida.

The high-frequency myths about normal breastfed infant behaviors regarding sleep and feeding adequacy may be because the US has been a predominately formula feeding culture as less than 20% of US infants are exclusively breastfed to six months of age (CDC, 2014). Infant feeding methods are learned behaviors that young mothers observe from the community of women in their social network (Baranowski, et al, 1983; Humphreys, Thompson, & Miner, 1998; Clifford & McIntyre, 2008). Frequently heard myths that play on maternal concerns about the breastfeeding process as difficult or inconvenient may be because of media portrayals of formula and bottle feeding (Bergevin, Dougherty & Kramer, 1983; Donnelly, Snowden, Renfrew, & Woolridge, 2007; Frerichs, Andsager, Campo, Aquilino, & Dyer, 2006; Government Accounting Office (GAO), 2006; Henderson, Kitzinger & Green, 2000; Parry, Taylor, Hall-Dardess, Walker & Labbok, 2013).

One of the two items that was reported to be heard very rarely, no breastfeeding after exercising, may be an artifact of the professionals who were the respondents in this study. Exercise concerns may not be heard frequently because the majority of respondents in this study worked with very early postpartum mothers. Concerns about exercise would more likely arise when the mother resumes normal activities at about six weeks postpartum. The other item that was reported as heard very rarely, the item pertaining to dying or perming their hair, was

probably more prevalent during an era when it was more common for young women to perm and/or add color to their hair. The experts who compiled the original lists of myths have been in practice for many years and likely included items reflecting this earlier time period. Also, beauticians have seen an increase in breastfeeding clients over the last 20 years. They have likely educated their clients regarding the use of cosmetic chemicals and breastfeeding.

The myths and misinformation listed in the survey are not inclusive of all myths and misinformation in circulation and there is anecdotal evidence that new myths are surfacing. For example, in a recent intervention study that used a game format to refute commonly heard myths, participants reported that formula is being promoted as a remedy for reflux (reflux formula) and fussy or colicky babies. Apparently, several new infant formulas have been developed to exploit this potential market. A recent study by Parry, Taylor, Hall-Dardess, Walker & Labbok (2013), also reported that infant formula advertisement led mothers to believe that formula could be used to solve infant fussiness and spitting up.

Limitations

WIC provides nutritional goods and education to about half the state's newborns, but providers from WIC were underrepresented in the sample. Likewise, pediatric physicians and nurse practitioners, nutritionists, and health educators were underrepresented. It is possible that more respondents from WIC and providers from professions that were underrepresented in this study could have produced different results. Also, given that the length of time the provider has been working with lactation clients may affect their perception of how frequently a myth was heard. It may be more meaningful to ask respondents to rate the myths heard within the past

year. There may also be subtle regional differences in the type and frequency of misinformation. This study did not investigate different geographic regions of practice.

Recommendations for Practice

Study finding provide information about which myths or misinformation about breastfeeding need to be corrected when providers are interacting with pregnant and breastfeeding women. For example, providers can educate women that lactation milk sufficiency is usually a lactation management issue rather than a physiological issue. The mother's milk supply balances itself with the infant's demand for milk; the greater the infant's demands for milk for greater the mother's supply.

Recommendations for Future Research

Additional research is needed to include possible variations in geographical region, client socioeconomic characteristics, practice setting, provider experience, and professional discipline. A nationwide, randomized, stratified sample of providers and settings would offer a more accurate picture of the myths and misinformation currently circulating among childbearing families in all regions of the US. Due to the recent surfacing of the "reflux formula" myth, it is likely that new myths will continue to arise. Therefore, reassessment and administration of the survey at regular intervals is warranted.

Conclusion

The influence of negative myths and misinformation about breastfeeding is a persistent barrier to breastfeeding success. This study provided empirical evidence regarding types and frequency of myths and misinformation about breastfeeding. Debunking myths, refuting

misinformation, and providing accurate, evidenced-based breastfeeding information will help mitigate a barrier to US mothers reaching Healthy People 2020 goals.

Tables and Figures

The tables and figures referenced in text are shown below.

Table 8. Prevalence of myth or misinformation

Mode	Mean	SD	
5	4.31	0.90	Bottle fed babies sleep longer than breastfed babies
5	4.26	0.93	You don't know how much milk the baby is getting
5	4.06	0.97	Breastfeeding is difficult
5	4.02	1.23	A baby should be fed for a specific number of minutes per breast
5	3.96	1.09	It easier and more convenient to bottle feed
4,5	3.81	1.05	Many women do not produce enough milk
4	3.79	0.90	Breastfeeding should be interrupted if the mother is taking medicine
4	3.72	0.96	Breastfeeding ties the mother down
4	3.65	1.12	Babies need routine and scheduled feedings
4	3.59	1.09	Breastfed babies want to be held all the time
3	3.57	1.05	A mother who is breastfeeding should not: drink any alcohol
4	3.52	1.16	Breastfeeding makes the breast sag
3	3.51	1.10	Breastfeeding should be interrupted if the mother's nipples are bleeding
4	3.44	0.94	Never wake a sleeping baby for feeding
3	3.41	1.16	The mother cannot or should not breastfeed if she is smoking
4	3.37	1.13	Babies need to know how to take a bottle
3	3.35	1.12	The mother cannot or should not breastfeed if she had breast reduction surgery
3	3.33	1.13	The mother cannot or should not breastfeed if she is pregnant
3	3.32	1.15	Breastfeeding should be interrupted if the mother is sick
3	3.27	1.10	Mothers must have a specified amount of calories, nutrients or liquids
3	3.20	1.04	The mother cannot or should not breastfeed if she had breast augmentation surgery
3	3.17	1.22	A mother who is breastfeeding should not: take birth control pills
3	3.02	1.32	Formula and breast milk are pretty much the same
3	2.90	1.11	Breastfeeding should be interrupted if the baby is sick
3	2.88	1.20	There is no such thing as nipple confusion
3	2.78	1.21	Breastfeeding should be interrupted if the mother has had an immunization
3	2.65	1.17	Breasts have to be just the right size to breastfeed successfully: not too big, not too small
2	2.64	1.12	Breastfeeding in public is not allowed
2	2.42	1.11	A mother who is breastfeeding should not: dye her hair or get a permanent
2	2.12	1.00	A mother who is breastfeeding should not: breastfeed after exercising

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APPENDIX A: DISSERTATION PROPOSAL

Dissertation Proposal Intervention to Help Mothers Resist Persuasion to Give Formula

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Abstract

Influences exerted by the infant food industry, coupled with negative social pressure from family friends and the community, are barriers for women who strive to achieve breastfeeding goals. There is a gap in the research literature about efforts to equip women with explicit strategies to resist dissuasive messages that attempt to interrupt or stop breastfeeding and persuade women to give formula to their babies. This proposed quasi-experimental study evaluates the effects of a group prenatal education intervention on breastfeeding behaviors. The intervention is introduced into an existing prenatal breastfeeding class as a board game activity, the *Breastfeeding Myth Busters Game,* which is based on the inoculation theory of resistance to influence. If effective, the intervention can be implemented more widely to increase breastfeeding initiation, duration, and exclusivity rates to approach those targeted by Healthy People 2020 (n.d.).

Keywords: breastfeeding, inoculation theory, prenatal education

Intervention to Help Mothers Resist Persuasion to Give Formula

Problem Statement

According to the Centers for Disease Control and Prevention (2008), breastfeeding rates of mothers lag behind goals set by the Healthy People 2020 (n.d.) agenda. Breastfeeding is a complex biopsychosocial task and many factors can hinder or enhance a woman's success. One component is the mother's ability to resist dissuasive messages. Dissuasive messages from the infant food industry, as well as from family, friends, and the community, are barriers to achieving target goals for increasing breastfeeding rates. Despite the availability of general information about the value of breastfeeding, there remains a gap in knowledge about helping women who intend to breastfeed to resist dissuasive influences and succeed in their infant feeding goals.

Significance

Breastfeeding is the preferred method of infant feeding and breast milk is superior to any substitute (American Academy of Pediatrics Workgroup on Breastfeeding, 2005). Each of the Healthy People agendas to date has included goals for breastfeeding, noting that breastfeeding is a powerful predictor of numerous health outcomes (Brown, 2009; Healthy People 2020, n.d.; U.S. Department of Health and Human Services, 1980). A report from the US Agency for Healthcare Research and Quality (AHRQ) determined that breastfeeding offers significant health benefits. This systematic review analyzed over 9,000 research studies and meta-analyses about the outcomes of breastfeeding for mothers and babies in developed countries. Their findings demonstrated that breastfed infants have decreased risks of acute otitis media, nonspecific gastroenteritis, severe lower respiratory tract infections, atopic dermatitis, asthma, obesity, type 1 and type 2 diabetes, childhood leukemia, sudden infant death syndrome, and necrotizing

enterocolitis. Mothers in developed countries who breastfeed have a reduced risk of type 2 diabetes, breast cancer, and ovarian cancer. Breastfeeding intensity, or how exclusively the baby is fed at breast, is also related to many of these health outcomes. In addition, there is evidence that mothers who breastfeed beyond the puerperium are less likely to experience postpartum depression (Ip et al., 2007). Bartick & Reinhold (2010) determined that if Healthy People 2010 breastfeeding goals were met, over 900 lives would be saved and U.S. families would save more than $13-billion annually.

There is a national agenda to overcome barriers to breastfeeding based on the facts that 25% of infants have never been breastfed and almost half of all infants are not breastfed by one month of age (Ahluwalia, Morrow, & Hsia, 2005; Centers for Disease Control and Prevention, 2008). Prenatal education has been recognized as means of increasing breastfeeding behaviors even though its success remains below goals put forth by Healthy People 2020 (Dyson et al., 2006). Prenatal breastfeeding education classes typically include cognitive, psychomotor, and affective learning as means to address potential barriers to breastfeeding, but they lack explicit strategies to prepare women for future confrontations with dissuasive messages. Adding an intervention to existing breastfeeding classes aimed at helping mothers resist dissuasive messages could increase breastfeeding behaviors closer to reaching Healthy People 2020 goals.

Literature Review

The decision to breastfeed is usually made in the prenatal period and can be influenced by family, friends, and the community. Mothers are vulnerable to messages that cast doubt on their ability to breastfeed (McBride-Henry, 2010). Attitudes from proximal relationships such as supervisors and coworkers, health professionals, friends, and family are key influences that

support or discourage breastfeeding (Arora, et al, 2000; Baranowski et. Al, 1983; Clifford & McIntyre, 2007; Heinig, et al, 2009; Hong, Callister & Schwart. 2003; Khoury, et al., 2002).

Mothers are also vulnerable to messages that lead them to believe that formula is a comparable substitute for breast milk. The infant food industry and its sophisticated marketing techniques is a pervasive influence that negatively affects attitudes towards breastfeeding. A content analysis of mass media demonstrated that increases in formula and hand feeding advertisements lead to declines in breastfeeding rates (Foss & Southwell, 2006). Distribution of formula company educational literature and free samples by hospitals and doctor's offices has a significant negative impact on breastfeeding behaviors (Bergevin, Dougherty & Kramer,1983; Donnelly, Snowden, Renfrew, & Woolridge, 2007; US Government Accounting Office (GAO), 2006). No study directly asked mothers if persuasion from external sources was a reason for supplementation or discontinuing breastfeeding.

Inoculation Theory of Resistance to Influence

According to the inoculation theory (McGuire, 1964), individuals can be taught to adhere more strongly to their beliefs and to resist persuasion. An *inoculation treatment* is a one-time, two-part intervention. The first part of the intervention exposes the participant to a dissuasive message, counterargument, or threat. The threat arouses a level of anxiety, which prepares the message recipient for learning and increases attention and retention in a learning situation (Yerkes & Dodson, 1908; Anderson, Revelle, & Lynch, 1989). The second part of the intervention exposes the participant to a detailed rebuttal of the counterargument, thereby providing a refutational defense (McGuire, 1964). The refutational defense specifically repudiates the threat and includes supporting statements. The exemplar not only provides information, but also models cognitive behavior that the participant can use when confronted

with a future dissuasive attack. The process is analogous to inoculating against a virus by preexposure to a weakened dose of the virus.

In their meta-analysis of inoculation theory, Banas and Rains (2010) found that people who experienced the inoculation treatment were significantly more resistant to future persuasive counterattack messages than were those who received supportive messages only or those who received no messages. Some researchers have noted that the ability to defend against persuasion following inoculation treatment is remarkably stable across time and thus recommend that the time for assessing post inoculation treatment effects can range from immediately post inoculation treatment to several months post inoculation treatment (Compton & Pfau, 2004; Pfau et al., 2006). However, Banas and Rains (2010) reported a noticeable decay in resistance after two weeks.

Inoculation theory is popular among many disciplines, especially marketing. Inoculation treatment has been reported to bolster brand loyalty (Szybillo & Heslin, 1973), strengthen support for political candidates (Pfau & Burgoon, 1988), protect against attitude change on corporate issues (Burgoon, Pfau, & Birk, 1995), and promote resistance to credit card marketing (Compton & Pfau, 2004). It has been successfully applied in health campaigns to discourage alcohol, smoking, and verbal aggression. People receiving the inoculation treatment were better able to resist pressures that encouraged drinking and driving behaviors (Duryea, 1982; Godbold & Pfau, 2000; Goldberg, Niedermeier, Bechtel, & Gorn, 2006), preserve attitudes to avoid smoking (Pfau & Van Bockern, 1994), and prevent increased verbal aggression (Rosenberg, 2004).

No research using inoculation theory has been conducted to increase breastfeeding behavior by helping mothers preserve the attitude to avoid formula. The proposed study will

include use of a board game activity based on inoculation theory. The board game activity is an intervention intended to increase breastfeeding initiation, duration, and exclusivity.

Purpose

The proposed study will test the efficacy of an intervention that offers instruction to pregnant women attending prenatal breastfeeding education classes to resist dissuasive influences that encourage the woman to interrupt or stop breastfeeding and to use formula. The intervention, based on McGuire's (1964) inoculation theory of resistance to influence, will be presented as an interactive board game activity. The proposed study will investigate the effect of an inoculation theory-based intervention on a woman's self-efficacy to resist dissuasive influences to give formula, her breastfeeding behaviors, and reasons for supplementing with formula or discontinuing breastfeeding. It is hypothesized that the intervention group will demonstrate significantly higher rates of breastfeeding behaviors and have significantly higher self-efficacy to resist dissuasive influences.

Use of inoculation theory and a board game activity to apply inoculation theory to enhance breastfeeding behaviors is a highly innovative approach to the problem of increasing breastfeeding rates. If the intervention proves to be effective, it can easily be added to prenatal classes offered at birthing facilities. Adapting the game to a computerized version for delivery via the Internet using a social networking venue such as Facebook could make the intervention even more widely accessible.

Methods

The proposed study will be quasi-experimental. A randomized design would risk diffusion of information about the game board activity from the intervention groups to the

comparison groups. Data will be collected during the prenatal breastfeeding class, at about two weeks after the class, and about one month after childbirth.

Setting and Sample

The proposed study will be conducted in a large birthing hospital in an urban area of Central Florida. Approximately 220 participants will be recruited from women attending the hospital's prenatal breastfeeding education classes. Inclusion criteria for study participation will be low-risk pregnancy, anticipation of a healthy singleton birth, having a support person present (e.g, spouse, other family member or friend) during class, and 32-weeks gestation or greater at the time of recruitment. Women who do not have a telephone and do not speak and read English will be excluded at the time of recruitment. Women who deliver before the first follow-up interview, who subsequently experience medical complications, or whose infants develop medical complications will be dropped from the study.

The hospital hosts more than 60 prenatal breastfeeding classes annually with a maximum attendance of 20 pregnant women (and a support person) per class. Not all classes will be at maximum attendance nor will all those in attendance consent to study participation. In addition, some attendees will not meet inclusion criteria and some will be lost to follow-up. Thus, it is anticipated that approximately 15 to18 cohorts of prenatal breastfeeding classes will be needed to recruit the required number of participants for the study.

The sample size of 200 was determined via power analyses and anticipation of attrition. Assuming a power of 0.8 and alpha of 0.05 a sample of 160 women should provide sufficient power to: (a) detect a nearly moderate effect size (f=.22 for ANCOVA) and (b) detect an OR of 2.24 to 2.58 using a one tailed test of hypothesis two in the logistic regression analysis. This translates to a 17-20% difference in breastfeeding initiation, duration, and exclusivity behavior

assuming a base rate for these behaviors of 39-68%. This number is based on data from CDC breastfeeding rates for 2008. It can be assumed that 74% of the women will initiate breastfeeding and about 70% will be breastfeeding at one month (56% will be exclusively breastfeeding in the hospital and 45% will be exclusively breastfeeding at one month). These assumptions are based on breastfeeding rates for 2008 (Centers for Disease Control and Prevention, 2008).

Two hundred participants will be recruited to allow for a 25% fallout/attrition rate. Attrition may be due to the mother's or newborn's medical condition (e.g., preeclampsia or prematurity), the mother is unable to complete data collection or is lost to follow-up, gives birth before the first follow-up interview, or otherwise no longer meets study criteria. A 25% attrition rate is comparable with rates of attrition reported in in several recent breastfeeding studies of middle and low income families (Bonuck, Trombley,Freeman & McKee, 2005; Noel-Weiss, 2008).

Procedure

Both the comparison and intervention groups will complete a demographic questionnaire, a questionnaire that measures breastfeeding intention, and receive two follow-up telephone interviews, which will be recorded to ensure accuracy (Marcus & Crane, 1986). The first interview will be conducted about two weeks after prenatal class participation and will assess the effects of the intervention on the self-efficacy to resist persuasion to give formula. The second interview will occur about one month after childbirth and will assess the effects of the intervention on breastfeeding behavior. A descriptive component will be incorporated during the second interview to compare reasons for formula supplementation or discontinuing breastfeeding. The inoculation treatment will also be delivered to support persons who accompany the mothers to the prenatal breastfeeding class. These support people are likely to

influence the mothers, perhaps bolstering their ability to resist persuasive influences. For this reason, women attending class who are unaccompanied by a support person will be removed from analyses about the efficacy of the intervention on breastfeeding behaviors.

The principal investigator (PI) will greet participants at the birthing hospital's prenatal breastfeeding class sign-in desk and remain in attendance throughout the class. During sign-in, each woman attending the class will be given a breastfeeding nursing cover-up as in incentive to encourage them to consider enrolling in the study. At the beginning of class, the PI will explain the study, invite study participation, and ask participants to sign the informed consent form, fill out the demographic and maternal characteristics form, maternal intention to breastfeed questionnaire, and the contact information form (see Appendix A, B, C, and D). The participants will be given a reminder magnet and a coded, preaddressed, stamped postcard with a blank space for the delivery date. They will be instructed to fill in the birth date and mail the card as soon as possible after childbirth. Class attendees who choose not to participate will not complete the study materials but be allowed to keep the nursing cover.

All attendees of the class will participate in watching the film (comparison group) or playing the game activity (intervention group) even if they are not eligible for or fail to provide consent for study participation. Enrollment into the comparison or intervention group will be sequential, with the comparison group being enrolled first. The PI will remain for the entire class, and remind participants about the two follow-up telephone interviews and the importance of mailing the postcard birth announcement. Documents will be securely stored and a tickler file will be generated to ensure timely post intervention follow-up. If the PI has not received a postcard birth announcement within 10 days after an expected delivery date, the PI or the research assistant will contact the mother by telephone.

Both groups will receive one of two possible 20-minute conditions (i.e., comparison or intervention) at about 15 minutes into the class. The breastfeeding educator who conducts the class will incorporate both the comparison and intervention content as additions to the regular class curriculum.

Comparison Group

People assigned to the comparison group will view the video, *Breastfeeding: Why To*. The content of this video repeats standard information that will be delivered didactically during class by the breastfeeding educator.

Intervention Group

The intervention group will receive instruction to play the Breastfeeding Myth Busters Game. This game board activity is designed to be played by a group of three to six people. Players will be comprised of the pregnant women and anyone who accompanies them. Because many of the women will be accompanied by a support person, up to ten groups are expected to play the activity simultaneously in each class. Each player will receive a movable game piece marker and a set of defense cards. Players will roll die and advance along the colored squares according to the number indicated by the die. Some squares contain directions to draw a myth card. Each group of players will confer and choose a defense card to be played before the next player's turn. Each group completes the activity when at least one of each type of defense card has been played. When all groups have completed play, the activity will be debriefed and regular class curriculum will resume (see Appendix E for preliminary game sketch and Appendix F for script).

The first follow-up interview will be conducted about two weeks after the comparison or intervention group experience depending on the participant's condition assignment, and will

include a six-item survey, *self-efficacy to resist formula* (SERF). Either the PI or the research assistant will conduct the interview. Participants will be reminded to notify the PI of their newborns' birth by using the preaddressed and stamped postcard provided during recruitment. The second interview will be conducted by either the PI or the research assistant at about one month after the birth of the baby and will include screening for complications of childbirth and obtaining information about breastfeeding behavior. Reasons for supplementation or discontinuing breastfeeding will be asked only if the mother did not breastfeed or did not breastfeed exclusively (see Appendix G for SERF, Appendix H for screening for complications, Appendix I for ICD-10, Appendix J for breastfeeding behaviors, and Appendix K for the reasons for supplementation and script for the second interview). An overview of this data collection schedule is given in Table 1.

Table 1. *Schedule for Data Collection*

Time	Measures
Baseline	Demographic and Maternal Characteristics questionnaire
	Maternal Intention to Breastfeed questionnaire
2 weeks post intervention	Self-efficacy to resist formula (SERF) questionnaire
1 month postpartum	Screening for Inclusion/Exclusion Criteria questionnaire
	Breastfeeding Behavior questionnaire
	Reasons for Discontinuing breastfeeding or Supplementation questionnaire

Preliminary Work: The Development of the Breastfeeding Myth Busters Game Activity

The intervention is the two-part inoculation treatment (threat and refutational defense), which will be administered in the form of a board game activity called "Breastfeeding Myth Busters Game." The threat will be operationalized as the myth game card, which contains a message attempting to persuade the participant(s) to interrupt breastfeeding and substitute formula. Refutational defense will be operationalized as the myth-buster defense card, which will allow the participant(s) to defend against the myth card and move ahead in the game.

The Breastfeeding Myth Busters Game activity was developed in three phases**.** In Phase I, common myths or misinformation about breastfeeding from three credible expert sources (Jack Newman, Lisa Marasco, and Valerie Finigan) were compiled into a single list. Myths and misinformation from credible sources were used rather than empirical data because an exhaustive electronic search (i.e., via Academic Search Premier CINAHL, MedLINE, PsychIN and Web of Science) and hand searching all volumes of the Journal of Human Lactation and The International Breastfeeding Journal yielded no assemblage of common myths and misinformation. Thematic analysis was conducted to determine basic categories and overarching themes.

In Phase II, the results of the thematic analysis were used to develop a 30-item, 5-point Likert survey. The purpose of the survey was to validate the myths. Eighty-nine professionals who provide care to Florida's breastfeeding mothers were recruited to complete the survey. All but two of the survey items were reported as being heard at least *sometimes* by the majority of participants; no item was reported as *never* heard by any participant. The majority also reported that fourteen items were heard *frequently* or *very frequently*. Of these, five items were reported as heard *very frequently* by greater than 70% of participants; no item was reported as frequently

heard by 100% of participants. A mean score was calculated for each item in the survey. An item with least 1/3 of participants rating it as *frequently* or *very frequently* heard was considered eligible for consideration as a concept for the Breastfeeding Myth Busting Game. Each of these items had a mean score greater than 3.5, meaning that the item was heard more than sometimes (see Appendix L survey results).

In Phase III, selected myth and defense statements of the inoculation treatment were developed. These statements were assessed for domain clarity, simplicity and relevance by a panel of human lactation experts (see Appendix M for Myth and Defense statements). A trial of the game was conducted with college students to obtain feedback regarding design of the game board as well as ease and length of time for play. The college students required about 10 minutes to complete the game activity. Feedback was used to refine the game design.

Before beginning the intervention study, the game board and pieces will be finalized and constructed. The game activity will be piloted again with one prenatal breastfeeding class before recruiting participants for the intervention. The PI rather than the educators will conduct the game playing for the pilot. The purpose of the pilot is to test the timing and procedures for the Breastfeeding Myth Busting Game and to prepare the educators to implement the intervention. If indicated, game procedures will be refined following the pilot. Data collected from the pilot will not be included in the analysis for the major study since the PI conducting the game playing could pose threats to internal validity.

Measures and Instrumentation

Demographic and maternal characteristics data will be collected via a paper and pencil questionnaire. These data will include maternal age, education, ethnicity, WIC participation, family income, previous breastfeeding experience, and previous breastfeeding experience of

close friends or relatives. The questionnaire will also ask the participants who accompanied them to the breastfeeding education class (Appendix B).

Maternal intention to breastfeed (MIB) data will be collected via a paper and pencil questionnaire. The MIB questionnaire is an adaptation of the Infant Feeding Intentions (IFI) scale that was developed by Nommsen-Rivers & Dewey (2009). The IFI is a 6-item Likert-type tool. The first two items in the IFI scale measure the participant's intention to initiate any breastfeeding. The participant's intention to exclusively breastfeed is measured by items three through six. Scores could range from a low of zero (never intending to breastfeed) to a high score of 16 (intends to breastfeed exclusively for six months). Content validity was established in a pilot study of 88 pregnant women (Nommsen-Rivers & Dewy, 2009).

Construct validity for the IFI was established in sample of 170 primiparous, low-income, multi-ethnic women who were recruited for a larger study about doula care. Cronbach's coefficient alpha was 0.90 which indicates strong internal consistency. There was significant association between scores of the IFI and actual exclusive breastfeeding (ANOVA, $p < 0.0001$). For example, a mean score for those participants who never intended to breastfeed was 4.6 (SD ± 2.9) compared to a mean score of 13.8 (SD ± 2.7) for participants who strongly intended to exclusively breastfeed for six months. Regression analysis showed that participants with higher scores had less risk of not exclusively breastfeeding "…each 1-point increase in IFI score decreased the hazard of not EBF [exclusive breastfeeding] by 23.4% at day 0 and 13.7% at day 30 (Cox proportional hazards model chi-square = 92.5, $P < 0.0001$)" (Nommsen-Rivers & Dewy, 2009). Results for "any" breastfeeding were not reported.

The MIB was adapted for this study to include an assessment of partial as well as exclusive breastfeeding at three time points in time: in the hospital, at one month, and five

months postpartum. Thus, the six MIB items ask how likely the mother is to give formula or exclusively breastfeed her baby at each of the three time points. Responses options range from 1=extremely unlikely to 5=extremely likely as in the original scale. Items 2, 4, and 6 of the MIB will be reversed scored. Responses to the six items will be summed to create a score that can range from 6 (indicating low likelihood to initiate breastfeeding) to 30 (indicating high likelihood to breastfeed exclusively at five months. Appendix C).

Self-efficacy to resist formula (SERF). The participants' self-efficacy to resist persuasion to give formula will be measured using six statements. Each statement confronts the participant with a situation that attempts to persuade her to give formula. Participants indicate a response to each statement according to a 5-point rating scale ranging from 1=not at all sure to 5=completely sure. Scores can range from a low score of 6 points (indicating low belief in ability to resist persuasion to give formula) to a high score of 30 points (indicating high belief.see Appendix G).

Screening for Inclusion/Exclusion Criteria. Five items ask for information that may disqualify the participant from data analysis according to the inclusion and exclusion criteria of the study. The first four questions ask for the newborn's birthdate, mode of delivery, weight, and gestation age. These items may indicate perinatal complications such as a large for gestational age infant. The last item asks if the mother or newborn experienced any problems that kept her from breastfeeding her baby. If the participant responds yes, she will be asked to explain the nature of the problem. Responses will be categorized using International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD 10), Chapter XV: Pregnancy, childbirth and the puerperium and Chapter XVI: Certain condition originating in the perinatal period (see Appendix H for screening for exclusion and Appendix I for the ICD-10 list).

Breastfeeding behavior questionnaire items. This questionnaire contains 4 items that assess initiation, duration, and exclusivity of breastfeeding. For the purposes of the proposed study, breastfeeding initiation is defined as any breastfeeding while in the hospital. Breastfeeding duration is defined as any breastfeeding at one month. Exclusive breastfeeding is defined according to the Joint Commission definition: "Newborn receives only breastmilk and no other liquids or solids except for drops or syrups consisting of vitamins, minerals, or medicines" (Joint Commission, 2011). The first two questions will ask the mother if she breastfed in the hospital (initiation) and breastfed exclusively in the hospital; these will require a yes/no response. The next two questions pertain to the infant feeding pattern of the last 24-hours (when the infant is approximately one month old). These questions will also require a yes/no response. The final question will ask the mother if the last 24-hours represented a typical feeding pattern. If the mother reports that the last 24-hours were atypical, she will be asked to further explain (Appendix J).

Reasons for Supplementation or Discontinuing breastfeeding. This is a checklist of reasons for supplementation or discontinuing breastfeeding, including (1) medical indication, baby or mother sick and couldn't breastfeed (2) perceived milk insufficiency (3) difficulty latching on (4) nipple or breast pain (5) perceived inconvenience such as returning to work or school (6) discouraged by someone and (7) other, which elicits a write-in response. These response options were derived from recent research papers that investigated reasons for breastfeeding cessation (Ahluwalia, Morrow & Hsia, 2005; Li, Fein, Chen & Grummer-Strawn, 2008). The mother is asked to endorse as many reasons as applicable. Responses are coded 1 if checked and 0 if not checked (Appendix K).

Data Analysis

Data analyses will be conducted using SPSS and include univariate descriptive statistical techniques to assess the mean, standard deviation, and frequency of various participant demographic characteristics. The comparison and intervention groups will be assessed for differences in demographic characteristics using Pearson's chi-square analysis or *t*-tests, depending on whether the data are categorical or continuous. Alpha will be set at .05 and the significance test will be two-tailed. Internal consistency of the Mother's Intention to Breastfeed (MIB) and Self-efficacy to Resist Formula (SERF) measures will be analyzed using Cronbach's coefficient alpha. If Cronbach's alpha scores are less than 0.7, item analysis will be conducted and items not consistent with the scale will be deleted in an effort to improve reliability. Group scores of the MIB measure, which will be given prior to the intervention intervention, will be compared using a *t*-test. The SERF will be given at about two weeks after the intervention . Group scores on the SERF will be compared, while controlling for maternal intention to breastfeed, using analysis of covariance. Analysis of breastfeeding behaviors in the hospital and at about one month of age, while controlling for maternal intention to breastfeed, will be conducted using logistic regression.

Hypothesis One: The members of the intervention group will have significantly higher mean score on self-efficacy to resist formula measure, after controlling for maternal intention to breastfeed, than the members of the comparison group.

The independent variable is group assignment (comparison, intervention). The covariate is the mother's intention to breastfeed. The dependent variable is the self-efficacy to resist persuasion to give formula (score on the SERF measure). Group scores from the sum of the six items from the SERF will be compared using one-way analysis of covariance; F-ratio

significance set at $p \leq .05$ with medium effect size (.06). Prior to running the ANCOVA, tests will be run to ensure that no assumptions were violated. Normality plots will include boxplots and histograms. Homogeneity will analyzed using Levine's test and ANOVA (Mertler & Vannatta, 2002).

Hypothesis Two: The intervention group will have a higher likelihood that mothers will report breastfeeding in the hospital, while controlling for maternal intention to breastfeed, than the members of the comparison group.

Hypothesis Three: The intervention group will have a higher likelihood that mothers will report breastfeeding at one month of age, while controlling for maternal intention to breastfeed, than the members of the comparison group.

Hypothesis Four: The intervention group will have a higher likelihood of breastfeeding exclusively in the hospital, while controlling for maternal intention to breastfeed, than the members of the comparison group.

Hypothesis Five: The intervention group will have a higher likelihood of breastfeeding exclusively at one month of age, while controlling for maternal intention to breastfeed, than the members of the comparison group.

These hypotheses will be addressed using a series of logistic regression analyses. The independent variable is the group assignment (comparison, intervention). The covariate is maternal intention to breastfeed (score on the SERF measure). The dependent variables are: any breastfeeding in the hospital; any breastfeeding at one month; exclusive breastfeeding in the hospital; and exclusive breastfeeding at one month. The option remains to include other maternal characteristics in the model as covariates if group differences in demographic characteristics are identified.

Research Question: What reasons do the participants give for using formula or discontinuing breastfeeding?

Reasons will be summarized using descriptive statistics (e.g., frequency, percentage) and compared for between group (comparison, intervention) differences using chi-square or Fishers Exact analysis. Write-in reasons (i.e., categories not included as fixed choices on the questionnaire) will be transcribed verbatim and coded into themes. The frequency of the themes that emerge from the content analyses will also be summarized using descriptive statistics and compared for between group differences using chi-square or Fisher's Exact analyses.

Time Frame

The proposed study is planned for one year (see Figure 1 for a proposed time line).

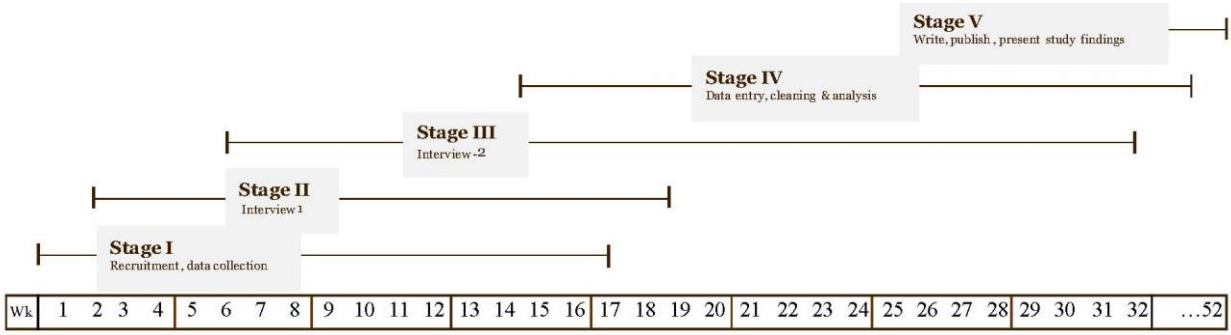

Figure 1. Proposed study time line.

Protection of Human Research Subjects

The Internal Review Boards of the University of Central Florida and Orlando Health will be presented with an application for permission to conduct the study. There is minimal risk to subjects; no greater than those normally encountered in the daily lives of healthy persons. Assurance of privacy, confidentiality, and voluntary participation will be given and informed consent will be obtained. Specific permission for audio recording each telephone follow-up interview will be obtained. Participants will be assigned a numerical code to be used as a means

of identifying data. Identifiable personal information (names, addresses, telephone numbers) will be stored on a laptop computer with password protection. Additionally, a hard copy will be kept in a locked drawer for three years. No financial or other significant conflicts of interest exist for this project. The project has been granted funding from the International Lactation Consultant Association ($7,000) and the Florida Nurses Association Evelyn Frank McKnight Research fund ($500). Preliminary support has been obtained from the study site (see Appendix N).

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APPENDIX B: DEMOGRAPHIC AND MATERNAL CHARACTERISTICS QUESTIONNAIRE ITEMS

Birthdate _____ / _____ / _____ **Today's date** _____ / _____ / _____

Education
( ) Less than High School
( ) High School
( ) Some College
( ) 4-yr Degree or Higher

Ethnicity
( ) African American
( ) Asian
( ) Caucasian
( ) Hispanic
( ) Other

Family Income
( ) Less than $14,000
( ) $14,000-$44,999
( ) $45,000-$68,000
( ) More than $68,000

WIC participation
( ) Yes
( ) No

Previous Breastfeeding Experience
( ) Yes
( ) No

Did someone close to you breastfeed?
(Check all that apply)
( ) My mother
( ) Close relative
( ) Friend
( ) No one
( ) Other _____

Who accompanied you to the class today?
(Check all that apply)
( ) My mother
( ) Significant other/partner
( ) Close relative
( ) Friend
( ) I came by myself to this class
( ) Other
_____

APPENDIX C: MATERNAL INTENTION TO BREASTFEED QUESTIONNAIRE ITEMS

		Extremely unlikely	**Unlikely**	**Neutral**	**Likely**	**Extremely likely**
1	How likely are you to breastfeed your baby while you are in the hospital?	1	2	3	4	5
2	How likely are you give your baby formula while you are in the hospital?	1	2	3	4	5
3	When your baby is one month old, how likely are you to breastfeed your baby?	1	2	3	4	5
4	When your baby is one month old, how likely are you to give your baby formula?	1	2	3	4	5
5	When your baby is five months old, how likely are you to breastfeed your baby?	1	2	3	4	5
6	When your baby is five months old, how likely are you to give your baby formula?	1	2	3	4	5

APPENDIX D: CONTACT INFORMATION

Name: _____

Address: _____

_____

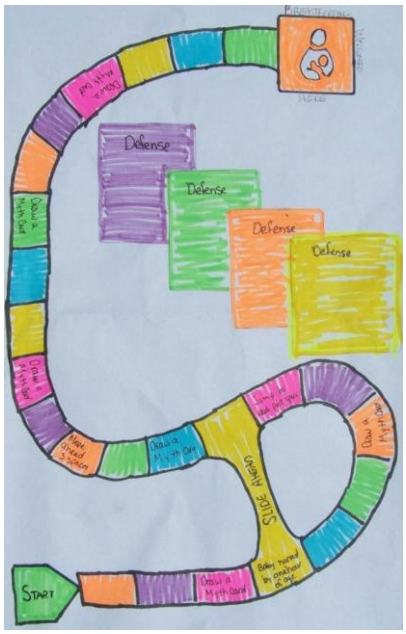
Preferred 9-digit telephone number: _____

Secondary Phone: _____

Can we text you? Yes No (circle one)

Due date: _____

APPENDIX E: BREASTFEEDING MYTH BUSTERS GAME ACTIVITY (PRELIMINARY SKETCHES)



You should formula-feed your newborn so you know how much he's getting	**MYTH**

DEFENSE

You may have heard that there is no way to know if your newborn is getting enough milk.

Actually, there are three ways you can know: (a) Your newborn has frequent wet and dirty diapers. At 1 week of age, your newborn has three or more yellow, dirty diapers and six or more wet diapers per day. (b) Your newborn appears satisfied after feeding, and is sucking and swallowing for 20-30 minutes each feeding, and nurses about every 1½ to 3 hours (eight to 12 times a day). (c) Your newborn is gaining weight. Once mother's milk comes in, the newborn gains ½ to 1 ounce per day.

DIRECTIONS

Contents of the Game

- One game board, one die, one deck of 12 myth cards, four decks of defense cards (1 yellow, 1 blue, 1 green, 1 pink), and 6 different colored movable game pieces.

Objective of the Game

- To travel along the colored path to the Breastfeeding Mothers Welcome sign until one each of the defense cards has been played.

Beginning the Game

- Each player is given one set of defense cards and chooses a playing piece. The myth cards are shuffled and placed face down on the game board.
- All players begin at the start arrow. Each player rolls the die; the player with the highest score goes first and the one with the lowest score goes last.

Taking Your Turn

- Roll the die and move your game piece ahead the number of spaces shown on the die.
- Players who land on the Slide space can take the shortcut.
- When a player lands on a myth card space, the top myth card is taken. Any player can lay down a defense card to defeat the myth. The defense card is placed on the colored defense holder on the game board and the myth card is placed at the bottom of the myth pile.

Winning the Game

- The game is won when at least one each of the four types of defense card has been played and placed on the gameboard.

APPENDIX F: SCRIPT FOR GAME INTRODUCTION AND DEBRIEFING

We are going to play a game about defending the decision to breastfeed and resisting persuasion to give formula to your newborn. The game is made for a team of three to six players. The educator will read/recite the directions aloud as the game and pieces are being distributed and then say. *For example, the myth card says "You should let someone else give the baby a bottle, so they can bond with the baby, too. Each person has several defense cards and you and your group of players must select the correct Defense Card to rebut the myth card. The correct card to play is a card that deals with someone else wanting to feed your newborn. The correct defense card will read something like this: "You may have heard that babies bond to the person who feeds them so other people should be allowed to feed the baby using a bottle. Babies bond to people that interact with them regularly such as bathing, diapering playing and comforting. Newborns are learning to breastfeed and introducing another method of feeding may confuse the baby and cause him to suck less well at breast and may cause pain to the mother. After the newborn period, when the baby is about one month old, the baby is more likely to learn another way of feeding and still breastfeed well.*

It typically requires 10 minutes to complete a game.

As each group of players wins by completing the game, the educator and PI will distribute a set of decoratively tied lactation cookie recipes (e.g., for lactation cookies). OR give out small bags of cookies from the woman who makes the cookies for the Mother-Baby Teas at Winnie Palmer. When all groups of players have defended successfully against the myths and won the game, or at the end of 10 minutes, remaining teams will receive cookie recipes and the educator will begin the debriefing.

Debriefing script

You have heard some myths and misinformation about breastfeeding. You may also hear these same myths from friends, your mom, at your doctor's office, or on TV. There is a lot of misinformation about breastfeeding. This game was designed to help you learn to defend against some of the myths and misinformation that people might tell you and help you respond to people who may tempt you to give formula to your baby.

APPENDIX G: SELF-EFFICACY TO RESIST FORMULA (SERF) QUESTIONNAIRE ITEMS

1 = not at all sure. 2 = slightly sure. 3 = fairly sure. 4 = very sure. 5 = completely sure.

Statement	1	2	3	4	5
I can say "no thank you" if a family member asks if they can help by giving the baby a bottle of formula.	○	○	○	○	○
I can say "no thank you" if my nurse suggests I put my baby in the nursery after delivery and let the nurses feed the baby for me so I can get more sleep.	○	○	○	○	○
I can check with my pediatrician before interrupting breastfeeding if another doctor tells me to stop for a few days and give formula.	○	○	○	○	○
If the hospital gives me a free sample of ready to feed formula, I can resist using it later when I am home.	○	○	○	○	○
If a friend offers to babysit and says she would be happy to give a bottle of formula if the baby gets hungry while I am gone, I can say "No thank you, I am not using formula. Please call me and comfort my baby until I can be there to nurse him/her."	○	○	○	○	○
I can detect misleading ad campaigns that are designed to persuade me to give my baby formula (e.g. an ad campaign saying the company's formula is *"the best breastmilk formula*")	○	○	○	○	○

Script for Telephone Interview at Two weeks Post Intervention

Hello, participant, this is PI and I am calling to conduct our first interview of the breastfeeding study in which you volunteered to participate. We will need a few minutes to complete the survey, is this a good time for us to talk? When would it be more convenient for me to call back? Or, if the interview commences, the participant will be advised that the conversation will be recorded to insure accuracy.

Administer SERF items.

Thank you for participating in the breastfeeding education study. Remember, you can call or email me anytime with questions or concerns about this study. I am looking forward to hearing about the birth of your baby.

APPENDIX H: SCREENING FOR INCLUSION/EXCLUSION CRITERIA

1. Your post card stated that your baby was born on ____/____/____.
2. Was the delivery vaginal or via C-section?
3. How much did your baby weigh?_____
4. What was your baby's gestational age?_____
5. Did you or your baby have any problems while you were in the hospital that kept you from breastfeeding? (Yes, No)

   If yes, describe
6. Did you or your baby have any problems since you have been home that kept you from breastfeeding? (Yes, No)

   If yes, describe

APPENDIX I: THE INTERNATIONAL STATISTICAL CLASSIFICATION OF DISEASES AND RELATED HEALTH PROBLEMS 10TH REVISION (ICD-10)

Chapter XV Pregancy, childbirth and the puerperium
(O00–O08) Pregnancy with abortive outcome
(O00.) Ectopic pregnancy
(O01.) Hydatidiform mole
(O02.) Other abnormal products of conception
(O03.) Spontaneous abortion
(O04.) Medical abortion
(O05.) Other abortion
(O06.) Unspecified abortion
(O07.) Failed attempted abortion
(O08.) Complications following abortion and ectopic and molar pregnancy
(O10–O16) Oedema, proteinuria and hypertensive disorders in pregnancy, childbirth and the puerperium
(O10.) Pre-existing hypertension complicating pregnancy, childbirth and the puerperium
(O11.) Pre-existing hypertensive disorder with superimposed proteinuria
(O12.) Gestational (pregnancy-induced) oedema and proteinuria without hypertension
(O13.) Gestational (pregnancy-induced) hypertension without significant proteinuria
(O14.) Gestational (pregnancy-induced) hypertension with significant proteinuria
(O14.1) Severe pre-eclampsia
HELLP syndrome
(O15.) Eclampsia
(O16.) Unspecified maternal hypertension
(O20–O29) Other maternal disorders predominantly related to pregnancy
(O20.) Haemorrhage in early pregnancy
(O21.) Excessive vomiting in pregnancy
(O21.0) Mild hyperemesis gravidarum
(O21.1) Hyperemesis gravidarum with metabolic disturbance
(O21.2) Late vomiting of pregnancy
(O21.8) Other vomiting complicating pregnancy
(O21.9) Vomiting of pregnancy, unspecified
(O22.) Venous complications in pregnancy
(O22.0) Varicose veins of lower extremity in pregnancy
(O22.1) Genital varices in pregnancy
(O22.2) Superficial thrombophlebitis in pregnancy
(O22.3) Deep phlebothrombosis in pregnancy
(O22.4) Haemorrhoids in pregnancy
(O22.5) Cerebral venous thrombosis in pregnancy
(O22.8) Other venous complications in pregnancy
(O22.9) Venous complication in pregnancy, unspecified
Gestational phlebitis NOS
Gestational phlebopathy NOS
Gestational thrombosis NOS
(O23.) Infections of genitourinary tract in pregnancy
(O24.) Diabetes mellitus in pregnancy
(O25.) Malnutrition in pregnancy
(O26.) Maternal care for other conditions predominantly related to pregnancy
(O26.0) Excessive weight gain in pregnancy
(O26.1) Low weight gain in pregnancy
(O26.2) Pregnancy care of habitual aborter
(O26.3) Retained intrauterine contraceptive device in pregnancy

(O26.4) Herpes gestationis
(O26.5) Maternal hypotension syndrome
(O26.6) Liver disorders in pregnancy, childbirth and the puerperium
(O26.7) Subluxation of symphysis (pubis) in pregnancy, childbirth and the puerperium
(O26.8) Other specified pregnancy-related conditions
(O26.9) Pregnancy-related condition, unspecified
(O28.) Abnormal findings on antenatal screening of mother
(O29.) Complications of anaesthesia during pregnancy
(O30–O48) Maternal care related to the fetus and amniotic cavity and possible delivery problems
(O30.) Multiple gestation
(O30.0) Twin pregnancy
(O30.1) Triplet pregnancy
(O30.2) Quadruplet pregnancy
(O30.8) Other multiple gestation
(O30.9) Multiple gestation, unspecified
Multiple pregnancy NOS
(O31.) Complications specific to multiple gestation
(O32.) Maternal care for known or suspected malpresentation of fetus
(O33.) Maternal care for known or suspected disproportion
(O33.0) Maternal care for disproportion due to deformity of maternal pelvic bones
(O33.1) Maternal care for disproportion due to generally contracted pelvis
(O33.2) Maternal care for disproportion due to inlet contraction of pelvis
(O33.3) Maternal care for disproportion due to outlet contraction of pelvis
(O33.4) Maternal care for disproportion of mixed maternal and fetal origin
(O33.5) Maternal care for disproportion due to unusually large fetus
(O33.6) Maternal care for disproportion due to hydrocephalic fetus
(O33.7) Maternal care for disproportion due to other fetal deformities
Conjoined twins
(O33.8) Maternal care for disproportion of other origin
(O33.9) Maternal care for disproportion, unspecified
Cephalopelvic disproportion NOS
Fetopelvic disproportion NOS
(O34.) Maternal care for known or suspected abnormality of pelvic organs
(O35.) Maternal care for known or suspected fetal abnormality and damage
(O36.) Maternal care for other known or suspected fetal problems
(O40.) Polyhydramnios
(O41.) Other disorders of amniotic fluid and membranes
(O41.0) Oligohydramnios
Oligohydramnios without mention of rupture of membranes
(O41.1) Infection of amniotic sac and membranes
Chorioamnionitis
(O42.) Premature rupture of membranes
(O43.) Placental disorders
(O43.0) Placental transfusion syndromes
(O43.1) Malformation of placenta
Abnormal placenta NOS
Circumvallate placenta
(O43.8) Other placental disorders
(O43.9) Placental disorder, unspecified

(O44.) Placenta praevia
(O45.) Premature separation of placenta (abruptio placentae)
(O46.) Antepartum haemorrhage, not elsewhere classified
(O47.) False labour
(O48.) Prolonged pregnancy
(O60–O75) Complications of labour and delivery
(O60.) Preterm delivery
(O61.) Failed induction of labour
(O62.) Abnormalities of forces of labour
(O63.) Long labour
(O64.) Obstructed labour due to malposition and malpresentation of fetus
(O65.) Obstructed labour due to maternal pelvic abnormality
(O66.) Other obstructed labour
(O66.0) Obstructed labour due to shoulder dystocia
(O67.) Labour and delivery complicated by intrapartum haemorrhage, not elsewhere classified
(O68.) Labour and delivery complicated by fetal stress (distress)
(O69.) Labour and delivery complicated by umbilical cord complications
(O69.0) Labour and delivery complicated by prolapse of cord
(O69.1) Labour and delivery complicated by cord around neck, with compression
(O69.2) Labour and delivery complicated by other cord entanglement
(O69.3) Labour and delivery complicated by short cord
(O69.4) Labour and delivery complicated by vasa praevia
(O69.5) Labour and delivery complicated by vascular lesion of cord
(O69.8) Labour and delivery complicated by other cord complications
(O69.9) Labour and delivery complicated by cord complication, unspecified
(O70.) Perineal laceration during delivery
(O71.) Other obstetric trauma
(O71.0) Rupture of uterus before onset of labour
(O71.1) Rupture of uterus during labour
(O71.2) Postpartum inversion of uterus
(O71.3) Obstetric laceration of cervix
(O71.4) Obstetric high vaginal laceration alone
(O71.5) Other obstetric injury to pelvic organs
(O71.6) Obstetric damage to pelvic joints and ligaments
(O71.7) Obstetric haematoma of pelvis
(O71.8) Other specified obstetric trauma
(O71.9) Obstetric trauma, unspecified
(O72.) Postpartum haemorrhage
(O73.) Retained placenta and membranes, without haemorrhage
(O73.0) Retained placenta without haemorrhage
Placenta accreta without haemorrhage
(O73.1) Retained portions of placenta and membranes, without haemorrhage
Retained products of conception following delivery, without haemorrhage
(O74.) Complications of anaesthesia during labour and delivery
(O75.) Other complications of labour and delivery, not elsewhere classified
(O80–O84) Delivery
(O80.) Single spontaneous delivery
(O80.1) Spontaneous breech delivery
(O81.) Single delivery by forceps and vacuum extractor

(O81.4) Vacuum extractor delivery
Ventouse delivery
(O82.) Single delivery by caesarean section
(O83.) Other assisted single delivery
(O84.) Multiple delivery
(O85–O92) Complications predominantly related to the puerperium
(O85.) Puerperal sepsis
(O86.) Other puerperal infections
(O87.) Venous complications in the puerperium
(O88.) Obstetric embolism
(O88.0) Obstetric air embolism
(O88.1) Amniotic fluid embolism
(O88.2) Obstetric blood-clot embolism
(O88.3) Obstetric pyaemic and septic embolism
(O88.8) Other obstetric embolism
Obstetric fat embolism
(O89.) Complications of anaesthesia during the puerperium
(O90.) Complications of the puerperium, not elsewhere classified
(O90.0) Disruption of caesarean section wound
(O90.1) Disruption of perineal obstetric wound
(O90.2) Haematoma of obstetric wound
(O90.3) Cardiomyopathy in the puerperium
(O90.4) Postpartum acute renal failure
(O90.5) Postpartum thyroiditis
(O90.8) Other complications of the puerperium, not elsewhere classified
(O90.9) Complication of the puerperium, unspecified
(O91.) Infections of breast associated with childbirth
(O92.) Other disorders of breast and lactation associated with childbirth
(O92.0) Retracted nipple associated with childbirth
(O92.1) Cracked nipple associated with childbirth
(O92.2) Other and unspecified disorders of breast associated with childbirth
(O92.3) Agalactia
(O92.4) Hypogalactia
(O92.5) Suppressed lactation
(O92.6) Galactorrhoea
(O92.7) Other and unspecified disorders of lactation
(O95–O99) Other obstetric conditions, not elsewhere classified
(O94.) Sequelae of complication of pregnancy, childbirth and the puerperium
(O95.) Obstetric death of unspecified cause
(O96.) Death from any obstetric cause occurring more than 42 days but less than one year after delivery
(O97.) Death from sequelae of direct obstetric causes
(O98.) Maternal infectious and parasitic diseases classifiable elsewhere but complicating pregnancy, childbirth and the puerperium
(O99.) Other maternal diseases classifiable elsewhere but complicating pregnancy, childbirth and the puerperium
(O99.0) Anaemia complicating pregnancy, childbirth and the puerperium
(O99.1) Other diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism

(O99.2) Endocrine, nutritional and metabolic diseases complicating pregnancy, childbirth and the puerperium
(O99.3) Mental disorders and diseases of the nervous system complicating pregnancy, childbirth and the puerperium
(O99.4) Diseases of the Circulatory system complicating pregnancy, childbirth and the puerperium
(O99.5) Diseases of the respiratory system complicating pregnancy, childbirth and the puerperium
(O99.6) Diseases of the digestive system complicating pregnancy, childbirth and the puerperium
(O99.7) Diseases of the skin and subcutaneous tissue complicating pregnancy, childbirth and the puerperium
(O99.8) Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium

ICD-10 Chapter XVI: Certain conditions originating in the perinatal period (P00-P96)

(P00–P04) Fetus and newborn affected by maternal factors and by complications of pregnancy, labour and delivery
(P00.) Fetus and newborn affected by maternal conditions that may be unrelated to present pregnancy
(P01.) Fetus and newborn affected by maternal complications of pregnancy
(P02.) Fetus and newborn affected by complications of placenta, cord and membranes
(P02.0) Fetus and newborn affected by placenta praevia
(P02.1) Fetus and newborn affected by other forms of placental separation and haemorrhage
(P02.2) Fetus and newborn affected by other and unspecified morphological and functional abnormalities of placenta
(P02.3) Fetus and newborn affected by placental transfusion syndromes
Placental and cord abnormalities resulting in twin-to-twin or other transplacental transfusion
(P02.4) Fetus and newborn affected by prolapsed cord
(P02.5) Fetus and newborn affected by other compression of umbilical cord
(P02.6) Fetus and newborn affected by other and unspecified conditions of umbilical cord
(P02.7) Fetus and newborn affected by chorioamnionitis
(P02.8) Fetus and newborn affected by other abnormalities of membranes
(P02.9) Fetus and newborn affected by abnormality of membranes, unspecified
(P03.) Fetus and newborn affected by other complications of labour and delivery
(P04.) Fetus and newborn affected by noxious influences transmitted via placenta or breast milk
(P05–P08) Disorders related to length of gestation and fetal growth
(P05.) Slow fetal growth and fetal malnutrition
(P05.0) Light for gestational age
(P05.1) Small for gestational age
(P05.2) Fetal malnutrition without mention of light or small for gestational age
(P05.9) Slow fetal growth, unspecified
Fetal growth retardation NOS
(P07.) Disorders related to short gestation and low birth weight, not elsewhere classified
(P07.0) Extremely low birth weight
(P07.1) Other low birth weight
(P07.2) Extreme immaturity
(P07.3) Other preterm infants
Prematurity NOS
(P08.) Disorders related to long gestation and high birth weight
(P08.0) Exceptionally large baby
(P08.1) Other heavy for gestational age infants
(P08.2) Post-term infant, not heavy for gestational age

Postmaturity NOS

(P10–P15) Birth trauma
(P10.) Intracranial laceration and haemorrhage due to birth injury
(P10.0) Subdural haemorrhage due to birth injury
(P10.1) Cerebral haemorrhage due to birth injury
(P10.2) Intraventricular haemorrhage due to birth injury
(P10.3) Subarachnoid haemorrhage due to birth injury
(P10.4) Tentorial tear due to birth injury
(P10.8) Other intracranial lacerations and haemorrhages due to birth injury
(P10.9) Unspecified intracranial laceration and haemorrhage due to birth injury
(P11.) Other birth injuries to central nervous system
(P12.) Birth injury to scalp
(P12.0) Cephalhaematoma due to birth injury
(P12.1) Chignon due to birth injury
(P12.2) Epicranial subaponeurotic haemorrhage due to birth injury
(P12.3) Bruising of scalp due to birth injury
(P12.4) Monitoring injury of scalp of newborn
(P12.8) Other birth injuries to scalp
(P12.9) Birth injury to scalp, unspecified
(P13.) Birth injury to skeleton
(P14.) Birth injury to peripheral nervous system
(P14.0) Erb's paralysis due to birth injury
(P14.1) Klumpke's paralysis due to birth injury
(P14.2) Phrenic nerve paralysis due to birth injury
(P14.3) Other brachial plexus birth injuries
(P14.8) Birth injuries to other parts of peripheral nervous system
(P14.9) Birth injury to peripheral nervous system, unspecified
(P15.) Other birth injuries
(P20–P29) Respiratory and cardiovascular disorders specific to the perinatal period
(P20.) Intrauterine hypoxia
(P21.) Birth asphyxia
(P22.) Respiratory distress of newborn
(P22.0) Respiratory distress syndrome of newborn
(P22.1) Transient tachypnoea of newborn
(P23.) Congenital pneumonia
(P23.0) Congenital pneumonia due to viral agent
(P23.1) Congenital pneumonia due to Chlamydia
(P23.2) Congenital pneumonia due to staphylococcus
(P23.3) Congenital pneumonia due to streptococcus, group B
(P23.4) Congenital pneumonia due to Escherichia coli
(P23.5) Congenital pneumonia due to Pseudomonas
(P23.6) Congenital pneumonia due to other bacterial agents
Haemophilus influenzae
Klebsiella pneumoniae
Mycoplasma
Streptococcus, except group B
(P23.8) Congenital pneumonia due to other organisms
(P23.9) Congenital pneumonia, unspecified

(P24.) Neonatal aspiration syndromes
(P24.0) Neonatal aspiration of meconium
(P25.) Interstitial emphysema and related conditions originating in the perinatal period
(P25.0) Interstitial emphysema originating in the perinatal period
(P25.1) Pneumothorax originating in the perinatal period
(P25.2) Pneumomediastinum originating in the perinatal period
(P25.3) Pneumopericardium originating in the perinatal period
(P25.8) Other conditions related to interstitial emphysema originating in the perinatal period
(P26.) Pulmonary haemorrhage originating in the perinatal period
(P27.) Chronic respiratory disease originating in the perinatal period
(P27.0) Wilson-Mikity syndrome
(P27.1) Bronchopulmonary dysplasia originating in the perinatal period
(P27.8) Other chronic respiratory diseases originating in the perinatal period
(P27.9) Unspecified chronic respiratory disease originating in the perinatal period
(P28.) Other respiratory conditions originating in the perinatal period
(P29.) Cardiovascular disorders originating in the perinatal period
(P29.0) Neonatal cardiac failure
(P29.1) Neonatal cardiac dysrhythmia
(P29.2) Neonatal hypertension
(P29.3) Persistent fetal circulation
(P29.4) Transient myocardial ischaemia of newborn
(P29.8) Other cardiovascular disorders originating in the perinatal period
(P29.9) Cardiovascular disorder originating in the perinatal period, unspecified
(P35–P39) Infections specific to the perinatal period
(P35.) Congenital viral diseases
(P35.0) Congenital rubella syndrome
(P35.1) Congenital cytomegalovirus infection
(P35.2) Congenital herpesviral infection (herpes simplex)
(P35.3) Congenital viral hepatitis
(P35.8) Other congenital viral diseases
(P35.9) Congenital viral disease, unspecified
(P36.) Bacterial sepsis of newborn
(P36.0) Sepsis of newborn due to streptococcus, group B
(P36.1) Sepsis of newborn due to other and unspecified streptococci
(P36.2) Sepsis of newborn due to Staphylococcus aureus
(P36.3) Sepsis of newborn due to other and unspecified staphylococci
(P36.4) Sepsis of newborn due to Escherichia coli
(P36.5) Sepsis of newborn due to anaerobes
(P36.8) Other bacterial sepsis of newborn
(P36.9) Bacterial sepsis of newborn, unspecified
(P37.) Other congenital infectious and parasitic diseases
(P37.0) Congenital tuberculosis
(P37.1) Congenital toxoplasmosis
(P37.2) Neonatal listeriosis (disseminated)
(P37.3) Congenital falciparum malaria
(P37.4) Other congenital malaria
(P37.5) Neonatal candidiasis
(P37.8) Other specified congenital infectious and parasitic diseases
(P37.9) Congenital infectious and parasitic disease, unspecified

(P38.) Omphalitis of newborn with or without mild haemorrhage
(P39.) Other infections specific to the perinatal period
(P39.0) Neonatal infective mastitis
(P39.1) Neonatal conjunctivitis and dacryocystitis
(P39.2) Intra-amniotic infection of fetus, not elsewhere classified
(P39.3) Neonatal urinary tract infection
(P39.4) Neonatal skin infection
(P39.8) Other specified infections specific to the perinatal period
(P39.9) Infection specific to the perinatal period, unspecified
(P50–P61) Haemorrhagic and haematological disorders of fetus and newborn
(P50.) Fetal blood loss
(P50.0) Fetal blood loss from vasa praevia
(P50.1) Fetal blood loss from ruptured cord
(P50.2) Fetal blood loss from placenta
(P50.3) Haemorrhage into co-twin
(P50.4) Haemorrhage into maternal circulation
(P50.5) Fetal blood loss from cut end of co-twin's cord
(P50.8) Other fetal blood loss
(P50.9) Fetal blood loss, unspecified
(P51.) Umbilical haemorrhage of newborn
(P52.) Intracranial nontraumatic haemorrhage of fetus and newborn
(P53.) Haemorrhagic disease of fetus and newborn
(P54.) Other neonatal haemorrhages
(P55.) Haemolytic disease of fetus and newborn
(P55.0) Rh isoimmunization of fetus and newborn
(P55.1) ABO isoimmunization of fetus and newborn
(P55.8) Other haemolytic diseases of fetus and newborn
(P55.9) Haemolytic disease of fetus and newborn, unspecified
(P56.) Hydrops fetalis due to haemolytic disease
(P57.) Kernicterus
(P58.) Neonatal jaundice due to other excessive haemolysis
(P59.) Neonatal jaundice from other and unspecified causes
(P60.) Disseminated intravascular coagulation of fetus and newborn
(P61.) Other perinatal haematological disorders
(P61.0) Transient neonatal thrombocytopenia
(P61.1) Polycythaemia neonatorum
(P61.2) Anaemia of prematurity
(P61.3) Congenital anaemia from fetal blood loss
(P61.4) Other congenital anaemias, not elsewhere classified
(P61.5) Transient neonatal neutropenia
(P61.6) Other transient neonatal disorders of coagulation
(P61.8) Other specified perinatal haematological disorders
(P61.9) Perinatal haematological disorder, unspecified
(P70–P74) Transitory endocrine and metabolic disorders specific to fetus and newborn
(P70.) Transitory disorders of carbohydrate metabolism specific to fetus and newborn
(P71.) Transitory neonatal disorders of calcium and magnesium metabolism
(P72.) Other transitory neonatal endocrine disorders
(P74.) Other transitory neonatal electrolyte and metabolic disturbances
(P75–P78) Digestive system disorders of fetus and newborn

(P75.) Meconium ileus
(P76.) Other intestinal obstruction of newborn
(P77.) Necrotizing enterocolitis of fetus and newborn
(P78.) Other perinatal digestive system disorders
(P78.0) Perinatal intestinal perforation
Meconium peritonitis
(P78.1) Other neonatal peritonitis
(P78.2) Neonatal haematemesis and melaena due to swallowed maternal blood
(P78.3) Noninfective neonatal diarrhoea
(P78.8) Other specified perinatal digestive system disorders
(P78.9) Perinatal digestive system disorder
(P80–P83) Conditions involving the integument and temperature regulation of fetus and newborn
(P80.) Hypothermia of newborn
(P81.) Other disturbances of temperature regulation of newborn
(P83.) Other conditions of integument specific to fetus and newborn
(P83.0) Sclerema neonatorum
(P83.1) Neonatal erythema toxicum
(P83.2) Hydrops fetalis not due to haemolytic disease
(P83.3) Other and unspecified oedema specific to fetus and newborn
(P83.4) Breast engorgement of newborn
(P83.5) Congenital hydrocele
(P83.6) Umbilical polyp of newborn
(P83.8) Other specified conditions of integument specific to fetus and newborn
(P83.9) Condition of integument specific to fetus and newborn, unspecified
(P90–P96) Other disorders originating in the perinatal period
(P90.) Convulsions of newborn
(P91.) Other disturbances of cerebral status of newborn
(P91.0) Neonatal cerebral ischaemia
(P91.1) Acquired periventricular cysts of newborn
(P91.2) Neonatal cerebral leukomalacia
(P91.3) Neonatal cerebral irritability
(P91.4) Neonatal cerebral depression
(P91.5) Neonatal coma
(P91.6) Hypoxic ischaemic encephalopathy of newborn
(P91.8) Other specified disturbances of cerebral status of newborn
(P91.9) Disturbance of cerebral status of newborn, unspecified
(P92.) Feeding problems of newborn
(P93.) Reactions and intoxications due to drugs administered to fetus and newborn
(P94.) Disorders of muscle tone of newborn
(P94.0) Transient neonatal myasthenia gravis
(P94.1) Congenital hypertonia
(P94.2) Congenital hypotonia
Nonspecific floppy baby syndrome
(P94.8) Other disorders of muscle tone of newborn
(P94.9) Disorder of muscle tone of newborn, unspecified
(P95.) Fetal death of unspecified cause
Deadborn fetus NOS
Stillbirth NOS
(P96.) Other conditions originating in the perinatal period

(P96.0) Congenital renal failure
(P96.1) Neonatal withdrawal symptoms from maternal use of drugs of addiction
(P96.2) Withdrawal symptoms from therapeutic use of drugs in newborn
(P96.3) Wide cranial sutures of newborn
(P96.4) Termination of pregnancy, fetus and newborn
(P96.5) Complications of intrauterine procedures, not elsewhere classified
(P96.8) Other specified conditions originating in the perinatal period
(P96.9) Condition originating in the perinatal period, unspecified
Congenital debility NOS

APPENDIX J: BREASTFEEDING BEHAVIORS QUESTIONNAIRE ITEMS

1. Have you ever breastfeed or fed this baby pumped breastmilk either in the hospital or after you went home? (Yes, No)
2. While you were in the hospital, was your baby fed anything other than breastmilk such as water, formula, or sugar water? (Yes, No)
3. In the last 24 hours, did you breastfeed or feed this baby your pumped breastmilk? (Yes, No)
4. In the last 24 hours, was your baby fed anything other than breastmilk such as water, formula, milk, juice, cereal, or sweet drinks? (Yes, No)
5. Is this a typical last 24-hours? If no, explain.

APPENDIX K: REASONS FOR SUPPLEMENTATION OR DISCONTINUING BREASTFEEDING QUESTIONNAIRE ITEMS

1. If your baby received fluids or nourishment other than breastmilk during the hospital stay, was this due to [select all that apply]

    (1.1) Mother or baby was sick.

    (2.2) Not enough milk to satisfy baby.

    (3.3) Pain in nipples or breasts.

    (4.4) The baby had difficulty latching on or getting started feeding.

    (5.5) Prepare to return to work or school.

    (6.6) Someone discouraged you from breastfeeding.

2. Is there another reason, other than those mentioned, that led to you supplementing or weaning your baby while you were in the hospital. If so, what is or are the reasons?

3. If your baby received fluids or nourishment other than breastmilk in the last 24 hours, was this due to [select all that apply]

    (3.1) Mother or baby was sick.

    (3.2) Not enough milk to satisfy baby.

    (3.3) Pain in nipples or breasts.

    (3.4) The baby had difficulty latching on or getting started feeding.

    (3.5) You have to return to work or school.

    (3.6) Someone discouraged you from breastfeeding.

4. Is there another reason, other than those mentioned, that led to you supplementing or weaning your baby while you were in the hospital. If so, what is or are the reasons?

Script for Second Telephone Interview

Hello, participant, this is PI and I am calling to finish our work on the breastfeeding study in which you volunteered to participate. Congratulations on the birth of your baby. We will need a few minutes to complete the survey, is this a good time for us to talk? When would it be more convenient for me to call back? Or, if the interview commences, the participant will be advised that the conversation will be recorded to insure accuracy

Administer questions for Breastfeeding behaviors and Reason for Supplementation or Discontinuing breastfeeding

Thank you for participating in the breastfeeding education study. Remember you can call or email me anytime with questions or concerns about this study.

Script for calls when Mother does not mail birth announcement card

Hello, participant, this is PI and I am calling to finish our work on the breastfeeding study in which you volunteered to participate. I haven't received your postcard and was calling to see if everything is alright.

If there has been a compilation or loss, encourage the mother to talk about the problem and her feelings. Ensure that she is aware of support services available through Winnie Palmer and make referral if needed.

Support Groups

Neonatal Parent Hour. This is a support group for parents and their family who currently have an infant in the NICU. Topics relevant to the sick newborn are presented. It is also an opportunity for parent to parent sharing time. Facilitator: Clinical Social Workers.

Where: Arnold Palmer Hospital. When: Second Wednesday of each month, 6:30pm – 7:30pm. For further information and registration, contact 407.841.5198

Perinatal / Neonatal Bereavement Support Group. This group is an open support group for parents who have experienced a perinatal loss (i.e., miscarriages, ectopic pregnancies, still birth, and newborn deaths.) Facilitator: Clinical Social Workers Where: Arnold Palmer Hospital When: Second Tuesday of each month, 6:00pm. For further information and registration, contact 407.649.6947

Post Partum Support Group. This is a support group for mothers who have recently given birth and are feeling tired, worried, sad or just not themselves. This support group provides you an opportunity to meet with other mothers. Facilitator: Clinical Social Workers When: First and third Wednesday of each month, 5:30pm – 6:30pm. For further information and registration, contact 321.841.3231

Florida Lactation Consultant Association Directory of board approved lactation specialists. http://www.flca.info/

APPENDIX L: RESULTS FROM KNIGHTENGALE SURVEY OF BREASTFEEDING MYTHS AND MISINFORMATION

Item		Mean	% Never	% Rarely	% Sometimes	% Frequently	% Very Frequently
Q1*	Formula and breastmilk are pretty much	3.0	18.0	12.4	37.1	16.9	15.7
Q2	Breasts have to be just the right size to breastfeed successfully: not too big, not too small	2.7	14.6	32.6	34.8	9.0	9.0
Q3*	Many women do not produce enough milk	3.9	1.1	11.2	20.2	33.7	33.7
Q4**	A baby should be fed for a specific number of minutes per breast	4.0	6.7	5.6	14.6	28.1	44.9
Q5**	You don't know how much milk the baby is getting	4.3	1.1	6.7	7.9	34.8	49.4
Q6*	Babies need routine and scheduled feedings	3.7	3.4	13.5	20.2	37.1	25.8
Q7*	Mothers must have a specified amount of calories, nutrients or liquids	3.3	3.4	21.3	33.7	27.0	14.6
Q8	Breastfeeding in public is not allowed	2.7	14.6	32.6	31.5	15.7	5.6
Q9	There is no such thing as nipple confusion	2.9	12.4	23.6	33.7	20.2	10.1
Q10**	Bottle fed babies sleep longer than breastfed babies	4.3	1.1	3.4	10.1	33.7	51.7
Q11*	Never wake a sleeping baby for feeding	3.5	1.1	14.6	31.5	41.6	11.2
Q12*	Babies need to know how to take a bottle	3.4	5.6	15.7	30.3	30.8	18.0
Q13**	Breastfeeding is difficult	4.1	1.1	4.5	19.1	33.7	41.6
Q14**	It easier and more convenient to bottle feed	4.0	2.2	9.0	14.6	33.7	40.4
Q15*	Breastfeeding ties the mother down	3.8	2.2	6.7	25.8	42.7	22.5

Q16*	Breastfeeding makes the breast sag	3.5	6.7	10.1	29.2	30.3	23.6
Q17*	Breastfed babies want to be held all the time	3.6	3.4	13.5	27.0	34.8	21.3
Q18a	Breastfeeding should be interrupted if the baby is sick	2.9	13.6	18.5	40.7	19.8	7.4
Q18b*	Breastfeeding should be interrupted if the mother is sick	3.3	9.9	9.9	33.3	32.1	14.8
Q18c*	Breastfeeding should be interrupted if the mother is taking medicine	3.8	1.2	3.7	32.1	37.0	25.9
Q18d*	Breastfeeding should be interrupted if the mother has had an immunization	3.8	17.3	22.2	33.3	18.5	8.6
Q18e*	Breastfeeding should be interrupted if the mother's nipples are bleeding	3.5	3.7	17.1	28.0	30.5	20.7
Q19a*	The following mothers cannot or should not breastfeed: Pregnant	3.3	8.5	11.0	32.9	32.9	14.6
Q19b*	The following mothers cannot or should not breastfeed: Smoking	3.4	6.1	13.4	32.9	26.8	20.7
Q19c*	The following mothers cannot or should not breastfeed: had breast reduction surgery	3.4	6.1	14.6	34.1	28.0	17.1
Q19d*	The following mothers cannot or should not breastfeed: had breast augmentation surgery	3.2	4.9	17.1	43.9	20.7	13.4

Q20a	The following mothers cannot or should not breastfeed: breastfeed after exercising	2.1	29.3	41.5	19.5	7.3	2.4
Q20b	The following mothers cannot or should not breastfeed: dye her hair or get a permanent	2.4	22.0	39.0	25.6	6.1	7.3
Q20c*	The following mothers cannot or should not breastfeed: drink any alcohol	3.6	1.2	14.6	34.1	26.8	23.2
Q20d*	The following mothers cannot or should not breastfeed: take birth control pills	3.2	11.0	19.5	25.6	26.8	17.1

APPENDIX M: MYTH AND DEFENSE STATEMENTS

Category A

Myth

A1. You should formula feed so you can go back to work.

A2. You should not breastfeed in public.

A3. You should bottle feed because it is easier.

Defense Statement

You may have heard bottle feeding is easier or more convenient than breastfeeding. Actually, bottle feeding requires special preparation and storage—especially during the first few months. Breastmilk is always readily available, in the right amount, at the right temperature, and is environmentally friendly. A mother may breastfeed her newborn any place she is allowed to be. Mother's milk can be collected quickly and easily at work or school.

Category B

Myth

B1. You should formula feed your newborn so you will get more sleep.

B2. You should put your newborn in the nursery for the night so you can get your sleep.

B3. You should give formula to your newborn at night so you will get more sleep.

Defense Statement

You may have heard mothers who bottle feed get more sleep than do mothers who breastfeed. Actually, evidence shows that parents of infants who were breastfed during the night slept an average of 40 to 45 minutes longer than parents of infants given formula. Mothers who breastfed exclusively got more sleep than mothers who fed their infants formula. Mothers who

breastfed exclusively had more night-time waking, but slept 20 minutes longer compared with mothers who did not breastfeed exclusively.

Category C

Myth

C1. You should not take medicines while breastfeeding.

C2. You should not breastfeed if you are sick.

C3. You should not breastfeed if you smoke.

Defense Statement

You may have heard that there are many times when you should not breastfeed because there may be something wrong with mother's milk. Experts believe there are very few times to interrupt breastfeeding. During illness, mother's milk delivers important disease-fighting factors to the newborn. Most medicines are safe to take when breastfeeding. Even when moms do not eat healthy foods or they smoke, it is still better for the baby to breastfeed.

Category D

Myth

D1. You should let a newborn sleep as long as he wants and not wake him for feedings.

D2. You should feed your newborn six times each day on a strict schedule; feed 10 minutes on each breast, every four hours.

D3. You should formula feed your newborn so you know how much he's getting.

Defense Statement

You may have heard incorrect advice about feeding frequency and duration and how to know that if your newborn is getting enough milk. You know your newborn is getting enough milk when at one week of age: (a) your newborn has three or more yellow, dirty diapers and six or more wet diapers per day (b) your newborn is sucking and swallowing for 20-30 minutes each feeding, nurses about every 1½ to 3 hours (8 to 12 times a day) and appears satisfied after feeding (c) your newborn is gaining weight, about ½ to 1 ounce per day.

APPENDIX N: SUPPORT FROM STUDY SITE

WINNIE PALMER HOSPITAL
For Women & Babies
Supported by Arnold Palmer Medical Center Foundation

83 W. Miller St.
Orlando, FL 32806
321.843.9792

winniepalmerhospital.com

25 April 2011

Dear Committee:

Orlando Health is delighted to give support to Kandis Natoli, MSN, RNC, IBCLC, doctoral candidate University of Central Florida College of Nursing for her dissertation research project "Group Prenatal Breastfeeding Education Intervention to Help Mothers Defend Their Decision to Breastfeed and Resist Pressure to Give Formula." The study will be conducted among clients of the Maternal Education Department. Approximately 140 pregnant women attending prenatal breastfeeding education classes over a period of 8-10 weeks will be invited to participate in the study. This innovative opportunity will benefit mothers and babies in the Greater Orlando Metropolitan Area.

Regards,

Jen Apple MHA, RNBC

Jen Apple, MHA, RNBC
Patient Care Administrator
Women's Services, Transport, F&N
Winnie Palmer Hospital

APPENDIX O: IRB 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: **Kandis Natoli**

Date: **March 23, 2010**

Dear Researcher:

On 3/23/2010, the IRB approved the following activity as human participant research that is exempt from regulation:

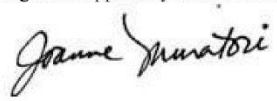
Type of Review:	Exempt Determination
Project Title:	Breastfeeding Myths Survey
Investigator:	Kandis Natoli, MSN
IRB Number:	SBE-10-06837
Funding Agency:	
Grant Title:	
Research ID:	n/a

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 03/23/2010 04:04:17 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, 407-882-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Notice that UCF will Rely Upon Other IRB for Review and Approval

From : **UCF Institutional Review Board**
FWA00000351, Exp. 10/8/11, IRB00001138

To : **Kandis Natoli, MSN**

Date : **June 26, 2012**

IRB Number: **SBE-12-08543**

Study Title: **Breastfeeding Education Study I**

Dear Researcher:

The research protocol noted above was reviewed by the University of Central Florida IRB Designated Reviewer on 6/15/2012. The UCF IRB accepts Orlando Health's Institutional Review Board review and approval of this study for the protection of human subjects in research. **The expiration date will be the date assigned by the [insert University name] Institutional Review Board and the consent process will be the process approved by that IRB.**

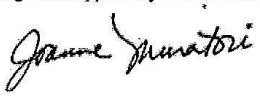
This project may move forward as described in the protocol. It is understood that Orlando Health's IRB is the IRB of Record for this study, but local issues involving the UCF population should be brought to the attention of the UCF IRB as well for local oversight, if needed.

All data, including signed consent forms if applicable, must be retained in a locked file cabinet for a minimum of three years (six if HIPAA applies) past the completion of this research. Any links to the identification of participants should be maintained on a password-protected computer if electronic information is used. Additional requirements may be imposed by your funding agency, your department, or other entities. Access to data is limited to authorized individuals listed as key study personnel.

Failure to provide a continuing review report for renewal of the study to the Orlando Health IRB could lead to study suspension, a loss of funding and/or publication possibilities, or a report of noncompliance to sponsors or funding agencies. If this study is funded by any branch of the Department of Health and Human Services (DHHS), an Office for Human Research Protections (OHRP) IRB Authorization form must be signed by the signatory officials of both institutions, and a copy of the form must be kept on file at the IRB office of both institutions.

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

Signature applied by Joanne Muratori on 06/26/2012 08:57:34 AM EDT



IRB Coordinator

ORLANDO HEALTH
When it matters most.

1414 Kuhl Ave.
Orlando, FL 32806
321.843.7000

orlandohealth.com

MDACCO FWA # 00000131
ORMC/APMC FWA # 00000384

DATE:	June 15, 2012
TO:	Kandis Natoli
FROM:	Arnold Palmer Medical Center (APMC) IRB
PROJECT TITLE:	[344179-2] Breastfeeding Education Study I
REFERENCE #:	12.032.03
SUBMISSION TYPE:	New Project
ACTION:	APPROVED
APPROVAL DATE:	June 15, 2012
EXPIRATION DATE:	June 14, 2013
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review categories #6 and #7

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

- Application Form - Application with Signatures (UPDATED: 06/15/2012)
- Consent Form - Informed Consent Form dated 4/12/2012 (UPDATED: 06/15/2012)
- Letter - Nursing Research Committee Letter (UPDATED: 06/15/2012)
- Letter - Dissertation Letter (UPDATED: 06/15/2012)
- Orlando Health - IRB Application - Orlando Health - IRB Application (UPDATED: 06/15/2012)
- Protocol - Protocol dated 4/12/2012 (UPDATED: 06/15/2012)

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 followed by a signed consent form. 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.

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 June 14, 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.

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.

APPENDIX P: INFORMED CONSENT

Breastfeeding Education Study I

INFORMED CONSENT FORM

Good medical care includes obtaining informed consent before beginning any experimental procedure. The patient or subject should be told the nature, purpose, alternative and possible side effects of the therapy. This research study is being conducted by Kandis M. Natoli.

Principal Investigator(s): Kandis M. Natoli, MSN, RNC, IBCLC

Co-Investigator(s): Harriet Miller, PhD, ARNP, CPN
Karen Aroian, PhD, RN, FAAN

Sub-Investigator(s): Annette Leary, BSN, IBCLC

Investigational Site(s): Orlando Health, Inc.
Winnie Palmer Hospital for Women and Babies

This consent form gives detailed information about the research study. Your principal investigator will discuss this information with you. Once you understand the study, you will be asked to sign this form if you wish to participate. You must be 18 years or older to take part in this research study.

1. PURPOSE OF RESEARCH STUDY:

The purpose of the research study is to test two types of educational activities that will help women meet their breastfeeding goals.

2. EXPECTED DURATION:

You can expect to be part of this research study during the prenatal breastfeeding education class and receive two follow-up telephone interviews. The first interview will occur about two weeks after class and will last about 5 minutes. The second interview will be about one month after your baby is born and last about 10 minutes. The entire study will be completed in one year.

3. PROCEDURES TO BE FOLLOWED:

All attendees of the prenatal breastfeeding education class will receive a brief educational activity. It is not necessary to enroll in the study to attend the breastfeeding class.

If you participate in this study, you will be asked be to fill out the demographic and maternal characteristics form, answer the maternal intention to breastfeed questions, and complete the contact information form. You will also be given a reminder magnet and a coded, preaddressed, stamped postcard with a blank space for the delivery day and month. Study participants will be asked to fill in the birth day and month and mail the card as soon as possible after childbirth.

You will be assigned to one of two study groups called Group A *or* Group B. It is not known if any group will be better for you.

- Participants in Group A will play a board game about breastfeeding
- Participants in Group B will view a video about breastfeeding

The class will be conducted by the Maternal Education staff member. The board game and video will be played during class and these activities will led by the principal investigator, Kandis Natoli.

Everyone in the study will receive two follow-up telephone calls. The first telephone interview will be in ten days to two weeks and should last about 5 minutes. This will consist of six survey questions about breastfeeding attitudes and beliefs. The second interview will be about one month after childbirth and last about 10 minutes. This interview will consist of six survey questions about your childbirth experience and eight survey questions about your infant feeding decisions in the hospital and at home. Both of these interviews will be recorded to ensure accuracy.

4. IDENTIFICATION OF EXPERIMENTAL PROCEDURES:

This study will test two different types of educational activities about breastfeeding (interactive board game versus watching a video).

5. POTENTIAL RISKS AND DISCOMFORTS:

There is minimal risk involved in this study. The only identified risk is exposure of your protected health information, which will be closely guarded at all times.

6. POTENTIAL BENEFIT TO SUBJECT OR OTHERS:

It is not possible to predict whether or not any personal benefit will result from participation in this research study. It is hoped that your participation in this research study will help you or others to meet their breastfeeding goals.

7. ALTERNATIVE PROCEDURES OR TREATMENTS:

There are no alternative procedures or treatments offered in this research study. You have the choice to not participate in this research study.

8a. CONFIDENTIALITY OF RECORDS:

Your study information will be kept in the locked office of Kandis Natoli or Annette Leary. The confidentiality of your record is carefully guarded. No information by which you can be identified will be published in any publication. No information by which you can be identified will be released to any persons other than the research team or as required by law.

This study is subject to review at any time by the Food and Drug Administration or the Arnold Palmer Medical Center Review board.

8b. AUTHORIZATION TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH:

The Federal Privacy Regulations explain how your personal health information will be used and to whom it will be disclosed (given to) for this research study. You will be provided with a copy of the Notice of Privacy Practices, which describes the Orlando Health, Inc. privacy practices. Your protected health information may be used or disclosed for research purposes.

What protected health information is collected in the study?
The following protected health information will be collected during this study:

- Name
- Address
- Telephone

Email

Who may Use or Disclose your Protected Health Information?
The following individuals / organizations may use or disclose your protected health information for this research study:

Study investigators and the study staff
Arnold Palmer Medical Center Institutional Review Board

To whom may your Protected Health Information be Disclosed?
As part of the study, the study doctor and the study staff may disclose the results of study-related tests and procedures that may identify you to the following:

Arnold Palmer Medical Center Institutional Review Board
Food and Drug Administration (FDA)
Office for Human Research Protection (OHRP)

By agreeing to participate in this research study and signing this informed consent, you are authorizing Orlando Health, Inc., Winnie Palmer Hospital, and Kandis M. Natoli to use and disclose your protected health information for the purpose of research related to this study. Only the smallest amount of protected health information necessary will be used. There is no expiration date for the use of your health information for this research study. It may be used until all follow-up procedures and all research/data collection has been completed. It may also be used until the federal regulatory agency check that the data requirements have been met. Your health information may be used in future additional re-checking of data accuracy (correctness). At the time that your records no longer need to be checked, t Orlando Health, Inc. will destroy (shred) your research records.

Additional information about confidentiality of and access to your protected health information while you participate in this research study:

- If your principal investigator wishes to use your identifiable information for any other reason than this research study, he/she must get your permission for that purpose.
- You may withdraw your permission to use your protected health information by talking with your principal investigator or research staff and making a request in writing. Use and release of information that was already gathered may continue when necessary in checking and reporting important events (such as accounting for your withdrawal from the study, adverse events reported to the FDA to monitor safety of participants, or federal regulatory agency audits (reviews).
- If you withdraw your permission to use your health information, neither Orlando Health, Inc. nor Kandis M. Natoli will release information collected after your withdrawal to any other third party.
- If you withdraw your permission to use and release your health information, you will no longer be able to participate in the study. However, if you decide to withdraw from the study, you will not be penalized or lose benefits to which you are otherwise entitled.
- Your principal investigator may discuss other research projects with you if he/she thinks the other projects relate to your condition. However, your health information cannot be given to another doctor or sponsor for the reason of asking you to enroll in another research study.

9. COMPENSATION:

All attendees of the prenatal breastfeeding class will receive a nursing cover regardless of study participation. You will not be paid for participating in this study.

10. RESEARCH RELATED INJURY:

Because this research is education only, research related injuries are not anticipated.

For more information about your rights as a research subject, you may call the Institutional Review Board Office, at (321) 841-5895. The study coordinator involved in your care is available to answer any

questions you have concerning participation in this research program. You are free to call Kandis Natoli (386) 423-4828 with any questions concerning this research study that you have now or in the future

11. VOLUNTARY PARTICIPATION:

You are free to refuse or stop participation in this research study at any time.

12. ADDITIONAL RISKS:

Because this research is education only, additional risks are not anticipated.

13. INVOLUNTARY TERMINATION:

Your participation in this study may be stopped by the study principal investigator under no circumstances.

14. PROCEDURES FOR WITHDRAWAL:

You may withdraw from this study at any time by contacting the principal investigator, Kandis Natoli.

15. NEW FINDINGS:

Significant new findings developed during the course of the research which may relate to your willingness to continue your participation will be provided to you.

16. NUMBER OF PARTICIPANTS:

The approximate number of subjects involved in the study at this site will be 220. The Winnie Palmer Hospital for Women and Babies is the only study site.

17. ADDITIONAL COST:

There are no costs at all associated with this study for you.

18. FINANCIAL DISCLOSURE:

This research study is being funded, in part, by grants from the International Lactation Consultant Association and the Florida Nursing Association.

19. ADDITIONAL INFORMATION:

Educational research designs often require that the full intent of the study not be explained prior to participation. Although we have described the general nature of the tasks that you will be asked to perform, the full intent of the study will not be explained to you until after the completion of the study. At that time, you will be provided with opportunity for a full debriefing which will include an explanation of the hypothesis that was tested and other relevant background information pertaining to the study. You will also be given an opportunity to ask any questions you might have about the hypothesis and the procedures used in the study.

Breastfeeding Education Study I

20. **SIGNATURES:** My signature indicates that I consent and authorize Kandis M. Natoli and whomever she may designate as her assistant(s) including Orlando Health, Inc., its employees and its agents to perform upon myself the research described above.

I AM MAKING A DECISION WHETHER OR NOT TO PARTICIPATE IN THIS STUDY. I HAVE READ, OR HAD READ TO ME IN A LANGUAGE THAT I UNDERSTAND, ALL OF THE ABOVE, ASKED QUESTIONS, RECEIVED ANSWERS CONCERNING AREAS I DID NOT UNDERSTAND, AND WILLINGLY GIVE MY CONSENT TO PARTICIPATE IN THIS STUDY. UPON SIGNING THIS FORM I WILL BE GIVEN A COPY.

_____ _____
Signature of Subject Date

_____ _____
Signature of Witness Date

I have explained and defined in detail the research procedure in which the patient has consented to participate.

_____ _____
Investigator's Signature Date

Translator/Interpreter

Name_____ Phone#_____

Address_____

For Signatures by Guardian or Legal Representative, please describe the authority to act on behalf of the participant below:

_____

_____

APPENDIX Q: PROTECTION OF HUMAN SUBJECTS RESEARCH TRAINING

CITI Collaborative Institutional Training Initiative

CITI Health Information Privacy and Security (HIPS) Curriculum Completion Report
Printed on 1/8/2012

Learner: Kandis Natoli (username: knatoli)
Institution: Orlando Health
Contact Information Department: Center for Nursing Research
Email: kandis.natoli@gmail.com

CITI Health Information Privacy and Security (HIPS) for Clinical Investigators: This course for **Clinical Investigators** will satisfy the mandate for basic training in the HIPAA. In addition other modules on keeping your computers, passwords and electronic media safe and secure are included.

Stage 1. Basic Course Passed on 01/08/12 (Ref # 7188872)

Required Modules	Date Completed	Score
About the Course	01/06/12	1/1 (100%)
Privacy Rules: Introduction to Federal and State Requirements*	01/06/12	9/10 (90%)
Privacy Rules and Research*	01/08/12	9/10 (90%)

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Return

APPENDIX R: CURRICULUM VITAE

KANDIS M. NATOLI, MSN, RNC, IBCLC

2501 35th St
Edgewater, FL 3141
386-423-4828
kandis.natoli@gmail.com

I. EDUCATION

DEGREE	INSTITUTION	CLINICAL MAJOR	ROLE
PhD, candidate*	University of Central Florida	Nursing	Researcher
MSN	University of Central Florida	Nursing	Nurse Educator
BSN	University of Central Florida	Nursing	Registered Nurse
AS	Daytona State College	Nursing	Registered Nurse
Certificate	Daytona State College	Nursing	Practical Nurse

*Anticipated deense November 2014

II. LICENSURE/CERTIFICATION

Registered Nurse, Florida # 2829752
Maternal-Newborn Certified Resisted Nurse (NCC) # NAT104261092
International Board Certified Lactation Consultant (IBCLC) # L-24298
BLS for Healthcare Providers Program. American Heart Association
Collaborative Institutional Training Initiative (CITI) Protection of Human Research Subjects
National Institute of Health Human Research Protection Certificate of training
The Center for Pranic Healing, Inc. Pranic Healing Level 1
University of Central Florida Graduate Teaching Assistant Certificate
Business Case for Breastfeeding: Train the Trainer

III. EMPLOYMENT

ACADEMIC APPOINTMENTS:

2007-11 University of Central Florida
2014- 4000 Central Florida Blvd; Orlando, FL 32816
(407) 823-6541
Angeline Bushy, PhD 386-506-4032 abushy@mail.ucf.edu
Adjunct/Graduate Teaching Assistant/ Intern
Clinical: Pediatric, Obstetrics, and Long Term Care, Public Health, Community
Classroom: Study Skills, Remediation for Research and Pathophysiology
Laboratory: Essential Nursing Skills and Physical Assessment
Online: Community (RN to BSN Program)

2011- Bethune-Cookman University
2008-09 640 Dr. Mary McLeod Bethune Boulevard, Daytona Beach, FL 32114
(386) 481-2000
Dean Sandra Tucker
Adjunct
Classroom: Health Assessment, Nursing Research, Obsterics & women's health, (Basic BSN program)
Clinical: Obstetrics, Community, Mental Health (Basic BSN program)
Online: Nursing Research (RN to BSN program)

CONSULTANT

2013- The Healthy Start Coalition of Flagler and Volusia Counties, Inc.
109 Executive Circle, Daytona Beach, FL 32114
(386) 252-4277
Rosha Loche
Contract: Fetal Infant Mortality Review Board - Abstractor

2014- Journal of Human Lactation - editoral review
Editor in Chief: Anne Meerwood

CLINICAL APPOINTMENTS:

1998-2004 Orlando Regional Healthcare Medical Education- Pediatrics
1414 Kuhl Avenue, Orlando, FL 32806-2093.
(407)841-5111
Registered Nurse/Lactation Consultant
Provide lactation services to childbearing families and outpatient care to children. Provide primary oversight for pediatric residents of the Education Department – Human Lactation elective. Provide continuing education for nurses and other allied health professionals. Teach prenatal education breastfeeding class for expectant parents. Develop patient education materials.

1990-1999 Halifax Medical Center.
303 N. Clyde Morris Blvd. Daytona Beach, FL 32111
(904)254-4000
Lactation consultant in the Women's Services Department.
Registered Nurse in the Family Birth Place (FBP), Mother-Baby unit.
Licensed Practical Nurse in the Women's Health Place and FBP

IV. PUBLICATIONS

Natoli, K. (2014). The Use of Inoculation Theory to Preserve Positive Health Behaviors
In preparation, dissertation.
Natoli, K. (2014). Myths and Misinformation About Breastfeeding.
Submitted for publication.
Natoli, K. (2014). Helping Mothers Defend Their Decision to Breastfeed.
In preparation, dissertation.
Natoli, K. (2014). Incivility in a Nursing Program: Exploration and Description.
In preparation.

V. RESEARCH AND GRANTS

YEAR	ROLE	TITLE	AGENCY	TYPE	AMOUNT
2014-15	PI	PENDING National Breastfeeding Myths and Misinformation Survey 2014	Florida Lactation Consultant	Extramural	$300.00
2012-13	PI	Incivility in a Nursing Program: Exploration and Description *(Faculty Mentor for SON Research Team)*	Bethune Cookman University	Intramural	$1,250.00
2011-13	PI	Group Prenatal Breastfeeding Education Intervention to Help Mothers Defend Their Decision to Breastfeed and Resist Pressure to Give Formula	International Lactation Consultant Association	Extramural	$7,000.00
2011	PI	Intervention to Help Breastfeeding Mothers Resist Pressure to Give Formula	Florida Nurses Foundation Evelyn Frank McKnight	Extramural	$500.00

2011 PI Dissertation Research Proposal:
Intervention to Help Mothers Resist Persuasion to Give Formula

2010 PI Dissertation Preliminary study:
Knightingale Breastfeeding Myths and Misinformation Survey

2007 Co-PI Author and co-investigator of BANNER Center Report:
High Fidelity Human Patient Simulators

VI. PRESENTATIONS

REFEREED NATIONAL/INTERNATIONAL

2014 *Podium & Poster* research presentation. Helping Mothers Defend Their Decision to Breastfeed. 2014 International Lactation Consultant Association Conference - Breastfeeding in the Real World: Meeting the Challenges. Phoenix AZ. *July 24, 2014.*

2009 Poster presentation. *Assessing Nipple Wounds: State of the Science.* International Lactation Consultant Annual Conference. Relating Evidence to Practice: An International Perspective. Orlando, Florida

2008 Podium presentation. *Conscientization: Infant feeding choice and the Code of Marketing of Breast-milk Substitutes.* Sigma Theta Tau. 19th International Nursing Research Congress Focusing on Evidence-Based Practice: Evidence-Based Practice Sessions. Singapore

2007 Poster Presentation: *Nipple Trauma During Breastfeeding: Evidence for Therapeutic Management* . Graduate Research Forum. University of Central Florida. Excellence Award.

REGIONAL/STATE/LOCAL PRESENTATIONS:

2015 Submitted: Poster presentation: *Myths and Misinformation about Breastfeeding* . Southern Nursing Research Society 29th Annual Conference "Conducting Research in Difficult Times: Come Revitalize Your Research Spirit." Tampa, FL

2013 Podium presentation. *Incivility in a Nursing Program: Exploration and Description.* Sigma Theta Tau International, Theta Epsilon 21st Annual Research Day. Winter Park, FL

2010 Poster. *Working, Mothering and Breastfeeding: Research Supporting the Business Case for Breastfeeding* . 5th Annual Sunshine Conference, The Volusia Flagler Advanced Practice

Nursing Council. Daytona Beach, Florida.

INVITED (NON-REFEREED) REGIONAL/STATE/LOCAL PRESENTATIONS:

2012 Podium: *Exploring Ethical Conduct.* 2012 Florida Lactation consultant Association Biennial Conference: Focus on Early Breastfeeding Success. Daytona Beach, FL

2010 Podium. *Business Case for Breastfeeding. C* ontinuing education presentation for District 6 Florida Nurses Association.

2007 Podium. *Nipple Trauma During Breastfeeding: Evidence for Therapeutic Management* College of Nursing Faculty Development Workshop: Information Fluency Communication. University of Central Florida.(Sigma Theta Tau, 2007)

2005 Podium: *Cultural Aspects of Breastfeeding* . Session in the Fundamentals of Lactation Management. Breastfeeding Education Center, Arnold Palmer Hospital for Children & Women, Orlando Regional Healthcare. (2004 FLCA, 2003)

2004 Podium: *Breast milk Biochemistry and Other Interesting Things.* Noon Conference: Arnold Palmer Pediatric Residency Program - Medical Education Pediatrics, Orlando Regional Healthcare. Orlando, Florida

2004 Podium: *4-hour Advanced Breastfeeding Course* . Arnold Palmer Hospital for Children and Women – Orlando Regional Healthcare (2003, 2002, 2001). Orlando, Florida

2004 Podium: *4-hour Basic Breastfeeding Education Class* . Arnold Palmer Hospital for Children and Women - Orlando Regional Healthcare.(2003, 2002, 2001). Orlando, FL

2004 Podium: *Prenatal Breastfeeding Class* . Childbirth Education Department. Orlando Regional Healthcare (2003, 2002, 2001, 2000). Orlando, FL

1999 Podium: *Breastfeeding and the Hospitalized Nursing Baby* . Orlando Regional Healthcare. Arnold Palmer Hospital for Children and Women. Orlando, FL

1999 Podium: Breastfeeding Basics. Continuity Presentation - Medical Education Pediatrics, Orlando Regional Healthcare. Orlando, FL

1999 Halifax Medical "Prenatal Breastfeeding Class. Daytona Beach, FL (1998, 1997)

1997 Halifax Medical Center "Breast Pumps" in-service. Daytona Beach, FL

VII. AWARDS

2011-12 USDHHS, Public Health Services: Advanced Education Nursing Traineeship

2010-11 USDHHS, Public Health Services: Advanced Education Nursing Traineeship

2009-10 USDHHS, Public Health Services: Advanced Education Nursing Traineeship

2008 University of Central Florida Graduate International Travel Award

2007-08 University of Central Florida Provost Fellowship

2007-08 Bert Fish Memorial Endowed Scholarship recipient

2007-08 GTA: Graduate Teaching Fellowship award

2007 University of Central Florida Graduate Research Forum. Certificate of Excellence

2006 Blue Cross/Blue Shield Nurse Educator Scholarship

2005-06 SUCCEED-Florida Scholarship

2006 Boy Scouts of America, Central Florida Council, Halifax District Award of Merit: Arrowhead

1998 International Lactation Consultation Consultant Examiners: Highest Scoring Candidate

VIII PROFESSIONAL ACTIVITIES & COMMUNITY SERVICE

UNIVERSITY SERVICE

School of Nursing Curriculum Committee: Bethune Cookman University
School of Nursing Resources and Technology Committee: Bethune Cookman University
Foundations in Excellence Roles and Purposes Dimension committee: Bethune Cookman University

PROFESSIONAL ORGANIZATIONS:

American Nurse Association, Florida East Central Region
International Lactation Consultant Association, Florida Chapter
Current Treasurer Florida Chapter
Current ILCA 2015 Conference Program Committee (2014)
FLCA Chair of the 2014 Florida Biennial Conference (Co-chair 2012)
Organization Doctoral Students in Nursing UCF; past Secretary: 2008-09
Southern Nursing Research Society
Sigma Theta Tau International, Theta Epsilon Chapter