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Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care

Lisette M. Allender
University of Texas at Tyler

QUALITY OF PRENATAL CARE AND PREGNANCY OUTCOMES: CENTERING PREGNANCY VERSUS TRADITIONAL PRENATAL CARE

by

LISETTE M. ALLENDER

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LISETTE M. ALLENDER

has been approved for the thesis/dissertation requirement on
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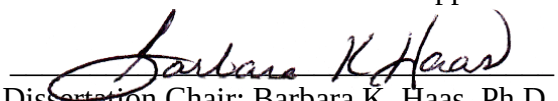

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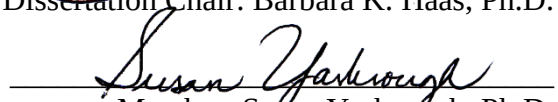

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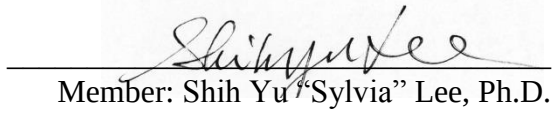

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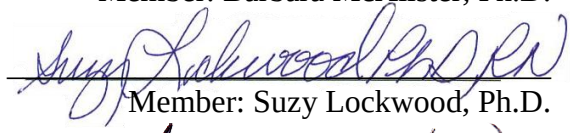

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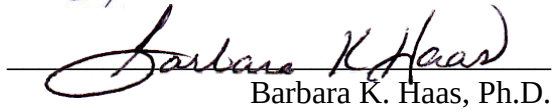
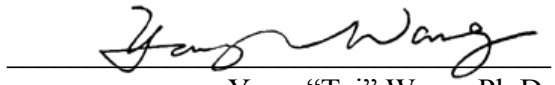


Barbara K. Haas, Ph.D.
Executive Director, School of Nursing



Yong "Tai" Wang, Ph.D.
Dean, College of Nursing and Health Sciences

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Abstract

QUALITY OF PRENATAL CARE AND PREGNANCY OUTCOMES: CENTERING PREGNANCY VERSUS TRADITIONAL PRENATAL CARE

Lisette M. Allender

Dissertation Chair: Barbara K. Haas, Ph.D.

The University of Texas at Tyler
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Prenatal care provides a unique opportunity for healthcare providers to improve outcomes for women and their families and by extension community health. Therefore, prenatal care has the opportunity to become the cornerstone of healthcare in our nation. It can influence the health of the mother, newborn, and family unit long beyond the course of a 9-month pregnancy. However, evidence supporting positive outcomes from current tradition based models of prenatal care is lacking.

The current United States prenatal system limits the patient-provider relationship, does not empower the patient, lacks emphasis on education, and is not woman-centered. The aim of the study was to compare an alternative prenatal care model, Centering Pregnancy, to individual prenatal care. An initial comparative concept analysis of power and empowerment focused on the nurse's role in cultivating empowerment in the pregnant woman. Subsequently, a study exploring the differences in outcomes for women in two different prenatal care groups was conducted. Differences examined included quality of prenatal care and pregnancy-related empowerment from the patient's

perspective. Also comparison of birth weight and gestational age at time of birth for a sample size of 51 pregnant patients (n =14 in Centering Pregnancy, n=37 in individual prenatal care).

Findings from this feasibility study revealed no statistical significance between the two independent groups in quality of prenatal care and gestational age. Differences in pregnancy-related empowerment ($p = 0.083$) and birth weight ($p = 0.088$) were noted to be approaching significance. Participants receiving individual prenatal care demonstrated higher post pregnancy-related empowerment. Centering Pregnancy participants had higher birth weights. The results call for further research into the effect of Centering Pregnancy on empowerment and birth weight with a larger sample size to determine if true significance exists.

Chapter One

Overview of the Program of Research

Prenatal care that is evidence-based and accessed early in pregnancy is vital to positively impact maternal and infant health outcomes. Prenatal care has become the focus of healthcare providers globally, as they seek out opportunities in which patient relationships can be utilized to improve patient care and health outcomes. Specifically, HealthyPeople 2020 has maternal, infant, and child health goals which include increasing number of women receiving prenatal care, reducing maternal complications related to pregnancy, decreasing preterm birth rate, and reducing the number of low birth weight babies (U.S. Department of Health and Human Services, 2017). Prenatal care was once seen as visit-based care; a higher number of visits was perceived as better and equated to "good" prenatal care. However, despite attending all required prenatal visits over the course of pregnancy, many patients lack important information about labor and birth and describe a lack of satisfaction with their care (Moos, 2006; Tandon, Cluxton-Keller, Colon, Vega, & Alonso, 2013; Vonderheid, Norr, & Handler, 2007).

Despite its importance, traditional prenatal care, hereafter referred to as individual prenatal care (IPC), is based upon a medical model that has limited patient engagement, education, and social support. As a women's health and labor and delivery nurse, the principal investigator has been interested in prenatal care and the observed limitations in women's understanding of pregnancy, self-care, and expectations for birth. As a clinic nurse and prenatal health care provider, it is evident that interactions between some providers and patients are extremely short. Furthermore, many women appear to be merely passive participants in their own health and well-being. Women often present to

the hospital to give birth with little knowledge related to options for care, interventions for pain and labor, or understanding of their role in healthcare decisions (Savage, 2006; Scaffidi, Posmontier, Bloch, & Wittman-Price, 2014). Klima (2001) states that with sharing of information and active engagement of the patient we can empower our patients to be involved in their own healthcare.

The current prenatal care model of IPC is focused on following a medical model with detection of maternal and fetal risk factors as a primary goal and continued focal point. However, despite a focus on reducing poor perinatal outcomes, there is a lack of consistency in educational talking points, active patient care, dedicated time for the patient, and the continued improvement of neonatal outcomes in the US. Prenatal care impacts fetal development, which in turn has repercussions throughout the lifetime of the child. Therefore, prenatal care should be a focus of all healthcare providers so the lives of mothers, babies, and communities can be improved. A growing body of research supports the use of a group model in prenatal care instead of IPC to improve maternal and fetal outcomes. Centering pregnancy (CP) is a popular and vetted group care model that has increased maternal satisfaction, breastfeeding rates, and reduced low birth weight (LBW), and preterm birth (PTB) numbers (Andersson, Christensson, & Hildingsson, 2013; Baldwin, 2006; Centering Healthcare Institute, 2012; Homer et al., 2012; Tanner-Smith, Steinka-Fry, & Lipsey, 2013).

The purpose of this research is to examine differences between CP and IPC. More specifically, quality of prenatal care is measured from the patient's perspective and how quality of care impacts pregnancy related empowerment and neonatal outcomes is explored. Furthermore, this study sought to utilize two newly developed instruments, the

Pregnancy Related Empowerment Scale and the Quality of Prenatal Care Questionnaire. These tools have previously been unstudied in a population of women in Texas.

Background

Though there is current research on group prenatal care, CP specifically, there is a need for replication studies and greater understanding of previous findings that indicated CP improves maternal and fetal outcomes. The Agency for Healthcare Research and Quality has identified CP as an innovative method with strong evidence showing improved outcomes. Specifically, the findings showed lower preterm birth rates, increased breastfeeding and an improved prenatal knowledge (Boyers, J., n.d.). Research comparing CP and IPC has demonstrated positive results with an improvement in depression, reduction in perceived stress and trait anxiety, lower preterm birth rate (Picklesimer, Billings, Hale, Blackhurts, & Covington-Kolb, 2012), and increased prenatal knowledge (i.e. appropriate weight gain, nutrition, smoking cessation) in women receiving CP care (Benediktsson et al., 2013; Kennedy et al., 2009; Trotman et al., 2015).

Research points to stress and anxiety as being a potential contributing factor to PTB (Heberlein et al., 2015). The CP model has been shown in multiple studies to decrease stress and anxiety, though often without understanding why this change occurs (Benediktsson et al., 2013; Kennedy et al., 2009; Risisky, Asghar, Chaffee, & DeGennaro, 2013). Reducing stress and anxiety through sharing information and social support may influence positive health behaviors. While patient satisfaction has been the focus of many studies related to care, there is a need for evaluation of the quality of prenatal standards of care (Nair et al., 2014). The idea that the number of appointments attended causes an improvement in outcomes is perfunctory. Consequently, there is a

need to take a detailed look at the content and quality of prenatal care and not simply the number of appointments attended.

The CP model seeks to demedicalize and normalize the condition of pregnancy and "embraces pregnancy and birth as natural, beautiful, and empowering" (Bell, 2012, p. 74). The empowering aspect of CP comes from the sharing of information, which changes the patient-provider relationship to one that is nonhierarchical and reduces the power differential to allow for equitability. The process of demystifying pregnancy and prenatal care allows women to gain a greater understanding of what is happening to their bodies and also share common discomforts (Rising, 1998). One qualitative non-experimental thematic study found that women who participated in CP saw themselves as influential partners in the process (Risisky, Asghar, Chaffee, & DeGennaro, 2013).

Preterm birth is one of the most consistently used litmus tests for perinatal outcomes and population health (Tilden, Hersh, Emeis, Weinstein, & Caughey, 2014). Preterm birth (PTB) is defined as birth prior to 37 weeks gestation. Low birth weight (LBW) is defined as birth weight less than 5 pounds, 8 ounces. These compromised neonates are at an increased risk of experiencing respiratory distress, necrotizing enterocolitis, retinopathy, intraventricular hemorrhage, anemia, infections, and death (March of Dimes, 2017). The gestational age at delivery and birth weight can both be negatively impacted by maternal health behaviors and also cause lifelong health consequences for the neonate. Previous studies have shown the prenatal care model can influence rates of LBW and PTB. Ickovics et al. (2003) linked CP to a reduction in poor neonatal outcomes in a matched cohort study in the US. Due to the historical use of these neonatal outcomes in previous studies and the importance of their indication of overall

health, gestational age, in weeks and days, and birth weight, in grams, were used to measure neonatal health in this program of research. The authors chose not to utilize Apgar scores as a measurement of neonatal outcomes as they relate to prenatal care model. This decision was made based upon the fact that Apgar scores both at one and five minutes were developed and are currently utilized as a method to determine need for intervention for resuscitation measures. This score does not indicate overall neonatal health or reflect poor or excellent prenatal care.

The information found throughout the literature guided the researcher to evaluate quality of prenatal care between models and how this might impact PTB and LBW. Furthermore, though CP was developed specifically to empower women, and though this has been a word found often in qualitative studies of CP, there has not any research to quantify pregnancy related empowerment in those participating in CP versus IPC. The study population was located in Fort Worth Texas, providing information on a very different population than previously studied in CP research which has included Canada (Benediktsson et al., 2013; McDonald et al., 2016), Australia (Teate, Leap & Hope, 2013), and specific groups such as military wives (Kennedy et al., 2011) and adolescents (Trotman et al., 2015). The population of Fort Worth Texas is diverse with a greater number of Hispanic women than previous locations. Furthermore, the population will have a wide range of ages and vocations.

Introduction to Articles

The research portfolio began with exploration of the concept of empowerment in pregnant women. Pregnancy related empowerment is defined for the purpose of these articles as a process whereby there is a progressively increased sense of power resulting

from a sharing or redistribution of power. The findings are reported in Chapter Two in the manuscript titled, *Power and Empowerment in Pregnancy and the Nurse's Role*. This article compares the concepts of power and empowerment to allow for thematic understanding and application of knowledge to the nurse's role in cultivating empowered patients. The manuscript is written based upon the guidelines of the Advances in Nursing Science (Appendix A). The manuscript was submitted and reviewed by the Advances in Nursing Science Journal, the author received revisions and recommendations which will be addressed and the article resubmitted.

With a deeper understanding of the concept of empowerment, the next step was a feasibility study on a pregnant population. Findings from a review of literature show positive results for CP and improved outcomes for mom and neonate across a variety of studies and populations. However, studies that define how CP results in a positive change in behavior and improved health in patients were not identified.

Chapter Three is a report of a quantitative feasibility study that was conducted to compare pregnant women receiving care via CP or IPC model. The manuscript was written following the guidelines of the Journal of Midwifery and Women's Health (Appendix B). Prior to study initiation, permissions from the authors of the two instruments utilized in the study were obtained, including the Quality of Prenatal Care Questionnaire (Appendix C) and the Pregnancy Related Empowerment Scale (Appendix D).

A study flow chart was created to facilitate training for the research team, which included several of the midwives providing care, research assistants, and the primary researcher. The midwives, research assistants, and primary researcher all recruited,

consented, and collected data. The primary researcher had sole responsibility for inputting data and ensuring protection of data. Training was conducted using voiceover PowerPoint and provision of all paper materials to each member of the team including recruitment script, consents used, and all instruments for the study. This process ensured consistency in recruitment. The flow chart (Appendix E) was used to describe movement of participants through the study including contact points: recruitment (T1), survey via email (T2), and survey via phone (T3).

Prior to beginning the study, Institutional Review Board approval was obtained from The University of Texas at Tyler (UT Tyler) (Appendix F), the University of North Texas Health Science Center (UNTHSC) (Appendix G), and Texas Christian University (TCU) (Appendix H). Modifications were made to increase the number of research team members to improve the recruitment process and IRB approval obtained to improve the recruitment process and study as a whole. Approval of modifications came from UT Tyler (Appendices I and J), TCU (Appendix K), UNTHSC (Appendix L and M), and TCU (Appendix N) consecutively. A recruitment script (Appendix O) was used to provide consistency in recruiting across the research team. Eligibility criteria questions were incorporated into the script for ease of use.

The study site was a clinic known by the PI to offer both CP and IPC. After eligibility was determined and patients had already self-selected their preferred method of prenatal care (CP or IPC), participants signed a written informed consent (Appendix P) and a HIPAA release form (Appendix Q). At the time consent was obtained, the participants completed a paper and pen Participant Contact Information Sheet (Appendix R). This included name, address, email, and date of birth (DOB) to allow contact for

other data collection points in the planned study. The DOB and last name were used as points of reference across the data collection process to ensure that participants' responses were followed over the course of their pregnancy. The participants also completed a paper and pen Demographic and Health History Questionnaire (Appendix S), and a baseline Pregnancy Related Empowerment Scale (Appendix T).

After the participant reached 36 weeks' gestation based upon provided estimated due date (EDD), they received a survey via email (Appendix U) inviting them to complete a Qualtrics survey that included a post-test Pregnancy Related Empowerment Scale and a Quality of Prenatal Care Questionnaire (Appendix V). Those that did not complete the survey, received a reminder email (Appendix W), at one and two weeks after the initial email.

After 42 weeks' gestation based upon EDD, participants were telephoned to determine their newborns' gestational ages and weights at birth utilizing a telephone script (Appendix X); responses were recorded on the paper and pen Neonatal Outcomes Survey (Appendix Y).

Findings of the study are reported in Chapter Three in a manuscript titled, *A Comparative Evaluation of Centering Pregnancy Versus Individual Prenatal Care Comparing Quality, Empowerment, Gestational Age, and Birth Weight*.

Chapter Four is a summary of the research to date focusing on empowerment of pregnant women and the differences between CP and IPC. It concludes with recommendations for future research based upon findings.

Chapter Two. A Concept Analysis of Power and Empowerment in Pregnancy and the Nurse's Role

Abstract

Aim: To conduct a comparative analysis of the concepts of power and empowerment within the context of nurse's care of pregnant women.

Background: Pregnant women are experiencing a time of great change and require healthy decision making, not just for their own wellbeing, but for their child. While being a patient makes one inherently powerless, transference of information and resources to the patient can help balance power.

Design: Walker and Avant's eight-step concept analysis was utilized and the concepts were then compared.

Data Sources: PubMed, CINAHL, and ESBCO databases were searched for articles, reviews, editorials, and any literature addressing power and empowerment.

Methods: A review of literature since 2007 produced sufficient data to define the concepts. Several older articles included were frequently cited or were considered pertinent due to a focus on power and empowerment within the patient-provider relationship.

Results: Antecedents to power include a relationship, motivation for control, and implied responsibility. Antecedents to empowerment include intrinsic motivation, resources, and motivation to have power. While the two concepts are related, the nurse's role for each is

different. Nurses must advocate for their patients in order to develop patient empowerment and help the patient accept their own power over health care.

Conclusion: The relationship between power and empowerment amongst pregnant patients and providers focuses on presence and ownership of knowledge and resources. Identification and understanding of the concepts will help nurses to appreciate their role in providing care for pregnant women and improve outcomes.

Keywords: Patient empowerment, power, nurses, pregnancy, concept analysis

Power and Empowerment in Pregnancy and the Nurse's Role

Nurses have historically sought to empower women to make healthy decisions during pregnancy as a way to improve outcomes. Nurses providing prenatal care seek to engage the patient in their own care and birth experience. However, it is not clear how much power nurses are actually willing to relinquish. It is unclear whether empowerment actually results in power for the pregnant woman. The purpose of this article is to analyze and compare the concepts of power and empowerment as experienced by pregnant women and how they impact the nurse's role. Empowerment and power over self are sought and experienced differently by individuals within a variety of contexts. As society has evolved, many industries worldwide have moved from the traditional idea of superiority for those with power and knowledge to one of shared power or shared-decision making (Hain & Sandy, 2013). Review of historically-relevant research and current use of the concepts was performed to capture a comprehensive picture of power and empowerment and the possible implications in the nurse's role in caring for pregnant women.

Although there are multiple methods to analyze a concept, the process utilized here was created by Walker and Avant (2011). Through this formal eight-step process, the essence of the concepts was captured, allowing for identification of the concepts, along with identification of tools that assist providers by appropriately and accurately measuring the concepts. A clear understanding of each concept, including its defining attributes, antecedents and consequences as described by Walker and Avant (2011), allows for future research to include the concepts and produce meaningful results. Furthermore, a comparison of the analysis of empowerment and power provides vital

information to nurses caring for patients through improved understanding of the concepts in question. Understanding the imperfect and fragile balance of power, and the need to empower patients, can help nurses improve patient experiences and outcomes.

Significance in Nursing

The nurse-patient relationship is one that has been studied extensively to determine how it can be improved and how nurses can create an environment that improves patient outcomes. Delmar (2012) states that being a patient makes one inherently powerless. Patients are reliant on others for information and their state of health. In the acute care setting, healthcare providers have control over diet, visitors, and even what a patient wears. Henderson (2003) states that due to the innate asymmetric state of power between nurses and patients, nurses should "share their power and facilitate empowerment in their patients by giving them information and support" (p. 501).

Forssen (2012) interviewed 20 elderly women to investigate how a woman's perinatal experiences impacted her life and reflection on her own birth story. Most of the women in this study experienced healthcare providers who exerted power over delivery, causing both physical and emotional pain. As a result of these experiences, a large portion of women consider giving birth traumatic. In the US alone, 20-34% of women consider the birth of their children as so traumatic that the author stated childbirth is PTSD inducing (Forssen, 2012). The traumatic nature of pregnancy and delivery was often associated with an overall sense of disempowerment.

Henderson (2003) found that nurses preferred to make decisions for the patients, thereby retaining power, instead of sharing decision-making. During a qualitative study,

McCauley and Casson (2015) reported healthcare providers across specialities believe involving patients in decision-making is a "major component" of patient empowerment (p. 10). The provision of information facilitates empowerment and helps to increase the ability of women to make decisions with a sense of autonomy. Henderson (2003) posits that "nurses need to be proactive in facilitating the process of empowerment in their patients" (p. 507). Through the exchange of information and resources, providers can improve the balance the experience of power and decision making with patients.

Concept Analysis of Power

A literature review reveals that many authors argue power is multidimensional with variations of its origin and uses. The literature reviewed included textbooks, articles, and online material from a variety of disciplines including mathematics, business, psychology, and science (Keltner, Anderson, & Gruenfeld, 2003). The relationship between power and control has led many to study how to create power and how power influences others. Despite the attention, power is often difficult to define or measure due to lack of consistency in definitions and according to the circumstance in question. Power has been defined in many ways including "the ability or right to control people or things" (Merriam-Webster, n.d.). Keltner et al. (2003) defined power as control over the giving or withholding of resources and the ability to punish. Robert Green stated "power is the measure of the degree of control you have over circumstances in your life and the actions of the people around you" (as cited in Feloni, 2015, para. 4). He goes on to state that power is best when it is not used directly on someone else, but instead is used indirectly to get another person to "voluntarily align" with the desired decision.

Hawks' (1991) concept analysis of power delineates power as either 'power to' or 'power over.' Within the nurse-patient relationship, the patient will experience both. A nurse can exert 'power over' through control of environment, knowledge, comfort, and support. Also, the patient can experience the transference of power to make decisions for their pregnancy, labor, and birth. Carlsson, Ziegert, Sahlberg-Blom, and Nissen (2012), in a qualitative study of women's early labor experiences, found that women identified maintaining power as vital when working towards a goal of delivery. The women stated that the expectations they brought into labor greatly influenced their feelings. The experiences identified speak directly to how a nurse must respect power when interacting with patients during prenatal care. Delmar (2012) further defined power in the nurse-patient relationship as important to facilitate trust and expand the patient's room for action.

Defining Attributes of Power

Walker and Avant (2011) state that through defining attributes of the concept, one can identify the phenomenon and differentiate it from other concepts. Defining attributes or characteristics are likened to signs and symptoms of the concept and can be determined through repetition of themes and ability to conjure the concept of power. The three defining attributes found to be recurring, when reviewing literature related to power, were that power is a social process (Delmar, 2012; Hawks, 1991), is the ability to attain desired goals (Hawks, 1991; Kuokkanen & Leino-Kilpi, 2000), and entails access to resources (Hawks, 1991). Power is a social process and does not occur within a vacuum. Power is focused on the ability or capacity to attain desired goals or objectives. If one has power, but does not seek to gain anything, then one is not exercising power,

which negates its presence. Finally, access to resources, including skills, knowledge, money, or authority, is a part of the conceptual boundaries of power. An inequality in access to resources identifies those with power and the powerless.

Antecedents of Power

Antecedents are factors that must be present and occur prior to the concept occurring, making antecedents and defining attributes mutually exclusive. The antecedents identified were a relationship between two or more people (Hawks, 1991; Rucker, Hu, & Galinsky, 2014), motivation for control, experience, and expectations (Carlsson et al., 2012; Rucker et al., 2014), and lastly implied responsibility (Delmar, 2012). For power to be present there must be a relationship, as power cannot be present in a single individual without comparison to resources of others. The existence of motivation to have control in light of options to utilize the motivation, sets people with power apart from the powerless, who are content with the current state of things. People with power experience a sense or feeling that generates understanding of how they can measure or affirm their own power level. Keltner et al. (2003) pointed out that individuals experience power both physically and psychologically. Delmar (2012) stated the role of the nurse or healthcare provider is to develop a trusting relationship and be a resource for the patient, thus having a direct role in power and empowerment for the patient.

Consequences of Power

Consequences are defined as the events that result from the concept occurring (Walker & Avant, 2011). The consequences of power include the achievement of desired objectives and goals (Hawks, 1991). Increase or maintenance of a person's power in turn

enhances the ability to attain what is needed or wanted. Those without power lack the resources or capacity to meet those goals.

Concept Analysis of Empowerment

The modern use of the term empowerment became popular through the writings of Brazilian educator, Paulo Friere, who advocated for civil and social rights (Herbert, Gagnon, Rennick, & O'Loughlin, 2009; McCarthy & Freeman, 2008). The term is currently used regularly in research within various disciplines including business, psychology, nursing, and education.

The World Health Organization (WHO, 2006) has identified empowerment as an influential variable in healthcare in two distinct ways. First, empowerment acts directly on improving decision-making. Secondly, the outcome of empowerment creates a supportive environment and improves the patient-provider relationship. Freire argued that empowerment directly relates to the product of education, which increases a person's ability to think and act with greater autonomy (as cited in Anderson & Funnell, 2010). Johnson (2011) reviewed literature and found that most studied patients valued empowerment, specifically shared-decision making with healthcare providers. Therefore, in order to understand the impact of patient education upon patient behavior modification, it is imperative that the concept of empowerment is understood and measurable (Kuokkanen & Leino-Kilpi, 2000). The lack of ability to measure empowerment stems from the need for clear defining characteristics for the abstract concept.

A review of literature was performed to determine definitions and attributes of the concept of empowerment. Empowerment is defined as "to make stronger and more

confident" and "give authority or power to do something" (Oxford University Press, n.d, para. 1). Other definitions include "interactions between the empowering and the empowered" (Panicker, 2013, p. 211), "enhancing the feeling of control" (Small et al., 2013, p. 2), and "contextual, participatory process, which enables individuals to achieve a sense of control over their lives" (Rappaport, 1981, p. 109). The World Bank defines empowerment as the "process of increasing the capacity of individuals or groups to make choices and to transfer those choices into desired actions and outcomes" (2011, para.1). Johnson (2011) summarized the characteristics of patient empowerment into three aspects including; patient-centered, focused on development of skills, and a centralized patient-provider relationship. The literature consistently suggests that empowerment is difficult to define due to the individual nature of the concept.

Defining Attributes of Empowerment

After review of literature, three defining attributes were identified for empowerment. The defining attributes are shared or transferred power (McCarthy & Freeman, 2008), feeling of control over decision making (Small et al., 2013), and confidence in the ability to achieve change (Small et al., 2013). Empowerment is a process whereby there is a progressively increased sense of power resulting from a sharing or redistribution of power (Conger & Kanungo, 1988; Gainger, 2012; Haine & Sandy, 2013; Herbert et al., 2009; McCarthy & Freeman, 2008; Rappaport, 1981). Patients can experience a sense of control that allows them to make decisions about their health. This feeling of control over decision making is due to a gained internal locus of control (Hermansson & Martensson, 2011; McCarthy & Freeman, 2008; Panicker, 2013; Rappaport, 1981). The last defining attribute is an increase in confidence that the actions

taken will create change which helps patients have a sense of health and capacity to impact their environment (Ledbetter & Finn, 2013; Porr, Drummond, & Richter, 2006; Small et al., 2013).

Antecedents of Empowerment

The following three antecedents were identified: "intrinsic motivation" (Seibert et al., 2004, p. 332), social and personal resources (Shearer, 2009), and a trusting relationship. In order for empowerment to occur, there must be an inner-driven motivation for a decision to be made or change to occur. If an individual is not motivated to gain power or make decisions, or if this drive is being forced or willed by another person, then they will not participate in the process of empowerment due to lack of meaning (Sun, Zhang, Qi, Chen, 2012). Within the workplace, individual empowerment is defined as the experience of intrinsic motivation as it relates to the individual's role at work (Seibert et al., 2004). The theory of health empowerment states that in order for empowerment to occur there must be both social and personal resources present (Shearer, 2009). An example of an imbalance of resources would be if there is a desire to control decisions, but outside sources do not ever offer the opportunity. Another example would be if a manager would like to transfer power to make decisions or impact change, but the individual does not want this role due to lack of self-confidence, inexperience, or simple indifference. This leads into the next antecedent which is a trusting relationship. There must be a relationship in place that allows for transference of power and also support for the empowerment. Social resources, as defined by Shearer (2009), include a social network and support.

Consequences of Empowerment

The consequences identified for the concept of empowerment were identified as a perception or feeling of greater power, the ability to empower others (Porr et al., 2006), the ability to make decisions and achieve goals (World Bank, n.d.), and the confidence to take action. Kuokkanen and Leino-Kilpi (2000) described empowerment as a positive process that is associated with shared power. The process of empowerment creates sustained power for the individual, community, or organization. With this power and confidence in their ability to change things, empowerment of others will occur. In an article discussing low-income women's health literacy, findings showed the community was strengthened by thinking it was their problem and sharing knowledge as a group. The group became cohesive and gained confidence in their abilities, empowering others in the process (Porr et al., 2006). Hermansson and Martensson (2011) note that empowerment offers "resources, strengths, responsibilities and availability of options" which then allows the emergence of possible goals to achieve (p. 812). The World Bank (n.d.) defines empowerment as the ability to evaluate choices or goals and attain them, which would be a logical consequence to gaining control.

Pregnancy and Empowerment in Pregnancy Care

Pregnancy information is available through numerous resources including websites, literature, friends and family, and providers. However, erroneous pregnancy information can be overwhelming influential causing women to feel disempowered from their own pregnancy and experiences. Rodgers (2015) studied two of the most prominent pregnancy texts for healthcare providers, one in the US and one in France. The author surmised both texts assert that women know nothing about pregnancy. Information in the

texts infers that women require healthcare providers' supervision and must relinquish power during birth. The supposition that women should hand over power to providers, including nurses, tips the balance of power away from women during pregnancy and birth.

The influence of nursing care on pregnant patients is so profound that 72.5% of women surveyed believe they receive their main source of support from nurses and midwives (Kozłowiec, Kozłowiec, & Ksiazek, 2014). This finding underscores the importance of the nurse's role is in provision of information, care, and support for women, both during pregnancy and delivery. The nurse can impact how a woman experiences power and empowerment during pregnancy and birth, but also how this experience will echo throughout her lifetime, influencing all other interactions with healthcare providers.

The goal for nurses should be to *empower* women to acknowledge their *power* over their pregnancy and delivery, i.e. to take ownership of their situation and direct the process. Table 1 shows the relationship between the concepts of power and empowerment leading to the role that nurses would assume in promoting power and empowerment in pregnant women. The concepts are different, resulting in different priorities, but both lead to the goal of better patient outcomes, i.e. a healthy baby and a confident mother.

While both concepts work within a relationship, and within this context of specifically addressing the nurse to patient relationship, there is a difference in where control lies. With power there is an assumption of responsibility or control over decisions. However, with empowerment there is a giving of this power, a sharing or

transference of power. Empowered patients go beyond making a difference through the decisions they make in their lives but also can influence others through confidence they have in their knowledge and actions. Empowered patients are more important than powerful providers to the health of communities. Therefore, nurses must assess themselves and the relationship they have with their patient to determine any bias or judgments they feel coming into the relationship about having the patient be the expert and make those decisions. Through assessment of how to transfer power to a patient, nurses can advocate for patient decision making through sharing of knowledge and through inclusion of the patient into the healthcare team.

Conclusion and Recommendations

Power and empowerment both play a part in a nurse's role in the care of pregnant women. Hildegard Peplau's Theory of Interpersonal Relationship focused on the interaction between the nurse and patient (Peplau, 1992). Peplau said that the nurse can directly influence the patient during their interaction. Influence from nurses can be both positive and negative. There are several reasons why nurses do not relinquish power or cultivate empowerment in patients. Many nurses may not even realize the power that they possess. Without acknowledging the asymmetry of the relationship of power, nurses hold control without including patients. By discussing and understanding power and its place in the nurse-patient relationship, nurses can help patients attain health and a sense of ownership over their decisions. Another reason that a nurse may not transfer power to the patient is due to a sense of responsibility to protect patients from themselves. There are times when nurses, due to information gained through education or experiential learning, feel they are helping the patient by making decisions for the patient. Nurses

instead should transfer control to the patient with the understanding that the patient is the expert and sole proprietor of decisions related to their body.

Nurses are in a position to delegate and share power with the patient, cultivating shared decision-making through contribution of support and resources. Nurses can also advocate for patients to take ownership of their own healthcare situation to both engage in the process and gain confidence in making personal decisions about care. Through a reciprocal relationship, both nurse and patient will gain something from the process. Hermansson and Martensson (2011) described empowered parents as being "better prepared" and having control in "their own lives" (p. 816).

The midwives in this study gained an understanding of the available external resources for the empowered patients and also experienced an increase in satisfaction with the process. Researchers should seek to determine how the relationship of power and empowerment influence antenatal patients to make decisions and impact patient and baby outcomes. Future research is needed to identify appropriate tools to determine the presence of power and empowerment and the impact they have on the patient.

Through study of the concepts of power and empowerment, nurses can develop strategies, such as being purposeful in exchanging information with the patient regarding healthcare decisions and encouraging the patient to make decisions. Through this process nurses can improve the nurse-patient power relationship and empower patients to improve their ability to think and act in an autonomous nature, thereby improving their sense of control. Honest self-assessment by the nurse as to how and why to relinquish the power inherent in the nurse-patient relationship can help shift the power to the patient. Promoting a sense of empowerment in pregnant women can have positive effects

well beyond the pregnancy. Transcending the feelings of threat and loss when nurses hand over power to the patient is the point when they truly take on the role of patient advocate and partner in care.

Table 1. *Relationship of Power and Empowerment to Nurses Role in Pregnancy*

	Defining Attributes	Antecedents & Consequences	Nurse self-assessment	Conceptual Contrast
Power	Social process Ability to attain desired goals Access to resources	Antecedents: Prior relationship between 2+ people Motivation to control situation Implied responsibility or control Consequences: Achievement of objectives or goal	1. Do I want the patient to be in charge? 2. What will I do if the patient's decision conflicts with mine? 3. What is my risk if the patient's decision has harmful outcomes?	Nurse priority is DELEGATION: Both the nurse and patient usually believe the nurse has the power. Essence of true patient-centered care is to delegate the power to the patient. Decision to "share power" belongs to the patient, not the nurse. Nurse moves to consultant/assistant role; no longer "in charge."
Empowerment	Shared or transferred power Feeling of control over decisions Confidence in the ability to achieve change	Antecedents: Intrinsic motivation Social and personal resources Internal motivation to have power Consequences: Perception of having and being able to use power Ability to empower others Ability to set goals and make decisions Confidence to take action	1. How do I transfer the decision making power to the patient? 2. How do I know if she is ready to be in control of the situation? 3. How can I build up her confidence to make good decisions?	Nurse priority is ADVOCACY: Nurse must encourage the patient to accept power and take control through confidence building and reinforcement of decisions. Knowledge is shared to support patient's decisions. Nurse advocates for patient's autonomy to other providers.

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Chapter Three Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy versus Traditional Prenatal Care

Abstract

Introduction. Centering Pregnancy (CP) is group prenatal care that is women-centered and improves pregnancy outcomes. Specifics regarding how the CP prenatal care model improves maternal and fetal outcomes remain unclear. The purpose of this feasibility study was to determine the viability of a study to compare quality of prenatal care, pregnancy related empowerment, and neonatal outcomes of women participating in Centering Pregnancy with women who received individual prenatal care from certified nurse midwives in the same clinic.

Methods. A non-experimental, longitudinal, descriptive study of two independent groups was conducted with 51 women receiving self-selected prenatal care either in the form of individual prenatal care (n=37) or Centering Pregnancy (n= 14) at a clinic in Texas. Outcomes analyzed included perceived quality of prenatal care, pregnancy related empowerment, gestational age at birth, and neonatal birth weight.

Results. The results showed no statistical significance between the individual prenatal care and Centering Pregnancy groups with regard to quality of prenatal care total and subtotals, nor was there any significance with regard to gestational age at birth. However, both pregnancy related empowerment ($p = 0.083$) and birth weight ($p = 0.088$) were approaching significance. Therefore, those receiving individual prenatal care had higher pregnancy-related empowerment after receiving care for their pregnancy. Those receiving Centering Pregnancy care had higher birth weight at delivery.

Discussion. Patients of midwives inherently receive care that is not medicalized or desensitized to the needs of the patient. Rather, the care is based upon a nursing model that is woman and family focused and strives to engage the patients in their own healthcare. The results found that patients receiving care from a midwife have high quality of prenatal care overall, despite the model of prenatal care received.
Keywords: *Centering Pregnancy, group prenatal care, empowerment, quality of prenatal care, birth weight, gestational age*

Quality Prenatal Care and Pregnancy Outcomes:

Centering Pregnancy versus Traditional Care

Prenatal care is often seen as a doorway to women's health through prevention, detection and treatment of maternal-fetal conditions, thus frequently ameliorating outcomes. Prenatal care is often seen as a doorway to women's health through detection and treatment of adverse maternal and fetal outcomes. Despite the importance of prenatal care to healthcare, current prenatal care models lack adequate contact between patient and health care provider, patient education, patient satisfaction, and support for women (Hanson, VandeVusse, Roberts, & Forristal, 2009; Massey, Rising, & Ickovics, 2006; Ruiz-Mirazo, Lopez, & McDonald, 2012). The goals for prenatal care have evolved over time as the health of our nation has changed, validating the need to rehabilitate the prenatal care model to achieve improved outcomes in maternal and fetal health.

Prenatal care remains a focus of legislation, funding, and research to determine what works and where change is needed. Current legislation and national health organizations, including the Department of Health and Human Services, Centers for Disease Control and Prevention, and Centers for Medicare and Medicaid, have recognized the need for an evaluation of traditional prenatal care. Transformation of traditional prenatal care, hereafter referred to as individual prenatal care (IPC) towards an evidence-based model of care (Rotundo, 2011). The Agency for Healthcare Research and Quality has developed a National Quality Strategy that has six priorities to address current health in the US (Agency for Healthcare Research and Quality, 2017). The national move to improve patient care extends to inclusion of the patient in healthcare

decisions. Innovative prenatal care models can address several of the national priorities including patient safety, person-centered care, and care coordination.

Current research findings have shown differences between group prenatal care and IPC. Patients are more likely to be satisfied and gain comfort and continuity with group care (Bell, 2012; DeCesare & Jackson, 2014). However, further research is needed to quantify the impact on maternal and fetal outcomes, including psychosocial wellbeing.

Background

Current practice of providing prenatal care is based largely on a medical model created from the U.S. Department of Labor Children's Bureau report on prenatal care in 1920s (Thielen, 2012). Historically, prenatal care has focused on prevention of eclampsia, low birth weight (LBW), and preterm birth (PTB) (Alexander & Kotelchuck, 2001). The current one-on-one prenatal care model has been criticized for being unfocused and fragmented (Risiky, Asghar, Chaffee, & DeGennaro, 2013). There is a need to broaden the focus of prenatal care to include family wellbeing thereby having a ripple effect on community health as a whole. Despite women seeking prenatal care earlier in pregnancy, health care disparities, poor fetal outcomes, and high healthcare costs continue in the US (March of Dimes, 2014). Texas, in particular, has poor pregnancy outcomes with 10.2% PTBs, compared to 9.6% nationally. For the last decade, Texas has consistently had a higher PTB rate than the national average, and currently has a greater number of LBW babies. The March of Dimes has a goal of reducing the PTB rate to 8.1% nationally by the year 2020 (March of Dimes, 2016).

Centering Pregnancy (CP) is an alternative approach to prenatal care developed in 1993 by Sharon Schindler Rising, a certified nurse midwife at the Childbearing

Childrearing Centre at the University of Minnesota, in response to patients who were dissatisfied with traditional care (Bell, 2012). The CP model is focused on women-centered and empowered group care. This prenatal model is one answer to a call for evidence-based prenatal care. There are three components that are the foundation for Centering Pregnancy; assessment, education, and support. The major underpinnings for centering pregnancy include feminism, social cognitive theory, midwifery, and learning theory. Based upon the concepts of assessment, education, and support, CP provides increased time with providers and facilitates patient empowerment through a community foci (Centering Healthcare Institute, 2014; Rising, Kennedy, & Klima, 2004; Risisky, Asghar, Chaffee, & DeGennaro, 2013). Manant and Dodgson (2011) posit that Centering Pregnancy is currently used in approximately 300 sites in the US. Based upon the literature review, the model is also currently being used in international sites in areas such as Sweden, Denmark, and the United Kingdom (Andersson, Christensson, & Hildingsson, 2012; Andersson et al., 2013; Carlson & Lowe, 2006; Gaudion et al, 2011).

Centering pregnancy has been in popular use for fewer than 20 years and during this time barriers to the use of the model have been identified. Barriers for both patients and providers identified in the studies include; process implementation (Reid, 2007; Rotundo, 2011), difficulty for patients with families, discomfort with group setting (Phillipi & Myers, 2013), and inconsistency in research findings (Andersson et al., 2013; Gagnon & Sandall, 2007; Homer et al., 2012; Thielen, 2012). While there were fewer barriers identified, addressing them is necessary to understand how Centering Pregnancy can improve health outcomes and patient satisfaction even further.

The purpose of this feasibility study was to determine the viability of a study to compare quality of care, empowerment, and pregnancy outcomes, of women participating in Centering Pregnancy with women who received individual prenatal care from certified nurse midwives in the same clinic. The structure and process of delivery of prenatal care will be evaluated as well as the outcomes of care itself including pregnancy-related empowerment, gestational age at birth, and birth weight of the neonate.

Quality of Prenatal Care

The study of quality of care is omnipresent, as organizations such as the Institute of Medicine (IOM) and Quality and Safety Education for Nurses (Quality and Safety Education for Nurses, 2014) focus on the degree to which quality improvement can increase positive health outcomes (Institute of Medicine, 2001). Qualitative studies have sought to define quality of care from the woman's perspective. Common themes identified to describe quality of care include access to care, active listening, spending appropriate time, respect, and education, have been identified (Armstrong et al., 2006; Sword et al., 2012; Wheatley, Kelley, Peacock, & Delgado; 2008). These identified themes were utilized to determine the presence of quality prenatal care. Due to the lack of agreement on a specific definition of quality of prenatal care, it is important to explore patients' perceptions of quality prenatal care.

Pregnancy Related Empowerment

The World Health Organization (WHO) has identified empowerment as an important variable in quality of care by influencing decision-making and creating a supportive environment through an improved patient-provider relationship (2006). Freire argued that empowerment directly relates to the product of education, which increases a

person's ability to think and act with greater autonomy (as cited in Anderson & Funnell, 2010). Haines, Hildingsson, Pallant, & Rubertsson (2013) found that women who were fearful of pregnancy perceived their care to be lacking in emotional support, understanding, and respect. Empowerment counters the experiences of those with pregnancy-related stress or fear. Patient empowerment increases with CP, thereby decreasing negative experiences with pregnancy and birth and improving health behaviors (Bell, 2012; Gaudion et al., 2011).

Centering Pregnancy

Centering pregnancy was developed in response to patients who were dissatisfied with traditional care (Bell, 2012; Rising, Kennedy, & Klima, 2004). This group-based antenatal care model was created to provide education and culturally sensitive care that empowers women. Some of the major themes identified through analysis of qualitative and quantitative studies on CP include an increase in the patient's sense of knowledge and readiness, enhanced patient and provider satisfaction, increased breastfeeding rates, longer contact with provider, and improved fetal outcomes (Baldwin, 2006; Benediktsson et al., 2013; Davis-Floyd, Barclay, Daviss, & Tritten, 2009; Herrman, Rogers, & Ehrenthal, 2012; Teate, Leap, Rising, & Homer, 2011).

Centering Pregnancy was created with the pregnant woman and family unit in mind, providing social support and maximum time with a provider. IPC is often a series of 10-15 minute appointments, totaling approximately two hours contact with the provider over the course of the pregnancy, in which the provider assesses the patient and provides education. These visits often do not allow enough time for education or relationship building between the patient and provider. Centering Pregnancy consists of

groups of 8-10 women with similar estimated due dates (EDD) meeting 10 times over the course of the pregnancy, for 90-120 minutes an appointment, or approximately 20 hours of time with a provider. Centering Pregnancy not only gives each patient and family two hours of group education and discussion each meeting, but also provides an individual meeting with a provider for 5-10 minutes (Bell, 2012). Throughout these hours of contact with the provider, the patient is actively engaging in the three main components of CP: assessment, education, and support (Centering Healthcare Institute, 2012). Through grouping of patients with similar due dates, the facilitators can help them find social support in other pregnant women having the same experiences.

Shared experiences are shown to improve patient satisfaction with this model as well as provide psychosocial benefit (Andresson, Christensson, & Hildingsson, 2012; Grady & Bloom, 2004). Through community building with patient engagement, the facilitators are working to empower women to make decisions and ask questions about their own pregnancy. Moving away from the traditional medical model utilized in IPC, Rising designed to make the process of healthcare a mutual one. There is a self-monitoring component in which women are taught how to take their own blood pressure, test their urine using dipsticks, weigh themselves, and document all findings in a log. Women become empowered through engagement with their physiological changes of pregnancy and by actively participating in their own health care.

Facilitators utilize the CP curriculum which is provided in the manual developed by Sharon Rising and includes specific discussion topics based upon gestational age (see Table 1). While individual prenatal care also includes education topics, these are more subjective and less consistent in nature (Centering Healthcare Institute Manual, n.d.).

Much of the group discussions are guided by questions and needs of the participants. Another benefit to the group model is the ability of guest speakers to attend, including pediatricians, dentists, and lactation consultants (Bell, 2012).

Table 1. Centering Pregnancy Discussion Topics

Prenatal Testing
Nutrition
Healthy Behaviors
Common Discomforts of Pregnancy
Dental Health
Breastfeeding
Family Planning
Sex during Pregnancy
Domestic Violence/Abuse
Preterm Labor Signs
Labor
Birth Facility
Pain Management during Labor and Birth
Newborn's First Days
Pediatrician
Circumcision
Postpartum Depression
Newborn Safety
Growth and Development
Family Unit Changes
Postpartum Norms

Centering Pregnancy Manual, n.d.

Theoretical Framework

The theoretical framework of Donabedian's quality of care (QCM), developed in 1966, guided this study. The QCM has been utilized in various nursing research studies including one study focused on outcomes of preconception care and another on the quality of prenatal care questionnaire instrument development. Donabedian (2005) attests to the abstract nature of the concept of quality noting that "quality may be almost anything anyone wishes it to be" (p. 692). Donabedian stated that in order for quality improvement to occur there must be a known connection between structure, process, and

outcome (1988). With this in mind, the study investigated the construct of quality of prenatal care to better discern its boundaries, attributes, and outcomes as defined by the pregnant woman.

The model (Figure 1) focuses on a three-part approach to quality assessment that includes structure, process, and outcome. The first arm, titled structure, focuses on the particulars of the setting where the care occurs. Process, the second arm, is what actually occurs during the giving of care. Outcomes, the third arm of the QCM, seek to identify the result of the care. The outcomes arm involves measurement of patient knowledge, behaviors, and patient satisfaction with care. This framework was chosen for the study as it was utilized in the development of one of the primary tools, the Quality of Prenatal Care Questionnaire.

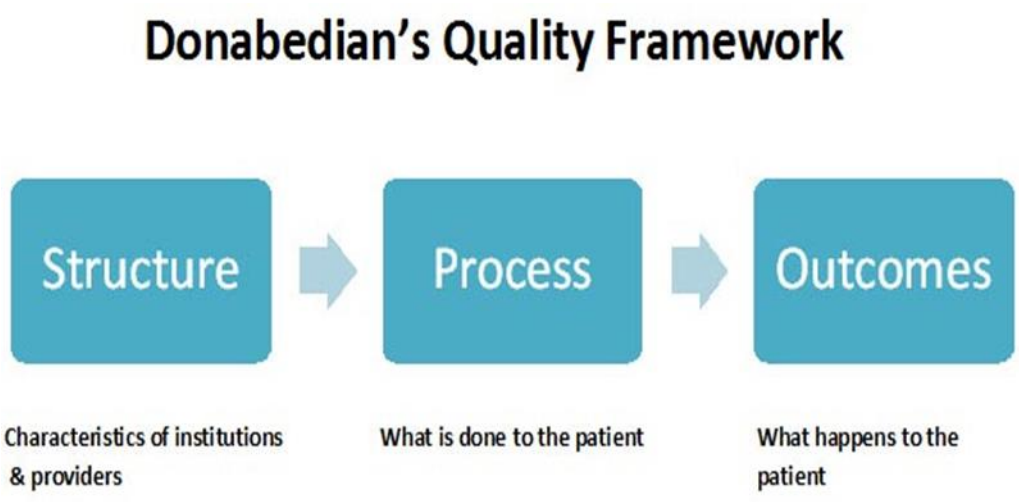

Figure 1. Donabedian's Quality of Care Model

Structure was evaluated through collection of data on the health care system which, for this particular study, will focus on which method of prenatal care the participant has chosen as well as quality of prenatal care. The Quality of Prenatal Care Questionnaire (QPCQ) was developed to measure the structure and process aspects of the

framework as it related to the actual provision of care. The QPCQ has two factors which speak directly to structure of quality of care (see Figure 2). Sufficient time is defined as the time that the provider spends with the patient answering questions and the actual length of the appointment. Availability is considered structural and is defined as the knowledge of how to contact the patient's provider and the ease of communication and availability of office staff (Heaman et al., 2014).

Process was evaluated by measuring the interpersonal relationship between patient and provider, including clinical aspects of process such as health promotion and illness prevention, screening, shared information, continuity of care, non-medicalization of pregnancy, and women-centeredness (Sword et al., 2012). More specifically, the QPCQ has four factors that speak directly to measurement of the process of quality of care; information sharing, anticipatory guidance, approachability, and support and respect (Sword, Heaman, and QPCQ Research Team, 2013). Information sharing and anticipatory guidance are both focused on clinical and technical processes. Information sharing is defined as ensuring confidentially and sharing of information to explain tests and results. How prepared the patient feels to make decisions and knowledge of options are covered by anticipatory guidance. The interpersonal process aspect is covered by approachability and support and respect in the QPCQ. Approachability is defined within this study, as the comfort with asking questions of the provider. Support and respect, which are addressed by the largest number of survey items, are defined as feeling respected and supported by the provider.

The outcomes arm of the QCM included gestational age at delivery, newborn birth weight, and empowerment. The gestational age at delivery was determined based

upon last menstrual cycle. Preterm birth is a consistent variable that was used to evaluate perinatal outcomes and infant mortality and morbidity (Tilden et al., 2014). The newborn birth weight was the weight that is taken after delivery and calculated in grams. Pregnancy related empowerment was measured utilizing the Pregnancy Related Empowerment Scale (PRES). The difference in the post PRES and the baseline PRES is another important outcome as it establishes if a patient feels she has gained control over making decisions after receiving care.

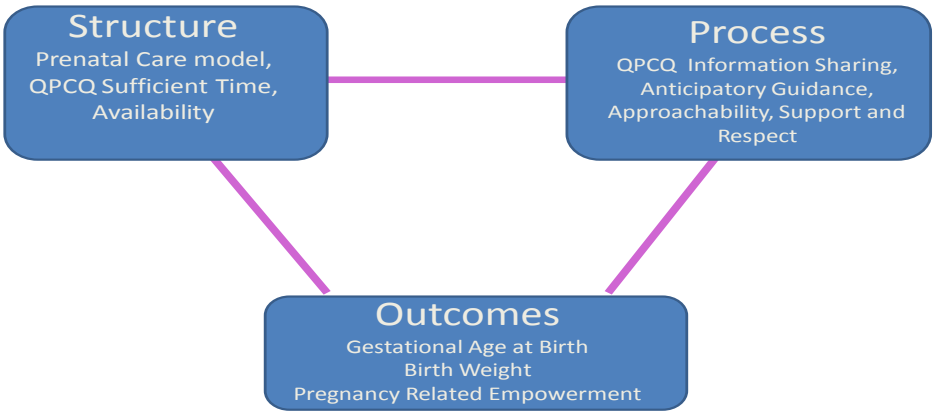

Figure 2. Variables measured for Quality of Care Model

The PRES measures four major domains that represent the concept of empowerment: provider connectedness, skillful decision-making, peer connectedness, and gaining voice. Provider connectedness is a relationship between the patient and provider that is built upon respect and trust. Skillful decision-making is the process of decision making through which the woman evaluates her choices and their possible impact on her health. Peer connectedness is the bond a woman has with others based upon the idea of active support. Finally, gaining voice is the ability of the woman to be

knowledgeable about her own health and advocate for herself (C. Klima, personal communication, August 27, 2014).

Methods

Participants

Prior to starting the study, approval was obtained from the Institutional Review Boards of the University of Texas at Tyler, the University of North Texas Health Science Center, and Texas Christian University. This study was conducted at a large Certified Nurse Midwives (CNM) clinic in Northern Texas, providing both CP and IPC.

Convenience sampling was used to obtain study participants. A prior power analysis was performed and a target sample of 176 participants with 88 in each group was desired. Women were recruited at the clinic as they attended their prenatal appointments with the CNM. A woman would be brought back to an exam room for their first obstetric visit with the provider or the first prenatal visit after a confirmation visit at either a different provider or the same. A member of the research team would then approach potential participants in order to determine interest in the study as well as eligibility (T1).

Participants were divided into two groups, those who self-selected IPC and those who self-selected to participate in CP. The participants self-selected their prenatal care method instead of randomization so that factors such as comfort, motivation, and cost were appreciated. A research team member explained the study in detail, answering any questions, and obtained informed written consent after eligibility was determined. Eligibility criteria included the ability to read and write English, no previous prenatal care outside of pregnancy confirmation visit, 18 years old or older, no prior fetal demise (death after 20 weeks' gestation), and carrying a singleton pregnancy. Women were

excluded if they did not complete prenatal care with the same clinic for their entire pregnancy, which was indicated by the participant when telephone contact was made for data collection. Women were considered to be part of the CP cohort if they attended at least one meeting. Due to the nature of the CP model and how it could influence a woman's viewpoint of quality of prenatal care, then even one CP meeting was deemed by the author to be sufficient to influence perception of quality of prenatal care. If a woman dropped from CP prior to starting care, and instead sought IPC, she was included in the IPC group.

To ensure intervention fidelity the same providers, certified nurse midwives, provided care for women receiving IPC and also for those receiving CP care. The women who received IPC care would sit in an office waiting room until they were called back individually to their assigned appointment time, which they scheduled based upon their scheduling needs. They would be weighed by the medical assistant and taken to a small exam room for assessment of blood pressure after providing a urine sample. These women could bring significant others or family to the exam room with them if they desired. Those that were enrolled in CP would come to a predetermined 2-hour appointment time. The women would not wait in the waiting room but instead would arrive to a Centering Pregnancy specific conference room across the hall from the clinic with family or friends they desired to attend the appointment. Any individual assessments such as weight, blood pressure, and urine dip were assessed by the patient themselves in the Centering room. Therefore, the women in each group were not in direct contact with each other in the waiting area.

Intervention

The intervention for this study was the method of prenatal care; the differences in experience and application of prenatal care influenced the measure dependent variables. Women who chose IPC met one-on-one with their provider (CNM) and received traditional care following the assessment of risk medical model. Their appointments did not include any self-assessment or monitoring but instead was characterized by passive partnership in their healthcare. Women participating in CP met with groups throughout their pregnancy, and a CNM facilitated their appointments following the discussion topics of the CP curriculum. In order to ensure consistency during appointments and across CP groups, the providers followed a manual and curriculum created by the Centering Healthcare Institute (CHI). The CHI has specific requirements to be a CP provider including use of their materials. Each participant received a manual of their own to document their assessments, note questions, and read upon important pregnancy related topics. When participants reached 36 weeks' they were contacted for the second data collection point (T2). Participants were again asked if they participated in CP or IPC to ensure that those that dropped from CP due to difficulty with scheduling or other conflicts were included in the IPC group. Participants received prenatal care provided by the CNM at the study site until the delivery. All participants were delivered by 42 weeks' gestation due to maternal and fetal risk increasing with gestation. (Briscoe, Nguyen, Mencer, Gautam, Kalb, 2005).

The study addressed two research questions: 1) Do women in CP or IPC have higher quality of prenatal care and pregnancy-related empowerment? 2) Do neonates

born to women in CP or IPC have higher birth weight and greater gestational age at delivery?

Data Collection

The primary outcomes that were measured included quality of prenatal care evaluated by the Quality of Prenatal Care Questionnaire (QPCQ), pregnancy-related empowerment as appraised by the Pregnancy Related Empowerment Scale (PRES), gestational age at delivery in weeks and days, and birth weight of the neonate in grams. Additional data collected included overall health perception and chronic health conditions such as obesity, hypertension, or asthma. This information was utilized to determine overall health of the group to ensure that a poor neonatal outcome was not directly related to a poor health population. Instruments were chosen for this study based upon availability and their ability to measure the variables of interest. Participants were contacted for data collection at baseline at the time of consent when they attended their first prenatal visit for the current pregnancy (T1), 36 weeks' gestation or greater (T2), and after 42 weeks' gestation (T3) (see Figure 3).

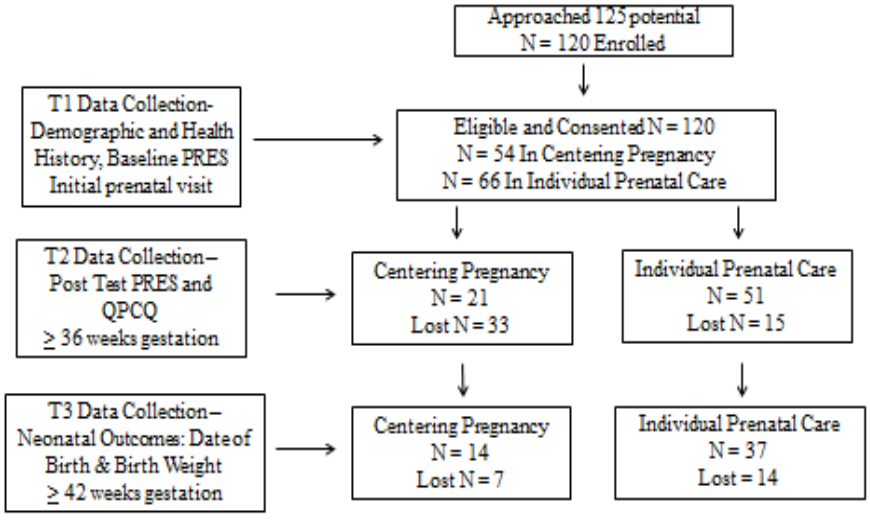

Figure 3. Flow Chart of Participants in Study

Instruments

At the time of consent, demographic and health history information was collected from all participants. The characteristics included age, race, marital status, education, household annual income, overall health, chronic diseases, alcohol or drug use during pregnancy, obstetric history (including total number of pregnancies, term, preterm, late preterm, and cesarean section).

The 46-item Quality of Prenatal Care Questionnaire (QPCQ) was developed by Heaman, Sword, Akhtar-Danesh, Bradford, Tough, Janssen, Young, Kingston, Hutton, and Helena in 2014. The instrument measures quality of prenatal care on a 5 point Likert scale with 1 (strongly agree) and 5 (strongly agree). The QPCQ measures quality of prenatal care through six subscales: information sharing, anticipatory guidance, sufficient time, approachability, availability, support and respect.

The subscales were developed based upon exploratory factor analysis with 422 participants. Information sharing has nine items and focuses on providers sharing information, and educating patients on reasons for testing and results. Anticipatory guidance has 11 items that measure how the participants felt their provider discussed options with them for their labor and birth experience. Sufficient time, often seen in studies related to quality of care, has 4 items that measure how much time the provider spent talking with the participant and addressing any questions they may have. There are four items which measure approachability of the provider by the participant. Availability of the provider is addressed in five items of the instrument and included availability of the office staff and the provider to answer to questions or concerns. Finally, support and respect comprise the largest portion of the instrument with 12 items. These items

measure whether the participant felt respected and supported by the provider during their care and if the provider showed presence when discussing participants concerns or decisions.

The sum value of the QPCQ is computed as a total score and can range from 46-230, with higher values indicating higher quality of prenatal care. The instrument has reverse scores for five items to ensure that participants read the questions and do not merely respond based upon boredom or ease. The instrument had previously been validated for construct validity and reliability (Heaman et al., 2014). The QPCQ previously had a Cronbach's alpha = 0.96 and a test-retest correlation coefficient of = 0.88 after being administered to 844 pregnant women 5-14 days after initial testing during the development study (Heaman et al., 2014). For this feasibility study, the Cronbach's alpha was exactly the same as previously at alpha = 0.96. The subscales Cronbach's for this study were as follows; information sharing (alpha = 0.94), anticipatory guidance (alpha = 0.87), sufficient time (alpha = 0.72), approachability (alpha=0.84), availability (alpha = 0.91), support and respect (alpha = 0.96).

The Pregnancy Related Empowerment Scale (PRES), developed and studied by Klima, Vonderheid, and Norr (2007), is a 21-item instrument with a reported Cronbach's alpha = 0.90. The four subscales, which were validated by pregnant women and a panel of experts comprise the multidimensional PRES, include provider connectedness, skillful decision-making, peer connectedness, and gaining voice. All participants respond to the first 16 items. Only those enrolled in CP answer five additional items. The PRES score is a total of the items answered on a 4-Likert scale with 0 (strongly disagree) and

4(strongly agree). Scores range from 21-84 for those participating in CP, and 21-64 for those in IPC. The higher the total score, the higher the pregnancy-related empowerment.

The neonatal outcomes utilized included gestational age at birth and birth weight, were collected by contacting the participants via phone. Gestational age is measured in weeks and days and was determined through the use of the provided estimated due date (EDD) and the date of delivery. Birth weight was requested from each participant and converted from pounds and ounces to grams. Babies that are born with a low birth weight are also another potential pregnancy outcome that is monitored by national and international organizations as a method to determine fetal health. Though not completely telling of perinatal health, LBW are at risk for serious health problems and must be monitored carefully. Furthermore, there are maternal health behaviors that can influence LBW including weight gain, smoking, drinking alcohol, abusing illegal or prescription drugs, and chronic health conditions (March of Dimes, 2017). Maternal information could positively impact follow-up, well-being of the newborn, and impact future pregnancies. Apgar scores were purposely excluded as a neonatal outcome as the variables were self-reported and it was anticipated most women would be unaware of the Apgar scores. In addition Apgar scores indicate fetal wellbeing and the need for resuscitation at one minute and five minutes of age. An Apgar score does not measure overall fetal wellbeing, but in fact may be a response to labor and birth.

The certified nurse midwives provided care for all study participates both in CP and IPC. This allowed for control over provider as an influence over outcomes. The instruments used, in particular the QPCQ, have been shown to be reliable in measuring their prescribed construct. To control for compensatory equalization of treatments, the

participants were not surveyed until they were a minimum of 36 weeks' gestation, allowing for participation in the majority of their prenatal care. Selection bias was managed by approaching all potential new obstetric patients for participation in the study. A comparison of the groups (CP and IPC), showed no statistically significant differences between groups demographically or with health history, including obstetric history. This allows for the researcher to ensure that the findings are related to the intervention of interest and not related to characteristics of each participant in a group.

Analyses

All analyses were performed using the Statistical Package for Social Sciences (SPSS) version 24. Recruitment ran from May to August 2016 with the final data collection completed by March 2017. A total of 125 obstetric patients were approached by the research team for potential enrollment in the study. Of those, five women were not enrolled either due to declination or not meeting eligibility requirements (e.g. pregnant with multiples). Of the 120 women that completed T1 survey (n = 54 in CP and n = 66 in IPC), 72 (60%) completed T2 survey and 51 (42.5%) completed T3 data collection (see Figure 3). Between recruitment and baseline data collection, several patients decided to select a different prenatal care model than originally reported; one participant changed from IPC to CP, and 12 from CP to IPC. Common reasons for changing prenatal care model included timing of appointments and lack of child care. Analysis used complete cases for each outcome. Future studies should include comparison of participants who changed chosen prenatal model as well as identification of barriers and solutions to impairment of provision of care method desired by the participant.

Demographic statistics were run to determine frequency of data distribution and ensure equality between groups. Demographic statistics for the participants by group indicated that there were very few demographic differences between those with IPC and CP. Exceptions to this included significant differences in race ($p = 0.007$), education level ($p = 0.044$), and near significance in Hispanic identification ($p = 0.051$). In all other areas, the two groups were similar in demographic makeup, which helped control for individual differences when comparing the two groups for other variables of interest. Detailed demographic statistics per group are illustrated in Table 2.

The groups were predominately white, married, with most having at a minimum some college education. One participant in each group did not complete the income question on the survey. The overall health of most participants was self-rated as good or excellent (see Table 2). The obstetrical histories of the groups, based on Fischer's exact test, were statistically similar prior to the study starting (see Table 3).

Table 2. Demographic Statistics Comparison between Groups using Fisher's Exact Test

Categorical Variable	**Individual (n=37) Frequencies**	**Centering (n=14) Frequencies**	**Significance *p***
Race	Black: 5.4% (2) White: 86.4% (32) Other: 8.1% (3)	Black: 7.1% (1) White: 50% (7) Other: 42.8% (6)	0.007*
Hispanic	No: 86.5% (32) Yes: 13.5% (5)	No: 57.1% (8) Yes: 42.9% (6)	0.05**
Marital Status	Married: 89.2% (33) Separated/Divorced: 0% (0) Never Married: 10.8% (4)	Married: 71.4% (10) Separated/Divorced: 7.1% (1) Never Married: 21.4% (3)	0.16*

Education	HS Degree: 10.8% (4) Some College: 35.1% (13) College Degree: 24.3% (9) Any Post-Grad: 29.7% (11)	HS Degree: 35.7% (5) Some College: 14.3% (2) College Degree: 42.9% (6) Any Post-Grad: 7.1% (1)	0.04*
Income	Less than 10K: 5.4% (2) 10K up to 20K: 5.4% (2) 20K up to 40K: 13.5% (5) 40K up to 60K: 8.1% (3) 60K up to 80K: 13.5% (5) 80K or more: 51.4% (19)	Less than 10K: 14.3% (2) 10K up to 20K: 7.1% (1) 20K up to 40K: 7.1% (1) 40K up to 60K: 14.3% (2) 60K up to 80K: 14.3% (2) 80K or more: 35.7% (5)	0.73*
Categorical Variable	**Individual (n=37) Frequencies**	**Centering (n=14) Frequencies**	**Significance *p***
Health	Average: 8.1% (3) Good: 40.5% (15) Excellent: 48.6% (18)	Average: 35.7% (5) Good: 35.7% (5) Excellent: 28.6% (4)	0.10*
Blood Pressure	No: 91.9% (34) Yes: 8.1% (3)	No: 100% (14) Yes: 0% (0)	0.55*
Heart Disease	No: 100% (37) Yes: 0% (0)	No: 100% (14) Yes: 0% (0)	NA
Renal Disease	No: 100% (37) Yes: 0% (0)	No: 100% (14) Yes: 0% (0)	NA
Obesity	No: 97.3% (36) Yes: 2.7% (1)	No: 92.9% (13) Yes: 7.1% (1)	0.47*
Asthma	No: 91.9% (34) Yes: 8.1% (3)	No: 92.9% (13) Yes: 7.1% (1)	1.00*
Alcohol	No: 100% (37) Yes: 0% (0)	No: 100% (14) Yes: 0% (0)	NA
Drugs	No: 100% (37) Yes: 0% (0)	No: 100% (14) Yes: 0% (0)	NA

*Fisher's Exact Test
**Chi-Square

Table 3. Obstetric History Comparison between Groups Using Fisher's Exact Test

Numerical Variable	**Individual (n=37)**	**Centering (n=14)**	**Significance *p***
Age	M = 28 SD = 4.466	M = 27.57 SD = 4.620	0.76
Number of Births	0-2 = 95% (35) 3+ = 5% (2)	0-2 = 79% (11) 3+ = 21% (3)	0.12*

Number of Term Births	0-2= 97% (36) 3+ = 3% (1)	0-2 = 93% (13) 3+ = 7% (1)	0.47*
Number of Preterm Births	0 = 78% (36) 1-2 = 22% (1)	0 = 93% (13) 1-2 = 7% (1)	0.47*
Number of Late-Term Births	0: 97% (29) 1-2: 3% (8)	0: 93% (13) 1-2: 7% (1)	0.21*
Number of Cesareans	0: 84% (31) 1-2: 16% (6)	0: 93% (13) 1-2: 7% (1)	0.37*

*Fisher's Exact Test

A multivariate analysis of variance (MANOVA) was run to determine if there was a significant difference in the quality of prenatal care for those women participating in Centering Pregnancy care versus Individualized Pregnancy Care. This test allowed for comparison of multiple dependent variables and decreasing Type I error. All participants completed the Quality of Prenatal Care Questionnaire (QPCQ), which consists of an overall quality score and six sub-score factors, including information sharing, anticipatory guidance, sufficient time, approachability, availability and support/respect. These seven scores were the dependent variables in the MANOVA, with type of care as the independent variable.

The assumption of multivariate normality was estimated by observing the normality of each dependent variable for both pregnancy care types. While there were a few outliers in some of the dependent variables across pregnancy types, there were no significant deviations from normality, roughly meeting the multivariate assumption. Testing for homogeneity of variance-covariance matrices in this analysis was not needed, as there were only two levels of the independent variable and thus Box's M test was not valid for testing. Levene's test for equality of variances for each dependent variable was run, and none were found statistically significant. A correlation matrix between the

dependent variables also indicated no visible deviations from linearity, meeting the linearity assumption.

Finally, multicollinearity was tested to ensure that none of the dependent variables exhibited highly significant correlation with identification of a few violations of this assumption. These high correlations can make MANOVA results unreliable, so the analysis was run both with and without the QPCQ Total and QPCQ IS variables.

Results for the MANOVA indicate that there were no significant differences found between types of care for any of the seven dependent variables (Table 4). When the two variables QPCQ Total and QPCQ IS were removed due to problems with multicollinearity, MANOVA results still indicated no significant differences, as did individual t-tests for the two removed dependent variables when run separately. Thus, it appears that there were no significant differences found between the two prenatal care models with regard to quality of prenatal care.

Table 4. MANOVA of Dependent Variable Quality of Pregnancy Care Questionnaire

Dependent Variable	**F**	**Significance**	**Partial Eta Squared**
QPCQ Total	0.297	.598	0.007
QPCQ Information Sharing	1.260	.268	0.031
QPCQ Anticipatory Guidance	0.247	.622	0.006
QPCQ Sufficient Time	0.140	.711	0.003
QPCQ Approachability	0.464	.500	0.011
QPCQ Availability	0.690	.411	0.017
QPCQ Support/Respect	0.581	.450	0.014

QPCQ = Quality of Prenatal Care Questionnaire

A one-way analysis of covariance (ANCOVA) was run to determine if there was a significant difference in pregnancy related empowerment for those women participating in CP care versus IPC. All participants completed the Pregnancy Related Empowerment Scale both before receiving prenatal care (Pre-PRES scores) and at a minimum of 36 weeks' gestation, providing time for the participant to receive a majority of their care (Post-PRES scores). The Pre-PRES scores were used as a covariate to statistically control for individual differences, with the Post-PRES scores as the dependent variable in the ANCOVA tested across the two types of pregnancy care. The total scores of the first 16 questions were utilized for comparison between groups. The five questions for Centering only participants were excluded due to low sample size and a focus on the first 16 which all 51 participants completed.

Assumptions for the ANCOVA were addressed and there was no significant interaction between type of care and Pre-PRES ($F(2,48)=1.830$, $p=0.171$). While there were some outliers found in the Post-PRES score boxplots (see Figure 4) for the CP group the boxplots indicated no significant deviation from normality.

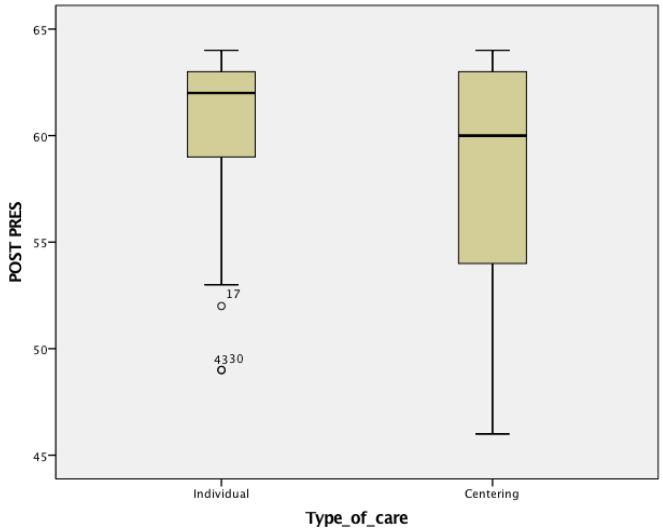

Figure 4. Boxplot of Post-PRES

The Levene's Test between the two types of care was significant ($F(1,49)=5.894$, $p=0.019$). Finally, a scatter plot of predicted values vs. residuals exhibited random scatter, indicating that the assumption for homoscedasticity was met.

The mean Post-PRES score for those participating in IPC was 60.22, with a standard deviation of 4.308. This was slightly higher than that for the CP group, which had a mean Post-PRES score of 57.64 and a standard deviation of 6.16. After controlling for the Pre-PRES covariate, the estimated adjusted marginal means were almost identical, with IPC having a mean of 60.263 and CP a mean of 57.519. Results of the ANCOVA indicated that there was no significant difference found between the two types of prenatal care with respect to Post-PRES scores, even while controlling for Pre-PRES scores ($F(1,48)=3.141$, $p=0.083$. A follow-up unequal variances t-test for the differences (Post mines Pre) in scores resulted with similar findings ($t=1.797$, $df=19$, $p=0.088$).

Two independent t-tests were used to answer the hypothesis related to type of prenatal care (CP or IPC) and gestational age and birth weight. They were run to determine whether there was a significant difference in these variables between the two different types of pregnancy care. Assumptions for an independent t-test include approximate normality for the dependent variable (gestational age and birth weight) across both levels of the independent variable (type of care). To test for this, boxplots (see Figures 5 and 6) for both gestational age and birth weight were examined and although there were a few outliers, there were not any significant deviations from normality.

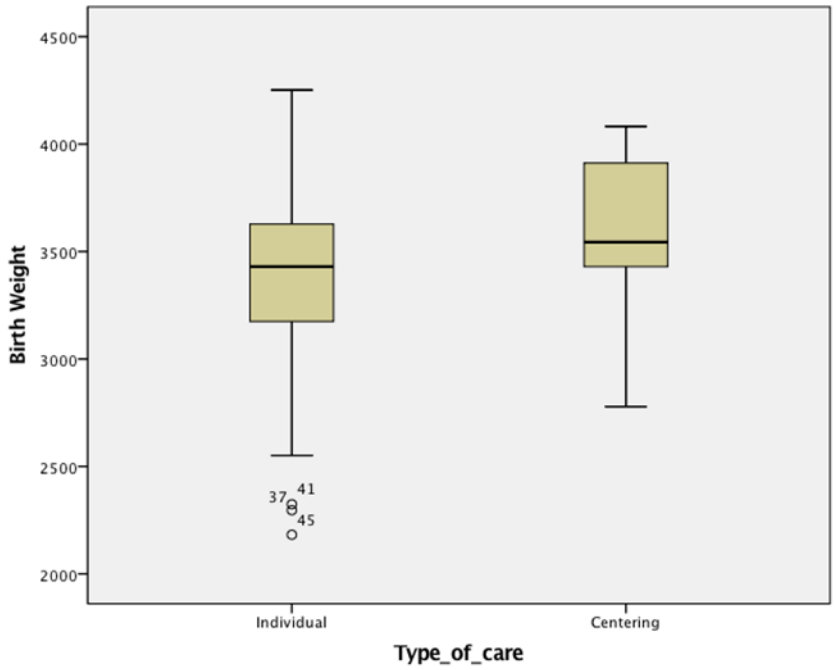

Figure 5. Boxplot of birth weight for type of Prenatal Care Received

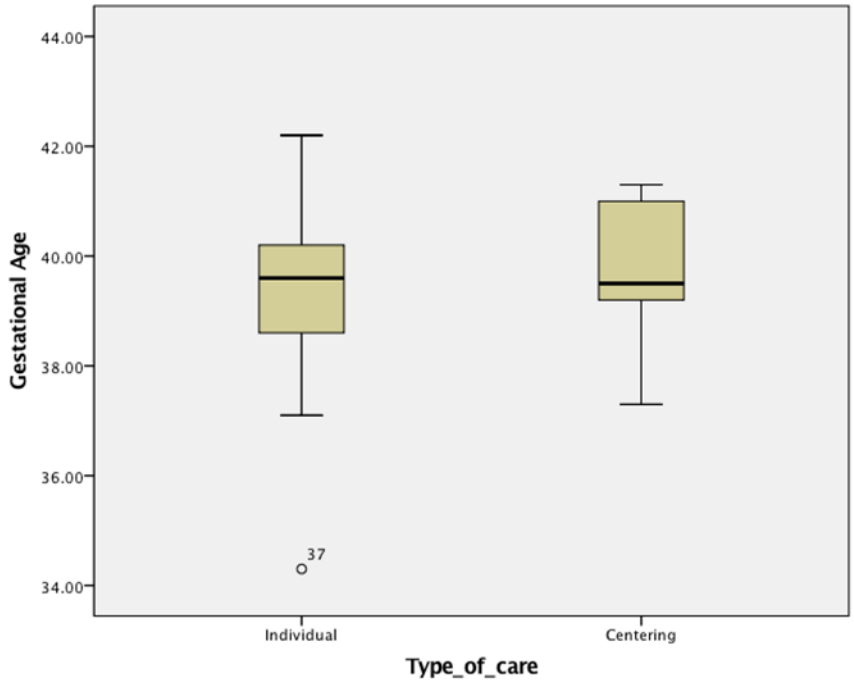

Figure 6. Boxplot of Gestational Age in Weeks for Prenatal Care Received

Results from the t-test indicated no significant differences in birth weight or gestational age between the Centering Pregnancy care and Individualized Pregnancy Care

at the 0.05 level of significance. However, there was near significance in birth weight between the two pregnancy care types (p = 0.088). Results and summary statistics are illustrated in Table 7.

Table 5. T-Test for Gestational Age and Birth Weight between Prenatal Care Models.

Dependent Variable	**Individual Care (n=37)**	**Centering Care (n=14)**	**Significance**
Gestational Age	M = 39.441 SD = 1.375	M = 39.650 SD = 1.246	t=-0.497 p = 0.621
Birth Weight	M = 3371.97 SD = 483.40	M = 3583.71 SD = 338.66	t=-1.501 p = 0.088

M = mean
SD = standard deviation

Discussion

Findings from this study did not support the theory that women who attend CP will have increased empowerment and better fetal outcomes. Donabedian's Quality of Care Framework did, however, identify that those who participated in both IPC and CP experienced similar structure and process quality of prenatal care. Due to lack of significance between groups in the QPCQ, it can be stated that IPC and CP participants in this clinic, receiving care from the same group of certified nurse midwives, experienced the same healthcare structure and clinical and technical processes during their prenatal visits. In addition, the process of development and implementation of the study lead to discoveries by the author that will be utilized in future research. Determination of the feasibility of a replication of the study with a larger sample size was deemed viable.

The results of this study show that while there was not statistical significance between prenatal care model (CP or IPC) and quality of prenatal care, pregnancy related empowerment, and neonatal outcomes, there were intriguing findings which require

further investigation. When comparing structure and process arms of the QCM there is no significance difference. However, when comparing outcomes there was near significance found which requires increased rigor in replication of study to ensure adequate sample size and equal groups.

There was some variance between groups on race, ethnicity, and education. There are more women in Centering Pregnancy who identified as Hispanic. Culturally, Hispanic women are known to be more family oriented and therefore exploration into the social aspect of CP may shed light onto why this population was overrepresented in the CP group. This can be equated to the Latina Paradox which notes that despite lower socioeconomic status Latina women have more favorable birth outcomes than expected (McGlade, Saha, & Dahlstrom, 2004). Therefore, community and socializing pregnancy care may be very culturally relevant for this population. Women in IPC were more likely to have some college education or higher. There are several potential explanations for this finding. One can postulate that those with higher education may feel that they will not gain anything from participating in CP. Another possibility is that those with higher education have careers that do not easily allow for time away for a two hour appointment. This will require additional examination to determine if there is a perceived barrier to participating in CP for those with higher education.

One major setback for the statistical power of the study was the longitudinal nature of the study and lack of access to medical records. Due to this, the author was reliant on contacting the participant directly via email or phone. Many participants were lost to incorrect email addresses or disconnected phone. Previous research on retention of participants in longitudinal studies has found that one key is collecting comprehensive

contact information, to the point of multiple methods of contact for the participant and family. Tansey, Matte, Needham, and Herridge (2007) found that thoroughly explaining the need for contact and follow up the participant and encourage them to inform their family will attenuate participant drop-out. There is the possible link to lower socioeconomic status and having a disconnected phone. A comparison of the differences of those lost to the study was not completed but should be for future studies to determine if there are any differences between those lost and those remaining in the study.

Another potential explanation for lack of significant findings is the providers themselves. The midwives provided care for both the CP and IPC patients and this was viewed as an advantage for the study as it took into account the variable of provider influence on quality of prenatal care. However, the subscales of the QPCQ; information sharing, anticipatory guidance, sufficient time, approachability, availability, support and respect are all factors that could be seen by all patients of midwives. Sandall, Devane, Soltani, Hatem and Gates (2010) found that midwife-led care is very women-centered, respectful of and responsive to individual patient preferences, needs, and values" (p. 257).

Patients experienced no differences in the process of care. And despite having different care model types the structure was not different in any other aspects as the providers were available and spent sufficient time with the patients. The only differences found between CP and IPC were with outcomes. Other influences must be sought to determine what aspects of Centering would impact the outcomes of the patients. Quality of prenatal care was not statistically significant between the two groups. This was not a surprise to the researcher, as patients of midwives are actively seeking a provider who is

more engaged, is less intervention based, and provides care based upon a philosophy of feminism rather than medicalizing the pregnant state. The use of a midwife as a provider for both groups, and therefore a constant, was purposeful to ascertain if the prenatal model itself influences the quality of prenatal care. However, overall the participants in both prenatal model groups had high values on the QPCQ.

Gestational age and birth weight are measurements of neonatal health often found throughout literature. In this study, gestational age was not significant, while birth weight was significant ($p = 0.088$). There is a need to determine if through increased empowerment through active engagement in self-assessment (weight, urine testing, and blood pressure assessment), healthy behaviors that can impact neonatal weight are influenced. Without further information on health behaviors such as diet, exercise, pregnancy weight gain, and smoking, it is difficult to be sure the impact on birth weight.

Centering Pregnancy was developed to empower women and yet this is the first study to determine if there is pregnancy-related empowerment utilizing a new instrument created for Centering Pregnancy comparison. Based upon results, there is enough evidence to warrant further investigation with a larger sample. The Post-PRES scores of those participating in IPC was slightly higher than those in CP. The author interprets this to possibly mean that those in CP gain insight into their health and pregnancy. Gaining knowledge can also give the participants a realistic understanding of how empowered they truly are about their pregnancy. While this deviates from the hypothesis prior to beginning the study it may also indicate that the PRES measurement became more accurate after participation in prenatal care.

Determining the number of appointments participants attended to ensure all curricular information was received by those in the CP group proved difficult. Furthermore, it must be determined if participants that changed their preferred prenatal care model due to structure, which would impact the QPCQ scores. As measured by the Pre-PRES, this particular study population was empowered prior to prenatal care; this might be a function of being under care of a midwife. The midwife model, being feminist, non-medical in nature, is fundamentally supportive in nature. This type of care would therefore be sought by patients who would desire to be more active and engaged in their own care.

Due to the nature of the sample participants demographics (predominately white, married, highly educated, and high household income), generalizability is limited. Future studies that seek a more diverse group of women including those with lower education and socioeconomic status are recommended to determine if demographic variables influence perceived quality of prenatal care and pregnancy-related empowerment.

The study results were not in congruence with multiple studies identifying CP as improving neonatal outcomes. Two new instruments were utilized for this study and therefore, further studies with a larger sample size are recommended in order to determine validity of the instruments in a population from Texas, an area with higher numbers of LBW and PTB than the national average.

Strengths and Limitations

The strengths of this study include the use of two reliable, though new, instruments, the QPCQ and PRES. Utilizing the QPCQ in the study allowed for determination of its reliability with a population that is more representative of the United

States, specifically Texas. Due to the defined gap in the research, the study results will add to science and more specifically help to support evidence-based care. Other strengths of the study include the limited risk to the participants and use of participants from one identified prenatal health care system. The use of one group of midwifes as the provider for all participants holds the provider as a constant while truly evaluating the quality of prenatal care.

The QPCQ has a limitation of a Flesch-Kincaid grade level of 8.7 per the authors (Heaman et al., 2014). The attrition rate across the longitudinal study is a limitation as it ended with a small sample size, which does not give adequate power to findings. Another limitation was the small variance between groups in IPC and CP with regard to the CP group having a larger number of women identifying themselves as Hispanic and less educated. One final limitation is the self-reporting nature of surveys. Self-reporting relies on the participant to provide all required data and reliant on their honesty and understand the innate bias that might influence responses.

Several limitations may have influenced the outcomes including the small sample size and non-randomization to treatment or control groups. Participants were able to self-select to receive CP or IPC and this may be influenced by the empowerment level prior to receiving care. Lack of retention of participates impacted the statistical power. A larger sample size could help to clarify if there is a difference in pregnancy related empowerment and birth weight as both were approaching significance.

Recommendations

Future research should consider utilizing text reminders to encourage participants to check their email for the survey. Studies should review the demographics of those lost

across the data collection points to determine the impact attrition had on demographic significance. The author recommends future studies to investigate health behaviors of mothers receiving IPC and CP before and after attending prenatal care appointments to determine if health behaviors changes based upon education received and active engagement in self-care.

The focus on one type of provider in one clinic was seen as an advantage for this particular feasibility study. However, inclusion of different providers including medical practitioners to determine if midwives, as a group or even specific to this clinic, can be directly attributed to quality of prenatal care based upon philosophical differences in approach to pregnancy and patient interaction.

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Chapter Four

Summary and Conclusion

Discussion among nurses within the area of women's health has focused on improvement of outcomes and enhancement of empowerment of the patient as a part of the labor and birth process. The idea of "my birth, my way" can be difficult for nurses as they are taught to make decisions about provision of care based upon information received through assessment of the patient. However, inclusion of the patient in the healthcare decision-making allows for greater understanding of health by the patient and increases likelihood of ownership of healthcare behaviors. Through empowerment and improvement of quality of care we can improve healthcare behaviors which in turn can improve the health of mother, child, and community. By gaining a greater understanding of the current state of quality of prenatal care and determination of areas that require improvement focus on innovative and evidence based solutions can progress.

Previous research in the area of prenatal care has shown that group prenatal care improves outcomes for mother and baby. However, there is a need for more research that is both rigorous and replicated to ensure reliability and generalizability. Through research we can gain a greater understanding of the constructs being measured, such as empowerment. Mixed method research or utilization of qualitative studies can assist in discovery of how patients perceive empowerment and the nurse's role. Nurses can influence maternal and fetal outcomes through purposeful and consistent sharing of information and inclusion of the patient and family unit.

Chapter two, *Power and Empowerment in Pregnancy and the Nurse's Role*, compared the concepts of power and empowerment in the pregnant patient to understand

how the nurse should approach a patient to improve their sense of empowerment. Sharing of power is inherent to the midwifery philosophy and is demonstrated throughout the continuum of care. Nurses must self-assess their perception of empowerment and learn to advocate for their patient, the true expert regarding her body.

The study of quality of care is omnipresent, as organizations such as the IOM and Quality and Safety Education for Nurses (QSEN) have focused on the degree to which quality of care can increase positive health outcomes (IOM, 2001). The World Health Organization's essentials for quality perinatal care include a need for holistic care that is "concerned with intellectual, emotional, social, and cultural needs of women, their babies, and families" (Chalmers, Mangiaterra, & Porter, 2001, p. 203). Centering pregnancy is a holistic, social, and empowering way to improve maternal and fetal outcomes.

Chapter three, *Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care*, investigated the differences between a group prenatal care model, Centering Pregnancy and individual prenatal care. This feasibility study makes several contributions to the prenatal care literature and suggests additional research is needed. First, the study helped identify limitations within the study design including recruitment and retention of the population. By incorporating new instruments to measure pregnancy-related empowerment and quality of prenatal care, a determination can be made of the reliability of these tools. Quantitative research exploring empowerment in pregnant women can provide guidance in identifying additional research questions necessary to truly understand the multidimensional construct within the context of pregnancy.

By measuring the quality of prenatal care perception by the patient we can determine qualities of the model that impact empowerment. Though the results were not statistically significant between the two groups for quality of prenatal care or gestational age at birth, there was approaching significance for birth weight and pregnancy-related empowerment. These results help to guide the researcher for future studies to determine what aspects of the CP model would influence health behaviors or birth weight by extension. Furthermore, CP was built as a model out of dissatisfaction with the traditional prenatal care model. CP was developed by a CNM to empower women to take responsibility and be active in their health. The author posits that based upon results further research is needed to assess pregnancy-related empowerment and CP. Empowerment can decrease anxiety and stress by changing the patient-provider relationship and power struggle. Through further studies, the CP model should be evaluated with a larger and more diverse sample to determine if variables such as education level influence pregnancy-related empowerment prior to exposure to CP. Populations of those that have poor outcomes due to low socioeconomic status or low health literacy can benefit from a group prenatal care model that empowers them and changes their health along with their child and community.

The study and articles written provide information related to quality of prenatal care, pregnancy related empowerment, and fetal outcomes. Through these findings, the researcher hopes that delivery of health care to pregnant women can be improved.

The plan for future research includes the desire to determine differences in providers, both Obstetricians and Gynecologists and Certified Nurse Midwives to determine if midwives already have a higher number of empowered patients or higher

quality of prenatal care. Also, a qualitative follow up study is planned that will include focus groups of participants in Centering Pregnancy so that the principal investigator may gain greater insight into empowerment through this model. Through interviews the researcher hopes to find salient themes of CP that help providers understand how to improve prenatal care and what aspects improve maternal health behaviors. The outcomes of the feasibility study allow for greater understanding of development and implementation of a longitudinal study and allow for replication.

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Appendix A: Advances in Nursing Science Manuscript Guidelines

Manuscript components

Every component of your manuscript is important and we encourage you to follow these instructions carefully. Consider in particular your title, keywords and abstract because these are the elements that enhance the discoverability of your work.

Titles: While fun, catchy titles can be intriguing, we highly recommend that you use a title that is a succinct, precise and descriptive "label" for the content of your work.

Keywords: In considering your keywords, think about the search terms that you used in the background research you completed for your manuscript; these often are the same search terms another reader will use when they are looking for content you have provided in your article. The National Library of Medicine "Suggestions for Finding Author Keywords using MeSH Tools" is an excellent resource to help select your keywords, but you do not need to be limited to these terms only. Review the various sections of your manuscript, and make sure that you have included keywords that are relevant for each section. Avoid using acronyms as keywords.

Abstract: Your abstract should be a succinct summary of your article, and provide an overview of the content of your manuscript.

The following components are required for all submissions. Manuscripts that do not meet these requirements will be returned to the corresponding author for technical revision before undergoing peer review.

- **Abstract:** The Abstract is inserted into a designated box during the submission process. You can compose the abstract using your word processor and copy and paste into the designated box on the web. Limit the abstract to 100 words. Do not cite references in the abstract. Limit the use of abbreviations and acronyms. The abstract should briefly summarize the major issue, problem or topic being addressed, and the findings and/or conclusions of the article.
- **Key words:** Key words are inserted into a designated box during the submission process. Provide up to ten key words that describe the contents of the article like those that appear in Cumulative Index to Nursing & Allied Health Literature (CINAHL) or The National Library of Medicine's Medical Subject Headings (MeSH). The key words are used in indexing your manuscript when it is published.
- **Title page:** The title page will be submitted as a separate file when you are instructed to attach files to your submission. Compose your title page using your word processor, then attach this file when you reach the "attach files" step in the submission process. Include on the title page
    - complete manuscript title;
    - authors' full names, highest academic degrees, and affiliations [NOTE: We do not allow the use of "PhD(c)" as a degree];

  - name and address for correspondence, including fax number, telephone number, and e-mail address;
  - any acknowledgements, credits or disclaimers; include acknowledgement of all sources of funding; and
  - disclosure of funding received for this work from any of the following organizations: National Institutes of Health (NIH); Wellcome Trust; Howard Hughes Medical Institute (HHMI); and other(s).
- **Statement of Significance:** The statement of significance will be submitted with your manuscript. The statement should be written in the first person, active voice, directly addressing the reader of your article. The significance statement includes two parts:
  - "What is known, or assumed to be true, about this topic." and
  - "What this article adds."
- **Manuscript:** The manuscript will be submitted as a separate file when you are instructed to attach files to your submission. Do not include any identifying information in your manuscript. If you are citing your own works, list them as "Author, YYYY" in the citation and the reference list in order to maintain your anonymity for the review process. Compose your manuscript using your word processor, then attach this file when you reach the "attach files" step in the submission process.

Manuscript Format and Style

Your manuscript will be assessed for standardized format and style requirements prior to entering the review process. If your manuscript does not adequately meet these requirements, it will be returned to the corresponding author with a request to revise the manuscript style and format. The requirements are:

- Prepare the article double spaced using the most current version of Microsoft Word for PC or Mac. Note in particular that the reference list should also be double-spaced. Leave a one-inch margin on all sides. Do not right justify.
- Type all headings on a separate line.
- Number all article pages consecutively in the upper right-hand corner (text, references and legends for tables and figures only).
- All legends for Tables and Figures are to be included with the manuscript. They should be brief and specific, and they should appear on a separate manuscript page after the references.
- Tables and Figures are attached as separate files when you reach "attach files" in the submission process. (See guidelines for preparing tabels and figures below.)
  - Cite figures consecutively in your manuscript.
  - Number figures in the figure legend in the order in which they are discussed.
  - Upload figures consecutively to the Editorial Manager web site and enter figure numbers consecutively in the Description field when uploading the files.
- Write out the full term for each abbreviation at its first use unless it is a standard unit of measure.

- Manuscript length (including all references, tables, figures) should be within a range of 15 to 30 pages (standard 8.5 x 11 inch page size). Excessively long manuscripts are seldom published in order to accommodate as much diversity as possible within each issue.
- Use the AMA Manual of Style, Ed. 10, Copyright 2007, for citations and references. See detailed guidelines for citations and references below.
- The list of references is not to exceed 50 entries.
- No identifying information (authors' names) should be included on the manuscript. If you cite your own works, list them as "Author, YYYY" in the citation and the reference list in order to maintain your anonymity for the review process.
- If your word processor tracks changes in your manuscript, then these may be visible to reviewers and will reveal your identity. To assure the anonymity of your manuscript, BE SURE to approve (or remove) all changes in your word document before uploading. In MS Word, go to the tools menu, then select "track changes". You can either highlight the changes (to check them before you approve them), or go directly to "approve or reject changes". Once you approve the changes, then they are no longer visible, and they will not show up on the pdf file that is built in the ANS Editorial Manager system.

References

Authors are responsible for the accuracy of the references. Include the references (double-spaced) at the end of the manuscript. Cite the references in text in the order of appearance. Cite unpublished data—such as papers submitted but not yet accepted for publication and personal communications, including e-mail communications—in parentheses in the text. If you cite your own works, list them as "Author, YYYY" in the citation and the reference list in order to maintain your anonymity for the review process.

The citations and reference list is to be styled according to the AMA Manual of Style, Ed. 10, Copyright 2007, AMA. Examples of citations within the text and reference list style are as follows:

Citation: Reliability has been established previously,1,2-8,19

Citation following a quote: Jacobsen concluded that "the consequences of muscle strength..."5(pp3,4)

Reference list:Books

1. Gregory CF, Chapman MW, Hanse ST Jr. Open fractures. In: Rockwood CA Jr, Green DP, eds. Fractures. Philadelphia: JB LIppincott Co; 1984: 169-218.
2. Yando R, Seitz U, Zigler E., et al. Imitation: A Developmental Perspective. New York: John Wiley & Sons; 1978.

Reference list: Journal articles (with abbreviated journal names)

3. Stevens, PE, Hall, JM. Appyling critical theories to nursing in communities. Public Health Nurs. . 1992; 9(1):2-9.

Reference list: unpublished material

4. Sieger M. The nature and limits of clinical medicine. In: Cassell EJ, Siegler M., eds. Changing Values in Medicine. Chicago: University of Chicago Press. In press.

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5. Raymand CA. Uncovering Ideology: Occupational Health in the Mainstream and Advocacy Press, 1970-1982. Ithaca, NY: Cornell University; 1983. Thesis.

Reference list: World Wide Web

6. Advances in Nursing Science Author's Guide. http://ans-info.net/ANSathgd.htm. Published June 30, 2006. Accessed June 13, 2007.

Reference list: Online Journal

7. Duchin JS. Can preparedness for biological terrorism save us from pertussis? Arch Pediatr Adolesc Med. 2004;158(2):106-107. http://archpedi.ama-assn.org/cgi/content/full/158/2/106. Accessed June 1, 2004.

Figures

We encourage authors to include illustrations to enhance the message of your manuscript. We have provided a useful guide for creating your own digital artwork here: http://links.lww.com/ES/A42. Once you have prepared your artwork, you will upload each item as a separate file to Editorial Manager.

Here are the basics to have in place before submitting your digital artwork:

- Artwork should be saved as TIFF, EPS, or MS Office (DOC, PPT, XLS) files. High resolution PDF files are also acceptable.
- Crop out any white or black space surrounding the image.
- Diagrams, drawings, graphs, and other line art must be vector or saved at a resolution of at least 1200 dpi. If created in an MS Office program, send the native (DOC, PPT, XLS) file.
- Photographs, radiographs and other halftone images must be saved at a resolution of at least 300 dpi.
- Photographs and radiographs with text must be saved as postscript or at a resolution of at least 600 dpi.

- Each figure must be saved and submitted as a separate file. Figures should not be embedded in the manuscript text file.

Supplemental Digital Content

Supplemental Digital Content (SDC) can be media of any type that enhances that article's text but that cannot be included in the traditional print or PDF version of the article. SDC is submitted via Editorial Manager as an integral part of the submission. SDC may include any standard media such as text documents, colored photographs, graphs, audio, video, drawings, etc. When you reach the section of Editorial Manager to attach files, you can select Supplemental Audio, Video, or Data for your uploaded file as the Submission Item. If an article with SDC is accepted, our production staff will create a URL with the SDC file. The URL will be placed in the call-out within the article. SDC files are not copy-edited by LWW staff, they will be presented digitally as submitted. All acceptable file types are permissible up to 10 MBs. For audio or video files greater than 10 MBs, authors should first query the journal office for approval. For a list of all available file types and detailed instructions, please visit http://links.lww.com/A142.

SDC Call-outs: Supplemental Digital Content must be cited consecutively in the text of the submitted manuscript. Citations should include the type of material submitted (Audio, Figure, Table, etc.), be clearly labeled as "Supplemental Digital Content," include the sequential list number, and provide a description of the supplemental content. All descriptive text should be included in the call-out as it will not appear elsewhere in the article.

Example:

We performed many tests on the degrees of flexibility in the elbow (see Video, Supplemental Digital Content 1, which demonstrates elbow flexibility) and found our results inconclusive.

A listing of Supplemental Digital Content must be submitted at the end of the manuscript file. Include the SDC number and file type of the Supplemental Digital Content. This text will be removed by our production staff and not be published.

Example:

Supplemental Digital Content 1.wmv

Tables

Tables are submitted as a separate file when you are instructed to attach files to your submission. Follow these guidelines to create your tables:

- Create tables using the table creating and editing feature of Microsoft Word. Do not use Excel or comparable spreadsheet programs.

- Include each table in a separate file, properly numbered to coincide with the list of Tables and Figures at the end of the manuscript file.
- Cite tables consecutively in the text, and number them in that order. Each table should include the table title, appropriate column heads, and explanatory legends (including definitions of any abbreviations used).
- Do not embed tables within the body of the manuscript. They should be self-explanatory and should supplement, rather than duplicate, the material in the text.

Style of Writing and Presentation

ANS insists on a readable, interesting voice and style that addresses a wide audience. The tone of the article should be scholarly but not "stiff." Your approach should be both informative and interpretive with some emphasis given to the implications of information presented and to the provision of fresh insights. Please use an active voice, including first person pronouns for sections that require your own voice.

Research papers should include all pertinent information related to the study, including the purpose of the study, a brief summary of background literature and justification of the study, a summary of the theoretical framework on which the study is based, the research problems or hypotheses, methodology and design, analysis of data, and a summary of conclusions and recommendations for further research and for nursing practice. Articles that deal with research methodologies and designs, concept analysis, theory analysis, value or ethical problems, application of theory and/or research findings in practice should be organized in a logical manner consistent with the author's purpose.

Here are a few guidelines for recommended language related to ethnicity, illnesses, disabilities and handicaps:

- Always put the person first, then the descriptor. Say or write "person with a disability" or “person living with a chronic condition” rather than “disabled person” or “chroncially ill persion” or even worse “the chronically ill.”
- Use language that is inclusive of all genders, unless you are specifically referring to people who identify as a specific gender.
- Use disability to describe a functional limitation that interferes with a person's ability to walk, hear, see, talk, learn. Use handicap to describe a situation or barrier imposed by society, the environment, or oneself.
- Don't be concerned if you find yourself using words like "see" to a person who is blind, or "hear" to a person who is deaf. These words won't offend.
- Do not refer to a person in a wheelchair as "confined" to a wheelchair. It's better to say or write "uses a wheelchair."
- Do not say "normal person" as compared to a person with a disability. Say able-bodied or nondisabled.

- Avoid such words as victim, oppressed, stricken with, crippled, mute, deaf and dumb, or afflicted. For example, refer to a person who has had a stroke as a stroke survivor, not as a stroke victim.
- Do not say arthritic or cerebral palsied. It's better to say "he has arthritis" or "she has cerebral palsy."
- Do not say birth defect. It's better to say a person who has a disability since birth; a congenital disability.
- Remember that a person with a disability or an illness is a person like anyone else--they just happen to have a condition that influences their daily living patterns.

Appendix B: Journal of Midwifery and Women's Health Manuscript Guidelines

Journal of Midwifery & Women's Health www.jmwh.org

Instructions for Authors

The *Journal of Midwifery & Women's Health* (*JMWH*) is the official journal of the American College of Nurse-Midwives. This peer-reviewed journal presents new research and current knowledge across a broad range of clinical and interdisciplinary topics including maternity care, gynecology, primary care for women and newborns, public health, health care policy, and global health. With a focus on evidence-based practice, *JMWH* is dedicated to improving the health care of women throughout their lifespan and promoting excellence in midwifery.

SUBMITTING A MANUSCRIPT

JMWH uses an online manuscript submission and peer review system. Please visit http://mc.manuscriptcentral.com/jmwh to submit a manuscript. A manuscript may be accepted as a submission with the understanding that: (1) it has not been published previously; (2) it is not simultaneously under consideration by any other journal; (3) the content is not fraudulent or plagiarized; (4) the material does not infringe or violate any copyright agreements or other personal or proprietary rights; and (5) all financial support for the work described in the manuscript and any conflicts of interest are disclosed. Copies of articles that are published or in press elsewhere that have any similar material (eg, data from the same dataset) should be provided at the time of submission. Authors must upload signed Author Disclosure and Copyright Transfer Agreement forms for each author. Please contact the editorial office at jmwh@acnm.org with questions about manuscript submission.

TYPES OF ARTICLES

Original Research

Original reports of research should include an introduction with study objective(s), methods, results, discussion, and conclusion. Include clinical, and policy if applicable, implications in the discussion section. For qualitative research, choose exemplar quotes judiciously. Readers should be able to clearly see the relationship between the quotes and your study findings. Length limit is 4000 words, 50 references. For pilot studies, length limit is 2500 words, 30 references.

Reports of research involving human participants must state in the methods section of the manuscript that institutional review board (IRB) or independent ethics review committee approval was obtained or an exemption was granted. The name of the IRB or ethics review committee must be included. *JMWH* may request documentation of the IRB or ethics committee approval or exemption. The methods section should also indicate how informed consent was obtained from all participants (ie, written or oral). Research in which members of the American College of Nurse-Midwives were solicited as participants must be conducted in accordance with the organization's policy regarding soliciting members for research purposes, which is available at www.acnm.org. Adherence to this policy must be noted in the methods section of the manuscript. Clinical trials started aft er May 2005 must be registered with a central registry.[1–3]

Reporting guidelines are used to improve the quality and transparency of research reports.[4] Reporting guidelines specify what information should be included in a research report. Many reporting guidelines include checklists, flow diagrams, and other resources that can be valuable for organizing a manuscript and ensuring the content is complete. Following reporting guidelines will improve your manuscript and may enhance its chances for eventual publication.

Use of the following reporting guidelines is encouraged for original research manuscripts:

- Randomized controlled trials: Consolidated Standards of Reporting Trials (CONSORT) Statement[5]
- Observational studies: Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement[6]
- Nonrandomized evaluations of behavioral and public health interventions: Transparent Reporting of Evaluations with Nonrandomized Designs (TREND)[7]
- Qualitative research: Standards for Reporting Qualitative Research (SRQR)[8] and Consolidated Criteria for Reporting Qualitative Research (COREQ)[9]
- Quality improvement studies: Standards for Quality Improvement Reporting Excellence (SQUIRE)[10]
- Diagnostic accuracy studies: Standards for the Reporting of Diagnostic Accuracy Studies (STARD)[11]
- Online surveys: The Checklist for Reporting Results of Internet E-Surveys (CHERRIES)[12]

Wiley will post the accepted version of any manuscript authored by National Institutes for Health (NIH) grant-holders to PubMed Central upon acceptance. This accepted version will be made publicly available 12 months after publication in accordance with the NIH Public Access Policy. For further information, see http://www.wiley.com/go/nihmandate. Wiley also offers open access via OnlineOpen (http://wileyonlinelibrary.com/onlineopen). Upon payment of the OnlineOpen fee, the published version of the article will be deposited into PubMed Central, with public availability in PubMed Central and on the Journal's website immediately upon publication.

Review

A review may address, but is not limited to, clinical practice; education; health care policy; or legal, ethical, environmental, cultural, or international issues affecting women's health. Systematic reviews, integrative reviews, and meta-analyses are welcome and should follow the same format as research reports (ie, introduction, methods, results, discussion, and clinical implications). Length limit is 5000 words, 50 references.

Use of the following reporting guidelines is encouraged for systematic reviews and meta-analyses:

- Systematic reviews and meta-analyses: Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) Statement[13]
- Systematic reviews of observational studies: Meta-analysis of Observational Studies in Epidemiology (MOOSE)[14]

Brief Reports

Brief reports may include, but are not limited to, innovative practice initiatives; assessment tools, resources, or evidence-based protocols that address a specific clinical topic; instructional techniques, technologies, and programs of interest for midwifery and other health professions educators; professional affairs updates; and historical perspectives. While manuscripts may focus on an

1526-9523/09/$36.00 doi:10.1111/jmwh.12605

individual practice or education program, the content must include broader implications and applicability. Length limit is 3000 words, 30 references.

Quality Improvement Reports

Quality improvement reports summarize the process and outcomes of systematic efforts undertaken to improve the quality and safety of health care. These manuscripts should include the following sections: introduction, process, outcomes, discussion, and conclusion. The Guidelines for Quality Improvement Reports, located at www.jmwh.org, provide an outline of suggested content for each section. Length limit is 2500 words, 30 references.

Commentary

Controversial points of view cogently presented in the form of position papers or editorials may be submitted. This section provides a forum for authors to express varied points of view, propose new ideas, or generate relevant debate on controversial topics. Length limit is 2000 words, 20 references.

Clinical Rounds

This column begins with a description of a case that is unusual, educational, or highlights an area in which the management is controversial, followed by a brief review of the evidence for management and/or discussion of the controversy. The Clinical Rounds Guidelines, located at www.jmwh.org, provide more detailed instructions for these manuscripts. Length limit is 3000 words, 30 references.

Share With Women

Health professionals may copy and distribute these patient education handouts without permission. The entire series is available at www.sharewithwomen.org. Limited to 2 typeset pages (front and back). Length limit is 1200 words.

Letters to the Editor

Letters to the Editor should be no longer than 400 words and must include a complete citation of the published work that generated the letter. All letters must be submitted via the online manuscript submission system. A letter's submission will be viewed as de facto permission for its publication. The Editorial Board reserves the right to select, edit, and condense letters for publication and to publish an author or editor response to letters.

MANUSCRIPT STYLE AND PREPARATION

JMWH has adopted the *AMA Manual of Style, 10th ed.*[15] for grammar, punctuation, and style. The *Journal of Midwifery & Women's Health Manuscript Preparation and Style Guide* contains necessary information about manuscript preparation and style specific to *JMWH* and is available at www.jmwh.org.

Manuscripts must be in English. Authors who are not fluent in English should seek assistance to ensure manuscript readability. Authors for whom English is a second language may choose to have their manuscript professionally edited before submission. A list of independent suppliers of editing services can be found at http://wileyeditingservices.com/en/. Use of an English-language editing service does not guarantee acceptance or preference for publication.

MANUSCRIPT COMPONENTS IN ORDER OF PRESENTATION

The manuscript components will be uploaded as separate files in the following order: (1) cover letter (optional); (2) title page, including author biographic sketch(es), conflict of interest disclosure, and acknowledgements; (3) blinded manuscript, including précis, abstract, keywords, Quick Points, text, references, tables, figure titles and legends, and appendices; (4) figures; and (5) supporting information. The title page and manuscript files should be uploaded as Microsoft Word files.

Title Page

A separate title page file is required to ensure that manuscripts sent for review do not include identifying author information that would prevent a blinded review. The title page includes (1) full title of manuscript with no abbreviations; (2) authors' names and credentials in the order of authorship for publication; (3) the name, mailing address, telephone and fax numbers, and e-mail address of the author to whom communications should be sent (corresponding author); (4) word count of the text (excluding précis, abstract, references, and tables); (5) author biographic sketch(es); (6) conflict of interest disclosure; and (7) acknowledgements. Choose a concise, specific manuscript title that summarizes the main idea of the manuscript, is fully explanatory, and includes terms likely to be used by readers searching for articles on the topic. The title must be able to stand alone, and the subtitle should complement or amplify the main title.

Author biographic sketch(es)

Provide a biographic sketch for each author. The biographic sketch should be 1 to 2 sentences, and include name, credentials (earned academic degrees, certification, and/or licensure), position(s), and current affiliation(s). For example, Jane Doe, CNM, MSN, is in clinical practice at Alaska Family Health & Birth Center in Fairbanks, Alaska, and a clinical instructor at the University of Alaska.

Conflict of Interest

Provide full disclosure of any conflicts of interest for all authors. If there are none, note "The author(s) has(have) no conflicts of interest to disclose."

Acknowledgements

Identify sources of financial or other support that contributed to the manuscript. Acknowledge contributors who are not included as authors. Obtain written permission from any individuals named in the acknowledgements section. *JMWH* may request the author provide documentation of permission from individuals acknowledged.

Manuscript

Précis (only required for Original Research, Review, Brief Report, and Quality Improvement Report submissions)

The précis is a description of the manuscript conclusions, which appears under the title in the Table of Contents. Describe the primary findings in 25 or fewer words that do not repeat the manuscript title. Use present tense and be specific. Tell what was found, not what was done.

If a figure is constructed or reprinted from text or figures in another publication, the figure legend must give appropriate credit to the original source. Figures that are constructed or reprinted from figures in other publications must be accompanied by written permission for their use from the copyright holder. Photographs of potentially identifiable people must be accompanied by written permission to use the photograph as a figure. Permission must be acknowledged in the figure legend. The legend wording depends upon the construction of and permission for the figure. The instructions for source and permission legend wording in the preceding section on tables should also be used for figures.

Appendices

Appendices appear at the end of an article in both the print and online versions of the Journal. Items better presented as an appendix, as opposed to a table that is typeset within the text, include questionnaires and lists of additional resources. Appendices must be cited in the text of the manuscript. Number appendices consecutively according to where they are cited in the text. Appendix titles follow the same format as table titles.The editors reserve the right to change appendices to online-only supporting information.

Figures

Figures include diagrams, flow charts, line drawings, and photographs. Figures can highlight patterns or trends in data and display complex relationships. Figure(s) should be high quality and submitted as a TIFF, JPEG, PDF, or EPS electronic file. Do not include the figure title or legend as part of the figure itself. They should be placed on a separate page of text in the manuscript file. Please save line artwork (vector graphics) as EPS files, and bitmap files (halftones or photographic images) as TIFF files, with a resolution of at least 300 dpi at final size. Please do not send native file formats (eg, Excel, PowerPoint, Word).

Supporting Information

Supporting information appears only in the online version of the Journal. Supporting information is content that cannot be accommodated within the normal printed space allocation for an article, but provides important complementary information for the reader. All Microsoft Office formats (eg, Word, Excel, PowerPoint), PDFs, graphics, video, and audio can be submitted for review. If accepted by the editors, supporting information will be posted on the Journal's website and directly integrated into the full-text HTML article. Make explicit reference to the supporting information in the main body of the text of the article (eg, see Supporting Information: Appendix S1) and caption the material above the reference list. Supporting information will be published as submitted and will not be corrected or checked for scientific content, typographical errors or functionality. The responsibility for scientific accuracy and file functionality remains entirely with the authors. A disclaimer will be displayed to this effect with any supporting information published.

EDITORIAL POLICIES

The Journal's editorial policies address publication and research ethics. All of the *JMWH* editorial policies are available online at www.jmwh.org. *JMWH* follows the International Committee of Medical Journal Editors' (ICMJE) *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*.[1] *JMWH* is a member of the Committee on Publication Ethics (COPE) and adheres to its principles.[16] In addition, *JMWH* uses recommendations from the World Association of Medical Editors (WAME),[17] Council of Science Editors (CSE),[18] and *AMA Manual of Style*[15] in developing editorial policies.

REFERENCES

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Appendix C: Permission Letter for use of QPCQ tool

From: Sword, Wendy [mailto:sword@mcmaster.ca]
Sent: Wednesday, July 30, 2014 11:47 AM
To: Sally Northam
Cc: 'Maureen Heaman'
Subject: RE: quality of prenatal care questionnaire

Dear Sally:

I am pleased to let you know that the Quality of Prenatal Care Questionnaire (QPCQ) is now available for use. The QPCQ has been licensed under a Creative Commons Attribution-NonCommercial-No Derivatives 4.0 International License. © 2013 Wendy Sword, Maureen Heaman, and the QPCQ Research Team. McMaster University.

Thank you for your interest in using this questionnaire. Attached please find the QPCQ and scoring instructions. Please note that no derivatives (adaptations) of the questionnaire are allowed.

I would kindly ask that you let me know when you have published the findings of any studies that used the QPCQ as the team that developed and tested the instrument is interested in seeing how and where it has been used.
Please do not hesitate to contact me if you have any questions.

Kind regards,
Wendy

Wendy Sword, RN, PhD
Professor and Assistant Dean (Research), School of Nursing
Associate Member, Department of Clinical Epidemiology and Biostatistics
HSC 3H48B
McMaster University
1280 Main Street West
Hamilton, ON L8S 4K1

Phone: 905-525-9140 ext. 22307
Fax: 905-523-9092

Appendix D: Permission Letter for use of PRES Instrument

Allender, Lisette

From: Klima, Carrie <cklima@uic.edu>
Sent: Monday, August 31, 2015 3:07 PM
To: Allender, Lisette
Subject: RE: PRES Request

Yes thanks for filling me in

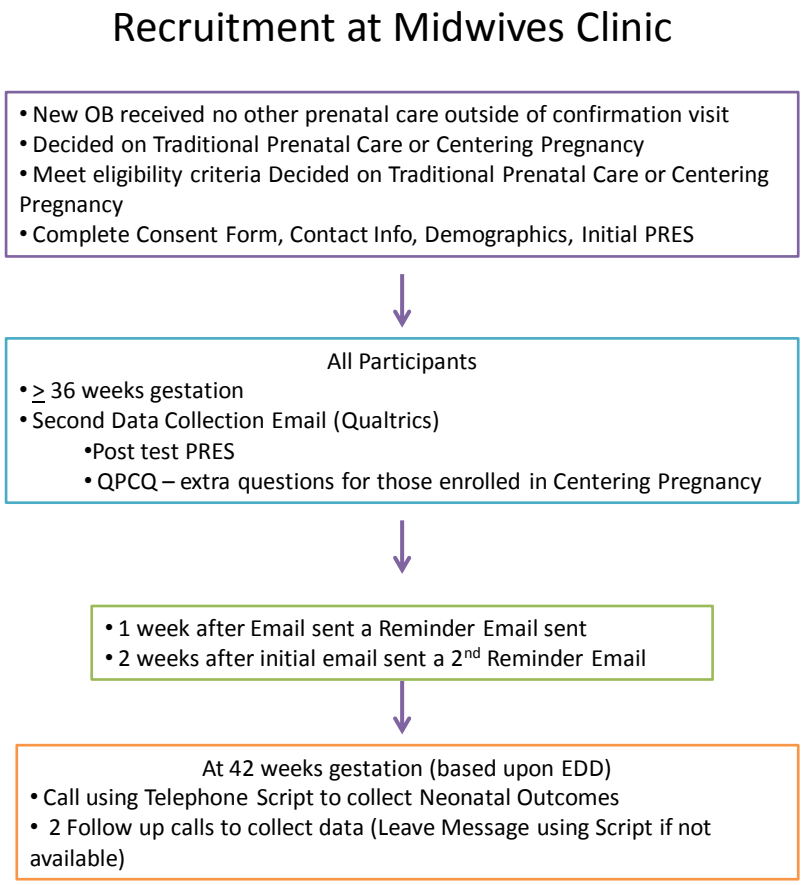
From: Allender, Lisette [mailto:L.M.allender@tcu.edu]
Sent: Monday, August 31, 2015 3:03 PM
To: Klima, Carrie <cklima@uic.edu>
Subject: PRES Request

Dr. Klima,
Thank you for notifying me that you received my request. I am requesting use of the PRES for my dissertation work Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy versus Traditional Prenatal Care
I had previously spoken with Dr. Vonderheid regarding proper administration of the PRES. Therefore,based upon discussion with her I will be gathering participants in both groups of prenatal care (CP and TPC) and comparing them using the PRES (given at 16 weeks or less and again after 36 weeks) and also the Quality of Prenatal Care Questionnaire, which came out of Canada which will be administered after 36 weeks. Also, I will look at outcomes of gestational age at delivery and birth of the newborn. I will compare the groups on the different variables as well as look at quality of prenatal care and empowerment. That is a very brief and long winded synopsis so I apologize. Please let me know if you have any further questions. I realize that permission to utilize the instrument also requires sharing of data which I will gladly do upon completion. Do I have your permission to utilize the Pregnancy Related Empowerment Scale for my dissertation study? Thank you so much for your time.

Lisette Allender MSN, RNC-OB
Texas Christian University
Harris College of Nursing and Health Sciences
817-257-4773
l.m.allender@tcu.edu

1

Appendix E: Study Flow Chart



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Office of Research and
Technology Transfer

Institutional Review Board

November 10, 2015

Dear Lisette Allender,

Your request to conduct the study: *Quality of Prenatal Care and Pregnancy Outcomes: Covering Pregnancy Versus Traditional Prenatal Care*, IRB #F2015-24 has been approved by The University of Texas at Tyler Institutional Review Board under expedited review. This approval includes the written informed consents that are attached to this letter, and your assurance of participant knowledge of the following prior to study participation: this is a research study; participation is completely voluntary with no obligations to continue participating, and with no adverse consequences for non-participation; and assurance of confidentiality of their data.

In addition, please ensure that any research assistants are knowledgeable about research ethics and confidentiality, and any co-investigators have completed human protection training within the past three years, and have forwarded their certificates to the IRB office (G. Duke).

Please review the UT Tyler IRB Principal Investigator Responsibilities, and acknowledge your understanding of these responsibilities and the following through return of this email to the IRB Chair within one week after receipt of this approval letter:

- This approval is for one year, as of the date of the approval letter.
- **The Progress Report form must be completed for projects extending past one year.** Your protocol will automatically expire on the one year anniversary of this letter if a Progress Report is not submitted, per HHS Regulations **prior** to that date (45 CFR 46.108(b) and 109(e); http://www.hhs.gov/ohrp/policy/contrev0107.html
- Prompt reporting to the UT Tyler IRB of any proposed changes to this research activity

- **Prompt reporting to the UT Tyler IRB and academic department administration will be done of any unanticipated problems involving risks to subjects or others**
- Suspension or termination of approval may be done if there is evidence of any serious or continuing noncompliance with Federal Regulations or any aberrations in original proposal.
- Any change in proposal procedures must be promptly reported to the IRB prior to implementing any changes except when necessary to eliminate apparent immediate hazards to the subject.

Best of luck in your research, and do not hesitate to contact me if you need any further assistance.

Sincerely,

Gloria Duke, PhD, RN

Gloria Duke, PhD, RN
Chair, UT Tyler IRB

Appendix G: UNTHSC IRB Approval 4/20/16

UNT | HEALTH SCIENCE CENTER

Institutional Review Board

DATE: 20 April 2016

TO: Kathleen Donaldson, MS, CNM, NP
with Shanna Combs, MD, Candis Hicks, CNM and Lisette Allender, MSN, RNC-OB
Department of Obstetrics and Gynecology
Texas College of Osteopathic

PROTOCOL: # 2015-200

"Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care"

IRB BOARD ACTION AND NOTICE OF APPROVAL

The Institutional Review Board (IRB) has reviewed your protocol under Expedited Review Procedures and has granted approval under the provisions of 45 CFR 46.110 (b) (1) Category (5) and (7)

Approval is effective April 20, 2016 through April 20, 2017

You are responsible for complying with all UNTHSC IRB and OReC policies, decisions, conditions and requirements. You are responsible for insuring that the research is implemented as specified in the approved protocol. Unless otherwise authorized by the UNTHSC-IRB, you are responsible for obtaining and documenting informed consents in accordance with applicable Federal Regulations (45 CFR 46 and 21 CFR 50) using ONLY the IRB approved consent forms designated for this protocol.

You must report to the Chair of the IRB any changes affecting the protocol upon which this certification is based. **No changes may be made without prior approval by the IRB** except those necessary to eliminate immediate hazards.

Should your project period extend beyond this expiration date, you must submit a Progress Report for Continuing Review to the IRB. You must allow sufficient time for the request for renewal to be reviewed and approved **before expiration of the current approval.** Be sure to *prepare for a renewal 2 months prior to the protocol expiration date.* If the project is finished before the approval expiration date, you must submit a final Progress Report (Continuing Review) either at the time the project is completed or before the expiration.

The Office of Research Compliance (OReC) will send out a reminder notice for your Progress Report (Continuing Review), however it is the responsibility of the Principal Investigator to prepare such a report in order for continuing review to occur BEFORE the expiration date.

Sincerely,

Scott Penzak, PharmD
IRB Chair, UNTHSC Institutional Review Board

Texas College of Osteopathic Medicine • Graduate School of Biomedical Sciences • School of Public Health
School of Health Professions • UNT System College of Pharmacy • Health Institutes of Texas • UNT Health
3500 Camp Bowie Boulevard, Fort Worth, Texas 76107 • 817-735-0409 • Fax 817-735-0124 • www.unthsc.edu
An EEO/Affirmative Action Institution

UNT Health Science Center
Office of Research Compliance
Institutional Review Board
BOARD ACTION

IRB Project #: 2015-200 Date Submitted: New Protocol

Principal Investigator: Kathleen Donaldson, MS, CNM, NP with Shanna Combs, MD, Candis Hicks,CNM & Lisette Allender, MSN

Project Title: Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care

Sponsor Protocol #:

Department: Obstetrics and Gynecology Contact Info:

In accordance with UNT Health Science Center policy on the protection of human subjects, the following action has been taken on the above referenced project. Approval, when given,is **only** for the project as submitted. **No changes** may be implemented without first receiving IRB review and approval.

The Principal Investigator must notify the IRB immediately if any new potential Conflict of Interest arises or if CITI educational training lapses for any of the Key Personnel involved with the study.

☑ Project has received approval through: **April 20, 2017**

☑ Informed consent(s*) approved as submitted on : **April 20, 2016**

You **MUST** use the version (s) attached rather than previously approved versions. In addition, only consent documents which bear the official UNTHSC IRB approval stamp can be used with subjects.

*Including: Research Consent Form/Parental Permission and HIPAA Authorization

☑ Study Protocol dated **April 20, 2016** approved as submitted.

☐ Investigator's Brochure approved as submitted.

☑ Protocol Synopsis approved as submitted on: **April 20, 2016**

☐ Amendment to the protocol approved as submitted.

☐ Progress Report/Continuing Review completed, project has received approval through:

☐ Project has been reviewed. In order to receive approval, you must incorporate the attached modifications. You must submit one "tracked changes" version showing the markup and one "clean" copy of the revised protocol synopsis, informed consent, and advertisements to the IRB for review. ***YOU MAY NOT BEGIN YOUR PROJECT UNTIL NOTIFIED BY THE IRB.***

☐ Project is disapproved for the reason(s) outlined (see attached).

☐ Consideration of the project has been **DEFERRED** pending resolution of the issues(s) outlined (see attached).

☐ Completion of project is acknowledged and all required paperwork has been received.

☑ Special Findings/Other

The IRB Chair found the study, which involves surveying pregnant women and collecting clinical measures of infants, meets the necessary requirements to qualify for Expedited category of research and a minimal risk determination.

Chair / Vice Chair, Institutional Review Board

4/20/16
Date

IRB Form 2 (revised March2015)

Board Action-page 2

PI: Kathleen Donaldson, MS, NP, CNM

IRB Project #: 2015-200

Date: 04/20/2016

SPECIAL FINDINGS:

☑ CHILDREN: The Board found the participation of children to be approvable under Subpart D of the federal regulations. Specifically, the research satisfies the requirements of:

☑ **45 CFR 46.404** ☐ **21 CFR**

☐ COGNITIVELY IMPAIRED: The Board found the participation of cognitively impaired subjects to be approvable under federal regulations. Specifically, the research satisfies the requirements of:

☐ **45 CFR 46.111 (b)** ☐ **21CFR 56.111 (b)**

☑ PREGNANT WOMEN: The Board found the participation of pregnant female subjects to be approvable under Subpart B of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR 46.204 (a) - (i)**

☑ FETUSES/NEONATES: The Board found the involvement of fetuses/neonates to be approvable under *Subpart B* of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR 46.205 (d)**

☐ PRISONERS: The Board found the participation of prisoners to be approvable under *Subpart C* of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR 46.305 (a), (b) and (c)**

☐ OTHER:

OTHER

☑ **Expedited Review Procedures (under 45 CFR 46)**

Project ☑ Approved ☐ Approved for Continuation ☐ Modifications approved **under the provisions of:**
45 CFR 46.110 (b) (1) category (5) **45 CFR 46.110 (b)(1) category (7)**

Category (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis); and Category (7) Research on individual or group characteristics or behavior... or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

☐ **45 CFR 46.110 (b) (2)** minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

☐ **HIPAA Waiver:** The Board finds this study meets all legal requirements for a Waiver of Individual Authorization under HIPAA pursuant to 45 CFR 164.512 (i) (2) (i)-(v) and approves the request under:

☐ **Informed Consent Waiver:** The Board finds this project qualifies for a _____ under the provisions of _____

☑ **Other IRB Approved Research Documentation Includes:**

Flowchart, Recruitment, Name/Contact Sheet, Reminder & Follow-up Scripts, Research Surveys (Demographic/Health, Pregnancy Related Empowerment Scale, Quality of Prenatal Care, Online Survey), Telephone Script/ Neonatal Outcome

☑ **Other Comments:**

Other UNTHSC IRB Determinations: 1) The IRB Chair found parental permission from the mother (pregnant women) to be sufficient and appropriate for the involvement of the neonate/infant (i.e., parental self-report of infant's clinical measures); (2) given the nature of the study, child assent is waived; and (3) reviewing of appointment schedule considered to be preparatory to research under HIPAA Regulations. NOTE: Notify and submit to UNTHSC IRB any revisions or modifications to the protocol for review and approval prior to implementation.

Appendix H: TCU IRB Approval 5/3/16

TCU INSTITUTIONAL REVIEW BOARD

Approval Form

Institutional Review Board (IRB) approval refers to research involving human subjects whether on or off Campus. **Significant changes in design, participants, or measures must be approved by the IRB. Multiyear projects must be submitted annually for approval. Any unexpected adverse effects on human subjects due to procedure should be reported immediately.**

Date: May 3, 2016

Principal Investigator: Lisette Allender

Project Title: Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care

Multi-year Project: Yes X No

Proposed Participants:

TCU students, faculty, or staff
X Non-TCU Participants
X Special Populations (e.g. children) – specify: Pregnant women

Approval Period: 5/3/16-5/2/17

Board Comments: Reviewed by Anna Petursdottir, IRB Chair. Research is minimal risk and review expedited according to 45 CFR 46.110 (7). Previously approved by UT Tyler and UNTHSC.

Approval Number: 1604-044-1605

Board Decisions:

Approved, Minimal Risk

X Approved, Expedited

Approved, Exempt Status

Conditional Approval, with following stipulations:

Not Approved for these reasons:

IRB Chair Date 5/3/2016

Appendix I: UTTyler IRB Modification 5/6/16

From: Gloria Duke <GDuke@uttyler.edu>
Sent: Friday, May 6, 2016 12:54 PM
To: Lisette Allender; Angela Nunez
Cc: Sally Northam
Subject: RE: IRB Modificaton Request F2015-20

Hello Lisette!

I am so sorry, but not surprised, you have run into these IRB-related challenges. These modifications have been approved by UT Tyler IRB so that you can proceed with your study, hopefully with no further obstacles in your way!

Sending much luck!!

Angela, no further action on your part is needed other than placing in her folder.

Thank you and have a great weekend! Gloria

Gloria Duke, PhD, RN
Professor and Associate Dean, Office of Research
College of Nursing & Health Sciences
Bart Brooks Professor of Ethics & Leadership
Director, UT Tyler Center for Ethics
Chair, UT Tyler Institutional Review Board
3900 University Blvd
Tyler, TX 75799

903-566-7023--ofc
903-565-5533--fax

THE UNIVERSITY OF TEXAS AT TYLER
INSTITUTIONAL REVIEW BOARD

IRB MODIFICATION REQUEST

IRB: F2015-20

Approved by**: G Duke**
Date: May 6, 2016

Date: 5-4-2016

Principal Investigator: Lisette Allender MSN, RNC-OB

Department: Nursing

IRB #: F2015-20

Project Title: Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care

Original Approval Date: November 10, 2015

Please complete all sections as appropriate and submit to the UT Tyler IRB Chair.

IDENTIFICATION OF CHANGE(S)

A. GENERAL

☐Change in Title of Protocol
☐Resubmission to Grant/Contract Agency
☐Change in Extramural Sponsor
☐Change in Cooperating Institution
☐Change in Status of Protocol (e.g., from "active" to "hold")

Explain any related changes: **N/A**

Explain rationale for changes: N/A

B. DESIGN

☒Change in Study Design

Explain any related changes: **Kathleen Donaldson CNM (Faculty at UNTHSC) and Candis Hicks CNM (Faculty UNTHSC) were added to research team as UNTHSC requires a faculty member be on research protocol. Addition of Leah Zimmerman as part of research team to assist in data collection. Also added Dr. Shanna Combs (Faculty UNTHSC) as a consultant due to previous experience in Ob/Gyn research at UNTHSC. Removal of information about research study form (previously added on modification 1-15-2016. Participants will be recruited and consented on site (UNT Midwives Clinic). Added back in UNTHSC into all study components (Consent form, protocol) due to addition of midwives, Dr. Combs, and Leah Zimmerman. Since the study is now under UNTHSC perview as well all data will be stored on a secure computer on site with their server and security. Aggregate data will be sent to a statistician and data will be maintained on site (UNT Midwives Clinic) in Kathleen Donaldson's locked officer per UNTHSC request. Removal of all incentives for participation including gift cards/raffle due to UNTHSC request. Furthermore, will approach approximately 500 patients to obtain approximately 100 in each group (Centering Pregnancy and Traditional Prenatal Care). Addition of a HIPAA consent form (Appendix M) to be signed by each participant per the request of UNTHSC due to sensitive information about the participant and their newborn. Will provide a signed copy of the informed consent form and HIPAA form. Minor changes made to informed Consent Form (Appendix C) include verbiage regarding the surveys and number of questions, under #6 side effects – inclusion of the possibility of breach of confidentiality due to temporary identifiable info with data, and under #9 addition of statement regarding privacy and collaboration between institutions (UTTyler, TCU, and UNTHSC), and addition of newborn information as part of consent. Modifications to the recruitment script (Appendix B) included addition of a bullet point for midwife to complete the script, removal of incentives discussion, addition of a question regarding if they have already decided to participate in Centering Pregnancy or Traditional Prenatal Care as an eligibility question, and clarification of language used when discussing fetal demise on the recruitment script eligibility questions (Appendix B).Per the modified flow chart (Appendix A) now Reminder Email (Appendix F) will be emailed approximately 1 week and approximately 2 weeks after the second data collection email (Appendix E). A follow up telephone call x 2 will be made for those we are unable to contact during the first phone call at approximately 42 weeks. Script is included on the telephone script in case a message must be left to return the phone call (Appendix J).**

Explain rationale for changes: **The change was made per UNTHSC request after consultation that faculty were necessary as well as Leah Zimmerman and Dr. Combs to consult and assist with data collection to ensure adequate recruitment. Further modifications were made at the request of UNTHSC per their protocols for research and requirements for security of sensitive patient data. Several changes such as addition of approximately were made per the request of UNTHSC to allow the PI flexibility in study implementation.**

C. PERSONNEL

☒Change in investigators, faculty or staff:

Name: **Kathleen Donaldson CNM and Candis Hicks CNM**

Credentials: **Faculty UNTHSC, Consultant**
Contact Information: **817-735-2352**

☒Change in Consultant/Collaborator

Explain any related changes: **Addition of midwives back into study to increase number of participants recruited and allow for further consultation on data analysis. Dr. Shanna Combs was added to consult due to past experience in Ob studies including IRB experience. Furthermore an Ob/Gyn that works with the UNT Midwives and has knowledge of workings of the office and implementation possibilities**

Explain rationale for changes: **Addition was suggested by UNTHSC. Recommendation excepted**

D. RISK

☒Change In Risk/Benefit Ratio (e.g., emergence of new side effects)

Explain any related changes: **Addition of possible breach of confidentiality due to DOB and Last Name associated with data during second data collection to ensure linkage of data across pregnancy.**

Explain rationale for changes: **UNTHSC Request this addition to ensure the participant understood the risks associated with including this information.**

E. COST

☐Change in Subject Expense
☒Change in Subject Reimbursement

Explain any related changes: **Removal of incentives (previously gift cards) for participating**

Explain rationale for changes: **UNTHSC recommended removal of incentives for participants due to state law regarding raffle prizes.**

F. PROCEDURES INVOLVING SUBJECTS

☐Change in collection of blood or other body fluids
☐Change in subject evaluation (e.g., number of visits, etc.)
☐Change in administration or dosage of drug
☐Change in drug formulation
☐Change/Deletion of any test

☐Change/deletion of device

Explain any related changes: **N/A**

Explain rationale for changes: **N/A**

G. STUDY POPULATION

☐Change in sample size
☐Change in eligibility criteria
☐Change in exclusion criteria
☐Alteration of study groups
☐Other: **Click here to enter text.**

Explain any related changes: **Click here to enter text.**

Explain rationale for changes: **Click here to enter text.**

H. SUBJECT RECRUITMENT

☒Change in recruitment procedures
☐Change in ads, flyers, etc.

Explain any related changes: **Will include UNTHSC Faculty/Staff on research team (Kathleen Donaldson, Candis Hicks CNM, and Leah Zimmerman) in recruitment. All have completed CITI training and COI Forms through UNTHSC. Will approach approximately 500 to obtain approximately 100 in both prenatal groups.**

Explain rationale for changes: **Addition of team members with access to participants helps increase likelihood of effective recruitment to reach desired numbers.**

I. OTHER

☐Any other significant changes

Explain any related changes: **N/A**

Explain rationale for changes: **N/A**

EXPLANATION OF CONSEQUENCES OF CHANGES

J. Modifications identified above require changes in:

☒Informed consent form (describe by highlighting or tracking of originally approved form)

K. Will these changes result in a change of the risk/benefit ratio?

☐ **Yes** ☒ **No**

If Yes, please explain: **Click here to enter text.**

ELECTRONIC ENCLOSURES AS NEEDED FOR CHANGES INDICATED:

☒Revised Informed Consent Form(s)
☐Letter from Sponsor
☐Letter from Investigators indicating their removal or addition to study
☒Revised Protocol (Date of Revised Protocol: **Click here to enter text.**)
☐Revised IRB Full Board Review Application
☐Revised Investigator's Brochure
☒Other: **Appendices**

SIGNATURE OF PRINCIPAL INVESTIGATOR

Lisette Allender	5-4-2016
Principal Investigator Signature (Electronic submission of this form by PI indicates signature)	Date

THE UNIVERSITY OF TEXAS AT TYLER
INSTITUTIONAL REVIEW BOARD

IRB MODIFICATION REQUEST

IRB: *F2015-20*

Approved by: *G Duke*
Date: May 27 2016

Date: *5/26/2016*

Principal Investigator: *Lisette Allender MSN, RNC-OB*

Department: *Nursing*

IRB #: *#F2015-20*

Project Title: *Quality of Prenatal Care and Pregnancy Outcomes: Centering Versus Traditional Care*

Original Approval Date: *November 10, 2015*

Please complete all sections as appropriate and submit to the UT Tyler IRB Chair.

IDENTIFICATION OF CHANGE(S)

A. GENERAL

☐Change in Title of Protocol
☐Resubmission to Grant/Contract Agency
☐Change in Extramural Sponsor
☐Change in Cooperating Institution
☐Change in Status of Protocol (e.g., from "active" to "hold")

Explain any related changes: *Click here to enter text.*

Explain rationale for changes: *Click here to enter text.*

B. DESIGN

☐Change in Study Design

Explain any related changes: *Click here to enter text.*

Explain rationale for changes: *Click here to enter text.*

C. PERSONNEL

☒Change in investigators, faculty or staff:

Name: *Katie Hopkins*
Credentials: *DNP, CNM*
Contact Information: *817-735-2352*

☐Change in Consultant/Collaborator

Explain any related changes: *Addition of midwife currently working in UNT Midwives office*

Explain rationale for changes: *Increase in number of research team members able to recruit participants, collect data, and analyze data.*

D. RISK

☐Change In Risk/Benefit Ratio (e.g., emergence of new side effects)

Explain any related changes: *Click here to enter text.*

Explain rationale for changes: *Click here to enter text.*

E. COST

☐Change in Subject Expense
☐Change in Subject Reimbursement

Explain any related changes: *Click here to enter text.*

Explain rationale for changes: *Click here to enter text.*

F. PROCEDURES INVOLVING SUBJECTS

☐Change in collection of blood or other body fluids
☐Change in subject evaluation (e.g., number of visits, etc.)
☐Change in administration or dosage of drug
☐Change in drug formulation
☐Change/Deletion of any test
☐Change/deletion of device

Explain any related changes: *Click here to enter text.*

Explain rationale for changes: *Click here to enter text.*

G. STUDY POPULATION

☐Change in sample size
☐Change in eligibility criteria
☐Change in exclusion criteria
☐Alteration of study groups
☐Other: *Click here to enter text.*

Explain any related changes: *Click here to enter text.*

Explain rationale for changes: *Click here to enter text.*

H. SUBJECT RECRUITMENT

☐Change in recruitment procedures
☐Change in ads, flyers, etc.

Explain any related changes: *Click here to enter text.*

Explain rationale for changes: *Click here to enter text.*

I. OTHER

☐Any other significant changes

Explain any related changes: *Click here to enter text.*

Explain rationale for changes: *Click here to enter text.*

EXPLANATION OF CONSEQUENCES OF CHANGES

J. Modifications identified above require changes in:

☐Informed consent form (describe by highlighting or tracking of originally approved form)

K. Will these changes result in a change of the risk/benefit ratio?

☐ **Yes** ☒ **No**

If Yes, please explain: *Click here to enter text.*

ELECTRONIC ENCLOSURES AS NEEDED FOR CHANGES INDICATED:

☐Revised Informed Consent Form(s)
☐Letter from Sponsor
☐Letter from Investigators indicating their removal or addition to study
☐Revised Protocol (Date of Revised Protocol: *Click here to enter text.*)
☐Revised IRB Full Board Review Application
☐Revised Investigator's Brochure
☒Other: *CITI Training for Katie Hopkins*

SIGNATURE OF PRINCIPAL INVESTIGATOR

Lisette Allender MSN, RNC-OB
Principal Investigator Signature
(Electronic submission of this form by PI indicates signature)

5-26-2016
Date

Appendix K: TCU IRB Modification Approval 6/6/16

TCU INSTITUTIONAL REVIEW BOARD

Approval Form

Institutional Review Board (IRB) approval refers to research involving human subjects whether on or off Campus. **Significant changes in design, participants, or measures must be approved by the IRB. Multiyear projects must be submitted annually for approval. Any unexpected adverse effects on human subjects due to procedure should be reported immediately.**

Date: June 6, 2016

Principal Investigator: Lisette Allender

Project Title: Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care

Multi-year Project: Yes X No

Proposed Participants:

TCU students, faculty, or staff
X Non-TCU Participants
X Special Populations (e.g. children) – specify: Pregnant women

Approval Period: 6/6/16-6/5/17

Board Comments: Reviewed by Anna Petursdottir, IRB Chair. Personnel change; no effect on risk.

Approval Number: 1604-044-1606AM

Board Decisions:

Approved, Minimal Risk

X Approved, Expedited

Approved, Exempt Status

Conditional Approval, with following stipulations:

Not Approved for these reasons:

IRB Chair Date 6/6/2016

UNIVERSITY OF NORTH TEXAS HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD

APPLICATION FOR CHANGE OF STUDY PERSONNEL
(OTHER THAN PRINCIPAL INVESTIGATOR)

Instructions: You must report additions, deletions, or changes in function of study staff on this form. This applies to study personnel, students, and trainees. **DO NOT USE THIS FORM TO REPORT CHANGES IN PRINCIPAL INVESTIGATOR.** For Principal Investigator (PI) change, you must revise the protocol synopsis to reflect the new PI.

RECEIVED
JUN 0 3 2016
UNTHSC Research Compliance

IRB Project #: 2015-200
Principal Investigator: KathJeen Donaldson, CNM
Project Title: Quality of Prenatal Care Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care

Sponsor Protocol #: ____ **UNTHSC Department:** OB/GYN
Contact Person: Leah Zimmerman **Phone:** 735-0141

Include with this form, a copy of the CITI training certificate and a signed Conflict of Interest (COI) disclosure for each added key personnel. Approval for adding personnel cannot be made without these additional documents, or without appropriate IRB/human subjects training. New (added) personnel may not begin involvement on project *prior* to IRB approval.

Katie Hopkins, CNM	Co-Investigator	Yes	6/1/2016
		___	Co per PI (see email dated 06/08/16)
		___	Co-I has not yet started study activities.
		___	
		___	

NOTE: The planned start date cannot precede the date this form is submitted for IRB review.

I hereby certify that the above information is correct and that the added personnel have complied with OPHS Conflict of Interest Disclosure requirements. I also certify that each of the persons listed above have met all aspects of the CITI required training for research involving human subjects, and that each person has complied with the CITI Integrity Assurance Statement. Therefore, I assume responsibility for the above personnel and their activities on this study.

Signature – Principal Investigator 5/27/16 Date

Signature – Chairman, IRB 6/9/16 Date

IRB Form 1a (revised February 2013)

Appendix M: UNTHSC IRB Modification Approval 6/17/16

UNT Health Science Center
Office of Research Compliance
Institutional Review Board
BOARD ACTION

IRB Project #: 2015-200 Date Submitted: June 10, 2016

Principal Investigator: Kathleen Donaldson, MSN, CNM, WHNP

Project Title: Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care

Sponsor Protocol #:

Department: Obstetrics and Gynecology Contact Info:

In accordance with UNT Health Science Center policy on the protection of human subjects, the following action has been taken on the above referenced project. Approval, when given,is **only** for the project as submitted. **No changes** may be implemented without first receiving IRB review and approval.

The Principal Investigator must notify the IRB immediately if any new potential Conflict of Interest arises or if CITI educational training lapses for any of the Key Personnel involved with the study.

☐ Project has received approval through:

☐ Informed consent(s*) approved as submitted on :

You **MUST** use the version (s) attached rather than previously approved versions. In addition, only consent documents which bear the official UNTHSC IRB approval stamp can be used with subjects.

*Including:

☑ Study Protocol dated **June 17, 2016** approved as submitted.

☐ Investigator's Brochure approved as submitted.

☑ Protocol Synopsis approved as submitted on: **June 17, 2016**

☑ Amendment **dated June 17, 2016** to the protocol approved as submitted.

☐ Progress Report/Continuing Review completed, project has received approval through:

☐ Project has been reviewed. In order to receive approval, you must incorporate the attached modifications. You must submit one "tracked changes" version showing the markup and one "clean" copy of the revised protocol synopsis, informed consent, and advertisements to the IRB for review. ***YOU MAY NOT BEGIN YOUR PROJECT UNTIL NOTIFIED BY THE IRB.***

☐ Project is disapproved for the reason(s) outlined (see attached).

☐ Consideration of the project has been **DEFERRED** pending resolution of the issues(s) outlined (see attached).

☐ Completion of project is acknowledged and all required paperwork has been received.

☐ Special Findings/Other

The IRB Chair found the proposed amendment involving a change to inclusion/exclusion criteria and minor update to the protocol does not increase risk to subject. The Amendment and study documents receive IRB approval.

Chair / Vice Chair, Institutional Review Board

6/17/2016
Date

IRB Form 2 (revised March 2015)

Board Action-page 2

PI: Kathleen Donaldson, MSN, CNM, WHNP

IRB Project #: 2015-200

Date: 06/17/2016

SPECIAL FINDINGS:

☐ CHILDREN: The Board found the participation of children to be approvable under Subpart D of the federal regulations. Specifically, the research satisfies the requirements of:

☐ **45 CFR** ☐ **21 CFR**

☐ COGNITIVELY IMPAIRED: The Board found the participation of cognitively impaired subjects to be approvable under federal regulations. Specifically, the research satisfies the requirements of:

☐ **45 CFR 46.111 (b)** ☐ **21CFR 56.111 (b)**

☐ PREGNANT WOMEN: The Board found the participation of pregnant female subjects to be approvable under Subpart B of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR 46.204 (a) - (i)**

☐ FETUSES/NEONATES: The Board found the involvement of fetuses/neonates to be approvable under *Subpart B* of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR**

☐ PRISONERS: The Board found the participation of prisoners to be approvable under *Subpart C* of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR 46.305 (a), (b) and (c)**

☐ OTHER:

OTHER

☑ **Expedited Review Procedures (under 45 CFR 46)**

Project ☐ Approved ☐ Approved for Continuation ☑ Modifications approved **under the provisions of:**

Amendment: The protocol was revised to remove the gestational age requirement (16 weeks) for study eligibility. Researchers still plan to target women who are seeking prenatal care (i.e. not yet received care), but now intend to include women at any gestation age. The Protocol Synopsis and relevant study documents were updated to reflect the change. The Protocol Synopsis was also revised to update the list of active, IRB approved research personnel.

☑ **45 CFR 46.110 (b) (2)** minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

☐ **HIPAA Waiver:** The Board finds this study meets all legal requirements for a Waiver of Individual Authorization under HIPAA pursuant to 45 CFR 164.512 (i) (2) (i)-(v) and approves the request under:

☐ **Informed Consent Waiver:** The Board finds this project qualifies for a _____ under the provisions of _____

☑ **Other IRB Approved Research Documentation Includes:**

Recruitment Script and Study Flow Diagram

☐ **Other Comments:**

Appendix N: TCU IRB Modification Approval 6/29/16

TCU INSTITUTIONAL REVIEW BOARD

Approval Form

Institutional Review Board (IRB) approval refers to research involving human subjects whether on or off Campus. **Significant changes in design, participants, or measures must be approved by the IRB. Multiyear projects must be submitted annually for approval. Any unexpected adverse effects on human subjects due to procedure should be reported immediately.**

Date: June 29, 2016

Principal Investigator: Lisette Allender

Project Title: Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care

Multi-year Project: Yes X No

Proposed Participants:

- TCU students, faculty, or staff
- X Non-TCU Participants
- X Special Populations (e.g. children) – specify: Pregnant women

Approval Period: 6/6/16-6/5/17

Board Comments: Reviewed by Anna Petursdottir, IRB Chair. Proposed modifications of eligibility criteria do not increase risk.

Approval Number: 1604-044-1606AM2

Board Decisions:

Approved, Minimal Risk

X Approved, Expedited

Approved, Exempt Status

Conditional Approval, with following stipulations:

Not Approved for these reasons:

IRB Chair Date 6/29/2016

Appendix O: Recruitment Script

Excuse me. My name is _____ I am a state appropriate role:

- research assistant and I am working on a research study with Lisette Allender a doctoral student at University of Texas Tyler]
- a midwife of the clinic, assisting Lisette Allender, a doctoral student at University of Texas Tyler conducting a study here at the clinic.
- doctoral student at University of Texas Tyler conducting a study here at the midwives clinic.

I am approaching you to see if you would like to be in the research study. This study is not part of your care here at the UNT Midwives clinic. We are approaching all pregnant women early in their care. This research is separate from the care you are receiving and whether or not you decide to hear more about the research won't affect your care. If you agree to participate, I will ask you questions to determine if you are eligible to participate in the study. If you are eligible you will be asked today to answer questions on basic information about yourself such as age, ethnicity, and income. You will also be asked to complete surveys about your quality of prenatal care and pregnancy related empowerment. This will take anywhere from 5-10 minutes. The first survey will be paper and pencil and include questions such as: "I can tell when I have made a good health choice."
The second set of surveys will be emailed to the email you once you are further along in your pregnancy. This will consist of questions on your pregnancy related empowerment and quality of prenatal care and will take approximately 10 minutes. An example would be: "My prenatal care provider respected me."

Finally, after you deliver you will be called and asked about your baby's weight and what day you delivered.

The information that is obtained will be reported as aggregate data with no personal identification of you. If at any time you don't want to answer one of the survey questions please tell me. You may decide not to participate in the study or withdraw from the study at any time. Participation is completely voluntary.
Do you have any questions about the study before we begin?
If they agree to participate a let the potential participant know you must first ask several questions to determine if they are eligible.
Ask the participant – Have you already decided if you are going to participate in Centering Pregnancy or traditional prenatal care?

- If they say yes, continue to the next question, if they say no, let them know they are note eligible yet, once they decide they might be eligible and we can speak with them again then.

Appendix F (Continued)
Ask the participant - Are you 18 years old or older?

- If they say yes continue to the next question, if they say no, let them know they are not eligible and thank them for their time.

Ask the participant – Are you pregnant and receiving prenatal care at the clinic?

- If they say yes continue to the next question, if they say no, let them know they are not eligible and thank them for their time.

Ask the participant – Are you less than or equal to 16 weeks? If the participate is unsure, ask their due date and use the wheel provided to determine gestation in weeks. If they are not 16 weeks or less then let them know they are not eligible and thank them for their time.

Ask the participant – Are you pregnant with only one baby or more than one baby?

- If they are pregnant with more than one baby then let them know they are not eligible and thank them for their time

Ask the participant – Have you had any previous fetal loss (if they don't know what that means ask if they have lost a baby after 20 weeks gestation. A fetal demise is death after 20 weeks, a miscarriage is fetal death before 20 weeks gestation). Therefore, if they have had a miscarriage they can continue to be eligible, if they have had a fetal demise they are no longer eligible.

- If they have then let them know they are not eligible and thank them for their time.

If they are eligible then you can continue on to the consenting process.

Appendix P: Informed Consent

THE UNIVERSITY OF TEXAS AT TYLER

University of North Texas Health Science Center

Texas Christian University
Informed Consent to Participate in Research

Institutional Review Board # F2015-20
Approval Date: November 20, 2015

1. Project Title: Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care

Principal Investigator: Kathleen Donaldson CNM, UNTHSC
Co-Investigators: Shanna Combs,MD (UNTHSC), Lisette Allender MSN, RNC-OB,(TCU) and Candis Hicks CNM (UNTHSC)

2. Participant's Name: _____

To the Participant:

You are being asked to take part in this study with The University of Texas at Tyler, University of North Texas and Health Science, and Texas Christian University. This permission form explains:

- Why this research study is being done.
- What you will be doing if you take part in the study.
- Any risks and benefits you can expect if you take part in this study.

After talking with the person who asks you to take part in the study, you should be able to:

- Understand what the study is about.
- Choose to take part in this study because you understand what will happen

3. Description of Project

The purpose of this study is to see what you think about the type of care you get and how the care that you get while you are pregnant impacts your baby at birth and how empowered you feel.

We want to measure how long your pregnancy was, how much your baby weighed, and to measure your pregnancy related empowerment.

We will be looking at the differences between women enrolled in Centering Pregnancy and those

who received traditional prenatal care.

Findings from this study may help nurses and doctors improve healthcare and pregnancy outcomes for pregnant women.

5. Research Procedures

<u>If you agree to be in this study, we will ask you to do the following things:</u>

- You will provide your contact information (name, address, phone #, email, and date of birth) to allow researchers to send out electronic surveys, contact for birth outcome information, re-contact to collect missing data, and allow for linking of data from initial surveys to second and third.
- You will be asked to answer questions on basic information about yourself such as age, ethnicity, and income. You will also be asked to complete a survey about your pregnancy related empowerment. Each survey collection will take anywhere from 5-10 minutes. The initial surveys will be completed with a member of the research team. The first survey will be paper and pencil.
    - Example question: "I can tell when I have made a good health choice."
- Around the time you reach 36 weeks gestation, we will send you a follow up survey by email to the email you provide. You will also receive reminders to complete the survey. The second set of surveys take approximately 10 minutes to complete about your pregnancy related empowerment and quality of prenatal care.
    - Example question: "My prenatal care provider respected me."
- Finally, after you deliver you will be contacted by phone to ask about your baby's weight and what day you delivered.

6. Side Effects/Risks

You may become slightly distressed when completing your surveys about your experience of prenatal care as it will take some time, though we do not expect this to be a common problem.

You may experience discomfort when answering questions asking about personal demographic information and obstetric history. To minimize any discomfort caused by answering study questions, you may skip any questions you do not feel comfortable answering. Should you become distressed, the researcher can help you if needed.

Due to the fact that information will be kept temporarily identifiable to ensure complete data collection for each participant there is the potential for a breach of confidentiality.

However, the researchers have taken multiple precautions to minimize this risk. No personal or identifiable information will be published.

7. Potential Benefits

Findings from this study may help nurses and doctors improve healthcare and pregnancy outcomes for pregnant women.

Understanding of Participants

8. You have been given a chance to ask any questions about this research study. The researcher has answered my questions.

9. If you sign this consent form you know it means that:

- You understand that this is a collaboration between the University of Texas at Tyler, University of North Texas Health Science Center, and Texas Christian University and involves their respective IRB and personnel.

- You understand you are taking part in this study because you want to. You chose to take part in this study after having been told about the study and how it will affect you.

- Participation or non-participation in the study will not affect the healthcare or clinical services that you will receive from UNTHealth, or your relationship with the UNT midwives.

- The information you provide will be kept private, only approved research tem members will have access to it.

- You know that you are free to not be in this study. You will still receive your prenatal care regardless of participation.

- You know that you have been told that if you choose to be in the study, then you can stop at any time. You know that if you do stop being a part of the study, then nothing will happen to you.

- You will be told about any new information that may affect your wanting to continue to be part of this study.

- The study may be changed or stopped at any time by the researcher or by The University of Texas at Tyler, University of North Texas Health Science Center, or Texas Christian University.

The researcher will get your written permission for any changes that may affect you.

10. You have been promised that that your name will not be in any reports about this study unless you give your permission.

11. You also understand that any information collected during this study may be shared as long as no identifying information such as your name, address, or other contact information is provided. This information can include health information. Information may be shared with:

- Sigma Theta Tau, Beta Alpha Chapter who gave money to be able to conduct this study
- Other researchers interested in putting together your information with information from other studies
- Information shared through presentations or publications

12. You and your child's research information will be kept confidential as possible under current local, state, and federal laws. However, the Office of Human Research Protections, possible other federal regulatory agencies and the Institutional Review Board may examine the study data. Your identity will not be revealed in any publication and/or study information.

13. You have been told about any possible risks that can happen with you taking part in this research project.

14. You also understand that you will not be given money for any patents or discoveries that may result from you taking part in this research.

15. If you have any questions concerning your participation in this project, you will contact the principal researcher: Kathleen Donaldson, CNM (817735-2352) or Co-Investigator Lisette Allender, MSN, RNC-OB (817-480-4047) or by email (lallender@patriots.uttyler.edu).

16. If you have any questions concerning your rights as a research subject, you will contact Dr. Gloria Duke, Chair of the IRB, at (903) 566-7023, gduke@uttyler.edu, or UNTHSC IRB Chairperson (817-735-0409), or Dr. Anna Petursdottir, Chair (TCU Institutional Review Board) (817) 257-6436, or Dr. Bonnie Melhart (TCU Research Integrity Office) (817) 257-7104, or the University's Office of Sponsored Research:

The University of Texas at Tyler
c/o Office of Sponsored Research
3900 University Blvd
Tyler, TX 75799

You understand that you may contact any of the above persons with questions about research-related injuries.

17. CONSENT/PERMISSION FOR PARTICIPATION IN THIS RESEARCH STUDY

You have read and understood what has been explained to you. You give your permission and your newborn to take part in this study as it is explained to you. You give the study researcher permission to register you and your newborn in this study. You have received a signed copy of this consent form.

_____ _____
Signature of Participant Date

_____

Participant Printed Name

_____
Signature of Person Responsible (e.g., legal guardian)

_____
Relationship to Participant

_____
Witness to Signature

18. You have discussed this project with the participant, using language that is understandable and appropriate. You believe that you have fully informed this participant of the nature of this study and its possible benefits and risks. You believe the participant understood this explanation.

_____ _____
Researcher/Principal Investigator Signature Date

_____

Researcher/Principal Investigator Printed Name

Appendix Q: HIPAA Form

UNT HEALTH SCIENCE CENTER

HIPAA Research Authorization

Authorization For the Use of Protected Health Information for Research

Research Title:	Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care
Lead researcher:	Kathleen Donaldson, Director of Midwives, Department OB/GYN
Institution of lead researcher:	University of North Texas Health Science Center (UNTHSC)

A. Purpose of this form

The purpose of this form is to give your permission to the research team to obtain and use your protected health information (PHI). This health information will be used to do the research named above.

This document is also used for parents to provide permission to obtain the individual health information of their minor children, and for legally-authorized representatives of subjects (such as an appropriate family member) to provide permission to obtain individual health information of individuals who are not capable themselves of providing permission. In such cases, the terms "you" and "your health information" refer to the subject rather than the person providing permission.

State and federal privacy laws protect your health information. These laws say that, in most cases, your health care provider can release your identifiable health information to the research team only if you give permission by signing this form.

You do not have to sign this permission form. If you do not, you will not be allowed to join the research study. Your decision to not sign this permission will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits.

B. The individual health information that will be obtained and used

"Individual health information" means the health information in your medical or other healthcare records. It also includes information in your records that can identify you. For example, it can include your name, address, phone number, birthdate, and medical record number.

1. Location of health information

By signing this form you are giving permission to the following organization(s) to disclose your patient or health information for this research.

IRB APPROVED
APR 20 2016
University of North Texas Health Science Center

Name of health care organization(s) or provider(s):
UNT Midwives Clinic

2. Individual health information that will be released for research use

This permission is for the health care provided to you during the following time period: From the start of your prenatal care until the end of this research study.

The specific information that will be released and used for this research is described below:

- Medical history / treatment
- Obstetric History and Post Delivery Information
- Neonatal Outcomes - Date of Delivery & Newborn Birth Weight

C. How your patient information will be used

The researcher will use your individual health information only in the ways that are described in the research consent form that you sign and as described here.

The research consent form describes who will have access to your information. It also describes how your information will be protected. You can ask questions about what the research team will do with your information and how they will protect it.

The privacy laws do not always require the receiver of your information to keep your information confidential. After your information has been given to others, there is a risk that it could be shared without your permission.

D. Expiration

This permission for the researchers to obtain your individual health information:

until the end of the study

E. Canceling your permission

You may change your mind at any time. To take back your permission, you must send your **written** request to:

Kathleen Donaldson CNM
Klabzuba Building on Harris Campus
1300 West Terrell Ave, Suite 360
Fort Worth, TX 76104

If you take back your permission, the research team may still keep and use any individual health information about you that they already have. But they can't obtain more health information about you for this research unless it is required by a federal agency that is monitoring the research.

If you take back your permission, you will need to leave the research study. This means that you would not have any more research involvement or tests. Changing your mind will not affect any other treatment, payment, health care, enrollment in health plans or eligibility for benefits.

F. Giving permission

You give your permission to release your information by signing this form.

Printed Name of Research Subject _____ Birthdate

Signature of Research Subject | Date of signature

Printed Name of Person Authorized to Give Permission

Signature of Person Authorized to Give Permission | Date of signature

Relationship to Subject and Description of Authority
(Examples: parent of a young child; sister of an individual who is in a coma; researcher who signs for a subject who is unable to physically sign the authorization but was observed by the researcher to read and otherwise agree to the authorization.)

You will receive a copy of this signed form. Please keep it with your personal records.

Appendix R: Participant Contact Information

Participating in this Study

In order to be in the study "Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care" you must provide contact information which will be used to send you the follow up surveys by email. As part of this form, we ask that you give us your birth date. This will be used only to make sure that we have collected all of your surveys to finish the study. Also, if data is missing we will contact you by phone to make sure we have complete data. Please remember that participation is voluntary and you can withdraw at any time. Your personal information will not be included in the study discussion but is simply a method to contact you and ensure that all participants provide all necessary data to make sure this study is a success.

Contact Information:

Name: _____

Address: _____

_____

Phone Number: _____

Email: _____

Participant Birthday MM/DD/YY)_____

Appendix S: Demographic and Health History Survey

Participant Code # _____

I understand that completion of this questionnaire means I agree to be part of a research study.

PERSONAL INFORMATION

1. What is today's date? (enter in a form like 06-04-15) __- __- __

2. What is your age? ____

3. Which of the following best describes your race? (select one item)

☐1 American Indian or Alaskan Native
☐2 Asian
☐3 Native Hawaiian/Other Pacific Islander
☐4 Black/African-American
☐5 White/Caucasian
☐6 Other

4. Are you Hispanic? ☐1 Yes ☐2 No

5. Which of the following best describes your current marital status? (select one item)

☐1 Married ☐2 Widowed ☐3 Separated ☐4 Divorced ☐5 Never married

6. What is the highest grade you completed in school? (select one item)

☐1 8th grade or less
☐2 Some high school
☐3 High school graduate
☐4 Some college
☐5 College graduate
☐6 Any post-graduate work

7. Which of the following best describes your household annual income? (select one item)

☐1 Less than $10,000

☐2 $10,000-$19,999

☐3 $20,000- $39,999

☐4 $40,000- $59,999

☐5 $60,000-$79,999

☐6 ≥$80,000

8. How would you rate your health overall?

☐1 Very Poor ☐2 Poor ☐3 Average ☐4 Good ☐5 Excellent

9. Do you have any of these conditions/behaviors?

High blood pressure ☐1 yes

Heart disease ☐1 yes

Renal disease ☐1 yes

Obesity ☐1 yes

Asthma ☐1 yes

Alcohol use during pregnancy ☐1 yes

Drug use during pregnancy ☐1 yes

10. What is the due date of this pregnancy? (enter in a form like 03-14-15)__- __- __

11. How many times have you given birth? _____

12. How many deliveries were born at term (at 40 weeks)? _____

13. How many preterm deliveries have you had (20-37 weeks gestation)? _____

14. How many late term births have you had (38-39 weeks gestation)? ____

15. How many cesarean sections (surgery) have you had for delivery? _____

16. What type of prenatal care did you have during this pregnancy?

Centering Pregnancy _____ Standard Clinic care_____

Appendix H

Pregnancy Related Empowerment Scale

Please read each statement and then choose the response that best describes how you feel.
"Health care provider" refers to your midwife, doctor, or other health care provider.

1. I can ask my health care provider about my pregnancy.	Strongly Disagree	Disagree	Agree	Strongly Agree
2. I have enough time with my health care provider to discuss my pregnancy.	Strongly Disagree	Disagree	Agree	Strongly Agree
3. My health care provider listens to me.	Strongly Disagree	Disagree	Agree	Strongly Agree
4. My health care provider respects me.	Strongly Disagree	Disagree	Agree	Strongly Agree
5. I expect my health care provider to respect my decisions about my pregnancy.	Strongly Disagree	Disagree	Agree	Strongly Agree
6. My health care provider respects my decision, even if it is different than her/his recommendation.	Strongly Disagree	Disagree	Agree	Strongly Agree
7. I take responsibility for the decisions I make about my pregnancy like eating healthy food.	Strongly Disagree	Disagree	Agree	Strongly Agree
8. I can tell when I have made a good health choice.	Strongly Disagree	Disagree	Agree	Strongly Agree
9. Since I began prenatal care, I have been making more decisions about my health.	Strongly Disagree	Disagree	Agree	Strongly Agree
10. Women need to share experiences with other women when they are pregnant.	Strongly Disagree	Disagree	Agree	Strongly Agree

Appendix H

Pregnancy Related Empowerment Scale

Please read each statement and then choose the response that best describes how you feel.
"Health care provider" refers to your midwife, doctor, or other health care provider.

11. I share my feelings and experiences with other women.	Strongly Disagree	Disagree	Agree	Strongly Agree
12. I know if I am gaining the right amount of weight during my pregnancy.	Strongly Disagree	Disagree	Agree	Strongly Agree
13. I have a right to ask questions when I don't understand something about my pregnancy.	Strongly Disagree	Disagree	Agree	Strongly Agree
14. I am able to change things in my life that are not healthy for me.	Strongly Disagree	Disagree	Agree	Strongly Agree
15. I am doing what I can to have a healthy baby.	Strongly Disagree	Disagree	Agree	Strongly Agree
16. If something is going wrong in my pregnancy, I know who to talk to.	Strongly Disagree	Disagree	Agree	Strongly Agree
STOP Answer questions below ONLY if you were in a CenteringPregnancy® group				
17. I have enough personal attention from my health care provider in groups to meet my needs.	Strongly Disagree	Disagree	Agree	Strongly Agree
18. Women in the group listen to me.	Strongly Disagree	Disagree	Agree	Strongly Agree
19. Taking my own blood pressure helps me to know if my blood pressure is normal.	Strongly Disagree	Disagree	Agree	Strongly Agree
20. When I weigh myself I know if I am gaining the right amount of weight during my pregnancy.	Strongly Disagree	Disagree	Agree	Strongly Agree
21. Using the self-assessment sheets during group help me to understand my pregnancy.	Strongly Disagree	Disagree	Agree	Strongly Agree

Appendix U: Survey Email

Email Subject Line: Pregnancy Research Survey Reminder

Dear Study Participant,
Thank you for agreeing to volunteer to participate in Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care. As part of the research study we are asking that you complete the follow up Pregnancy Related Empowerment Scale and Quality of Prenatal Care Questionnaire. Please follow the included instructions to complete the survey:

1. Please click on the link provided in this email. The survey will pop up.
   Link Here
2. Please input your last name only into the textbox for name and your birthdate in the next box. This information helps us to link information for participants during the study. It is not included in the study results and only assists the researchers with ensuring that all participants complete all needed surveys.
3. Please complete all questions by clicking on the answer that best represents your answer to each question.
4. Scroll down to see all of the questions that are included in the surveys.
5. Once you are done please click Submit.
6. If you experience any technical difficulty please feel free to contact me directly.

This is the second part of the study you agreed to participate in. This part includes a repeat of one of the initial surveys you took. It includes questions about your empowerment. An example of a question is "I can tell when I have made a good health choice." Additionally, you will be asked to complete a survey that has questions about the quality of your prenatal care. An example of a question is "My prenatal care provider respected me." Remember, that participation will not influence the care you are provided by the UNT Midwives. You can withdraw from the study at any time. Also, remember that as part of the study the research team will call you in the days/weeks following your delivery to collect the date that you gave birth and the baby's birth weight. Congratulations on your upcoming birth and thank you again for your time!

Lisette Allender and Research Team
lallender@patriots.uttyler.edu
817-257-4773

Appendix V: Quality of Prenatal Care Questionnaire

Quality of Prenatal Care Questionnaire (QPCQ)

This questionnaire asks about the prenatal care you received from a physician, midwife, or other health care providers during your pregnancy. You might have seen more than one health care provider for your care but please think of the prenatal care you received **overall** when completing this questionnaire. Please read each statement carefully and indicate how much you agree or disagree with it by circling the appropriate number.

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
1. I had as much time with my prenatal care provider(s) as I needed	1	2	3	4	5
2. My prenatal care provider(s) gave me options for my birth experience	1	2	3	4	5
3. I was given adequate information about prenatal tests and procedures	1	2	3	4	5
4. I was given enough information to meet my needs about breastfeeding	1	2	3	4	5
5. My prenatal care provider(s) respected me	1	2	3	4	5
6. I was always given honest answers to my questions	1	2	3	4	5
7. My prenatal care provider(s) respected my knowledge and experience	1	2	3	4	5
8. My prenatal care provider(s) was rushed	1	2	3	4	5
9. I knew how to get in touch with my prenatal care provider(s)	1	2	3	4	5
10. My prenatal care provider(s) prepared me for my birth experience	1	2	3	4	5
11. Everyone involved in my prenatal care received the important information about me	1	2	3	4	5
12. Someone in my prenatal care provider(s)'s office always returned my calls	1	2	3	4	5
13. My prenatal care provider(s) spent time talking with me about my expectations for labour and delivery	1	2	3	4	5
14. My decisions were respected by my prenatal care provider(s)	1	2	3	4	5

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
15. My prenatal care provider(s) was abrupt with me	1	2	3	4	5
16. I was given enough information about the safety of moderate exercise during pregnancy	1	2	3	4	5
17. I was screened adequately for potential problems with my pregnancy	1	2	3	4	5
18. My prenatal care provider(s) always had time to answer my questions	1	2	3	4	5
19. My prenatal care provider(s) was patient	1	2	3	4	5
20. I received adequate information about my diet during pregnancy	1	2	3	4	5
21. I was supported by my prenatal care provider(s) in doing what I felt was right for me	1	2	3	4	5
22. The results of tests were explained to me in a way I could understand	1	2	3	4	5
23. I was rushed during my prenatal care visits	1	2	3	4	5
24. My prenatal care provider(s) was interested in how my pregnancy was affecting my life	1	2	3	4	5
25. My prenatal care provider(s) supported me	1	2	3	4	5
26. My prenatal care provider(s) paid close attention when I was speaking	1	2	3	4	5
27. I was linked to programs in the community that were helpful to me	1	2	3	4	5
28. My prenatal care provider(s) made me feel like I was wasting their time	1	2	3	4	5
29. My concerns were taken seriously	1	2	3	4	5
30. My prenatal care provider(s) made time for me to talk	1	2	3	4	5

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
31. I received adequate information about alcohol use during pregnancy	1	2	3	4	5
32. My prenatal care provider(s) was available when I had questions or concerns	1	2	3	4	5
33. My prenatal care provider(s) gave straightforward answers to my questions	1	2	3	4	5
34. I was in control of the decisions being made about my prenatal care	1	2	3	4	5
35. I could always reach someone in the office/clinic if I needed something	1	2	3	4	5
36. My prenatal care provider(s) supported my decisions	1	2	3	4	5
37. I was at ease with my prenatal care provider(s)	1	2	3	4	5
38. I could reach my prenatal care provider(s) by phone when necessary	1	2	3	4	5
39. My prenatal care provider(s) gave me enough information to make decisions for myself	1	2	3	4	5
40. I was afraid to ask my prenatal care provider(s) questions	1	2	3	4	5
41. My values and beliefs were respected by my prenatal care provider(s)	1	2	3	4	5
42. I was given adequate information about depression in pregnancy	1	2	3	4	5
43. My prenatal care provider(s) kept my information confidential	1	2	3	4	5
44. My prenatal care provider(s) took time to listen	1	2	3	4	5
45. I fully understood the reasons for blood work and other tests my prenatal care provider(s) ordered for me	1	2	3	4	5
46. My prenatal care provider(s) took time to ask about things that were important to me	1	2	3	4	5

Appendix W: Reminder Email

Dear Participant,

We are emailing to follow up on the research study Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care that you signed up as a participant when visiting the midwives clinic.

You have received an email from us with a link to two surveys we would like you to complete. If you have already completed these, we apologize for the inconvenience as we work to collect all information from participants. If you have not completed the survey please follow the instructions below.

1. Please click on the link provided in this email. The survey will pop up.
Link Here
2. Please input your last name only into the textbox for name and your birthdate in the next box. This information helps us to link information for participants during the study. It is not included in the study results and only assists the researchers with ensuring that all participants complete all needed surveys.
3. Please complete all questions by clicking on the answer that best represents your answer to each question.
4. Scroll down to see all of the questions that are included in the surveys.
5. Once you are done please click Submit.
6. If you experience any technical difficulty please feel free to contact me directly.

You can withdraw from this study at any time. Thank you very much for your time.

Sincerely,

Lisette Allender MSN, RNC-OB
lallender@patriots.uttyler.edu

Appendix X: Telephone Script

Appendix J

Telephone Script – Neonatal Outcome

Hello, I am _____. May I speak with (participant name)?

If they are available continue. If they are not available, do not leave a message we will call back at a later time. Note you were unable to get ahold of them.

I am calling to follow up on the research study Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care that you signed up as a participant when visiting the midwives clinic.

This is the last time you will be contacted for this research study with a short two question survey. You can withdraw from this study at any time. The information you give me will be confidential. If you have any questions about the survey, I will provide you with a telephone number for you to call to get more information.

What date did you give birth to your child? (Be sure to collect month, date, year)

How much did your child weigh at birth? (Participants may provide pounds or ounces, please note which one they say)

Thank you very much for your time. Congratulations on your new addition!

Goodbye.

Voicemail Message Script:

Hi, my name is _____, I part of the research team of the research study Quality of Prenatal Care and Pregnancy Outcomes: Centering Pregnancy Versus Traditional Prenatal Care that you signed up to participate in. I am calling for the final data collection of the two questions related to the birth of your baby. If you could please call me back at 817-257-4773 at your earliest convenience so that we may collect this final piece of information. Thank you for your time. Goodbye.

Appendix Y: Neonatal Outcomes

Appendix L

Neonatal Outcomes

Participant Code #_____

1. What was the **gestation of this pregnancy** at delivery? (weeks/days)_____
2. What was your infant's **birth weight** at delivery? (grams)_____

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Lisette Allender	Lecturer

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	MM/YY	FIELD OF STUDY
University of Texas at Tyler, Tyler, Texas	PhD	05/2017	Nursing
Texas Woman's University, Dallas, Texas	MSN	08/2012	Nursing Education
Texas Christian University, Fort Worth, Texas	BSN	08/2008	Nursing
Tarrant County College, Fort Worth, Texas	ADN	12/2005	Nursing
Texas Christian University, Fort Worth, Texas	BS	05/2002	Psychology, Business minor

A. Personal Statement

The purpose of this quantitative study was to examine the difference between Centering Pregnancy and traditional prenatal care, as provided by a certified nurse midwife on pregnancy related empowerment, neonatal birth weight, and gestational age at delivery. Furthermore, the study seeks to understand what aspects of care (structure or process) of Centering Pregnancy potential influence these same outcomes and should become the focus of future research.

B. Positions and Honors

2012-present Texas Christian University (TCU) - Lecturer
2010-2012 Texas Health Resources Harris Southwest Hospital – Newborn Nursery RN
2009-2010 Medical Clinic of North Texas (MCNT) – Ob/Gyn RN
2009-2006 Texas Health Resources Harris Fort Worth Hospital – L & D RN

Other Experiences and Professional Memberships

2006 – present – AWHONN - Member
2007 – present - Certified Inpatient Obstetric Nurse
2012 – present - Sigma Theta Tau, Beta Alpha Chapter Member
2012 – present – National League of Nursing - Member