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Protocol Title: Effects of Healing Touch on Pain and Anxiety in Women After Cesarean Delivery
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Inova Health System
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ABSTRACT

Title: Effects of Healing Touch on Pain and Anxiety in Women After Cesarean Delivery

Short Title: Healing Touch After Cesarean

Rationale: Pain and anxiety are the most common complications after cesarean birth. Pain and anxiety can impair the mother's ability to optimally care for herself and her newborn. It is important for health care providers to evaluate options post-operatively to maximize symptom management and quality of care for these patients, including the option of complementary therapies such as Healing Touch (HT).

Objectives: Primary outcomes will include the differences between the intervention and control groups' pre-/post-intervention levels of pain (Numeric Rating Scale) and anxiety (Numeric Rating scale). Secondary outcomes include the relationship between HT and demographic information of the subjects. As well, the feasibility of introducing HT as a therapy for postpartum women will be assessed.

Study Type: Randomized Control Trial

Study Design: The total sample size for the proposed study will include 160 participants. The study will include patients' age ≥18 years having a scheduled cesarean delivery at Inova Loudoun Hospital (ILH), Inova Fair Oaks Hospital (IFOH), Inova Alexandria Hospital (IAH), and Inova Fairfax Medical Campus (IFMC) who will be enrolled prior to their scheduled cesarean delivery. Inclusion criteria for the HT group are (1) the ability to ensure informed consent and completion of study assessments; (2) the ability to speak, read, and understand English; (3) scheduled cesarean delivery; (4) ≥18 years of age. Exclusion criteria for the HT group are (1) Non-English speaking due to the fidelity and variability of the research (2) Prisoners, (3) Isolation precautions, (4) active psychosis and impaired cognition, and (5) cesarean delivery who delivers prior to scheduled cesarean date. The study is expected to last about one year from study initiation through analysis.

Study Methodology: One to two weeks prior to a scheduled cesarean delivery, a member of the research team will call and screen women for eligibility on the study. If the woman electronically completes the consent form, they will be enrolled in the study and randomized into either the intervention or control group. Based on their randomization, the study coordinator at each site will schedule either 1) a Healing Touch (HT) practitioner for the intervention group OR 2) a non-HT practitioner who will collect data for the control group, and complete demographic information from the participant's medical chart. For the intervention group, the HT practitioner will verify consent, then ask the woman to complete baseline measurements of pain and anxiety. The practitioner will administer the HT intervention. Levels of pain and anxiety will be reassessed post-intervention. For the control group: a member of the research team, will ask the woman to complete baseline measurements of pain and anxiety. The subject will then be encouraged to have 15 minutes of quiet time, with the lights dimmed. After the 15 minutes of quite time, the team member will again measure the subject's levels of pain and anxiety.

Statistical Methodology: Descriptive and inferential statistical techniques will be used to determine differences between the intervention and control groups.

1. INTRODUCTION

1.1. Specific Aims

The purpose of this clinical research project is to determine the impact of a Healing Touch intervention on pain and anxiety among patients who have undergone scheduled cesarean delivery. Additionally, the project aims to introduce HT to the obstetrical setting and examine its feasibility on an obstetrical unit.

1.2. Hypothesis

Hypothesis: Scheduled cesarean delivery patients receiving a Healing Touch (HT) intervention will report decreased levels of pain and anxiety when compared to a control group.

Study Aims

Aim 1: To test the efficacy of a Healing Touch intervention on pain scores among scheduled cesarean delivery patients.

Hypothesis 1: Scheduled cesarean delivery patients will report lower pain scores after receiving a Healing Touch intervention when compared to a control group.

Aim 2: To test the efficacy of a Healing Touch intervention on anxiety scores among scheduled cesarean delivery patients.

Hypothesis 2: Scheduled cesarean delivery patients will report lower anxiety scores after receiving a Healing touch intervention when compared to a control group.

Aim 3: Explore the feasibility of providing a HT intervention on an obstetrical unit.

This will be assessed and evaluated through the course of the study as to the number of patients that are approached and decide to enroll. The research team will also be monitoring how the HT sessions can best be integrated into the daily care of the study participants.

1.3. Background and Significance

During the past two decades, cesarean delivery rates have increased dramatically worldwide. Currently in the United States, nearly one third of all newborns are born by cesarean.[1] Inova Health System performed over 7 000 cesarean deliveries in 2019 (IAH 1201; IFOH 950; IFMC 4,031; ILH 872). "Women who experience cesarean births are at risk for anesthetic, surgical, and postoperative complications. They have longer hospitalizations and recoveries after childbirth compared with women who experience vaginal births".[2] Pain and anxiety are the most common complications after cesarean delivery. Pain is ranked highest among undesirable clinical outcomes associated with post-operative cesarean deliveries. Conventional methods of managing pain following cesarean delivery include intrathecal morphine and post-operative oral narcotic pain medications. The use of these opioids is accompanied by side effects including nausea, vomiting, pruritus, sedation, dizziness, bladder dysfunction, reduced gastrointestinal motility, and sleep pattern disturbance.[3]

The traditional practice of administering opioids for pain control may impair the women's abilities to remain awake and alert during the critical transition to parenting, to provide effective care for and feeding of their newborns, develop positive maternal-infant bonds, and return to optimal health. Non-pharmacological strategies for the management of postoperative pain and anxiety play an important role in routine clinical practice after cesarean delivery. Effective relief of pain and anxiety can cause comfort, enhanced quality of life, faster return to everyday life, shorter hospital stays and lower hospitalization costs. The importance of alternative pain and anxiety management strategies and decreased opioid administration cannot be overstated for this population.

One such integrative modality, Healing Touch (HT), with a foundation in holistic nursing, is a gentle therapy that uses touch to promote health and well-being by balancing the human energy system.[4] Healing Touch (HT) is a biofield therapy in which practitioners use their hands in a heart-centered and intentional way to provide energetic balance to support physical, emotional, mental and spiritual health. It is safe for all ages and works in harmony with, is complementary to, and may be integrated with standard medical care.[5] Healing Touch is a collection of standardized, noninvasive techniques that clear, energize, and balance the human and

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1 Martin J. A, Hamilton B.E, Osterman M.J.K, Driscoll A.K. (2019)Births: Final data for 2018. National Vital Statistics Reports; vol 68, no 13. Hyattsville, MD: National Center for Health Statistics.

2 Simmoneli, M. C., Doyle, L. T., Columbia, M. A., Wells, P. D., Benson, K. V., and Lee, C. S. (2018) Effects of Connective Tissue Massage on Pain in Primiparous Women After Cesarean Birth. Journal of Obstetric, Gynecologic & Neonatal Nursing 47(5) ,591-601

3 Benyamin R, Trescot AM, Datta S, et al. Opioid complications and side effects. Pain Physician. 2008;11(2 Suppl):S105–S120.

4 Anderson, J.G., Anselme, L.C. Hart. L.K. (2017). Foundations and practice of Healing Touch. Healing Beyond Borders. Lakewood.CO.

5 "Healing Beyond Borders." https://www.healingbeyondborders.org/. Accessed 28 Nov. 2020.

environmental energy fields. Given the lack of harm associated with biofield therapies and the potential benefit to reduce pain and anxiety, it appears Healing Touch is an intervention worthy of exploration.

Studies have been conducted to measure the effects of Healing Touch on both acute and chronic pain. In a small study of chronic and severe pain resulting from spinal cord injury, participants who received the Healing Touch intervention reported decreased pain compared to those who received progressive muscle relaxation.[6] There are no contraindications for using energy work to relieve pain and it can be valuable in supplementing traditional approaches or when other approaches are not successful.[7] Studies on biofield therapies have been conducted in patients experiencing acute pain and have shown that these therapies can effectively reduce pain.[8]

Studies specifically focused on cesarean delivery pain using Reiki, another biofield energy therapy, have reported promising results. Midilli and Gunduzoglu (2016) conducted a single blinded, randomized, and double-controlled study to determine the effects of Reiki on pain and vital signs when applied to the incision area of the body after cesarean delivery.[9] The Reiki group was observed to use fewer analgesics throughout the study and to need them after a longer time than the control groups. They concluded that after Reiki was applied for 15 minutes to the incision area after a cesarean delivery, less pain was felt and the need for analgesics was less that in the control group, but Reiki had no effect on vital signs. Another randomized-controlled clinical trial investigated the effect of Reiki on pain, anxiety, and hemodynamic metrics post cesarean delivery patients.[10] The trial indicated Reiki reduced pain intensity, the value of anxiety, and breathing rate, as well as analgesic requirements post-cesarean delivery ; however, it did not affect pulse rate, and blood pressure.

Clinical effectiveness of many complementary and alternative medicine interventions has been successful in pain reduction for post-cesarean patients. Despite a growing body of research about Healing Touch as an effective intervention for postsurgical and cancer pain management, there is a paucity of literature on Healing Touch use with women during pregnancy, labor, or in the postpartum period. Since there are no adverse effects reported with the use of Healing Touch and it is a patient-centered, non- pharmacologic approach to pain management, it would seem a prudent and innovative intervention to reduce pain and anxiety. The holistic nursing concept of Healing Touch returns the nurse to the essence of nursing. Incorporating Healing Touch into nursing practice nurtures the idea of holistic nursing care and adds depth, spiritually, and individualized approach to healing. Encouraging a healing and nurturing environment for mom will enhance her ability to best care for herself and her newborn.

Inova is uniquely situated to explore holistic modalities such as Healing Touch because it builds on a culture of human caring that was developed and supported by generous philanthropic community support[11] and a grant from the Health Resources and Services Administration.[12] The philosophy of Nursing Care at Inova is predicated on Jean Watson's Human Caring theory[13] and has evolved from 2008 to the

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6 Wardell, D.W. & Weymouth, K. (2004). Review of studies of Healing Touch. Journal of Nursing Scholarship, 36(2), 147-154.

7 Wardell, D. Rintala, D. Tan, G., & Duan, Z. (2006). Pilot study of Healing Touch and progressive relaxation for chronic neuropathic pain in persons with spinal cord injury. Journal or Holistic Nursing, 24(4), 231-240.

8 Jain, S., Hammerschlag, R., Mills, P., Cohen, L., Krieger, R., Vieten, C., & Lutgendorf, S. (2015). Clinical Studies of Biofield Therapies: Summary, Methodological Challenges, and Recommendations. Global advances in health and medicine, 4(Suppl), 58–66. https://doi.org/10.7453/gahmj.2015.034.suppl

9 Midilli, T., Gunduzoglu, N. (2016). Effects of Reiki on Pain and Vital Signs When Applied to the Incision Area of the Body After Cesarean Section Surgery. Holistic Nursing Practice, 30(6), 368-378.

10 Midilli, T., Eser, I. (2015). Effects on Reiki on Post-Cesarean Delivery Pain, Anxiety, and Hemodynamic Parameters: A Randomized, Controlled Clinical Trial. Pain Management Nursing, 16(3), 388-399.

11 Swengros, D., Herbst, A. M., Friesen, M. A., Mangione, L., & Anderson, J. G. (2014). Promoting caring-healing relationships: bringing healing touch to the bedside in a multihospital health system. Holistic nursing practice, 28(6), 370–375.

12 Drenkard KN. (2008) Integrating human caring science into a professional nursing practice model. Critical Care Nursing Clinics of North America . 2008;20(4): 403-414. Centers of Disease Control and Prevention Births – National Center for Health Statistics. Method of Delivery https://www.cdc.gov/nchs/fastats/delivery.htm

13 Watson J. (1979) Nursing: The Philosophy and Science of Caring. Boulder, CO: University Press of Colorado and Watson J. (2005) Caring Science as Sacred Science. Philadelphia, PA: FADavis Company.

present nursing leadership which place a high value on holistic and person center care that is congruent with the Inova mission and values and strategic plan. The emphasis on holistic care has been supported by a Holistic Council which includes over 100 members from across the Inova Health Care System. The Chief Nurse Executive appointed two co- chairs: a doctoral prepared nurse and clinical bedside nurse. Inova nurses and researchers have conducted 5 studies on healing touch to date with positive outcomes for patients[14] [15] and for nurses.[16] [17] There are 538 nurses at Inova who have received Healing Touch training. In summary, Inova is able to support a Healing Touch study given the culture, support by leadership and the availability of nurses trained in Healing Touch. This research will build on previous HT studies conducted at Inova to assist the research team in understanding the impact of HT on patient-centered and patient-reported outcomes. This is the first study with HT being conducted on post-cesarean patients.

1.4. Preliminary Studies

This research will build on previous HT studies conducted at Inova to assist the research team in understanding the impact of HT on patient-centered and patient-reported outcomes (Anderson et al., 2015; Davis et al 2020). This is the first study with HT being conducted on post-cesarean patients.

Anderson JG, Suchicital, L., Lang,M., Kukic,A., Mangione,L., Swengros,D., Fabian, J & Friesen, M.A. (2015). The effects of Healing Touch on pain, nausea and anxiety following bariatric surgery: a pilot study. Explore. 11(3), 208-216.

Davis, T. M., Friesen, M. A., Lindgren, V., Golino, A., Jackson, R., Mangione, L., Swengros, D., & Anderson, J. G. (2020). The Effect of Healing Touch on Critical Care Patients' Vital Signs: A Pilot Study. Holistic nursing practice, 34(4), 244–251.

14 Anderson JG, Suchicital, L., Lang,M., Kukic,A., Mangione,L., Swengros,D., Fabian, J & Friesen, M.A. (2015). The effects of Healing Touch on pain, nausea and anxiety following bariatric surgery: a pilot study. Explore. 11(3), 208-216.

15 Davis, T. M., Friesen, M. A., Lindgren, V., Golino, A., Jackson, R., Mangione, L., Swengros, D., & Anderson, J. G. (2020). The Effect of Healing Touch on Critical Care Patients' Vital Signs: A Pilot Study. Holistic nursing practice, 34(4), 244–251.

16 Anderson JG, Friesen, M.A., Fabian,J., Swengros, D.,Herbst, A.& Mangione, L., (2016) Examination of the perceptions of registered nurses regarding the use of Healing Touch in the acute care setting. Journal of Holistic Nursing. 34(2), 167-176.

17 Anderson, J., Friesen, M., Fabian, J., Swengros, D., Herbst, A., Mangione, L. (2017). Examination of the Use of Healing Touch by Registered Nurses in the Acute Care Setting, Journal of Holistic Nursing, 35(1), 97-107.

2. STUDY DESIGN AND SUBJECT SELECTION

2.1. Study Type

Experimental: Randomized Control Trial

2.2. Setting/Location

The intervention will take place during the postpartum stay. Participants in the HT intervention groups and control groups will be recruited from:
Inova Loudoun Hospital (ILH),
Inova Alexandria Hospital (IAH),
Inova Fair Oaks Hospital (IFOH),
Inova Fairfax Medical Campus (IFMC).

2.3. Duration of Study

The study intervention lasts approximately 15 minutes. Women will participate in the study during their postpartum stay after cesarean section, which may last between two and six days. They will receive one intervention or control session during their stay.

2.4. Number of Subjects

The total number of subjects expected to participate will be 160. Sample size estimates require a sample of 128 women, but to obtain an adequate sample size there will be an oversampling of up to 160 subjects, 40 at each study site.

2.5. Study Population

2.5.1.Gender of Subjects

Female

2.5.2.Age of Subjects

Study participants will be 18 years of age or older. The typical age range of persons undergoing cesarean delivery is 18 to 45 years of age.

2.5.3.Racial and Ethnic Origin

Within the limitations imposed by the population of the study sites, persons of diverse racial/ethnic backgrounds will be recruited equitably. The study limitations exclude women who are not English speaking. This is because of the limited number of Healing Touch practitioners available who speak a language other than English. Speaking with subjects is an integral part of the Healing Touch therapy session. The effectiveness of Healing Touch when there is a language difference between the subject and the practitioner has not been evaluated. Therefore for the fidelity of the study intervention only English speaking subjects will be recruited at this time. However, the study will equitably recruit English speaking subjects, which will allow for ethic and racial diversity within the eligible group of potential study subjects.

2.5.4.Vulnerable Populations

The women will be recruited for the study while they are pregnant, and are therefore a vulnerable population. However, the study intervention takes place after delivery, when they are no longer considered a vulnerable group. The women randomized into the intervention group will have recently undergone surgery, and may have received narcotic medications for pain control during and after surgery. To account for this vulnerable state, the research team will be consenting subjects for the study prior to surgery. Because the study sample criteria excludes women under the age of 18 years, there will be no children included in this study.

2.6. Recruitment

Obstetrical offices will distribute a Healing Touch informational brochure to their scheduled cesarean patients. Study personnel will look at the schedule for the operating room at their facility. Patients with a scheduled cesarean delivery at ILH, IAH, IFOH, IFMC will be introduced to and informed of the study by a member of the study team via a phone call or email 1-2 weeks prior to their cesarean date (Appendix H). The email includes an overview of the study with a link for the electronic consent form (Appendix I). Questions

may be submitted via email or direct phone call to the principal investigator. Participants who complete the electronic consent form have the potential to be enrolled in the study and randomized into either the intervention or control group. The email containing the link for study consent will also include contact information for the study PI. Therefore, if at any time prior to cesarean delivery the woman changes her mind about her consent she can contact the study team to redact her consent. If a participant does not complete the HIPPA authorization form or the consent form prior to their scheduled c-section date, a copy of the consent form will be offered to them when they sign in for their surgery by a research team member. If they are still interested in participating in the study, they can sign the hard copy of the consent or HIPAA then.

2.7. Inclusion Criteria

(1) the ability to ensure informed consent and completion of study assessments
(2) the ability to speak, read, and understand English
(3) scheduled cesarean delivery
(4) ≥18 years of age

2.8. Exclusion Criteria

(1) Non-English speaking due to the fidelity and variability of the research
(2) Prisoners
(3) Isolation precautions
(4) active psychosis and impaired cognition
(5) cesarean delivery who delivers prior to scheduled cesarean date

3. STUDY METHODS AND PROCEDURES

3.1. Study Treatment/Intervention

If the woman completes the consent form, they will be enrolled in the study and randomized into either the intervention or control group. When they are admitted to the postpartum unit after cesarean delivery, based on their randomization, the study coordinator at each site will schedule either 1) a Healing Touch (HT) practitioner for the intervention group OR 2) a non-HT practitioner who will collect data for the control group. The HT practitioners for this study will be registered nurses or HT practitioners who work in the Inova Health System and have received the minimum of Foundations of Healing Touch training. All study personnel entering patient care areas will abide by universal precautions, plus masks and face shields as required by the hospital system for infection control. For the intervention group, the HT practitioner will verify consent. Then they will ask the woman to complete baseline measurements of pain and anxiety. The practitioner will then administer the HT intervention consisting of a full body, pain management technique focusing on the surgical site, and wound sealing. HT techniques (Field Repatterning, Pain Syphon, Beak Fingers Lasering,) are techniques specific to management of pain and clearing of the energy field that have been used frequently by the nurses in their delivery of patient care. The HT intervention to be used in the proposed study has been developed by co-investigator, Diane Swengros, Certified Healing Touch Practitioner and Instructor, to focus on the symptom management needs of the study participants (post-cesarean delivery) and should take no more than 15 minutes to complete. Levels of pain and anxiety will be reassessed post-intervention. Nurses providing the HT intervention will document the session and other outcomes as described below. There is a risk that the patient will not receive Healing Touch if: there is not a HT provider available or the patient is discharged prior to availability of the HT provider.

Privacy will be maintained during the consenting process by calling potential study subjects on their personal phone number. During consent, the script will prompt the study personnel getting consent to ask if this is a good / safe time to speak. If not, the study personnel will call at a better time for the potential study subject. During the intervention (or control activity), the study personnel will first confirm that the study subject provided consent, and will confirm consent. They will be prompted to provide privacy for the woman when needed or requested by the study subject before the intervention begins. The intervention study personnel will confirm that they can place a "do not disturb" sign on the door of the study subject before they begin the study intervention, because the sign may indicate that the subject is receiving the intervention and may be a privacy concern for the subject. The study

personnel will also confirm that any family members or visitors at the bedside should stay or leave during the intervention, to maintain subject privacy.

3.2. Control Group

This study has a control group. For the control group: a member of the research team, who may or not be a HT practitioner, will verify consent. Then they will ask the woman to complete baseline measurements of pain and anxiety. The subject will then be encouraged to have a quiet time session equivalent to the length of a Healing Touch session, with the lights dimmed. After the quite time, the team member will again measure the subject's levels of pain and anxiety.

3.3. Randomization

Randomization will be done through using a computerized randomization through the use of the following website: https://www.random.org/coins/ For Heads=intervention, For Tails=control.

3.4. Endpoints/Outcomes Measurements

3.4.1.Primary outcomes.

Primary outcomes will include the differences between the intervention and control groups' pre-/post-intervention levels of pain (Numeric Rating Scale) and anxiety (Numeric Rating scale) (Appendix K).

Theoretical Concept and Measurement	# Items	Score Range	Reliability
Demographics			
As delineated in Data Retrieval Form	12	--	--
Pain (Primary outcome)			
Visual Analog Scale: Measures pain intensity. Higher scores indicate higher levels of pain	1	0-10	* r =0.96 literate patients r= illiterate
Anxiety (Primary outcome)			
Hospital Anxiety Scale: Measures intensity of anxiety. Higher scores indicate higher levels of anxiety	16	0-14	Cronbach's alpha 0.73**
Healing Touch			

* (Hawker, Mian, Kendzerska, & French, (2011). * Ferraz., Quaresma, Aquino, Atra, Tugwell, P., & Goldsmith,1990).

**Al Aseri, Suriya, Hassan, Hasan, Sheikh, Al Tamimi, Alshathri M, Khalid N. (2015).

3.4.2.Secondary outcomes

Secondary outcomes include the relationship between HT and demographic information of the subjects. As well, the feasibility of introducing HT as a therapy for postpartum women will be assessed.

3.5. Consent/Assent

All participants in the HT intervention group and control group will provide informed consent. Acquiring consent is a twostep process: (1) Participant returning and electronic consent via the survey platform, and then (2) the site PI/SUB-I has a conversation with the participant over the phone or face to face to review the consent. Once screened for eligibility, a member of the research team may call the potential participant using the consent phone call script (Appendix H). Whether over the phone or face to face, the study personnel will describe the study, answer any questions they may have, and if the participant is interested, email them an electronic consent form and the HIPPA authorization form if they haven't already received one. Both of these forms will be managed through an electronic platform, and securely load into the platform to be accessed by

the PI and study personnel. Participants who complete the electronic consent form will be included in the study, and randomized into either the intervention or control group. Informed consent will be confirmed again with the women prior to starting the study intervention or control session, since they may have changed their mind after delivery. One copy of the consent and HIPAA forms will be given to the participant (via email or face to face), and one will be kept in the research file for the participant, as well as being scanned into the electronic medical record.

3.6. Monitoring Subjects and Criteria for Withdrawal of Subjects from the Study.

Study participants may voluntarily withdraw from the study at any time. During the Healing Touch Therapy, the intervention would stop and a subject would be withdrawn if: The woman or her family at the bedside requested the intervention stopped, the woman reported an increase in pain and needs assistance, the woman had a self-identified change in clinical status and requested medical assistance, the woman needs to stop the session to care for the baby or get out of bed / leave the room for some reason.

4. STATISTICAL CONSIDERATIONS/DATA ANALYSIS

4.1. Sample Size

Power analysis for an independent sample t-test was conducted in G-POWER to determine a sufficient sample size using an alpha of 0.05, a power of 0.80, a medium effect size (d = 0.5), and two tails. There will be an equal allocation of participants into each group. Based on the aforementioned assumptions, the desired sample size is 128 (64 in each group). The team will over sample in order to meet sufficient sample size. Planned recruitment will = 160 women (40 per study site).

4.2. Method of Data Analysis

Exploratory and descriptive analysis will be completed for all study variables. Variables will be examined for normality and examined with means and standard deviations or medians and interquartile ranges accordingly. Statistical analyses will be conducted using a data management and analysis platform. Summary descriptive statistics will be analyzed for the main outcome variables. To examine the research question, an independent sample t-test will be conducted to assess if differences exist on pain and anxiety by Intervention or Control Group. An independent samples t-test is the appropriate statistical test when the purpose of research is to assess if differences exist on a continuous (interval/ratio) dependent variable by a dichotomous (2 groups) independent variable. The assumptions of normality and homogeneity of variance will be assessed. Normality assumes that the scores are normally distributed (bell-shaped) and will be assessed using the one-sample Shapiro-Wilk test (Razali & Wah, 2011). Homogeneity of variance assumes that both groups have equal variances and will be assessed using Levene's test for equality of variances (Levene, 1960). If the Levene's test for equal variance indicates that equal variances cannot be assumed ($p < .05$), a Welch's t-test will be used instead of the Student's t-test, which is more reliable when the two samples have unequal variances (Ruxton, 2006). The t-test will be two-tailed with the probability of rejecting the null hypothesis when it is true set at $p < 0.05$. This ensures a 95% certainty that the differences did not occur by chance.

4.3. Data Storage

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 HIPAA. Privacy and confidentiality of all enrolled participants will be maintained through the use of a password protected data management spreadsheet. The spreadsheet will only be accessed on Inova computers, which are also password protected, by members of the study team who have undergone human subjects training. The spreadsheet will list all potential study subjects, including their name, medical record number and phone number, identified from the pre-surgical lists for the scheduled cesarean deliveries at each hospital site. Once a potential study subject has been screened over the phone for study eligibility and enrolled, they will receive a de-identified study “ID” which will consists of numbers and letters. The key linking the study ID to a patient’s personal information will be maintained separately from collected data. Hard copies of the data collection forms will be kept in a locked metal storage file cabinet in the office of the Primary Investigator.

4.3.1.Data Management

Enrollment in the study consists of the following: A participant has signed and returned a consent form and HIPAA form in the electronic platform, AND a PI/SUB-I has confirmed consent via phone call or face to face conversation, AND the PI/SUB-I has signed the consent, AND the PI/SUB-I has screened the participant for continued eligibility AND assigned them to a study intervention. Women who complete a consent form but no other steps in the enrollment process will be reported on the spreadsheet as "healing touch provider not available", "inclusion criteria not met", "delivered before scheduled date".

Some participants may complete the consent process but cannot be scheduled for either Healing Touch or Quiet time due to availability of Healing Touch Providers. These participants will remain on the spreadsheet to maintain tracking of eligible participants, but will noted as "Healing Touch provider not available".

The study Sub-Investigators at each site will follow the same procedure. Once a potential study subject has been enrolled in the study they will receive a coded study "ID" which will consists of numbers and letters. Any data collected during the study will be coded with this study ID. After being randomized into the intervention group or control group, and based on their scheduled delivery date, the study site coordinator will schedule the subject for either a session with a Healing Touch practitioner, or a session of quiet time (the control) with a member of the study team. The Demographic Form (Appendix D) and Data Collection Form (Appendix K) will be labeled with the patient identification sticker. This is to ensure that study personnel can use the sticker to accurately identify study subjects. After the data is collected from the session, the form will be put into a sealed envelope and given directly to the study site coordinator. The site coordinator will enter the data from the subject into the spreadsheet with the coded ID. This coded data will be shared securely with the study Primary Investigator, who will synthesize the data from the various study sites.

4.3.2. Records Retention

Data will be stored securely for three years after the close of the study.

5. HUMAN SUBJECTS PROTECTION (RISKS, BENEFITS, AND ALTERNATIVES)

5.1. Risks

There are no potential risks that are more than minimal. Previous studies have shown that HT is safe and does not convey any physical or psychological risk to patients who participate in Healing Touch therapy.

5.2. Benefits

There are no direct benefits to the participant except for participating in a healing touch therapy session

5.3. Alternatives

The alternative is not to participate in the research.

5.4. Confidentiality

The study Sub-Investigators at each site will follow the same procedure. Once a potential study subject has been screened over the phone for study eligibility and enrolled, they will receive a coded study "ID" which will consists of numbers and letters. Any data collected during the study will be coded with this study ID.

After being randomized into the intervention group or control group, and based on their scheduled delivery date, the study site coordinator will schedule the subject for either a session with a Healing Touch practitioner, or a session of quiet time (the control) with either a member of the study team. The Demographic Form (Appendix D) and Data Collection Form (Appendix K) will be labeled with the patient identification sticker. This is to ensure that study personnel can use the sticker to accurately identify study subjects. After the data is collected from the session, the form will be put into a sealed envelope and given directly to the study site coordinator. The

site coordinator will enter the data from the subject into the spreadsheet with coded data. This coded data will be shared securely with the study Primary Investigator, who will synthesize the data from the various study sites.

6. SUBJECT COMPENSATION

6.1. Costs
There are no costs to participants.

6.2. Payment
There will be no payment for participation.

7. ADVERSE EVENT REPORTING
Safety monitoring will be conducted by the study PI, who will review the data collected from each study subject. The PI will also review any notes taken during the intervention and monitor for safety events. Weekly meetings of the study sub-investigators and PI will occur to review any issues that arise during intervention and data collection.

Any protocol deviations will be immediately reported to the IRB.

8. FUNDING
This study is funded through an Inova Health System Seed Grant.

9. CONFLICTS OF INTEREST
One study member, Dr. Mary Ann Friesen, is on the research council for the Healing Beyond Borders International Association. She receives no compensation for this role, and the Healing Beyond Borders Association is not affiliated in any way with this research study.

10. FACILITIES AND EQUIPMENT
All four hospital facilities have the same resources and equipment available to the study team. All study personnel have access to password protected computers in the facilities. Across the four facilities the postpartum rooms are all private, and allow for consistency of the intervention.

11. OUTSIDE CONSULTANTS/COLLABORATORS
None

12. CONTRACTURAL AGREEMENTS
None

13. REFERENCES
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