INSTITUTIONAL REVIEW BOARD at
KETTERING
HEALTH NETWORK

RESEARCH PROTOCOL

TO: Kettering Health Network Institutional Review Board

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STUDY TITLE: The Effect of Video Education on Skin-to-Skin at the Time of Delivery

VERSION # 1

Study Summary

The main purpose of this study is to determine the effect of prenatal video education on pregnant women's intention to practice and actual practice of skin to skin contact (SSC) after birth.

Purpose

This study hypothesizes that education in video format will increase patients knowledge about skin to skin in a way that will make them consider participating in skin to skin immediately after birth. Therefore our end point for this study is intention to participate in SCC measured by a single questionnaire item "Do you plan on participating in skin to skin (or kangaroo care) immediately after birth?" Our secondary end-point will measure whether or not the patient was able to participate in skin to skin within five minutes of delivery.

Background and Significance

Despite strong support of breastfeeding by organizations such as the American Academy of Pediatrics, the American Congress of Obstetricians and Gynecologists, and the American Academy of Family Physicians, the rate of breastfeeding initiation at the time of delivery and continuation at 6 months postpartum is below the Center of Disease Prevention's Healthy People 2010 goals (1). UNICEF and the World Health Organization (WHO) have estimated that if all babies were breastfed for a minimum of the first six months of their lives, the rate of morbidity and malnutrition would significantly decrease all over the world (2). The benefits of breastfeeding are numerous for both mothers and infants, with infants obtaining optimal nutrition and passive immunity, and mothers obtaining a more rapid return of postpartum uterine tone, postpartum weight loss, delay of ovulation, and decreased risk of breast, ovarian, and endometrial cancers (3). As a result of this information, in 1991 WHO and UNICEF launched the Baby-Friendly Hospital Initiative (BFHI) to encourage proper infant feeding practices starting at birth. It is based on ten steps, which the hospital must meet and maintain to obtain certification. In support of Step Four of the BFHI to "help mothers initiate breastfeeding within one hour of birth," the skin-to-skin variation of Kangaroo Mother Care was initiated (4).

Kangaroo position, or skin to skin contact (SSC) on a mother's chest, provides thermoregulation, physiological stability, appropriate stimulation, and encourages bonding and breastfeeding (5). In fact, early SSC was significantly associated with type of feeding at discharge through 3 months postpartum (6). Regrettably, according to the American Academy of Pediatrics, some obstacles to SSC and breastfeeding include insufficient prenatal education, disruptive obstetrical practices, and a lack of family and societal support (7). Delivery room and postpartum hospital routines may also significantly disrupt early maternal-infant interactions (8). These barriers to breastfeeding and SSC are more prevalent amongst vulnerable groups, which includes low income, low educational level, and black populations. While effective initiatives such as BFHI are present in hospital settings, guidelines for primary care based interventions originating in a clinician's office currently do not exist (3). Through encouraging education regarding SSC in a before the time of delivery, patients can actively participate in SSC during delivery and advocate for early SSC (9).

Education can easily influence behavior habits and does not need to require special difficulties on behalf of providers (9). In fact, educational programs have the single greatest effect of any single intervention on both initiation and short term duration for breastfeeding (3). Women who attended breastfeeding classes with lactation consultants - with or without video supplementation - had significantly increased breastfeeding at six months when compared to controls (1). Currently, common office practices include provision of written materials and discharge packets. Neither practice has been shown to be effective in increasing rates of breastfeeding. On the contrary, discharge packets have been shown to reduce the rates of breastfeeding (3). Ideally, breastfeeding education would use both individual or group sessions where both benefits of breastfeeding and SSC would be discussed (10). However, in a busy clinic setting filled with a vulnerable patient population, having the ability to get to extra educational classes is not always an option.

Regardless of amount of prenatal education provided, Southview Medical Center will study participating patients at the time of admission for delivery who watch an 8 minutes 52 second patient education DVD titled “Jumping into Kangaroo Care” by the Ohio Department of Health. Of importance, studies so far have shown no clear pattern for the outcome of breastfeeding in respect to intervention timing (7). In an analysis regarding video modeling, patients who viewed videotapes regarding treatment options had a greater understanding of the risks and benefits of those choices and were more apt to be active participants in decision making (11). Audio-visual material can also be entertaining and can be used by those who have limited literacy. Moreover, the information provided to patients on video has the advantage of being repeatable and consistent, which would allow us to provide the same information to all of our patients (12). By educating our patients in a video format at the beginning of their delivery admission, patients will have time to formulate questions and opinions to help them engage in an active dialogue with the staff that will be preforming the delivery. The goal of educating mothers is not only to increase their knowledge and skills but also to influence their attitudes (13). By providing a video which models SSC to all non-emergent anticipated vaginal deliveries upon admission to the hospital, our hope is to encourage patients to actively participate in SSC at the time of delivery and become their own advocates.

The main purpose of this study is to determine the effect of prenatal video education on pregnant women’s intention to practice SSC after birth. This study is critical for our hospital as quality measures for Southview Medical Center for quarter one of 2017 showed that we have only been 50% successful at initiating skin to skin in vaginal deliveries after 37 weeks gestation with a 5 minute APGAR of 7. Our goal as a hospital per BFHI is 82%. Our hypothesis is that 30% or more women who did not plan to use SCC would indicate their intention to use SSC post-intervention as compared to those who did not receive the intervention.

Human Subject Population

Method of Subject Identification

Patients will be recruited and consented to participate in the study at the time of admission to Labor and Delivery by a resident. In order to be asked to participate in the study, patients need to be admitted with anticipation of a normal spontaneous vaginal delivery within one

week at the time of admission, greater than 37 weeks gestational age, and over the age of 18.

Use of PHI for Prescreening/ Recruitment (Activities Preparatory to Research)

☒ Check if existing records (e.g. medical records, patient logs) will be queried or reviewed to identify or prescreen potential participants **and no** HIPAA waiver will be requested. By checking, investigator attests to the following:

- PHI will be collected or obtained (reviewed) only for recruitment/ prescreening purposes. PHI collected will be stored confidentially and will be destroyed per KHN standards as soon as no longer necessary for the research.
- The requested use or disclosure under this section is **solely** to review patient information / PHI as necessary for purposes preparatory to research (e.g. to identify or prescreen potential participants for recruiting purposes).
- The PHI will not be removed from KHN in the course of the review.
- The PHI for which use or access is requested is necessary for the research.

Recruitment / prescreening activities will be stopped by specify date.

PHI from ☒ ≥ 50 ☐ < 50 patients will be accessed for prescreening / recruitment activities. If PHI from < 50 patients will be accessed, specify who will track HIPAA disclosures.

Method of Recruitment

Patients will be recruited and consented to participate in the study at the time of admission to Labor and Delivery a resident.

Data / Tissue Sources or Repositories

Epic records will be accessed to obtain information pertinent to the study

Subject Payments

N/A

Gender of Subjects Females Only

Number of Subjects

Up to 240 subjects may participate at KHN.

Age Range of Participants

Over the age of 18

Inclusion/Exclusion Criteria

Inclusion Criteria

- Pregnant women at Southview Medical Center
- Over the age of 18

- Anticipating a vaginal delivery within one week of admission to labor and delivery
- English speaking
- Greater than 37 weeks gestation

Exclusion Criteria

- Not female
- Not pregnant
- Less than 37 weeks gestation
- A scheduled cesarean section
- Unstable medical status
- Expecting an unstable baby requiring medical resuscitation
- Under the age of 18
- Non-English speaking requiring translation services

Vulnerable Subjects

Pregnant women may be considered vulnerable subjects. Teach back method during the consent process will be used to ensure understanding regarding participation. This study poses no medical risks to pregnant women, fetuses, or neonates. Any pregnant woman appearing to be in a cognitive or emotional state that would prevent informed consent would be excluded.

Research Design and Methods

If participating in the study in the experimental group the patient would watch the video prior to delivery.

A sample size of 240 (120+120) will participate in this randomized control trial. Alternate patients will be randomized at the time of admission into no video (Group A) and video groups (Group B). 120 patients will be in Group A. 120 patients will be in Group B.

Randomization will occur in the order that they get enrolled into the study. If an eligible patient wishes to participate in the study, the resident obtaining consent will consult the list of patients to determine if that particular patient will be in Group A or Group B. The first patient enrolled would be in Group A and asked a pre-survey regarding:

- their intention to practice skin to skin at the time of delivery
- if they participated in skin to skin in a previous pregnancy
- if they had any formal education about skin to skin
- if they did have formal education was it either
    - a.) Provided at a prenatal appointment,
    - b.) A formal class led by either a nurse or a lactation consultant.

The second patient enrolled would be in Group B and take the same pre-survey, immediately watch “Jumping into Kangaroo Care”, and then immediately take the post survey which would ask if they intended to practice skin to skin at the time of delivery. The third patient enrolled would take only the pre-survey and be in Group A, etc.

The video the patients will watch is titled “Jumping into Kangaroo Care” by the Ohio Department of Health. The video is 8 minutes and 52 seconds in length. The video discusses the benefits and logistics of Kangaroo Care from professional’s perspectives and from new mother’s perspectives. By having patients watch this video before the time of delivery, we can see if patients intend to participate in skin to skin, regardless of their previous education.

In this study, we will examine patient’s medical record number, age, gestational age, any pregnancy complications, race, type of insurance, and the number of times the patient has been pregnant. We will also examine data that is already collected by this hospital after delivery regarding skin to skin. This includes gestational age in weeks at the time of delivery, 5 minute APGAR, delivery date/time, skin to skin initiation time, skin to skin end time, delivery to skin to skin duration (minutes), and skin to skin duration (minutes). We will also examine if skin to skin is not initated for patient acuity, maternal acuity, or if the patient refused.

If a patient has a baby with a 5 minute APGAR less than 7 at the time of delivery or needs to proceed to the operating room for cesarean delivery, the patient would not be included in data collection regarding skin to skin at the time of delivery. For this group, only intention would be measured

Surveys / Interviews / Questionnaires

Ob/gyn residents at Southview Medical Center will ask the survey questions. The survey will be asked in the patient’s labor room at the hospital once they are admitted. The survey will be administered one-on-one. A copy of the survey has been attached. They will then watch “Jumping into Kangaroo Care” by the Ohio Department of Health if they are in the experimental group. Copyright has been attached.

Risks / Discomforts

Physical risks or discomforts

No known risks

Psychological risks or discomforts

No known risks

Social risks or harms

Breach of confidentiality

Economic risks

No known risks

Legal risks

No known risks

Procedures to Minimize Risks (describe for each risk listed above)

- Breaches of confidentiality: see *Data Storage and Confidentiality* section

Specify who will evaluate adverse events / serious adverse events (AEs / SAEs) to identify and report unanticipated problems: Catherine Caponero, DO

Diagnostic/treatment (non-research) procedures to be used for the study

N/A

Benefits

Potential benefits to participants

Participants may benefit by learning the benefits of skin to skin care after delivery.

Potential benefits to others / contributions to knowledge

Others can benefit by learning if video education video education can positively contribute to patients intent and compliance with skin to skin at the time of delivery

Data Analysis

Preliminary data on both primiparous and multiparous women from our records indicate that compliance with skin-to-skin is about 50%. We hypothesize that a 30% improvement in intention along with compliance with SCC is attainable with video education. We also have the ability to recruit 120 eligible women per group (240 in total) into the study. Using z test for two proportions, 90% power with alpha of 0.05, two-tailed, we will need about 53 patients per arm (106 in total) based on assumption that 50% of no formal education group and 80% of video education group would indicate their intention to participate, and hopefully participate in SCC post intervention.

We will employ interim analysis, based on potentially recruiting 240 patients, and adopt “two looks”; one at the time when 120 (60 per group) women would be recruited and the other when 240 (120 per group) women would be recruited. We will use cut-off points of z=3.5 for first look and z=2.0 for second look, as suggested by O’Brien-Fleming (1979), as decision rules to stop or continue data collection. If calculated z statistics is greater than 3.5 during first interim analysis, we will stop data collection. If calculated z-statistics is less than 3.5, we will continue data collection and reject the null during final analysis only when calculated z-statistics is greater than 2.0.

Assuming 50% and 80% intention levels (30% difference in proportion) during first interim analysis, 50% interim sample size (120 patients) would result in absolute z- statistics of 4.89 to stop data collection.

If data collection continues due to proportion difference less than 30%, sample size of 240 during final analysis would produce absolute z-statistics of 2.20 to reject the null hypothesis based on assumption of 10% difference in end-point.

Mean (Standard deviation) and sample size (percentage) will be used to summarize normally distributed continuous data and categorical data respectively. Either t-test of independence or Chi-square test of independence will be used to test if significant differences exist between two groups on quantitative data or on categorical data respectively, at alpha of 0.05, two tailed. Z-test of two proportions would be used to test if significant differences exist between two groups.

Logistic regression would be used in order to account for other variables if necessary. SPSS version 22 will be used to analyze data. Dr. Heh, associated with Ohio University, will act as our statistician and help us to analyze our data.

Data Monitoring to Ensure Safety of Subjects

☒ Check if this study involves treatment or intervention and provide narrative of plan to monitor data to ensure safety of subjects below:

The video intervention involves minimal risk.

Privacy Protections

We will collect coded data to ensure patient's privacy. We will also recruit and consent in patient's private rooms on labor and delivery.

Data Storage and Confidentiality

Check all of the following which will be used to access (review), collect, receive, and/or transmit study information:

☒ **Email** ☐ **Camera/Camera Phone** ☐ **Portable media (flash drive, CD/DVD, hard drive, etc.)**
☒ **Laptop** ☐ **Wireless Device** ☒ **Internet data access/data entry**
☒ **Paper** ☒ **KHN Workstation** ☐ **Non-KHN computer**
☐ **Other (specify):** Click here to enter text.

Describe where data/ records/ samples will be stored and how they will be kept secure:
Data will be stored in two binders on labor and delivery at the resident work station. Only approved ob/gyn residents will have access to the study binders. One binder will have the patient's name and enumber along with a number assigned to each patient. The other binder will have the surveys with each survey having the number assigned to each patient.

Any email communication with PHI will be KHN only. If outside KHN email is needed it will be encrypted. Internet data access will be through Epic. All electronic records will be stored on the resident KHN workstation on L&D that is password protected and only accessable by the PI.

Specify who will have access to study information/ to whom it will be released (if applicable):
Ob/gyn residents approved to participate in this study will have access to the study information as they will help with the data collection

Describe plans for storage, destruction, and/or return of study data and records after closure:
Study records will be stored with Dr. Moussa and locked in her office at Kettering Hospital. Paper records will be destroyed six years after closure of the study due to HIPAA documentation being required. Paper records will be placed in confidential shredder bin for destruction. Electronic records will be stored on Dr. Moussa's KHN workstation and permenantly deleted after six years.

☐ Check if data or specimens will be saved or stored for future use and provide details:
Click here to enter text.

Estimated Period of Time to Complete the Study (after IRB Approval)

Recruitment/data collection/active participation: June 2017-December 2017

Follow up: N/A

Data analysis/write-up: January 2018

Consenting Process and Location(s)

Initial consenting process

The principal investigator and fellow ob/gyn residents will be involved in consenting of the subjects. The consent will take place in private labor rooms on labor and delivery. The consenting process is expected to take five to ten minutes.

Consenting process after first visit

N/A

Documentation of consent (check all that apply):

☒ **Subjects' written, signed consent will be obtained.**

☐ **Waiver of consent is requested (attach Consent Form – Application for Waiver*)**
(Information is collected without subject knowledge: e.g. chart reviews)

☐ **Waiver of a signed consent is requested (attach Consent Form – Application for Waiver*)**
(Individuals participate directly but do not sign a consent form: e.g. anonymous surveys)

☐ **Alteration of consent is requested (attach Consent Form – Application for Waiver*)**
(Consent to be signed is not accurate or complete: e.g. study involving deception)
**for non-exempt submissions*

Grant Application

N/A

Study Budget: Funding, Resources, and Expenses

Resources needed

- Paper, binders, and video

Expenses to be incurred

- Institutional Review Board administrative and review expenses

Funding and sources of funds

N/A

References

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