TITLE: Prenatal Interventions to Promote Exclusive Breastfeeding
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IRB Protocol

Assessing the Feasibility of a Breastfeeding Champion Intervention and a Positive Messaging Module during the Prenatal Period - a pilot

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Type of Study

- Questionnaire/survey study followed by chart review

Origin of protocol

- Investigator initiated

Introduction/background

Exclusive breastfeeding, feeding infants only breast milk, for the first six months of life is recommended by the American Academy of Pediatrics. The benefits to exclusive breastfeeding are numerous for both infant and mother. Direct benefits include, but are not limited to, improvement of gastrointestinal function and host dense of the infant, prevention of acute illnesses in the infant, and reduced risk of breast cancer and type 2 diabetes mellitus with lowered cardiovascular risk in the mother [1].

Due to the many known health benefits of breastfeeding, the Department of Health and Human Services includes several breastfeeding objectives as a part of its Healthy People 2020 plan. These include increasing the proportion of infants who are breastfed to 81.9%, exclusively breastfed through 3 months to 46.2%, and exclusively breastfed through 6 months to 25.5% [2]. As of 2016, the rates for these objectives were 81.1%, 44.4% and 22.3% respectively [3]. The fact that breastfeeding initiation rates are high while rates of exclusive breastfeeding at 3 and 6 months are significantly lower demonstrates that mothers may not be receiving adequate education and the necessary support for continued breastfeeding.

To promote exclusive and continued breastfeeding, the World Health Organization and United Nations Children's Fund previously developed a global program known as the Baby Friendly Hospital Initiative which includes ten breastfeeding-supportive maternity practices or steps. To achieve designation as "Baby-Friendly," hospitals must follow the ten steps, and comply with the International Code of Marketing of Breastmilk substitutes. Step 3 is to "inform all pregnant women about the benefits and management of breastfeeding" through prenatal intervention [4].

To date, many studies have investigated the effectiveness of several forms of prenatal intervention. Bonuck et al. evaluated the effectiveness of prenatal visits with lactation consultants and/or electronically prompted guidance from prenatal care providers. The study found that the use of these interventions increased breastfeeding intensity at 3 months postpartum [5]. Another study by Kronborg et al. evaluated the effectiveness of a structured prenatal training program for women mid-pregnancy. The study found that the intervention group breastfed significantly longer than the control group [6]. Despite the success of the interventions in these studies, they have some significant limitations. The interventions were considerably time consuming and required the use of breastfeeding specialists. In addition, these studies focused primarily on improving breastfeeding education rather than identifying and implementing avenues of support for mothers.

One simple method of support that is currently used by several organizations is the use of a champion. A champion is someone who provides an outlet of positive reinforcement and support for the mother as she prepares and begins to breastfeed. Although there are organizations that specifically train individuals to become champions, one organization, Coffective, advocates that any person trusted by the mother can be her champion, regardless of experience [7]. No research to date has investigated if this method has a positive effect on exclusive breastfeeding intention. Another simple method of support used by organizations, such as Women, Infants, and Children (WIC), is positive messaging [8]. Positive messaging aims to improve intention to exclusive breastfeed by communicating positive attitudes to expecting mothers in the prenatal care setting. Although used widely, no research to date has explored its effectiveness.
This pilot study aims to evaluate the effect of the champion intervention and the positive messaging intervention on prenatal breastfeeding intention and to determine the feasibility of these interventions to deliver increased breastfeeding support.

References

1. Eidelman, A. I., Schanler, R. J., Johnson, M., Landers, S., Nobel, L., Szucs, K. & Viehmann, L. (2012). Breastfeeding and the use of human milk. Pediatrics. 129(3), e827-e841
2. Office of Disease Prevention and Health Promotion. (2016). Maternal, Infant, and Child Health. In Healthy People 2020. Retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infantand-child-health/objectives
3. Centers for Disease Control and Prevention, & Centers for Disease Control and Prevention. (2016). Breastfeeding report card—United States, 2016.
4. The Ten Steps to Successful Breastfeeding. (2012). Retrieved from https://www.babyfriendlyusa.org/about-us/baby-friendly-hospital-initiative/theten-steps
5. Bonuck, K., Stuebe, A., Barnett, J., Labbok, M. H., Fletcher, J., & Bernstein, P. S. (2014). Effect of primary care intervention on breastfeeding duration and intensity. American journal of public health, 104(S1), S119-S127/
6. Kronborg, H., Maimburg, R. D., & Væth, M. (2012). Antenatal training to improve breast feeding: a randomised trial. Midwifery, 28(6), 784-790
7. Overview. (2015). Retrieved from http://www.coffective.com/learn/
8. Breastfeeding Promotion. (October 2016). Retrieved January 19, 2017, from http://www.health.state.mn.us/wic/localagency/training/nutrition/nst/bfpromotio n.pdf
9. Centers for Disease Control and Prevention. (2016). National Immunization Survey (NIS). Retrieved from https://www.cdc.gov/breastfeeding/data/NIS_data/

Purpose/Hypothesis
Objective:
To evaluate the acceptance and satisfaction of the champion and positive messaging prenatal interventions and to determine how these prenatal interventions affect exclusive breastfeeding intention and practice.

Aims:

1. To determine if intention to exclusively breastfeed changes from before to after the intervention is implemented
2. To determine the acceptance and satisfaction of the interventions
3. To determine and compare the rates of exclusive breastfeeding in-hospital and at 2-weeks postpartum among women who received the champion and positive messaging interventions

Local Performance Sites
Woman's Health Center
MacDonald 1200

- Projected study enrollment:
    - For first year: 250
    - For entire protocol: 250

Are human subjects at more than minimal risk? No
Has this study been registered on www.clinicaltrials.gov? Yes
Does the study use the Clinical Research Unit? No
Is the PI submitting this study to another IRB? No
Does the study involve cancer research or cancer related issues? No

Study Population

- Adults
- Minors: age 14-17 for mothers
    - Not greater than minimal risk

Vulnerable populations: minors, pregnant woman (being recruited for study participation), neonates, illiterate individuals

Discuss the special provisions to be made to allow the inclusion of vulnerable populations OR justify the exclusion of vulnerable populations.

- For any mothers age 14-17 verbal consent will be obtained from a guardian to approach the expectant minor for written informed consent. An information sheet (written explanation of the research) will be presented to the guardian.
- Pregnant women are the study population of interest and must be included to answer the research question
- Illiterate populations are not a target of the study but will not be excluded from participation. The questionnaire will be read to a subject if they wish to participate but are unable to complete the written survey.
- We are not able to recruit non-English speaking persons since the questionnaires are not validated in other languages.
- Information about the mother's infant will be gathered as it is needed to answer the study question of interest, however none of this information is PHI.

Sources of subjects for the study

- Subjects from the practice of a study investigator

Subject Population:

Provide Specific Inclusion criteria

1. Pregnant women – adult women age 18 and older
2. Pregnant women – minors between the ages of 14-17
3. Pregnant women – obtaining prenatal care from UH MacDonald Women's Hospital Women's Health Center or MacDonald 1200
4. Pregnant women who have previously signed the "Prenatal Breastfeeding Instruction Sheet" provided before or at the 28 week prenatal visit.

Provide Specific Exclusion criteria

1. Pregnant women – less than 13 years of age
2. Pregnant women – 14-17 years of age without her legal guardian present
3. Pregnant women – decline participation in the research study
4. Pregnant women – the primary care provider believes the patient should not be approached (any medical or social reason unspecified)
5. Known medical contraindication to breastfeeding, specifically HIV positive or planned chemotherapy postpartum

Recruitment:

We will review the daily prenatal care schedules of the WHC and Mac1200. The primary care providers responsible for the clinic will be asked if it is appropriate to approach potential participants who meet inclusion criteria and do not meet exclusion criteria. If appropriate to approach, then eligible potential participants ages 18 years and above will be approached in a private setting (their exam room) and asked if possibly interested in the study. If interested, the Informed Consent document will be presented and explained (see Informed Consent process). For approachable and eligible expectant mothers ages 14-17 years, their guardian will be approached in a private area and we will briefly explain the study (see verbal script) and request permission to approach the expectant minor. If permission is granted then the minor will be approached as above, and we will explain the study in a private setting to both the guardian and the minor using the Informed Consent document (see Informed Consent process).

Subject Informed Consent/Assent/Parental Permission

Where will the informed consent process take place?

- At local performance sites: UH MacDonald Women's Hospital Women's Health Center and MacDonald 1200

How will informed consent be obtained?

- Written and signed consent
    - English

Plans for obtaining informed consent

The primary care provider will be approached to obtain permission to contact the subjects. Subjects will be approached in a private area and all study activity will be performed during clinic wait times or following completion of the subject's clinic appointment.

Since PHI will be collected, the research assistant will provide and discuss an informed consent form with the participant.
The informed consent form will describe the survey topic, length and rational for the study, and the types of PHI that will be collected.
The research assistant will answer any questions the potential participant has.
If the participant is under 18 years of age, the adult guardian will be approached to obtain permission to approach the minor (see verbal script), and then the minor potential participant will be approached to obtain written assent/consent.
All participants who agree to complete the questionnaire and to participate in the study will sign the informed consent form.
Participants who agree to complete the questionnaire and are under the age of 18 will sign the informed consent form as assent to the study, as will their guardian.
All participants and the guardians of minor participants will be provided with a copy of the informed consent form.

Assent Plan for Minors

- **Written assent signed by minor on (adult) Informed Consent Form:** 14-17 years of age
- **Will an information sheet be used**: No (verbal script to approach guardian of minors)
- **Will you obtain parental/guardian permission for inclusion of minors**: Yes
    - How: Written, One parent/guardian signature

HIPAA Authorization

Does this study collect, access, use or distribute any PHI? Yes
How are HIPAA privacy regulations met:

- Privacy authorization language in the consent form

Study Procedures:

- Questionnaires
- Medical Record Review – Electronic
- Medical Record Review – Paper

Involves study staff performing procedures requiring special training? No
Genetic Testing: No
Gene therapy: No
Radiation/radioactive substances: No
Electrical devices not approved for clinical use: No
Require approval by ICU: No

Study Procedures – Descriptions:

Objective: To evaluate the acceptance and satisfaction of the champion and positive messaging prenatal interventions and to determine how these prenatal interventions affect exclusive breastfeeding intention and practice.
Aims:

1. To determine if intention to exclusively breastfeed changes from before to after the intervention is implemented
2. To determine the acceptance and satisfaction of the interventions

3. To determine and compare the rates of exclusive breastfeeding in-hospital and at 2-weeks postpartum among women who received the champion and positive messaging interventions

Methods:

- Study Design: The study is a pretest-posttest sequential group design chosen to evaluate the effect of two prenatal breastfeeding interventions on exclusive breastfeeding intention.
- Population:
    - Inclusion criteria
        - Currently pregnant, age >13 years
        - Obtaining prenatal care from UH MacDonald Women's Hospital Womens' Health Center or MacDonald 1200
        - Able to obtain consent from subject or guardian/parent (for minor expectant mothers)
        - Previously signed the "Prenatal Breastfeeding Instruction Sheet" provided before or at the 28-week visit
    - Exclusion criteria
        - Age 13 years or younger
        - OB provider believes patient should not be approached (any medical or social reason unspecified)
        - Known medical contraindication to breastfeeding, specifically HIV positive or planned chemotherapy postpartum Data Collection Plan
    - Structured Interview with questionnaire
    - Follow-up chart review

Data collection:

Pre-test survey (see pretest survey document)
Provision of intervention
Post-test survey (see posttest survey document)
Follow-up chart review (participant medical record and baby medical record - see below)

Patient Enrollment and Survey Administration:

The primary care provider responsible for the clinic will be asked to determine if it is appropriate to approach the potential participants. After informed consent is obtained, the pretest survey will be administered on a UH encrypted tablet. The subject has the option of completing the survey herself on the tablet while the researcher waits, or she can have the researcher read her the questions and complete the responses on her behalf (her choice of completion style will be documented). The researcher will not leave the room both since the tablet is study property, and also so any questions about the survey can be answered. The subject can skip any questions that she chooses not to complete for any reason. Once the pretest survey is completed, one of the two

interventions (Appendix A and B) will be preformed on the UH encrypted tablet with guidance from the researcher. The PI will guide the participant as she taps and scrolls through the intervention to which she is assigned. Once the participant has completed the intervention, the PI will perform a short teach back with the participant (Appendix A and B scripts). Next, a handout (one for each intervention) that summarizes the interventions will be given to the participant so that the she can take information home with her. The participant can ask questions at any time during the interventions. Finally, the subject will complete the posttest survey. The subject will receive her participation gift following completion of the intervention and return of the tablet. The researchers are not involved in the care of the woman, and will promptly defer to any procedures or time requests of the treating providers.

Data Collection Tool:
The pretest and posttest surveys will be administered electronically using a UH encrypted iPad and data will be directly entered into the REDCap system. The pretest will be administered before the intervention is given and the posttest will be administered on the same day after the intervention is given. The interventions and pre- and posttests will take no longer than 10 minutes to complete. PHI will be obtained to permit a follow-up medical records review. The survey sections regarding demographic information and feeding plan following delivery were developed by the researchers.

The pretest survey contains 3 sections and will take approximately 2 minutes to complete.

- Section 1: Identifiers (MRN, DOB, name) – completed by researcher
- Section 2: Demographic Information
    - Demographic Information: Maternal age, Gestational age of pregnancy at time of interview, Race, Ethnicity, Number of Children, Marital Status, Living Status, Highest Level of Education, Current School/Employment Status, Plan for School/Work After Delivery, Living with partner/marital status
- Section 2: Breastfeeding Plan[1]
    - How do you plan to feed your baby? (Just formula / Both breastmilk and formula / Just breastmilk / Unsure)
    - If you plan to breastfeed, how many months you plan to breastfeed for? (0-3 months / 4-6 months / 7-12 months / More than 12 months / Unsure / Other)
    - If you plan to give any breastmilk, how will you feed the baby? (Put the baby to breast / Pump and feed breast milk with a bottle only/ Both pump and put baby to breast/ Unsure)
    - Have you breastfed a child before this pregnancy? (Yes / No / This is my first pregnancy)
    - If you have breastfed in the past, long long did you breastfeed for? (0-3 months / 4-6 months / 7-12 months / More than 12 months / Unsure / Other)

The posttest survey contains two sections and will take approximately 1 minute to complete.

- Section 1: Intervention Quality
    - Did you finish the intervention? (Yes / No)
    - Was the intervention you received interesting and enjoyable? Please give us your overall impression! (Five-point Likert Scale)
- Section 2: Breastfeeding Plan

- How do you plan to feed your baby? (Just formula / Both breastmilk and formula / Just breastmilk / Unsure)
- If you plan to breastfeed, how many months do you plan to breastfeed for? (0-3 months / 4-6 months / 7-12 months / More than 12 months / Unsure / Other)

Medical records review will be completed electronically after participants have delivered. This review will begin 2 weeks after the last expected due date for each intervention group. Data collected from the participant's medical records and from the baby's medical records will include:

- Participant's medical record
  - Infant birth weight, gestational age, sex, singleton vs multiple, NICU vs not
  - 2 weeks postpartum feeding choice if recorded
- Baby's medical records
  - Postpartum discharge (in hospital) feeding method
  - 2 weeks postpartum feeding method

Risks:
There are no physical risks to subjects. There is a small risk of loss of confidentiality related to PHI and personal beliefs, which is protected against with careful data handling and encryption of the iPad on which questionnaires will be administered. There is also small risk of embarrassment answering personal questions related to feeding. Due to the sensitive nature of questions, participants will be informed they are not required to answer any questions that they are not comfortable disclosing answers to. No separate visit or expense is required. Questionnaires will be administered during normal office wait time or at the conclusion of participants' scheduled clinic visit.

Benefits:
There may be direct benefits to study participants although this cannot be guaranteed.
The study will improve general knowledge regarding the effectiveness of prenatal breastfeeding interventions on exclusive breastfeeding intention, and thus may inform future decisions about intervention best practices.

Alternatives to participation
The alternative is to choose to not participate.
If subjects do not wish to participate in the study, it will not affect their care in any way.

Withdrawal from study participation
Subjects may choose to discontinue or withdraw at any time.

Plans for subjects at the end of the protocol
Subjects will continue their routine medical care; the study does not provide any care so no transition plan is necessary. Should participants request more information or have questions that arise following completion of the questionnaire, we will refer them to their providers and make the provider aware (with the participant's permission) that she has a question.

Data Safety and Monitoring

Plan: The PI (Rebecca Farr) and Dr. Lydia Furman will meet every two weeks to monitor the data for accuracy, completeness and adherence to the protocol.

Is there a formal data and safety monitoring board/committee? No

How will data be maintained?

- Electronic subject files
- Hard copy subject files (signed consent forms)

Data will be maintained in REDCap which is a data capture system that fully protects identifiers and data. Only the study team will have access. Consent forms will be kept in a locked cabinet in Dr. Furman's office.

How long will research data be stored by PI after closure of study? 3 years

Subject Privacy

The PI will approach participants while they are waiting in the exam room at the clinic, only after obtaining permission from the primary care provider to approach the possible participant. The research assistant will introduce themselves and the study, provide the informed consent for the participant and accompanying adult to read, answer any questions the participant and accompanying adult may have. The research assistant will indicate that the participant is free to discontinue the presentation and decline to participate at any time. If the participant agrees to participate in the study, she will sign an informed consent form that includes discussion of the PHI collected in the study.

Data/sample confidentiality

PHI will be included with questionnaires so that follow-up medical record review may be completed at a later date. Surveys and interventions will be administered electronically with a UH encrypted iPad and data will be directly entered into the REDCap system, which secures PHI and can and will only be accessed by the study team. Paper copies of the signed consent forms will be kept on the research assistant's person while in clinic, and placed in a locked cabinet accessible only to the study team after leaving clinic in Dr. Furman's office.

Data/sample security

REDCAP is a secure system and will only be accessed on a password protected computer and UH encrypted iPad, and accessed only by the study team.
Paper copies of signed consent forms will be kept on the research assistant's person while in clinic, and placed in a locked cabinet accessible only to the study team after leaving clinic.
The locked cabinet will be located in the locked office of Dr. Furman, room 784 of old Rainbow.

Data Analysis Plan

Sample size considerations:

Aim #1 of the study is to determine if intention to exclusively breastfeed changes from before to after the interventions are implemented. There are no published data on this question utilizing these interventions with which to formulate a hypothesis and perform the requisite sample size to

test that hypothesis. This will be considered a hypothesis generating study and feasibility of enrollment will determine the sample size. We will approach all eligible women during 2-month study period. We anticipate that approximately 31 women per week will be eligible, of whom approximately 80% will agree to participate, and over a 2-month study period, 250 women could be enrolled.

Analysis plan:
Nominal variables will be described using frequencies and percentages. Normally distributed continuous variables will be described using means and standard deviations, and non-normally distributed continuous variables will be described using medians and IQRs (interquartile ranges). We will compare nominal variables, e.g. those who received differing interventions (champion versus positive messaging) using Chi squared analyses or Fisher's exact test as appropriate. Distributionally appropriate two-sample tests will be used to compare continuous variables. Additional analyses may be carried out as the data indicate, and will be considered exploratory.

Financial Information
Will subjects receive incentive/reimbursement/compensation? Yes
Other: Participants will receive a book and an infant toy, with a combined value of $2.20, as a token of thanks for their participation.

Payments to subjects
No financial compensation to subjects.
We plan to provide a book and an infant toy as a small token of thanks to subjects upon agreeing to participate.

Cost to subjects
There are no costs to subjects.

Compensation for research related injuries:
Questionnaire and medical record review study with extremely low risk of any adverse event.
Option #3