

INSTRUCTIONS: use in conjunction with the online Initial Review Application form when no sponsor authored protocol is available.

1) Protocol Title

Title: *Strengthening Babies Through Mobile Health*

Protocol Version Date: *1/7/2019*

2) Objectives

Cross-sectional survey: *prevalence of exclusive breastfeeding within the last 24 hours for 2, 4 and 6 month infants.*

Intervention:

Primary Outcome: *Proportion of exclusive breastfeeding within the last 24 hours in Roatan, Honduras for 2month old children.*

Secondary Outcomes:

- Diarrheal disease incidence at age 2 months, 4 months and 6 months in Roatan, Honduras*
- Proportion of infants exclusively breast feeding at 4 and 6 months of life*
- Proportion of infants with any breastfeeding at 2, 4 and 6 months of life*
- Other types of food being given, if any*

Hypothesis to be tested:

Intervention: Breastfeeding support and education through SMS technology will increase the proportion of exclusive breastfeeding infants in Roatan, Honduras at two months of life.

3) Background

Exclusive breastfeeding (EBF) for at least six months provides significant benefits to both infants and their mothers. Research shows that EBF decreases the incidence of pediatric infections, including: otitis media, gastroenteritis, necrotizing enterocolitis, meningitis, and pneumonia.¹ Additionally, EBF for six months is associated with lower rates of hospitalization for lower respiratory infections, lower incidence of sudden infant death syndrome and obesity. It has also been associated with higher neurodevelopment outcomes. In developing countries, EBF decreases infant exposure to contaminated water sources. The diarrheal prevalence within two weeks in infants less than six months in Honduras was estimated to be 12.4% in 2011 according to the DHS. Breastfeeding also confers a financial benefit as parents are not required to purchase replacement feeding (e.g. infant formula). Promotion of breastfeeding in developing countries has been found to be the single most effective method to improve survival of infants and young children.

Roatan is an island in the Caribbean Sea off the north coast of Honduras and has a population of 50,000. Estimated infant mortality in the island is 79 per 1,000 live births according to the most recent Honduran national data from 2012. This is compared to the national rate of 17 per 1,000 live births and global rate of 32 per 1,000 in 2015. In addition, leading causes of infant mortality in Honduras in infants 1-11 months of age are respiratory infection (23.7%), diarrhea (33.8%), and other infections (9.6%). A local partnering physician observes an estimated exclusive breastfeeding rate of 30% in Roatan. According to the DHS in 2011-2012, in the

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country of Honduras, it is estimated that 63.8% of mothers have early initiation of breastfeeding; however, the proportion of mothers exclusively breastfeeding under 6 months is only 31. In the bay islands, 53% of mothers initiate breastfeeding in the first hour and 73% initiate in the first day (DHS). Per the DHS, data regarding duration of breast feeding does not exist for the bay islands. Comparatively, the rate of exclusive breastfeeding in infants less than six months in developing countries in 2011 was approximately 39% according to UNICEF.

There are limited studies focusing on exclusive breastfeeding in Roatan, Honduras. Interventions trialed in other contexts with low exclusive breastfeeding rates may be a benefit in this setting. Anecdotally, barriers to breastfeeding in this area include lack of education on benefits of breastfeeding, technical difficulty, and cosmetic reasons among others which has been identified from the local population. More qualitative research is needed to better understand the barriers and obstacles to breastfeeding, a research question our team is pursuing in a sister project.

A systematic, community-based support system is needed to reach all new mothers to educate them on benefits as well as practical tips on breastfeeding. A study completed in Shanghai, China found that SMS education was effective in increasing duration of exclusive breastfeeding and delaying introduction of solid foods. Smart phones are used by an overwhelming majority of the island population, so we plan to explore SMS technology as a tool to achieve this. Our aim is to increase exclusive breastfeeding using SMS technology to reach a broad audience of new mothers with educational and motivational messages regarding breastfeeding and troubleshooting common challenges. This protocol describes a proposed study to evaluate the effectiveness of SMS text messaging in increasing the rate of exclusive breastfeeding in Roatan, Honduras.

Inclusion and Exclusion Criteria

Intervention Group

We will enroll mothers who recently delivered full term infants (>37 weeks) at Public Hospital Roatán who intend to breastfeed. Inclusion criteria are:

1. Recently delivered full term infants (>37 weeks gestation, less than 72 hours old)
2. 18 years of age or older, or emancipated minor, or if parent able to consent if <18 years of age
3. Intent to breast feed
4. Own a phone that can receive SMS messages
5. Be literate (self-report of ability to read English or Spanish)
6. Able to send SMS reply messages

This study will NOT include adults unable to consent, pregnant women or prisoners.

4) Study Timelines

- *The duration of an individual subject's participation in the study:* Approximately 6 months after enrollment
- *The duration anticipated to enroll all study subjects:* Two years
- *The estimated date for the investigators to complete this study (complete primary analyses):* September 2020

5) Study Endpoints

Intervention:

Primary Outcome: Proportion of exclusive breastfeeding within the last 24 hours in Roatan, Honduras for 2 month old children.

Secondary Outcomes:

- Diarrheal disease incidence within the last 2 weeks at age 2 months, 4 months and 6 months in Roatan, Honduras
- Proportion of infants exclusively breast feeding at 4 and 6 months of life
- Proportion of infants with any breastfeeding at 2, 4 and 6 months of life
- Other types of food being given, if any

6) Procedures Involved

1.Pre-Intervention Convenience Sample: To determine the current prevalence of exclusive breastfeeding in Roatán, Honduras we will perform a pre-interventional cross-sectional prevalence study to determine the baseline exclusive and any breastfeeding prevalence in Roatán within two weeks of two, four and six months of life. Mothers of infants that match this criteria who indicate they had an intention to breastfeed will be recruited in various pediatric clinic waiting rooms including public clinics in Flower's Bay, Coxen Hole, French Harbor, Oak Park as well as 2 clinics directly associated with the Public Hospital Roatan, Roatán Volunteer Pediatric Clinic and Clinica Esperanza. Once verbal consent is obtained, we will conduct verbal interviews in English or Spanish based on participant preference. The verbal interview will include questions regarding current infant feeding practices, infant age, types of foods that have been introduced and incidence of diarrheal illnesses in the last two weeks. This data will be compiled into a database with a unique study ID and no patient identifiers.

Data collection: A pre-intervention cross-sectional study will be conducted to determine baseline exclusive breastfeeding prevalence. Verbal consent will be obtained prior to surveying participants. Data will be collected with a verbal interview in English or Spanish per participant preference. This data will be transcribed to an excel spreadsheet. No patient identifiers will be collected and only a unique study ID will be linked to the data. This de-identified data set will be password protected.

This portion of the study is now complete.

2. Intervention: We will create targeted messages with animations to help mothers with breastfeeding. According to one of the pediatricians in Roatán, some of the barriers to breastfeeding include lack of education, cosmetic concerns and difficulty with technique. Therefore, the messages will provide education and advice regarding breastfeeding technique and encouragement to mothers. Messages will be written in both English and Spanish, and each participant will be asked to choose their preferred language at time of enrollment. Mothers who are interested in breastfeeding will be recruited and invited to participate in the study in the post-partum ward after delivery at Public Hospital Roatán. Written informed consent will be obtained. Once a mother is enrolled into the study, a sample text survey in the language of preference will be sent to ensure text messages will be received. A secondary contact method (i.e. phone number, email) will also be requested if available, in case current phone number changes or is disconnected. Mothers will be given 20 Lemipras worth of cellular phone plan credit at time of enrollment as compensation for costs associated with responding to SMS messages. In addition,

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mothers will be shown a sample completed survey in order to understand how to properly answer questions via the SMS survey system. Mothers will be asked to complete test survey in order to practice how to answer it properly. If mothers do not have their phone with them at enrollment, it will be verbally agreed that mothers will complete the test survey when possible. Mothers will be awarded 70 Lempiras worth of cellular phone plan credit after completing the survey of 2 months as compensation for completing surveys at 2, 4 and 6 months. Three animated videos will be shown to mothers at enrollment providing information regarding breastfeeding technique, breastfeeding encouragement and general breastfeeding information. Mothers can decline viewing these animations, but will still be eligible to participate in this study. SMS messages will start at time of enrollment and continue through six months after enrollment. Messages will be delivered through Telerivet, an SMS interactive platform designed to send the educational and motivational messages to mothers' cell phones. We will send text messages, limited to 160 characters. The content will include recognizing newborn hunger cues, latch methods, messages of encouragement, frequency of feeding and maternal milk production. All text messages are found in attachment. Content is informed by breastfeeding literature regarding common barriers and reasons for breastfeeding cessation as well as causes of frustration during early breastfeeding.

Data collection: The intervention group will be polled when infants turn two months, four months, and six months regarding their breast feeding status through Telerivet via SMS messaging. If participants do not respond to automated SMS messaging, participants will be contacted by the research site coordinator within two weeks of receiving the survey. They will be contacted through phone calls by local cellphone carrier. If participants do not respond, she will be contacted through Whatsapp messenger application via messaging and/or phone calling. The same survey questions will be asked: if they are breastfeeding at all, if they are breastfeeding exclusively in the last 24 hours, age of infant when they last gave breast milk, the incidence of diarrheal illness in the past two weeks, and any other foods / liquids given to infant. Exclusive breastfeeding will be defined as giving only mother's breastmilk in the 24 hours preceding the interview. Diarrhea is defined as any watery stool with frequency unspecified. We recognize the limitation of this lack of clear definition; however, this is the current diarrhea definition used by the DHS in Honduras. This has been used to determine the current prevalence of diarrheal illnesses in infants less than 6 months. All replies from mothers will be stored on a password protected, secure survey in Telerivet, and/or a password protected, secured excel sheet database (those responded to on phone verbally or by whatsapp), and then transferred to a password protected, secure Red Cap database.

7) Data and/or Specimen Management and Confidentiality

Pre-Intervention Group

Each participant will be assigned a study ID number and no identifying data will be obtained. We will ask each mother if they have participated yet in order to prevent double sampling. The list of the study ID numbers with associated responses will be transcribed on a master excel sheet. This will be stored on a password protected secured server. Only key study personnel who have received IRB training will have access to the database.

Intervention Group

Each participant will be assigned a study participant ID number. List of participants including name, phone number, and the date of their infants' birth and their ID will be kept in a master excel spreadsheet. Data will be collected on a separate excel sheet that identifies participants only by their study ID. Both of the documents will be stored in a password protected secured database. Minimally necessary number of team members will have access to the passcode to the data base. In addition, all team members will undergo IRB training.

Statistical Methods:

Descriptive statistics will be used to characterize demographics of participants in the interventional study, which will then be compared to the those in the baseline survey with Pearson Chi-square test and Student's t-tests. Differences in proportions of mothers practicing exclusive breastfeeding [EBF (receiving nothing besides breastmilk in the last 24 h)] and mixed feeding (breastfeeding and other type of feeds in the last 24 h) at 2,4 and 6 months in the intervention group vs. the pre-intervention baseline survey will be compared with Chi-square tests, as will proportion of infants experiencing diarrheal illness in the past 2 weeks at each age.

Descriptive statistics will be used to present information regarding types of food introduced at different ages, and chi-square to assess differences in specific foods introduced between pre-intervention and intervention samples. Data will be stored and accessed via REDCap. Analysis will be done with statistical assistance from UC Davis Clinical and Translational Science Center. An interim analysis is planned to ascertain that data capture from the electronic phone-based survey is successful.

Sample Size / Power Analysis:

In order to have power of 0.8 with a two-sided alpha value of 0.05, using an established baseline sample proportion of 10.9% (exclusively breastfeeding at 2 months of life) and assuming as our desirable detectable goal a true probability of 19.9% with intervention, we will need a sample size of at least 208 intervention respondents at 2 months. Recruitment is anticipated to continue until this number of participants have responded.

8) Data and/or Specimen Banking

N/A

9) Provisions to Monitor the Data to Ensure the Safety of Subjects

N/A

10) Withdrawal of Subjects

There are no circumstances under which subjects will be withdrawn from the research study without their consent. The only instance participants will be withdrawn will be due to consent of the primary phone user and/or study participant.

11) Risks to Subjects

Potential exposure of personal information is the only risk associated with participating in this study. This risk will be minimized by proper securement of data as described above.

12) Potential Benefits to Subjects

Benefits for participants in the intervention group include education on breastfeeding techniques and how to avoid or address common problems as well as additional support and encouragement for breastfeeding.

Although there is no direct benefit for mothers who will be interviewed in pre-intervention cross-sectional sample group, the data they provide will help establish the prevalence of breastfeeding on the island.

13) Multi-Site Research

Intervention: Public Hospital Roatan is the only public hospital on the island of Roatan. It has the only public birthing unit on the island.

Regular calls with the on-site study team will be conducted. All study personnel in Roatan, Honduras as well as those involved in the study at UC Davis will complete IRB training. IRB approval has been obtained in Honduras.

14) Community-Based Participatory Research

Prior to starting enrollment, a qualitative study was completed (separate IRB). The aims of this qualitative study were to discover what women perceived to be the barriers to breastfeeding, what influenced them when choosing their method of infant feeding, and what healthcare interventions might have encouraged them to breastfeed. The findings of the project will be used to ensure that our ensuing breastfeeding intervention will be culturally sensitive and community-based.

15) Sharing of Results with Subjects

The results of this study will not be directly shared with individual subjects.

16) Prior Approvals

IRB approval has been obtained in Honduras and is attached.

17) Provisions to Protect the Privacy Interests of Subjects

Intervention Group

Each participant will be assigned a study participant ID number. List of participants including name, phone number, and the date of their infants' birth and their ID will be kept in a master excel spreadsheet. Data will be collected on a separate excel sheet that identifies participants only by their study ID. Both of the documents will be stored in a password protected secured database. Minimally

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necessary number of team members will have access to the passcode to the data base. In addition, all team members will undergo IRB training.

18) Compensation for Research-Related Injury

N/A

19) Economic Burden to Subjects

Participants will be charged for sending text messages in response to our polls at 2, 4 and 6 months. To off-set any costs for participating in this study, we will provide 20 Lempiras at time of enrollment, and 70 Lempiras phone credits after responding to the 2 month poll (must include sending a response to exclusive breastfeeding in last 24 hour question).