Study Title: Improving Care Giver Adherence to Recommended Infant Care Practices (AKA SMARTER)

ClinicalTrials.gov number: NCT04387552

Research Consent Form: V3.1

Research Consent Form Date: 12/6/2021

RESEARCH CONSENT FORM

Basic Information

Title of Project: Social Media and Risk Reeducation Teaching Enhanced Reach (SMARTER)

IRB Number: H-39495

Sponsor: National Institute for Child Health and Development

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Study Phone Number: (617) 206-6269

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form. It is your decision whether or not to join the study.

We are doing this study to evaluate the effectiveness of 2 infant care educational programs called *TodaysBaby (Sleep emphasis)* and *TodaysBaby (Feeding emphasis)*. These programs are delivered to a participant's smartphone by text.

We are asking you to be in this study because you are pregnant and are a client of a Supplemental Nutrition Program for Women, Infants, and Children (WIC) office that is offering the TodaysBaby Programs to their clients. Your WIC office is not involved in the conduct of this study.

If you agree to participate in this study, you will receive one of the TodaysBaby programs or a combination of the TodaysBaby programs and complete up to 6 study surveys. You will be in the study until your baby reaches 6 months of age, if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risk of being in the study is that you may feel uncomfortable with some of the TodaysBaby materials and survey questions. You will find more information about risks later in this form.

You might benefit from being in the study because you may learn important information on how to take care of your baby. You will find more information about benefits later in this form.

You could get these benefits without being in the study by obtaining information on how to care for your baby from other sources. You will find more information about alternatives later in this form.

Your decision about participation in this study will not negatively affect your standing with WIC. We will not share any information about your participation in this study with WIC.

Purpose

The TodaysBaby programs have been developed by experts in the field of infant care and contains the up-to-date information on recommended infant care practices. The TodaysBaby programs includes a prenatal and postnatal component. The programs start when participants are in their 34th week of pregnancy and continues until their baby is 6 months old.

The TodaysBaby programs consist of short videos (between 30 seconds and 3 minutes in length) and text messages delivered to a participant's smartphone.

The purpose of this study is to help us determine what combination of the TodaysBaby programs is best for helping participants choose recommended infant care practices.

What Will Happen in This Research Study

You will be one of approximately 2,500 participants who will be asked to be in the study. If you agree to participate in the study we will ask you to complete the following study procedures:

1. A Short Enrollment Survey
   After you provide your consent to participate in this study, you will be asked to complete a short enrollment survey. This survey will ask you some demographic questions (ex. your race and ethnicity) along with some questions about how you plan to care for your baby after they are born. You will not be compensated for completing this survey.

2. Set-Up Your Mobile Phone to Receive Text Messages
   We are working with a company called Agile Health to deliver the TodaysBaby programs and study surveys to your smartphone. A few minutes after you complete the Enrollment Survey, a text message will be sent to your smartphone to confirm that you would like to participate in TodaysBaby. You will need to respond to that text message to confirm your participation.

3. Stay Engaged With Study Team Until You Are in Your 34th Week of Pregnancy
   You will begin to receive the TodaysBaby program when you are in your 34th week of pregnancy.

   Between now and your 32nd week of pregnancy: We will keep in touch with you with a *weekly* text message. Weekly text messages will include general questions and information about your pregnancy. Some of the text messages will include questions to make sure you are still eligible to participate in the study.

   Between your 32nd and 34th week of pregnancy: We will send you a *daily* text message. Some of these texts will include links to videos that will review information already contained in this consent form and will also provide additional details about the TodaysBaby program. We will also send you the second survey during this time.

If your pregnancy ends before your reach your 34th week of pregnancy, you will no longer be eligible for this study and we will have to stop your participation. You can notify us that your pregnancy has ended by:

- Responding to text messages when we ask if you are still pregnant.
- Calling the study office at 617-206-6269.
- Texting 'Birth' to 63141 or responding 'Birth' to any of the text messages you receive.

Should this occur a member of our study team will reach out to speak with you by phone.

4. Complete Additional Study Surveys

As part of your participation in this study you will be asked to complete up to 5 additional study surveys. Survey questions will be about the choices you are making around the care of your baby and your feelings about a variety of infant care practices. The surveys will also include questions about your home environment, health behaviors, and mood during and after your pregnancy. You may skip any question you are not comfortable answering.

Your responses to the survey questions are not monitored in real-time. That means it may take us several days to review your responses once you complete a survey. If your responses to survey questions about your mood suggest you might have feelings of anxiety or depression, the survey will provide you with additional information about resources that you may contact for support. In some cases, a physician working on the study may also contact you to discuss resources.

Each survey will take between 5 and 45 minutes to complete. You will receive a link to each survey by text message, and each survey can be completed on your smartphone. You will be reimbursed for your time completing the surveys. There is more information about reimbursement a bit later in this consent form.

5. Participate in the TodaysBaby Program

A. Randomization

When you reach your 34th week of pregnancy you will be randomized to receive one of two TodaysBaby infant care practice prenatal messaging programs.

Once you inform us that your baby has been born you will randomized again, to receive one of two TodaysBaby infant care practice postnatal messaging programs. The postnatal program will begin the day after we learn of your baby's birth.

Randomization means that the program you will receive is assigned by chance, like the flip of a coin. Your chance of receiving each TodaysBaby program is equal.

B. TodaysBaby Prenatal Program

You will receive the following text messages as part of the prenatal messaging program:

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- A text link for up to 27 TodaysBaby videos
  - 1 video a day from day 1 to 15 of the program
  - 1 video every 1 or 2 days from day 17 to 36 of the program

- A text message question
  - 1 every other day from day 2 to 26. These text message questions will include questions about how you plan to care for your baby after they are born, confirmation if you are still pregnant, and other information about TodaysBaby.
  - 1 every day from day 28 until the birth of your baby. These text message questions will ask you to confirm if you are still pregnant or if you have given birth.

- A text link to 1 study survey
  - The Prenatal Survey will be sent to you on day 16 of the program. If you do not complete the survey in a timely manner, you will receive text messages and phone calls to remind you to complete study survey.

The TodaysBaby programs are tailored for where you are in your pregnancy. In order to provide you with important postnatal information for the care of your baby, we would like you to let us know when your baby is born. You can let us know you have given birth by:

- Texting 'Birth' to 63141 or responding 'Birth' to any of the text messages you receive.
- Responding to our text message questions asking if you are still pregnant or have given birth.
- Calling the study office at 617-206-6269 to let us know your baby has been born.

If we do not hear from you regarding your pregnancy status we will attempt to reach you by phone. If we are unable to reach you by phone, we will automatically switch you to the TodaysBaby Postnatal program when you reach 40 weeks plus 6 days gestation.

C. <u>TodaysBaby Postnatal Programs</u>
You will receive the following text messages as part of the postnatal messaging program:

- A text link to 28 TodaysBaby videos
  - 2 videos a day until your baby is 5 days of age
  - 1 video every 2 days until your baby is 32 days of age
  - 1 video every 7 days until your baby is 2 months of age

- A text message question about how you are caring for your baby
  - 1 every day until you baby is 2 months of age
  - 2 a week until your baby is 6 months of age

- A text link to up to 3 study surveys
  - A short Birth Survey will be sent the day after your baby is born
  - The Postnatal Survey will be sent when your baby is 60 days of age.

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- You may also be asked to complete a short survey regarding your experience feeding your baby.

If you do not complete the surveys in a timely manner, you will receive text messages and phone calls to remind you to complete study survey.

We will keep all the information you provide during this study in a repository. We may share this information with other researchers. If we share this information with other researchers, we will not share any information that could identify you or your baby. Agreeing to allow us to keep your information is optional and you can agree to participate in the main study but not agree to having your information kept in the repository. If you do not want your information kept in the repository, you can opt-out by calling Dr. Michael Corwin at (617) 206-6269.

The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

Risks and Discomforts

Some of the text message questions, survey questions, and TodaysBaby videos may make you feel uncomfortable or upset. You may decline to answer any text question or survey question during the study. You also do not have to watch study videos and can stop watching videos at any time. Some of the survey questions will ask about your mood. Based on your responses to these questions a member of the study may call you to discuss how you are feeling and offer additional supportive resources.

There are additional risks in using texting in general, as a communication platform. There is a risk that someone could access your surveys and answers if you leave your phone unlocked. There is also a risk that someone will be able to see your responses when you respond to texts. This is because every cellular phone company has different levels of encryption when they send data from your phone. To avoid these risks, complete electronic surveys or save them for later, do not leave them unfinished on your phone.

Potential Benefits

A potential benefit of being in this study is that you may learn about recommended ways to care for your baby. However, you may not receive any benefit. The primary goal of this research is to collect information about the scientific questions asked in this study. Your being in the study may help the investigators learn what combination of the TodaysBaby programs is best in helping participants choose recommended feeding and sleeping infant care practices.

Alternatives

The following alternative procedures or treatments are available if you choose not to be in this study: You can obtain information on how to care for you baby from other sources.

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Costs

The TodaysBaby programs are provided to you at no cost. However, there may be some additional costs to you for being in the study. The program will be delivered to your smartphone and may include up to 4 messages per day. Standard text messaging and data rates may apply.

Payment

You will receive up to $50 in electronic gift cards for your participation in this study. You will receive a $10 gift card when you complete the Baseline Survey, a $10 gift card when you complete the Prenatal Period Survey, and a $10 gift card when you complete the Infant Birth Survey. You will receive a $20 gift card when you complete the Postnatal Period Survey. You will not receive a gift card for completing the Enrollment or Feeding Experience surveys.

Gift cards will be sent to you by text message within 48 hours of completing each survey.

You will also be eligible to participate in a monthly lottery for a $100 gift card. You are eligible to win up to 4 monthly lotteries. You will receive free entries into the lottery for completing the following study procedures:

- You will receive 1 lottery entry each time you respond to a text that begins with a '$'.
- You will receive 3 lottery entries for completing the following surveys: Baseline, Prenatal Period, Infant Birth, Postnatal Period and Feeding Experience.

Odds of winning the monthly lottery will depend on the number of entries received each month.

You will have your choice of gift card from Target, Walmart, or CVS Pharmacy.

The research may lead to the development of educational programs that might have commercial value. You will not get any money if products are developed from the research.

Confidentiality

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. Only the people listed later in this section will be given access to your information. However, we cannot guarantee complete confidentiality.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC**.** The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information in

connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in the study and sign this form, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.

- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- People who will get information from us. These people are expected to protect your information in the same way we protect it.

- We will use a service called "Agile Health" to send the video and survey text links as well as text messages to you. Agile Health is an authorized Business Associate of Boston University. Agile Health will have access to your mobile number, your name, your expected due date, your gender, your language preference, your gift card preference, your zip code, the texts we send you, and your responses. If you provide us with your baby's name, Agile Health will also have access to that so they can personalize text messages. These data will only be used for the purposes of this study and will not be shared with outside parties. The Agile Health platform is a secure system, with all data encrypted in transit and at rest, and messages are delivered with encryption.

- Any people who you give us separate permission to share your information.

You should know that we are required to report certain information that we might learn in this study to state or other agencies. The information includes child abuse or neglect.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Re-Contact

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

____Yes ____No You may contact me again to ask for additional information related to this study

____Yes ____No You may contact me again to let me know about a different research study.

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get. You will only be paid for the study activities that you complete before withdrawing.

If you decide that you want to stop being in the study, we ask that you let us know, by calling the study office at 617-206-6269. You can also text also 'STOP' to 63141 to cancel your participation in the TodaysBaby program at any time. If you text 'STOP', a member of the study staff may call you to ask you why you decided to stop receiving the TodaysBaby program. You will continue to receive the study surveys, unless we speak with you and you let us know that you do not want to receive them.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Dr. Michael Corwin at (617) 206-6269. Also call if you need to report an injury while being in this research.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Subject: _____

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Printed name of subject

By printing your name below, you are indicating that

- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and sharing of information that may identify you as described, including your health information.

_____ _____
Signature of subject Date

Researcher: _____
Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

_____ _____
Signature of person conducting consent discussion Date